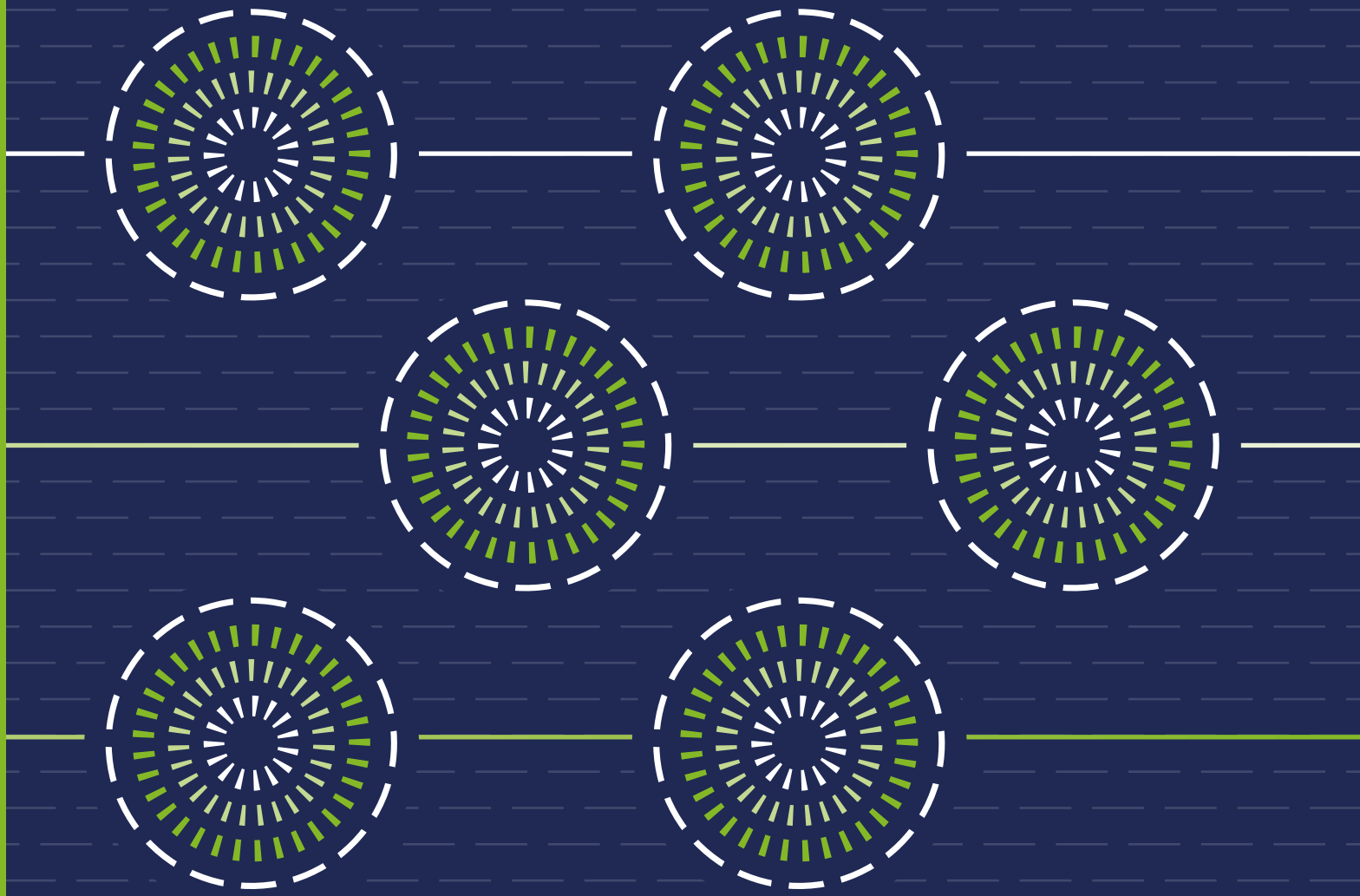
Global hepatitis report 2024

Action for access in low- and middle-income countries



World Health Organization

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ISBN 978-92-4-009167-2 (electronic version)
ISBN 978-92-4-009168-9 (print version)

Suggested citation. Global hepatitis report 2024: action for access in low- and middle-income countries. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at https://iris.who.int/.

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Foreword

In 2023, I had the honour of presenting Egypt with an official certification for becoming the first country to achieve gold tier status on the path to elimination for hepatitis C. This tremendous achievement could be within the reach of many other countries. We have the knowledge and tools to prevent, diagnose and treat viral hepatitis, and the ability to deliver services at the primary health care level - closer to communities in need. Yet despite this progress, most people around the world with chronic hepatitis B and C are still waiting to access the services they need, and deaths are on the rise.

This first consolidated WHO global report on viral hepatitis is a call to action for a simplified and equitable public health approach to eliminate viral hepatitis. The goal is feasible. More countries are adopting WHO guidelines, developing national plans, and including viral hepatitis services in universal health care packages. Vaccines, rapid diagnostic tests and generic medicines are available at affordable prices; and local production is making it possible to reach many more people. Affected communities are raising awareness, demanding access and advocating for change.

We have powerful tools to prevent and diagnose and treat hepatitis; the challenge we face is to implement them at scale. Many of the barriers shared in this report can be overcome with improved policies, targeted interventions and concerted efforts of all stakeholders. More countries need to vaccinate infants for hepatitis B on time, optimize case-finding strategies, improve linkages to care, take full advantage of price reductions, decentralize and integrate service delivery and develop investment cases - keeping the needs of people living with viral hepatitis at the centre of all efforts.

As a global health community, we have the collective responsibility to save lives today and protect the health of future generations. This report presents ten actionable recommendations for national health authorities, technical and funding partners, industry, civil society and research institutions to step up efforts towards our shared vision of a hepatitis-free future.

Dr Tedros Adhanom Ghebreyesus
Director-General
World Health Organization

Acknowledgements

This publication was developed by the WHO Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes jointly with the Department of Health Product Policy and Standards, Department of Immunization, Vaccines and Biologicals and Department of Regulation and Prequalification. An editorial team guided the development of the publication with representation from the following WHO departments: Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes (Diana Faini, Olufunmilayo Lesi, Daniel Low-Beer, Niklas Luhmann, Françoise Renaud), Department of Health Product Policy and Standards (Deirdre Dimanesco), Department of Immunization, Vaccines and Biologicals (Shalini Desai) and Department of Regulation and Prequalification (Christine Guillard). The process related to the Global Hepatitis Reporting System was led by Daniel Low-Beer with Diana Faini and Fuqiang Cui. The process related to access to health products for viral hepatitis was led by Françoise Renaud with Shalini Desai, Deirdre Dimanesco and Christine Guillard, under the coordination of Daniel Low-Beer and Meg Doherty.

WHO thanks the following WHO colleagues for their contributions:

Headquarters: Michel Beusenberg, Ana Aceves Capri, Fuqiang Cui, Jicui Dong, Philippa Easterbrook, Lisa Hedman, Carmen Rodriguez Hernandez, Benedikt Huttner, Swathi Iyengar, Olivier Lapujade, Erika Dueñas Loayza, Robert Luo, Lorenzo Moja, Francis Moussy, Antons Mozalevskis, Deusedit Mubangizi, Boniface Dongmo Nguimfack, Irena Prat, Anita Sands, Matthias Stahl, Georgios Stathopoulos, Klara Tisocki, Nathalie Van de Maele, Lara Vojnov, David Woo;

WHO Regional Office for Africa: Ikpeza Akudo, Mohamed Ismail, Frank John Lule, Casimir Manzengo Mingiedi;

WHO Regional Office for the Americas: Izabella Chinchilla, Murilo Freitas, Monica Alonzo Gonzales, Alexandre Lemgruber, Ruben Mayorga-Sagastume, Leandro Soares Sereno;

WHO Regional Office for South-East Asia: Rajat Adhikary, Polin Chan, Stephen Himley, Adrien Inoubli, Tiara Mahatmi Nisa, B.B. Rewari;

WHO Regional Office for Europe: Stela Bivol, Kees De Joncheere, Georgi Kuchukhidze, Marcelo Contardo Moscoso Naveira;

WHO Regional Office for the Eastern Mediterranean: Joumana George Hermez, Muhammad S. Jamil, Houda Langar, Ahmed Sabry, Mohamed Wehbi;

WHO Regional Office for the Western Pacific: Mohamed Amine Ghrabi, Geraldine Hill, Kiyohiko Izumi; and all colleagues in WHO country offices who facilitated data collection and review for the report.

WHO gratefully acknowledges the contributions of Parijat Baijal, consultant, who managed data collection and analysis, supported the work of the editorial team and wrote the report; and of Debi Boeras, consultant, who contributed data analysis and narrative related to diagnostics.

WHO thanks the following key informants from partner organizations who were interviewed for the report:

CDA Foundation (Homie Razavi and Shakhlo Sadirova)
Centre Muraz, Burkina Faso (Dramane Kania)
Clinton Health Access Initiative (Oriel Fernandes, Ritubhan Gautam, Robia Islam, Navya Sharma)
Coalition for Global Hepatitis Elimination (Lindsey Hiebert and John Ward)
Foundation for Innovative New Diagnostics (Elena Ivanova and Sonjelle Shilton)
Geneva University Hospitals (Olivier Ségéral)
Institut Pasteur, France (Yusuke Shimakawa)
International Treatment Preparedness Coalition (Othoman Mellouk)
Médecins du Monde (Enrst Wisse)
Medicines Patent Pool (Esteban Burrone and Mila Maistat)
Médecins Sans Frontières (Jessica Burry and Erin Da Costa)
Treatment Action Group (Joelle Dountio and Sara Helena Pereira e Silva Gaspar)
Unitaid (Karin Timmermans)
Université des Sciences de la Santé, Cambodia (Saphonn Vonthanak)
Université de Médecine et de Pharmacie de Hai Phong, Viet Nam (Pham Minh Khuê)
Université de Montpellier (Nicolas Nagot)
World Hepatitis Alliance (Cary James)

WHO particularly thanks colleagues from national health authorities who shared, reviewed and validated the data presented in this report.

WHO thanks the CDA Foundation for their contribution to country and regional data validation and the University of Bristol and Imperial College for their contributions to data alignment and triangulation. WHO also thanks colleagues in the Clinton Health Access Initiative, the Medicines Patent Pool and Unitaid for their input during the finalization of the report.

Unitaid kindly provided funding support for developing the report. WHO also thanks the other institutions that provided staff time and made other contributions to producing the report.

Abbreviations

COVID-19	coronavirus disease 2019
H-TAP	WHO Health Technology Access Pool
C-TAP	WHO COVID-19 Technology Access Pool
DAA	direct-acting antiviral (medicine)
DAC	daclatasvir
ETV	entecavir
FIND	Foundation for Innovative New Diagnostics
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
G/P	glecaprevir/pibrentasvir
HBsAg	hepatitis B surface antigen
HBeAg	hepatitis B e antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HCVcAg	hepatitis C core antigen
HDV	hepatitis D virus
HIV	human immunodeficiency virus
IVD	in vitro diagnostic medical device
LED	ledipasvir
MPP	Medicines Patent Pool
NAT	nucleic acid test
PrEP	pre-exposure prophylaxis
RDT	rapid diagnostic test
TAF	tenofovir alafenamide
TDF	tenofovir disoproxil fumarate
SOF	sofosbuvir
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VEL	velpatasvir
VOX	voxilaprevir

Executive summary

There are better tools and data than ever to prevent, diagnose and treat viral hepatitis, including vaccines and effective treatments for hepatitis B and a cure for hepatitis C. More product options are available, and their prices continue to fall. Decentralized, integrated and differentiated service delivery models are enabling primary health care to reach more people. Countries such as Egypt are leading the way for a public health approach to eliminating viral hepatitis – in October 2023, Egypt became the first country to achieve the gold tier status on the path to eliminating hepatitis C infection. With recent political commitments, policy updates and local production of viral hepatitis medicines, other low- and middle-income countries with a high burden of viral hepatitis, such as China, India and Pakistan, are well-positioned to scale up their viral hepatitis response.

Nevertheless, the latest data show that viral hepatitis is a major public health challenge of this decade, and the world is still far from achieving its elimination by 2030. Combined, hepatitis B and C cause 3500 deaths per day, and mortality is increasing. An estimated 254 million people are living with hepatitis B and 50 million people are living with hepatitis C worldwide, and 6000 people are newly infected with viral hepatitis each day. Many people remain undiagnosed in many countries, and even when hepatitis is diagnosed, the number of people receiving treatment remains incredibly low. Although medicines are available at affordable prices, many countries are still not taking full advantage of these treatments because of policy, programmatic and access barriers. Similarly, many infants do not receive the hepatitis B birth dose vaccination along with at least two additional recommended doses, despite the low cost of this intervention. Funding for viral hepatitis remains limited – viral hepatitis accounts for nearly eight times as many prevalent infections as HIV, and yet the viral hepatitis response has less than one tenth of the funding.

This is the first consolidated WHO report on viral hepatitis epidemiology, service coverage and product access, with improved data for action. Building on previous WHO reports published in 2016, 2018 and 2020, this report presents the latest estimates on the disease burden and the coverage of essential viral hepatitis services from 187 countries across the world – versus estimates from 130 countries in 2019 and 42 countries in 2018. The report also updates progress made since 2019 in improving access to health products for both hepatitis B and C in low- and middle-income countries, with information from 38 countries that together comprise nearly 80% of global viral hepatitis infections and deaths – versus information on health products for hepatitis C in 12 countries in the 2020 report. The report provides a regional perspective, analysing the barriers and opportunities for countries in each of the six WHO regions to expand access to health products for viral hepatitis. It presents actions for countries and stakeholders to accelerate the scaling up of effective viral hepatitis interventions within a public health approach.

The report comes at a key inflection point for the viral hepatitis response. The COVID-19 response provides important lessons for a primary health care approach that can be applied to scale up the viral hepatitis response in low- and middle-income countries. Taking action in 2024–2026 to expand equitable access to viral hepatitis interventions will enable countries to regain the trajectory to achieve the Sustainable Development Goals - saving lives; preventing a future generation of new infections, cancers and deaths; and reducing costs. A transition to a public health approach is necessary to eliminate viral hepatitis by 2030.

Key findings of the report

1 Viral hepatitis is one of the communicable diseases for which deaths are increasing. About 1.3 million people died of viral hepatitis in 2022, similar to the number of deaths caused by tuberculosis. Viral hepatitis and tuberculosis were the second leading causes of death among communicable diseases in 2022, after COVID-19.

a. Improved data from 187 countries show that the estimated number of deaths from viral hepatitis increased from 1.1 million deaths in 2019 to 1.3 million in 2022. Hepatitis B caused 83% of these deaths and hepatitis C 17%. The increase in estimated mortality since 2019 suggests that the number of hepatitis-related cancer cases and deaths are increasing. Access to effective interventions must be urgently expanded to save lives and prevent a future generation of new infections, cancer cases and deaths.

b. The estimated number of people newly infected by viral hepatitis declined from 3 million in 2019 to 2.2 million in 2022. Of the 2.2 million new infections, 1.2 million were hepatitis B and nearly 1.0 million hepatitis C. The revised estimates largely reflect improved data from prevalence surveys. They also suggest that hepatitis B and C prevention, including immunization and safe injections, and the initial impact of expanding hepatitis C cure, have had an impact on reducing incidence. Strengthening viral hepatitis prevention, and making hepatitis C cure more widely available, are important for a sustainable response.

c. Overall, about 304 million people were living with viral hepatitis B and C in 2022. An estimated 254 million were living with hepatitis B and 50 million were living with hepatitis C. Half the burden of chronic hepatitis B and C infection is among people 30–54 years old; and men account for 58% of all cases. An estimated 12% of the burden is among children, in particular for hepatitis B. Hepatitis B and C affect the general population in many regions but also specific populations such as those at higher risk of or with a history of exposure through unsafe blood supplies, medical injections and other health procedures; newborns and children at risk through vertical (mother-to-child) transmission of hepatitis B, notably in settings with high hepatitis B prevalence; indigenous populations and mobile and migrant populations from countries with higher prevalence; and key populations, including people who inject drugs, people in prisons and other closed settings, sex workers and gay men and other men who have sex with men, who may be disproportionately affected in different contexts.

d. There is regional variation in the viral hepatitis burden and response. The WHO African Region accounts for 63% of new hepatitis B infections, and yet only 18% of newborns in the Region receive the hepatitis B birth-dose vaccination. The Western Pacific Region accounts for 47% of hepatitis B deaths, and treatment coverage remains low. Among high-income countries, the United States of America has an increasing burden of hepatitis C among people who use drugs. Innovative approaches are needed to expand prevention and treatment for hepatitis B and C in varying regional and country contexts.

e. The global response is off-track towards 2030 goals. If action is taken now, universal access to viral hepatitis interventions will have a major public health impact - reducing incidence by 90%, mortality by 65% and the costs of achieving global targets by 15%. The benefits of achieving global targets will be apparent by 2030, saving 2.85 million lives and averting 9.5 million new infections and 2.1 million cases of cancer. Looking towards 2050, this will save nearly 23 million lives and prevent nearly 53 million new viral hepatitis infections and 15 million cases of cancer. There is a window of action in 2024–2026 to regain the trajectory to achieve the Sustainable Development Goals. Based on a range of results obtained from several country investment case studies, there is an estimated return on investment of US$ 2–3 for every dollar invested to prevent liver cancer deaths and increasing costs of cancer treatment and care in the future.

2 The global coverage of viral hepatitis prevention, diagnosis and treatment is too low, and people living with viral hepatitis and their communities continue to bear the heavy burden of the epidemics.

a. Only 13% of people living with chronic hepatitis B infection had been diagnosed and close to 3% had received antiviral therapy at the end of 2022. Only 36% of people living with hepatitis C had been diagnosed between 2015 and 2022, and 20% had received curative treatment; highlighting the opportunity for better linkages between diagnosis and provision of care. Overall, almost 7 million people were receiving hepatitis B treatment at the end of 2022 and 12.5 million people have received hepatitis C curative treatment, far below the global targets for eliminating viral hepatitis by 2030.

b. Globally, in 2022, an estimated 45% of infants received a dose of the hepatitis B vaccine within 24 hours of birth. Coverage varies by region, ranging between 18% in the African Region - the WHO region with the highest prevalence of hepatitis B – and 80% in the Western Pacific Region.

c. The COVID-19 pandemic severely affected hepatitis services. Getting back on track to achieve the Sustainable Development Goals requires treating an estimated 40 million people with hepatitis B and curing an estimated 30 million people with hepatitis C by the end of 2026.

d. This report presents information on access to health products from 38 WHO focus countries for the viral hepatitis response, which together account for about 80% of the global disease burden of viral hepatitis B and C. Of these, 10 countries – China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines and the Russian Federation – account for nearly two thirds of the burden. Universal access to prevention, diagnosis and treatment in these countries by 2026, together with a special effort in the African Region, will enable the global response to regain the trajectory needed to achieve the Sustainable Development Goals.

3 Countries have developed national plans and adopted WHO guidelines for scaling up viral hepatitis testing and diagnosis in the public sector; however, implementation is variable, and testing uptake and the availability of diagnostics at decentralized levels are limited so far. Clear case-finding strategies with simplified algorithms and in vitro diagnostic medical devices (IVDs) could lead to wider access, lower costs and better linkage to care if accompanied by increased testing uptake and funding.

a. Most countries have now developed national testing plans, policies and strategies for viral hepatitis. More than 70% of the reporting WHO focus countries have a national viral hepatitis testing approach, and 60% of reporting countries have developed or are developing a costed national viral hepatitis testing approach or investment case for scaling up access to viral hepatitis testing. Nearly all reporting countries have a national viral hepatitis screening strategy for priority population groups, with three reporting countries giving priority to the entire adult population.

b. Incorporation of viral hepatitis IVDs into national lists of essential IVDs is limited; 50% of reporting WHO focus countries have added or are planning to add viral hepatitis diagnostics to their national essential diagnostics list.

c. Access to high-quality viral hepatitis testing services is expanding as national hepatitis programmes mature. More than half the reporting focus countries apply the reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval. Nearly 60% of the reporting focus countries implement post-market surveillance activities to ensure high-quality viral hepatitis testing.

d. Available data from partners indicate a public sector procurement price of about US$ 1 per test for hepatitis B surface antigen rapid diagnostic tests and between <US$ 1 and US$ 2 for hepatitis C rapid diagnostic tests. The total cost for hepatitis B virus nucleic acid testing in selected countries ranged between US$ 9 and US$ 62 in 2022; and for hepatitis C virus nucleic acid testing between US$ 6 and US$ 56 in 2023. The lack of funding for viral hepatitis programmes, including for IVDs, has restricted the scaling up of testing. About 75% of the reporting WHO focus countries rely primarily on government funding or out-of-pocket expenditures on viral hepatitis diagnostics.

e. Limited decentralization is a key limiting factor in scaling up testing services. Shortages in funding, policies and human resources have limited the uptake of hepatitis testing overall, including approaches such as self-testing, nucleic acid testing at- or near-to point-of-care, dried blood spot specimen implementation and community-based case-finding and screening approaches. Primary care and community settings have limited use of rapid diagnostic testing.

f. Although viral hepatitis testing remains largely centralized, countries report progress on implementing diagnostic integration across diseases and testing services: 60% of the reporting focus countries share nucleic acid testing platforms with other disease programmes and 80% share other related services, such as human resources.

4 Access to viral hepatitis treatment has not yet shifted to a public health approach. Countries have adopted WHO guidelines, but implementation lags behind and the availability of affordable and simplified regimens is limited, especially in primary health care.

a. Generic viral hepatitis medicines continue to be inexpensive, but too many countries are still not procuring medicines at these prices. The prices paid across and within WHO regions vary greatly, and many countries pay higher prices than global benchmarks, even if the drugs are off-patent, or if countries are included in voluntary licensing agreements or produce generic products locally. Viral hepatitis programmes can save considerable money if more low- and middle-income countries are able to purchase generic medicines at available benchmark prices.

   Although tenofovir disoproxil fumarate (TDF) for treatment of hepatitis B is off patent and available at a global benchmark price of US$ 2.4 per month, only seven of the 26 reporting countries paid prices at or below the benchmark. The lowest reported monthly treatment prices reported by countries ranged from US$ 1.22 for 30 tablets in China and India to US$ 34.20 for 30 tablets in the Russian Federation. When countries report the prices of multiple products, the range of prices paid can be much higher. In Viet Nam, the reported prices of generics range between US$ 2.1 and US$ 1849.6 for a monthly supply of a generic product. The Democratic Republic of the Congo reports US$ 108 for a monthly supply of the originator product.

   Similarly, although the price of generic hepatitis C medicines is declining, many reporting countries are still paying higher prices than the benchmark prices available through global pricing agreements. A 12-week course of pangenotypic sofosbuvir/daclatasvir (SOF/DAC) is available at a global benchmark price of US$ 60, yet only four of 24 reporting countries paid prices at or below the benchmark. The lowest reported price of SOF and DAC combined for a 12-week course of treatment was from Pakistan at about US$ 33 for a generic course of treatment; and the highest reported price was from China, at about US$ 10 000, with similar prices for generic and originator products.

   The lowest reported price of the SOF/DAC fixed-dose combination was from Nigeria, at US$ 60 for the 12-week course of treatment. Low-income countries continue to pay prices much higher than the benchmark price, such as US$ 1050 in the Democratic Republic of the Congo and US$ 481 in Cameroon for the SOF/DAC fixed-dose combination.

b. Patent-related barriers remain an obstacle to product access in several countries. Strategies such as voluntary licensing are enabling low, lower-middle and upper-middle income countries to access generic versions of patented medicines. In 2015, Medicines Patent Pool (MPP) and Bristol-Myers Squibb signed a voluntary license for DAC that covered 112 low- and middle-income countries. In 2020, following the withdrawal of any remaining filed and granted patents by Bristol-Myers Squibb in these countries, with the exception of the Russian Federation, generic DAC should be available for procurement in all such countries and in several high-income countries. This is effectively equivalent to a license expansion because generic manufacturers that had developed and obtained quality assurance for DAC are now able to supply it in these additional countries.

   For SOF and velpatasvir (VEL), the number of countries included in the voluntary licence of Gilead, signed in 2018, has remained unchanged, and some countries with a high burden of hepatitis C remain excluded - including China and the Russian Federation.

   In addition, MPP and AbbVie signed a voluntary licensing agreement for glecaprevir/pibrentasvir (G/P) in 2018. The license enables quality-assured manufacturers to develop and supply generic G/P to 96 low- and middle-income countries. Some countries with a high burden of hepatitis C, such as China, India and the Russian Federation, will not be able to procure generic G/P under this agreement as generic G/P becomes available under the license in the coming years.

c. Most WHO focus countries have included WHO-recommended viral hepatitis treatment regimens in national guidelines, but less than half report that these treatments are available in primary health care to enable simplified and decentralized service delivery to affected populations.

d. Product registration is lagging behind, including for medicines for children. Of 33 reporting countries, 28 (85%) have registered at least one product for TDF. Twenty-four countries (73%) have registered SOF and DAC (both or a fixed-dose combination or co-blistered); and among these, only four – Cambodia, Myanmar, Nigeria and Uganda – reported registering the SOF/DAC fixed-dose combination. Less than half the WHO focus countries have registered viral hepatitis medicines for children. Of 33 reporting countries, 13 countries have registered ETV to treat hepatitis B in children, and 12 countries have registered SOF and DAC to treat hepatitis C in children.

e. About 60% of reporting WHO focus countries offer viral hepatitis testing and treatment services free of charge, either fully or partly, in the public sector. Financial protection is lower in the African Region, where only about one third of reporting countries provide viral hepatitis services free of charge. As a result, many affected populations need to pay out of pocket for viral hepatitis services, which poses a financial barrier to access.

f. Local manufacturing is playing a critical role in expanding the availability of hepatitis medicines in all regions. Of 31 reporting WHO focus countries for which information on local production was available, 14 (including at least one country in each WHO region) manufacture TDF locally, and eight countries (including at least one country in all WHO regions except the African Region) manufacture SOF and/or DAC locally. In some countries with comparable data, such as Colombia and Viet Nam, locally produced generic medicines were less expensive than equivalent imported generic products. In other countries, such as Brazil, China and Morocco, locally produced generic medicines and equivalent imported generic products remain more expensive than global benchmark prices.

Looking ahead: 10 actions to advance a public health approach

Based on the analysis of country gaps and barriers at the end of 2023, this report identifies 10 key actions to advance a public health approach to viral hepatitis.

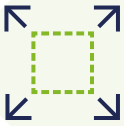
The actions are organized within the framework of the five strategic directions of the WHO global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 (*4*). Implementing these actions will be critical to advance the global health response towards the goal of the strategies to eliminate viral hepatitis by 2030.

Strategic Direction 1:
Deliver high-quality, evidence based, people-centred services

- **Action 1.** Testing: expand access to high-quality, affordable viral hepatitis testing and diagnostics services
- **Action 2.** Treatment: shift from policies to implementation for equitable access to viral hepatitis treatment and care
- **Action 3.** Prevention: strengthen investment in primary prevention of viral hepatitis to bridge the coverage gap in pregnancy, especially in Africa

Strategic Direction 2:
Optimize systems, sectors and partnerships for impact

- **Action 4.** Service delivery: simplify and decentralize the delivery of viral hepatitis services through a public health approach
- **Action 5.** Product regulation, procurement and supply: optimize product registration, procurement and supply, improve market transparency and support local production
- **Action 6.** Investment cases: develop investment cases in priority countries to rapidly shift to a public health approach
- **Action 7.** Financing: mobilize innovative financing from all sources



Strategic Direction 3:
Generate and use data to drive decisions for action

- **Action 8.** Data for action: use improved country data and strengthen country data systems and accountability for viral hepatitis

Strategic Direction 4:
Engage empowered communities and civil society

- **Action 9.** Community engagement: engage affected populations and civil society in the viral hepatitis response for advocacy and service delivery

Strategic Direction 5:
Foster innovations for impact

- **Action 10.** Innovation: advance the research agenda for viral hepatitis to improve diagnostics and work towards a hepatitis B cure

Strategic Direction 1: Deliver high-quality, evidence-based, people-centred services

Action 1. Testing: expand access to high-quality, affordable viral hepatitis testing and diagnostics services

Expanding access to viral hepatitis testing through people-centred and strategic approaches is the entry point to linking people to diagnosis and care. Countries should develop national viral hepatitis testing strategies with clear case-finding approaches and priorities if these are lacking and include viral hepatitis testing in universal health coverage packages. Strong political will is critical to give priority to viral hepatitis. Innovative solutions to support broader access to testing, including community-based screening approaches, dried blood spot for nucleic acid testing, in vitro diagnostic medical devices that can be used at- or near-to point-of-care and self-testing, should be considered. Diagnostic integration can reduce overall viral hepatitis programme costs for testing and maximize hepatitis-specific funding by improving efficiency.

Action 2. Treatment: shift from policies to implementation for equitable access to viral hepatitis treatment and care

The data show that most focus countries have included WHO-recommended viral hepatitis medicines in their national treatment guidelines, but the implementation of these guidelines is lagging behind, especially for medicines for children. Moving from policies to implementation requires countries to update national guidelines for adults, adolescents and children; include viral hepatitis medicines in national essential medicines lists; and train the general health-care workforce to support decentralization, integration and task shifting. Targeted approaches to expand treatment for vulnerable populations can be applied where prevalence is high, as shown in China. Eliminating out-of-pocket expenditure for viral hepatitis treatment and care is essential to expand treatment uptake and retention.

Action 3. Prevention: strengthen investment in primary prevention of viral hepatitis to bridge the coverage gap in pregnancy, especially in Africa

The incidence of viral hepatitis B and C remains high, and primary prevention needs to be strengthened further. Combining routine screening and antiviral prophylaxis for treating pregnant women with hepatitis B, along with the hepatitis B birth-dose vaccination for infants, will be critical to eliminate the mother-to-child transmission of viral hepatitis B, especially in regions such as sub-Saharan Africa with a high disease burden of hepatitis B. Strengthening linkage with maternal and child health services will enable countries to achieve triple elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus. It is equally important to increase coverage and integration of key viral hepatitis prevention services into existing health systems and services, including blood transfusion services, immunization programmes, national cancer programmes, HIV and sexually transmitted infection services and harm-reduction services for people who inject drugs.

Strategic Direction 2: Optimize systems, sectors and partnerships for impact

Action 4. Service delivery: simplify and decentralize the delivery of viral hepatitis services through a public health approach

An urgent transition to a public health approach is required to eliminate viral hepatitis in low- and middle-income countries. This transition should simplify service delivery protocols, integrate with primary health care and related health services, decentralize service delivery to lower-level health facilities by non-specialists and use community-based outreach. Expanding direct public health approaches to community prevention, testing and treatment, as shown by Egypt's successful public health programme to eliminate hepatitis C, can have a population-wide impact. The private sector should be engaged in the national response in countries in which it plays an important role in delivering health services for viral hepatitis.

Action 5. Product regulation, procurement and supply: optimize product registration, procurement and supply, improve market transparency and support local production

Countries can increase access to quality-assured medicines by registering and procuring WHO-prequalified products either nationally or through international procurement mechanisms. Greater market transparency is essential to enable low- and middle-income countries to access viral hepatitis products at the lowest possible prices that are available through global pricing agreements.

It is equally important for countries to be able to leverage available tools to address intellectual property barriers for patented direct-acting antiviral drugs for hepatitis C and use the off-patent status of TDF and entecavir for hepatitis B. Developing conducive ecosystems for producing health products locally can help to achieve sustainable supply of affordable, safe, effective and quality-assured health products. Support for strengthening regulatory capacity is important to ensure product safety, efficacy and quality.

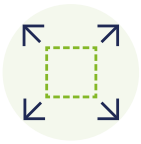
Action 6. Investment cases: develop investment cases in priority countries to rapidly shift to a public health approach

The public health response to viral hepatitis has been severely underfunded to date. Political action supported by investment cases for a public health approach are needed in 2024 and 2025 in the African Region and in the 10 countries that comprise nearly two thirds of the estimated global disease burden of viral hepatitis - China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines and the Russian Federation. Expanding access to viral hepatitis services in these countries by 2026 will enable the global response to regain the trajectory to achieve the Sustainable Development Goals. Investment cases will also inform strategic decision-making for impact and help to document returns on investment. WHO will also continue to support all countries in their path to elimination, especially the 38 focus countries that together represent 80% of the disease burden.

Action 7. Financing: mobilize innovative financing from all sources

It is essential to promote the inclusion of viral hepatitis services within essential health packages or national health insurance schemes in the context of universal health coverage, by unlocking additional funding specifically for viral hepatitis. This can be done by setting aside additional government funding and/or seeking support from national, regional and international funding partners where available, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, Gavi, the United States President's Emergency Plan for AIDS Relief, The Hepatitis Fund, and other innovative financing strategies or public-private partnerships. Based on results obtained from several country investment case studies, there is a return of US$ 2–3 dollars per dollar invested for hepatitis B and C interventions, and investments made now will result in declining costs before 2030. Other strategies to increase investments in viral hepatitis include optimizing the use of resources by integrating services, improving efficiency; and pursuing strategies to reduce prices.

Strategic Direction 3: Generate and use data to drive decisions for action



Action 8. Data for action: use improved country data and strengthen country data systems and accountability for viral hepatitis

This report provides improved global, regional and country data on the viral hepatitis burden and response. These data need to be utilized to support the scaling up of viral hepatitis services. Strengthening person-centred monitoring of prevention, testing and treatment of viral hepatitis services along the care cascade and improving disaggregated data analysis are important to capture different data components of viral hepatitis strategic information, analyse gaps and inform programme improvement. WHO has an important role to play by building on existing accountability frameworks of the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections to monitor and report on global progress.

Strategic Direction 4: Engage empowered communities and civil society

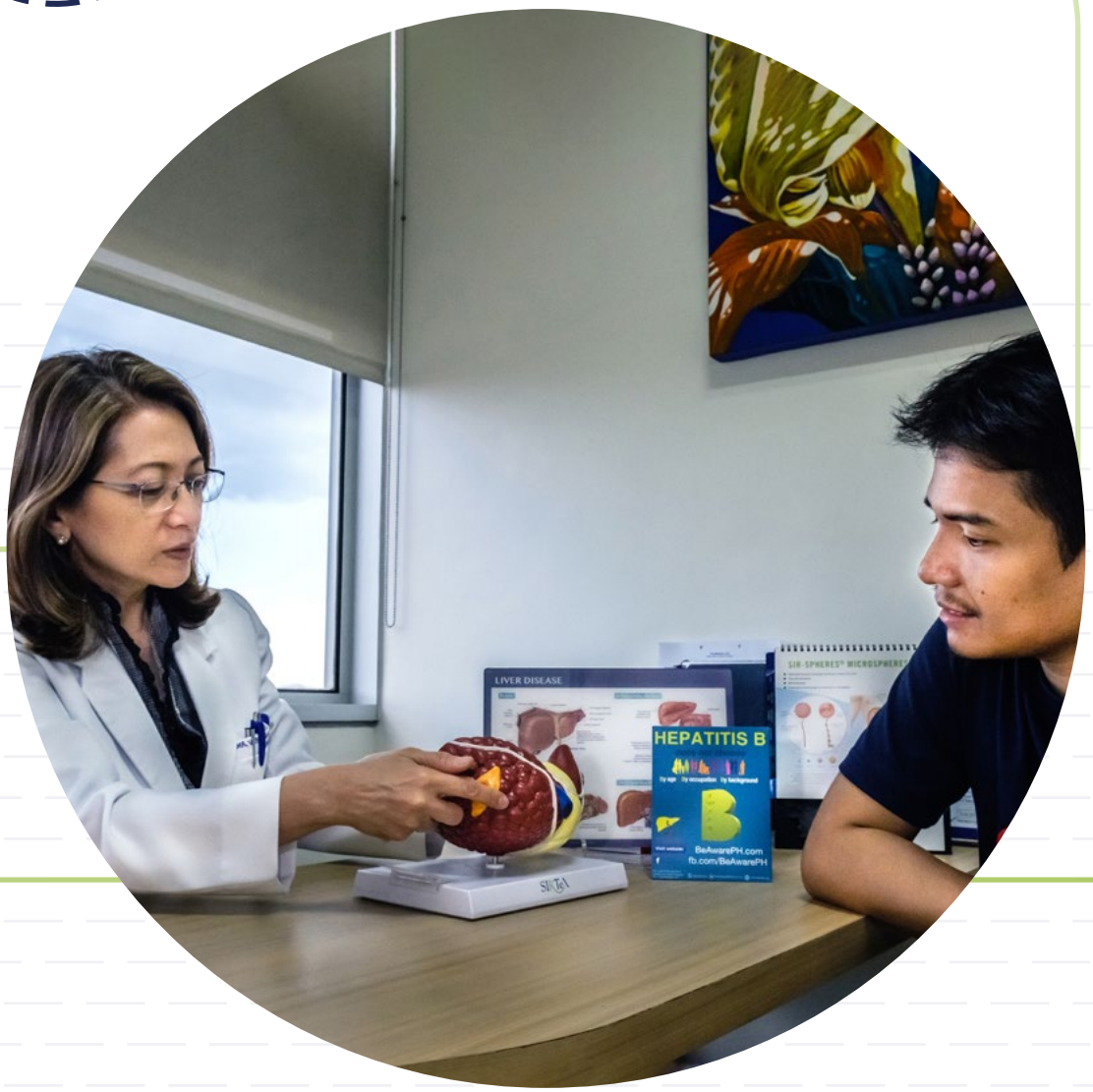
Action 9. Community engagement: engage affected populations and civil society in the viral hepatitis response for advocacy and service delivery

It is important to support and engage communities of people living with viral hepatitis and civil society organizations to play a central role in the viral hepatitis response, including in defining service delivery models to meet the needs of affected populations, addressing legal and policy barriers to access for these populations, raising awareness and engaging in advocacy, resource mobilization, policy-making, monitoring and evaluation and research.

Strategic Direction 5: Foster innovations for impact

Action 10. Innovation: advance the research agenda for viral hepatitis to improve diagnostics and work towards a hepatitis B cure

Research priorities for the viral hepatitis response include improved in vitro diagnostic medical devices and testing approaches for simplified, timely and accurate diagnosis of chronic hepatitis B and hepatitis C virus infections, including core antigen rapid diagnostic tests for hepatitis C virus; multiplex testing; and diagnostics for hepatitis D virus, including rapid diagnostic tests. Research on optimal doses and formulations of antiviral agents such as the development of long-acting therapy for hepatitis B and C virus infections; formulations for children; hepatitis C vaccine research; and hepatitis B cure research are equally critical over time. WHO has a key role to play in convening stakeholders to guide research priorities.



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1. Introduction

1. Introduction

The first consolidated WHO global report on viral hepatitis

For the first time, this report presents estimates on the disease burden and coverage of essential viral hepatitis services from 187 countries across the world – versus estimates from 130 countries in 2019 and 42 countries in 2018. The report also presents the status of access to health products for hepatitis B and C in 38 focus countries that together comprise nearly 80% of global viral hepatitis infections and deaths – versus information on access to health products for hepatitis C in up to 12 countries in previous reports in 2016, 2018 and 2020 *(1–3)*.

The report provides a baseline to monitor progress towards global hepatitis targets of the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 *(4)* (Box 1.1) and towards the health-related goals of the 2030 Agenda for Sustainable Development. It also contributes to monitoring progress towards other global health initiatives such as the WHO roadmap for access to medicines, vaccines and health products 2019–2023 *(5)* and the Immunization Agenda 2030 *(6)*. Advancing access to viral hepatitis services in low- and middle-income countries contributes to the goals of the WHO Thirteenth General Programme of Work 2019–2025 and the forthcoming WHO Fourteenth General Programme of Work 2025–2028, to promote, provide and protect the health and well-being of all people everywhere.

This report situates the response to viral hepatitis within the context of a rapidly evolving global health landscape, as countries face multiple health, humanitarian and environmental challenges that require collaborative efforts across stakeholders and sectors. By unpacking the various determinants of access to health products for viral hepatitis, the report aims to support decision-makers to address operational barriers and capitalize on opportunities to scale up access to these products. The report is a reminder of the importance of a primary health care approach to reduce the global burden of communicable diseases and to address the inequities in the coverage of essential health services, especially those faced by the world's most vulnerable people.

Box 1.1 Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 – strategic shifts to eliminate hepatitis B and hepatitis C as public health threats by 2030.

The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 *(4)* guide the health sector in implementing shared and disease-specific actions towards ending these epidemics and achieving the goals of the 2030 Agenda for Sustainable Development.

For viral hepatitis, the strategies recommend the following strategic and operational shifts to eliminate hepatitis B and C as public health threats by 2030:

- promoting greater public and political awareness of the importance of viral hepatitis B and C prevention, testing and treatment;
- allocating increased financial resources to hepatitis B and C, which may include external catalytic funding and domestic funding through including viral hepatitis prevention, testing and treatment as part of essential national health benefit packages;
- scaling up universal access to hepatitis B birth-dose vaccination and improved services for testing pregnant women for preventing the vertical (mother-to-child) transmission of hepatitis B;
- ensuring continued investment in primary prevention, including improved safety of medical injections and procedures, comprehensive prevention including harm reduction and other evidence-informed measures for people who use drugs and hepatitis B vaccination for infants and at-risk populations;
- substantially increasing access to hepatitis B and hepatitis C testing to reach people living with chronic hepatitis B virus (HBV) and hepatitis C virus (HCV) infection;
- substantially increasing treatment access by building on existing community- and health facility–based services;
- promoting simplified service delivery models that include decentralizing hepatitis B and C testing and treatment to lower-level health facilities, including primary care; integrating with other services, such as at harm-reduction and HIV services; and task sharing, with delivery of care and treatment by non-specialist doctors and nurses;
- addressing the barriers faced by populations most severely affected and at risk;
- strengthening community and civil society engagement and innovative partnerships; and
- advancing the research agenda, focusing on developing curative treatment strategies for hepatitis B and a preventive vaccine for hepatitis C.

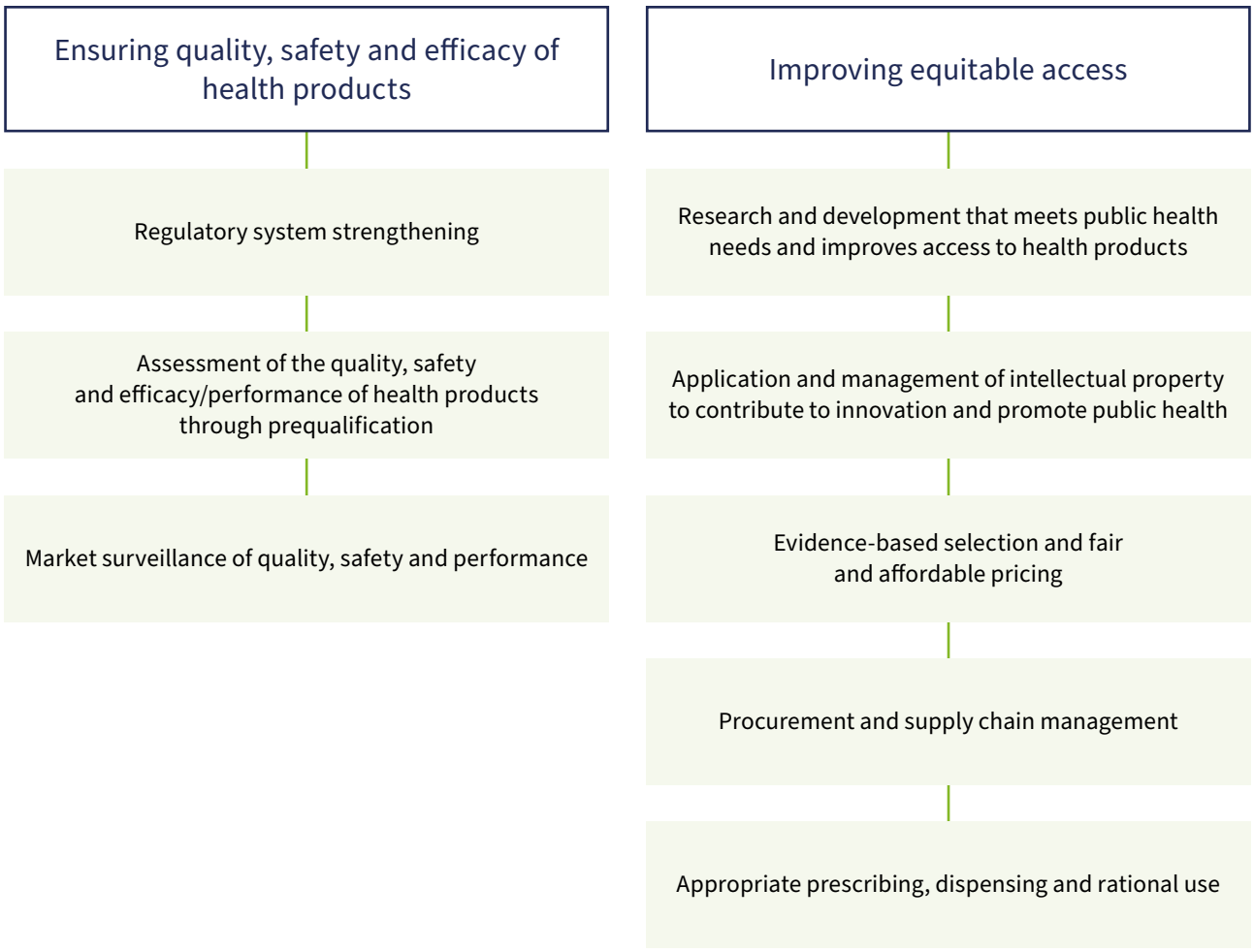
Framing the report – key determinants of access

This report analyses access to health products for hepatitis B and C within the framework of the right to health as a fundamental right to every human being, which requires that public health and health-care facilities, goods, services and programmes be available, accessible, acceptable and of high quality *(7)*.

Improving access to essential health products, especially in primary health care, depends on policies and strategies related to product selection, regulation, quality, pricing, procurement and supply and use of health products. This report aims to unpack the various dimensions of access, to support countries to make evidence-informed decisions to expand access to health products for viral hepatitis.

The report draws on the framework of the WHO roadmap for access to medicines, vaccines and health products 2019–2023 *(5)*, which outlines the principles of WHO's work on access to health products in two broad areas – ensuring the quality, safety and efficacy of health products and improving equitable access to these products (Fig. 1.1). Through this work, WHO aims to support countries in allocating resources more effectively to ensure that quality, safe, efficacious and cost-effective health products are included in a country's lists of essential medicines, in vitro diagnostic medical devices (IVD) or medicines eligible for reimbursement; in obtaining fair prices; in applying efficient procurement and supply processes; in promoting the rational use of medicines; and in reducing financial hardship associated with out-of-pocket health expenditure.

Fig. 1.1 WHO roadmap for access to medicines, vaccines and health products 2019–2023



Source: WHO roadmap for access to medicines, vaccines and health products 2019–2023 (5).

This report focuses on access barriers and opportunities in the public health sector in the WHO focus countries for the viral hepatitis response, to advance towards a public health approach to eliminating viral hepatitis. The private sector also plays a critical role in providing health care in many countries, and strong collaboration with the private sector is also critical to ensure that all health system actors work collectively towards public health goals to achieve universal health coverage.

Structure of the report

The report is organised as follows:

Chapter 1 presents the background to this report, its structure and key definitions.

Chapter 2 presents the global status of the viral hepatitis epidemics and analyses progress and gaps in impact and service coverage targets towards the goal of eliminating viral hepatitis by 2030.

Chapter 3 presents the global status of access to health products for viral hepatitis across the various dimensions of access, including product selection and use, quality and safety, pricing and intellectual property, procurement and local production.

Chapter 4 presents the status of access to health products for viral hepatitis by WHO region, with data for WHO focus countries for the viral hepatitis response.

Chapter 5 looks ahead with policy recommendations for key stakeholders including health ministries, technical partners, funding partners, civil society, industry and the research community.

Box 1.2 Focus on hepatitis B and C virus

There are five main strains of the hepatitis virus, referred to as types A, B, C, D and E. They all cause liver disease but differ in important ways, including modes of transmission, severity of illness, geographical distribution and prevention methods. In particular, hepatitis B and C lead to chronic disease for hundreds of millions of people and together are the most common cause of liver cirrhosis, liver cancer and hepatitis–related deaths. In particular, chronic viral hepatitis can lead to hepatocellular carcinoma, which accounts for 80% of all liver cancer cases and is the third most common cause of cancer deaths worldwide *(8)*.

This report focuses on HBV and HCV infections. Where relevant, it also addresses hepatitis D virus (HDV), which requires HBV for its replication. HDV and HBV coinfection is considered the most severe form of chronic viral hepatitis due to more rapid progression towards hepatocellular carcinoma and liver-related death. It is estimated that HDV affects nearly 5% of people globally who have a chronic infection with HBV and that HDV coinfection could explain about 20% of the cases of liver disease and liver cancer among people with HBV infection *(9)*.

Methods and data sources of the report

This report brings together data from multiple primary and secondary sources. The main data sources include the following.

Global Hepatitis Reporting System. The WHO Global Hepatitis Reporting System gathers data from all countries to monitor progress in global viral hepatitis targets towards eliminating viral hepatitis by 2030. In 2023, WHO invited countries to submit programme data on specified viral hepatitis indicators. Where programme data were not available, WHO provided WHO-validated partner estimates to countries for their validation. Data from 187 countries were received in total, including programme data submitted by countries, WHO estimates validated by countries, and other country-validated data submitted by WHO Regional Offices. Provisional estimates from the remaining WHO Member States were used to generate the overall global and regional estimates.

Country questionnaires on access to medicines and IVDs. In addition to the Global Hepatitis Reporting System, this report presents in-depth information on access to medicines, IVDs and vaccines from 38 WHO focus countries for the global viral hepatitis response (Box 1.3). Dedicated questionnaires on access to medicines and IVDs were sent to these focus countries in early 2023. By December 2023, information on medicines access was received from 33 countries and information on access to IVDs from 25 countries across the six WHO regions.

This is the first time that wide-ranging information on access to health products for hepatitis B and C was collected from 38 focus countries versus information on hepatitis C products in 12 countries in the previous report. The completeness of responses varied, and some analysis in this report may be based a small sample that is not fully representative of the global or regional picture. Efforts were made to present maximum data reported by national programmes through the questionnaires, and WHO will continue to work with countries to strengthen country-level data systems and reporting in the future.

Other WHO data on access to health products. The report also provides information related to viral hepatitis products from various other WHO sources, including the WHO Model List of Essential Medicines, the WHO Model List of Essential In Vitro Diagnostics and WHO databases on product prequalification and immunization, as indicated in the respective sections of the report.

Contributions from technical partners. The report reflects contributions from technical partners that gather and share information on specific dimensions of access to health products, such as market landscape information from the Clinton Health Access Initiative, data on the license status of health products from the Medicines Patent Pool (MPP) and information on innovations in viral hepatitis products and delivery from Unitaid.

Key informant interviews. The global response to viral hepatitis is supported by many multilateral and civil society organizations that play important roles in advocacy, policy development, service delivery, funding and commodity procurement and supply. The analysis of the report draws on qualitative input gathered from 15 scoping discussions and 17 key informant interviews held in 2023, representing technical expertise from international organizations, academic institutions and nongovernmental organizations engaged in the response to viral hepatitis.

Desk review. The report also includes information gathered through a desk review of publications from partner organizations, scientific literature and abstracts from scientific conferences related to viral hepatitis.

Box 1.3 WHO focus countries for the viral hepatitis response

Table 1.1 lists the 38 WHO focus countries for the viral hepatitis response. Together, these 38 countries account for nearly 80% of viral hepatitis infections and deaths and face unique challenges in their responses to the diseases (Table 1.2). The countries were selected based on a combination of epidemiological and other strategic and programmatic factors. The 38 countries represent diverse contexts in terms of their disease burden, sociopolitical situation, country commitment to the viral hepatitis response, innovative approaches in their national programmes and significant project sites. The list of countries includes large, populous countries where viral hepatitis elimination activities are integrated into broader efforts to expand universal health coverage; as well as smaller countries such as small island states and countries with concentrated epidemics among key populations, which can tailor approaches to progress on the path to elimination.

Viral hepatitis may also place a relatively significant burden of disease among specific populations or geographies in countries beyond these 38 focus countries. All countries should make full use of available opportunities to expand access to viral hepatitis prevention, testing and treatment for populations in need. WHO continues to provide support to all countries worldwide in their efforts towards the goal of eliminating viral hepatitis.

Table 1.1 WHO focus countries for the viral hepatitis response, by WHO region

African Region	European Region
Cameroon	Georgia
Côte d'Ivoire	Kyrgyzstan
Democratic Republic of the Congo	Republic of Moldova
Ethiopia	Russian Federation
Ghana	Ukraine
Nigeria	Uzbekistan
Rwanda	
South Africa	
Uganda	
United Republic of Tanzania	
Region of the Americas	**Eastern Mediterranean Region**
Brazil	Egypt
Colombia	Morocco
Mexico	Pakistan
Peru	Sudan
	Yemen
South-East Asia Region	**Western Pacific Region**
Bangladesh	Cambodia
India	China
Indonesia	Lao People's Democratic Republic
Myanmar	Mongolia
Thailand	Niue
	Philippines
	Vanuatu
	Viet Nam

Table 1.2. Distribution of viral hepatitis disease burden in 38 focus countries by WHO region, 2022

WHO region	Number of WHO focus countries for the viral hepatitis response, by WHO region	Percentage of total viral hepatitis infections among focus countries, by WHO region (%)			Percentage of new viral hepatitis infections among focus countries, by WHO region (%)			Percentage of hepatitis-related deaths among focus countries, by WHO region (%)		
		HBV	HCV	Total	HBV	HCV	Total	HBV	HCV	Total
African Region	10	58	52	57	66	51	63	56	53	55
Region of the Americas	4	32	30	31	19	8	9	35	40	39
South-East Asia Region	5	96	95	96	94	95	95	96	95	96
European Region	6	34	62	47	69	74	74	47	68	56
Eastern Mediterranean Region	5	53	87	68	44	76	66	45	89	67
Western Pacific Region	8	96	81	95	82	90	86	97	67	95
Global	38	80	72	79	71	65	68	82	70	80

Source: Global Hepatitis Reporting System, WHO.

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2.

Global progress towards impact

2. Global progress towards impact

This chapter presents the global status of the epidemics of hepatitis B and C and the coverage of diagnosis and treatment services. It also presents forecasts for service coverage and cost scenarios to 2025 and 2030 to achieve the goals of the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030.

Key findings

1 Improved data from 187 countries shows that viral hepatitis is a major public health challenge of this decade. An estimated 1.3 million people died from viral hepatitis in 2022, and viral hepatitis is one of the communicable diseases for which mortality is increasing. Of the 1.3 million deaths, hepatitis B caused 1.1 million deaths and hepatitis C 240 000 deaths. High-impact interventions are available, such as an effective cure for hepatitis C and vaccines for hepatitis B, but access to these interventions must be urgently expanded to save lives and prevent a future generation of new infections, cancers and deaths.

2 An estimated 254 million people are living with hepatitis B and 50 million people are living with hepatitis C. The estimated number of people newly infected by viral hepatitis declined from 3 million in 2019 to 2.2 million in 2022. Of these, 1.2 million are hepatitis B infections and nearly 1.0 million are hepatitis C infections. The revised estimates largely reflect improved data from prevalence surveys. They also suggest that hepatitis B and C prevention, including immunization and safe injections, and the initial impact of expanding hepatitis C cure, have had an impact on reducing incidence. Strengthening viral hepatitis prevention, and making hepatitis C cure more widely available, are important for a sustainable response.

3 Only 13% of people living with chronic hepatitis B infection had been diagnosed and close to 3% had received antiviral therapy at the end of 2022. Only 36% of people living with hepatitis C had been diagnosed between 2015 and 2022, and 20% had received curative treatment, highlighting the opportunity for better linkage between diagnosis and provision of care. Overall, almost 7 million people were receiving hepatitis B treatment at the end of 2022 and 12.5 million people have received hepatitis C curative treatment, far below global targets.

4 There is regional variation in the viral hepatitis burden and response. The WHO African Region accounts for 63% of new hepatitis B infections, but only 18% of newborns in the Region receive the hepatitis B birth-dose vaccination. The Western Pacific Region accounts for 47% of hepatitis B deaths, and treatment coverage remains low. Among high-income countries, the United States of America has an increasing burden of hepatitis C among people who use drugs. Innovative approaches are needed to expand prevention and treatment for hepatitis B and C in varying regional and country contexts.

5 Ten countries account for nearly two thirds of the global burden of viral hepatitis B and C: China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines and the Russian Federation. Scaling up prevention and treatment in these countries by 2026, together with a special focus on the African Region, will enable the global response to regain the trajectory needed to achieve the Sustainable Development Goals.

6 Results obtained from several country investment case studies suggest that the estimated return on investment is US$ 2-3 for every dollar invested, to prevent a generation of liver cancer deaths and increasingly costly cancer treatment and care.[1] If action to eliminate hepatitis C is taken now, incidence will decline by 90%, mortality by 65% and the costs of achieving global targets by 15% by 2030. The benefits of achieving global goals will be apparent by 2030, saving 2.85 million lives and averting 9.5 million new viral hepatitis infections and 2.1 million cases of cancer. Towards 2050, this will save nearly 23 million lives and prevent nearly 53 million new viral hepatitis infections and 15 million cases of cancer.

2.1 Disease burden

Viral hepatitis is one of the communicable diseases for which deaths are increasing. About 1.3 million people died of viral hepatitis in 2022, similar to the number of deaths caused by tuberculosis.[2] Viral hepatitis and tuberculosis were the second leading causes of death among communicable diseases in 2022, after COVID-19 *(10)*.

The disease burden estimates in this report are based on a major increase in the availability of viral hepatitis data from countries across the world enabled by collaborative efforts (Box 2.1).

Box 2.1 Global Viral Hepatitis Data Collaborative

In 2023, WHO convened the Global Viral Hepatitis Data Collaborative, bringing together key international partners engaged in strengthening strategic information for viral hepatitis. The main objectives of the meeting included aligning approaches towards validated disease burden estimates for HBV and HCV and strengthening collaboration to provide harmonized technical assistance to countries to strengthen viral hepatitis data systems. The Collaborative supported the development of the epidemiological estimates for this report. WHO plays a convening role in the Collaborative to coordinate the efforts of various stakeholders, share methods and results, identify and address gaps and promote synergy.

Among the partners of the Collaborative, the CDA Foundation plays a key role in supporting countries to triangulate data conduct disease burden and economic impact assessment for the viral hepatitis response and contribute to the WHO Global Hepatitis Reporting System. The CDA Foundation hosts the Polaris Observatory, an online database of epidemiological and disease-burden data for HBV and HCV, along with a database of publications to support the elimination of HBV and HCV globally by 2030. The CDA Foundation has worked with various countries to develop cost–effectiveness analysis for the viral hepatitis response, including Egypt, Mexico, South Africa, Türkiye and Uzbekistan.

Progress towards global targets. Table 2.1 summarizes overall progress towards the viral hepatitis targets of the global health sector strategies for, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030.

[1] Return on investment estimates obtained from several country investment case studies conducted in Cameroon, Ghana, Malaysia, Morocco, the Philippines, Uganda and Viet Nam *(91)*. Across these countries, the estimated return on investment ranged between a US$ 1.7 and US$ 3.34 return for every US$ 1 invested in an elimination scenario compared to a baseline "business as usual" scenario over the period 2020-2035, with variation by country. The return on investment is calculated by estimating the direct healthcare cost averted from the perspective of the health care system.

[2] Global Health Estimates, World Health Organization, 2019 *(92)*. Viral hepatitis is a determinant and cause of death, specially for liver cirrhosis.

Table 2.1. Progress towards global viral hepatitis targets, 2022

Indicator	Baseline – 2020	Progress – 2022	Targets – 2025	Targets – 2030
		Impact		
Number of new hepatitis B infections per year	1.5 million (1.11 million–2.09 million) 20 per 100 000 population	**1.23 million (0.81 million–1.53 million)** **16 per 100 000 population**	0.85 million (0.62 million–1.19 million) 11 per 100 000 population	170 000 (120 000–240 000) 2 per 100 000 population
Number of new hepatitis C infections per year	1.575 million (0.76 million–1.9 million) 20 per 100 000 population	**1.0 million (0.76 million - 1.34 million)*** **13 per 100 000 population**	1.0 million (0.49 million–1.26 million) 13 per 100 000 population	350 000 (170 000–420 000) 5 per 100 000 population
Percentage of people who inject drugs with new hepatitis C infections per year	8%	**9%**	3%	2%
Number of people dying from hepatitis B per year	0.82 million (0.56 million–1.23 million) 10 per 100 000 population	**1.10 million (0.88 million–1.74 million)** **14 per 100 000 population**	530 000 (360 000–800 000) 7 per 100 000 population	310 000 (210 000–470 000) 4 per 100 000 population
Number of people dying from hepatitis C per year	290 000 (200 000–350 000) 5 per 100 000 population	**240 000 (197 000–288 000)** **3 per 100 000 population**	240 000 (110 000–210 000) 3 per 100 000 population	140 000 (60 000–120 000) 2 per 100 000 population

Table 2.1. Progress towards global viral hepatitis targets, 2022 (continued)

Indicator	Baseline – 2020	Progress – 2022	Targets – 2025	Targets – 2030
Coverage				
Hepatitis B: percentage of people living with chronic hepatitis B diagnosed	10% against a target of 30%	**13.4%**	60%	90%
Percentage of people living with chronic hepatitis B treated	2% against target of 30%	**2.6%**	50%	80%
Hepatitis C: percentage of people living with hepatitis C diagnosed	21% against a target of 30%	**36.4%**	60%	90%
Percentage of people living with hepatitis C treated	13% against a target of 30%	**20%**	50%	80%
Percentage of newborns who have benefitted from a timely birth dose of hepatitis vaccine and from other interventions to prevent the vertical (mother-to-child) transmission of hepatitis B virus	43% against a target of 50%	**45%**	70%	90%
Hepatitis B vaccine coverage among children (third dose)	85% against a target of 90%	**84%**	90%	90%
Number of needles and syringes distributed per person who injects drugs	33 against a target of 200	**35**	200	300
Blood safety: proportion of blood units screened for bloodborne diseases	97% against a target of 95%	**97%**	100%	100%
Safe injections: proportion of safe health-care injections	96% against a target of 95%	**96%**	100%	100%

* Hepatitis C incidence is based on significantly new data from key countries. This data will also affect and reduce the baseline and mean that the decline is less significant than shown. The trendline will need to be recalculated as part of the 2026 review of the Global health sector strategies 2022-2030 *(4)*.

Fig. 2.1 and 2.2 show trends in mortality and incidence of hepatitis B and C respectively, in relation to the 2015 baseline of the first Global Health Sector Strategy on Viral Hepatitis 2016-2021, the baseline in 2020, and targets for 2025 and 2030. The sections below further describe the progress towards the key impact and coverage indicators.

Fig. 2.1. Trends in incidence and mortality of hepatitis B, 2015–2030

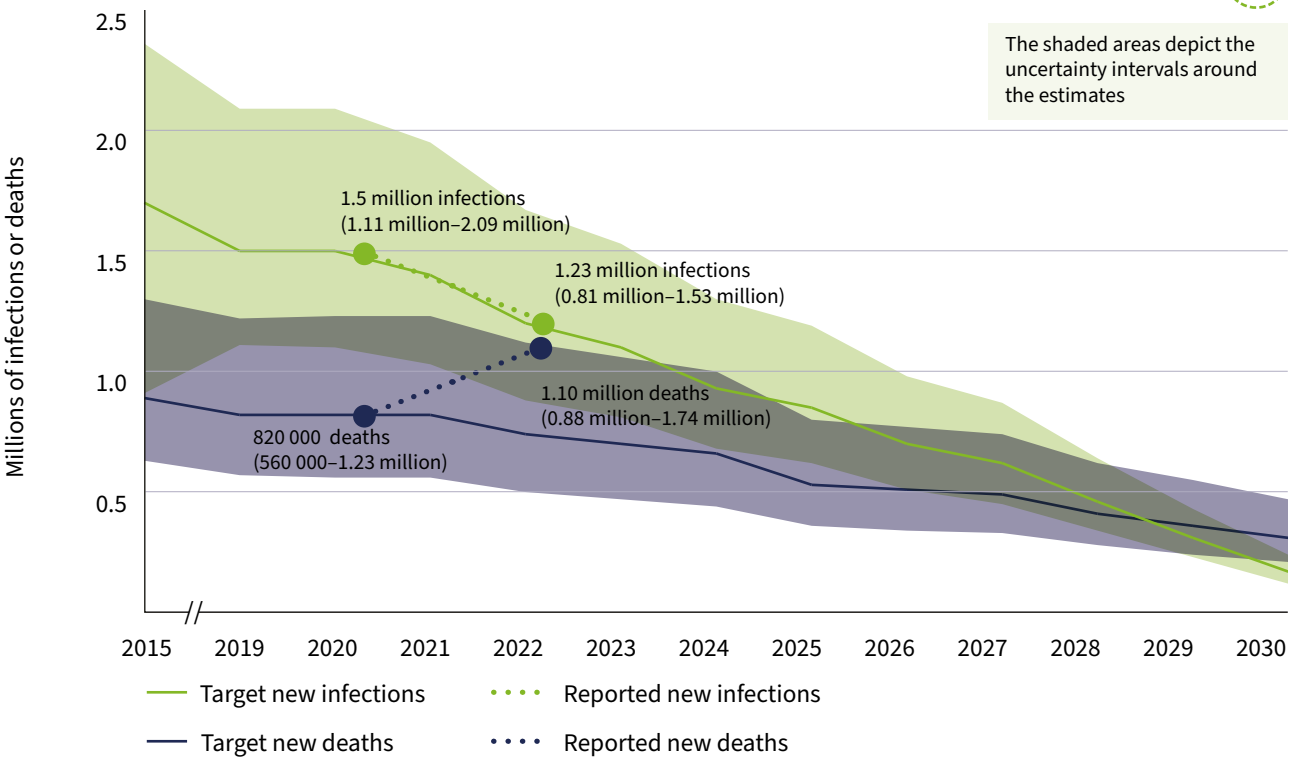
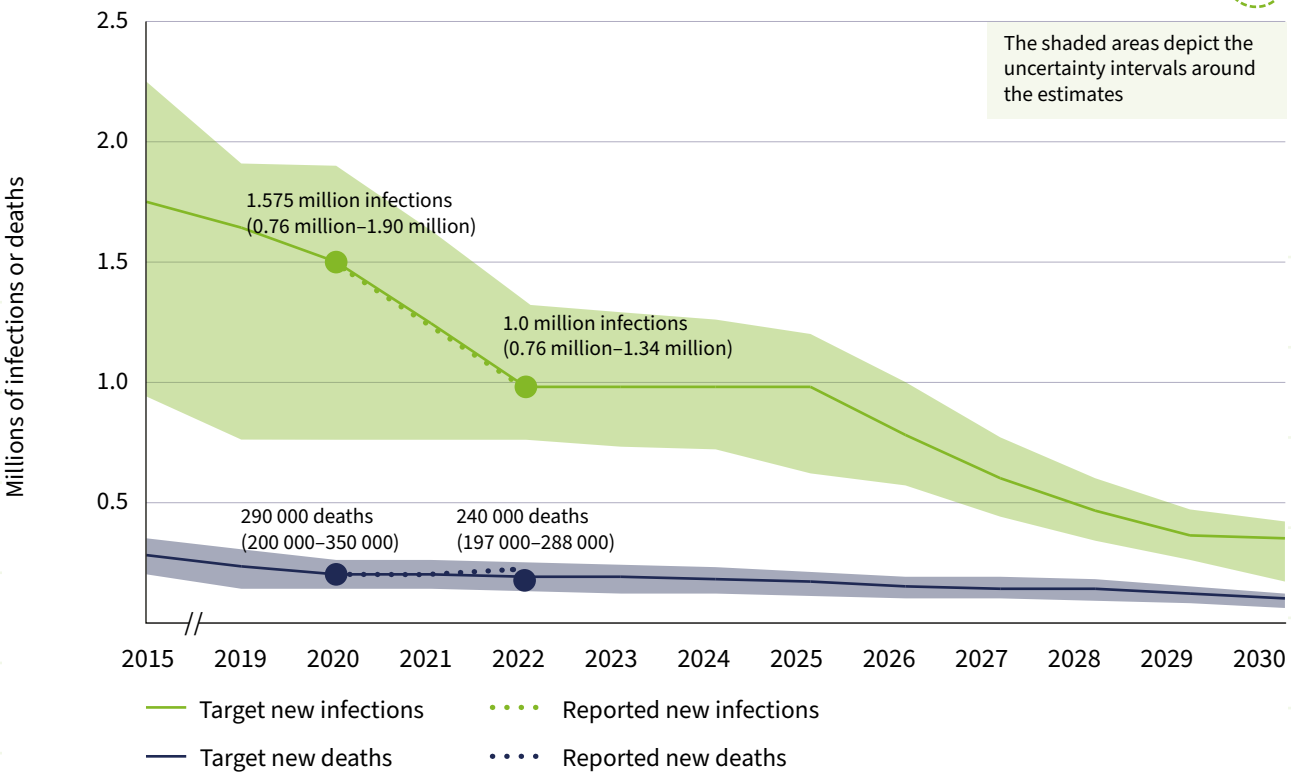


Fig. 2.2. Trends in incidence and mortality of hepatitis C, 2015–2030



Incidence. There were 2.2 million new viral hepatitis infections in 2022, including 1.2 million new HBV infections and nearly 1.0 million new HCV infections, versus 3 million new infections in 2019. The revised estimates of new viral hepatitis infections are based on improved data from national prevalence surveys, such as from China, which were incorporated into the global estimates. They also suggest that hepatitis B and C prevention, including immunization and safe injections, and the initial impact of expanding hepatitis C cure, have had an impact on reducing incidence. The decline in incidence underscores the importance of prevention interventions, and access to hepatitis C treatment, for a sustainable response to viral hepatitis.

An analysis of new hepatitis C infections shows the importance of three major transmission routes: injecting drug use, unsafe medical injections and unsafe medical and non-medical practices and injections (Box 2.2).

Box 2.2. Contribution of injection drug use and unsafe medical injections to the transmission of hepatitis C virus

The incidence of hepatitis C is difficult to measure, but estimates are improving. In 2023, WHO collaborated with the University of Bristol to review and update country, regional and global estimates of the contribution of injecting drug use and unsafe medical injections to hepatitis C transmission. The proportion of new hepatitis C infections attributed to each risk exposure at the country level was estimated based on *(i)* new hepatitis C infections attributed to injecting drug use at the country level; *(ii)* new hepatitis C infections attributed to unsafe medical injections and *(iii)* WHO estimates of total incident country-level hepatitis C infections for 2019.

The analysis showed three important transmission routes for hepatitis C. The sharing of equipment among people who inject drugs accounts for the largest number of new hepatitis C infections in the world. In addition, unsafe medical injections as well as other unsafe medical and non-medical practices and injections are also an important source of hepatitis C infection.

Sharing of injection material in the context of injecting drug use:

The estimated incidence of hepatitis C among people who inject drugs was derived from data from 1995 to 2020 for 105 countries. Unsafe injecting drug use practices are estimated to contribute 43.6% (33.9% – 52.5%) of new hepatitis C infections globally. Table 2.2 shows projections for the population-size weighted hepatitis C incidence among people who inject drugs and the contribution of injecting drug use to hepatitis C incidence by WHO region. A sensitivity analysis that used data from 2015 onwards only did not show any substantial changes in these estimates.

Table 2.2. Hepatitis C incidence among people who inject drugs (1995–2020) and the contribution of injecting drug use to total hepatitis C incidence, by WHO region

WHO region	Number of countries included	Population-size weighted hepatitis C incidence rate per 100 person-years	Contribution of injecting drug use to new hepatitis C infections
African Region	13/50 (26%)	2.1 (1.3–3.2)	13.5% (10.9–15.6%)
Region of the Americas	9/39 (23%)	14.3 (10.9–18.2)	92.4% (91.3–93.4%)
South-East Asia Region	8/11 (73%)	11.7 (9.9–13.7)	35.4% (28.8–43.4%)
European Region	50/51 (98%)	14.8 (12.5–17.3)	72.9% (58.3–78.6%)
Eastern Mediterranean Region	13/22 (59%)	7.9 (6.8–9.2)	7.9% (6.6–9.4%)
Western Pacific Region	12/27 (44%)	15.8 (13.2–18.9)	90.4% (87.7–91.7%)
Global	105/200 (52%)	12.2 (10.8–13.9)	43.6% (33.9%–52.5%)

Based on this analysis, ten countries are estimated to account for nearly 80% of all global hepatitis C infections among people who inject drugs. These 10 countries, in descending order of absolute numbers of hepatitis C infections among people who inject drugs, are: United States of America, China, Russian Federation, India, Ukraine, Italy, Viet Nam, Kazakhstan, Japan and Pakistan. Efforts to expand access to evidence-informed harm-reduction interventions and to hepatitis C testing and treatment in these countries is essential to reduce new hepatitis C infections worldwide. In addition, this will also reduce the costs of the global hepatitis response, given the high costs of hepatitis C treatment in countries with a large disease burden and high costs of hepatitis C medicines, such as China, or in high-income countries such as the United States of America.

Unsafe medical injection:

The estimated contribution of unsafe medical injections to hepatitis C transmission was derived from data in 60 countries that represent about 45% of the world's population. Unsafe medical injections are estimated to contribute 13.8% (8.8––19.8%) of new hepatitis C infections globally, with regional variation (Table 2.3). Pakistan accounts for 44% of all new hepatitis C infections attributed to unsafe medical injections in these 60 countries. These infections can be prevented through safer medical injection practices at all levels of health systems.

There are some uncertainties in these estimates. Uncertainty in the estimated contribution of injecting drug use is driven by potentially unprecise estimates of the population size of people who inject drugs, different population groups of people who inject drugs included in various studies and limited empirical incidence measurements in recent years. Uncertainty in the estimated contribution of unsafe medical injections is driven by limited data from low- and middle-income countries on medical injections and their safety and limited data on the probability of hepatitis C transmission during unsafe medical injections.

The analysis also highlights that additional unsafe medical and non-medical practices are an important source of hepatitis C transmission. There is a clear need to improve surveillance systems for hepatitis C and to better understand this third transmission route in order to design effective hepatitis C prevention responses.

Table 2.3. Contribution of unsafe medical injections to new hepatitis C infections, by WHO region, 2023

WHO region	Number of countries included	Contribution of unsafe medical injections to new hepatitis C infections
African Region	35	5.0% (3.2–7.5%)
Region of the Americas	7	4.0% (2.4 –6.2%)
South-East Asia Region	7	21.2% (13.8–30.0%)
European Region	5	17.9% (10.9–27.3%)
Eastern Mediterranean Region	3	14.3% (9.0–20.4%)
Western Pacific Region	3	6.1% (3.8–9.4%)
Global	60	13.8% (8.8–19.8%)

Mortality. Viral hepatitis–related deaths increased from 1.1 million in 2019 to 1.3 million in 2022. Hepatitis B causes an estimated 1.1 million deaths (83% of all viral hepatitis deaths) and hepatitis C 240 000 deaths (17% of all viral hepatitis deaths). The increase in the number of hepatitis B–related deaths from 820 000 in 2019 to 1.1 million in 2022 can be attributed to various factors, including the ageing of the population cohort with hepatitis B infection and COVID-19-related disruptions that slowed down the scale-up of treatment access in many low- and middle-income countries. The estimated decline in hepatitis C mortality from 290 000 in 2019 to 240 000 in 2022 is largely due to improved data from prevalence surveys, together with initial evidence of progress in hepatitis C cure.

Prevalence. There were an estimated 254 million prevalent hepatitis B infections and 50 million prevalent hepatitis C infections worldwide in 2022. Half the burden of chronic hepatitis B and C is among people 30–54 years old and 12% among children under 18 years of age. Men account for 58% of all cases.

The lower prevalence of hepatitis C compared with previous estimates suggests a modest impact of providing simplified and decentralized hepatitis C treatment to 12.5 million people between 2015 and 2022. For hepatitis B, improved data, especially the recent hepatitis B national seroprevalence survey in China, have enabled greater accuracy in the global figures that largely account for the lower hepatitis B prevalence estimate of 254 million. The revised estimates also suggest the impact of prevention interventions, including vaccination for hepatitis B.

Regional variation. The regional distribution of viral hepatitis B and C varies (Tables 2.4 and 2.5, Fig. 2.3 and 2.4).

About 5% of the general population in the WHO African Region and Western Pacific Region are living with hepatitis B. In the European Region and the Region of the Americas, this prevalence is about 1%.

Among children younger than five years, the hepatitis B prevalence is less than 1% in all regions except the African Region. The African Region accounts for 63% of all new hepatitis B infections, highlighting the importance of a focus on scaling up access to viral hepatitis services in Africa, including the hepatitis B birth-dose vaccination and hepatitis B treatment among pregnant women (Box 2.3). An additional 22% of new hepatitis B infections occur in the South-East Asia Region, showing the importance of these two regions in the global response.

The Western Pacific Region accounts for 47% of the nearly 1.1 million deaths from hepatitis B. Rapid scale-up of treatment is therefore critical in this Region to prevent many hepatitis B–related cancer cases and deaths in the future, despite the success of vaccination and prevention efforts. A further 20% of deaths occur in the South-East Asia Region and 25% in the African Region.

As a result of the success of Egypt's countrywide public health programme to eliminate hepatitis C, the Region accounts for only 19% of global hepatitis C–related deaths. However, other countries in the Region show increasing hepatitis C incidence. The prevalence of hepatitis C in the Eastern Mediterranean Region remains high at 1.8%, the only region with a prevalence above 1%. This represents 11.7 million hepatitis C infections, or 23% of the global total. This is followed by 9.1 million hepatitis C infections in the South-East Asia Region, or 18.5% of the global total. All other regions have significant numbers of hepatitis C infections, between 5 and 7 million, and account for 55% of the global total.

Table 2.4. Incidence and mortality of hepatitis B and C virus by WHO region, 2022

WHO region	Incidence		Mortality	
	New hepatitis B infections	New hepatitis C infections	Number of deaths caused by hepatitis B	Number of deaths caused by hepatitis C
African Region	771 000	172 000	272 000	35 000
Region of the Americas	8 000	176 000	20 000	38 000
South-East Asia Region	266 000	225 000	218 000	42 000
European Region	18 000	126 000	32 000	21 000
Eastern Mediterranean Region	86 000	183 000	41 000	65 000
Western Pacific Region	83 000	98 000	518 000	43 000

Source: Global Hepatitis Reporting System, WHO.

Table 2.5. Prevalence of hepatitis B and C virus infection by WHO region, 2022

WHO region	Prevalence of chronic viral hepatitis B among the general population (%)	Prevalence of chronic viral hepatitis C among the general population (%)	Total hepatitis B infections (all ages)	Total hepatitis C infections (all ages)
African Region	5.8	0.7	64 700 000	7 800 000
Region of the Americas	0.5	0.5	5 000 000	5 300 000
South-East Asia Region	3.0	0.5	61 400 000	9 100 000
European Region	1.2	0.9	10 600 000	8 600 000
Eastern Mediterranean Region	2.1	1.8	15 100 000	11 700 000
Western Pacific Region	5.0	0.4	96 800 000	7 100 000

Source: Global Hepatitis Reporting System, WHO.

Fig. 2.3 and 2.4 show the prevalence of hepatitis B and C in 2022 by WHO region. The estimates have significant uncertainty limits, especially on the upper range.

Fig. 2.3. Prevalent cases of chronic hepatitis B by WHO region, 2022

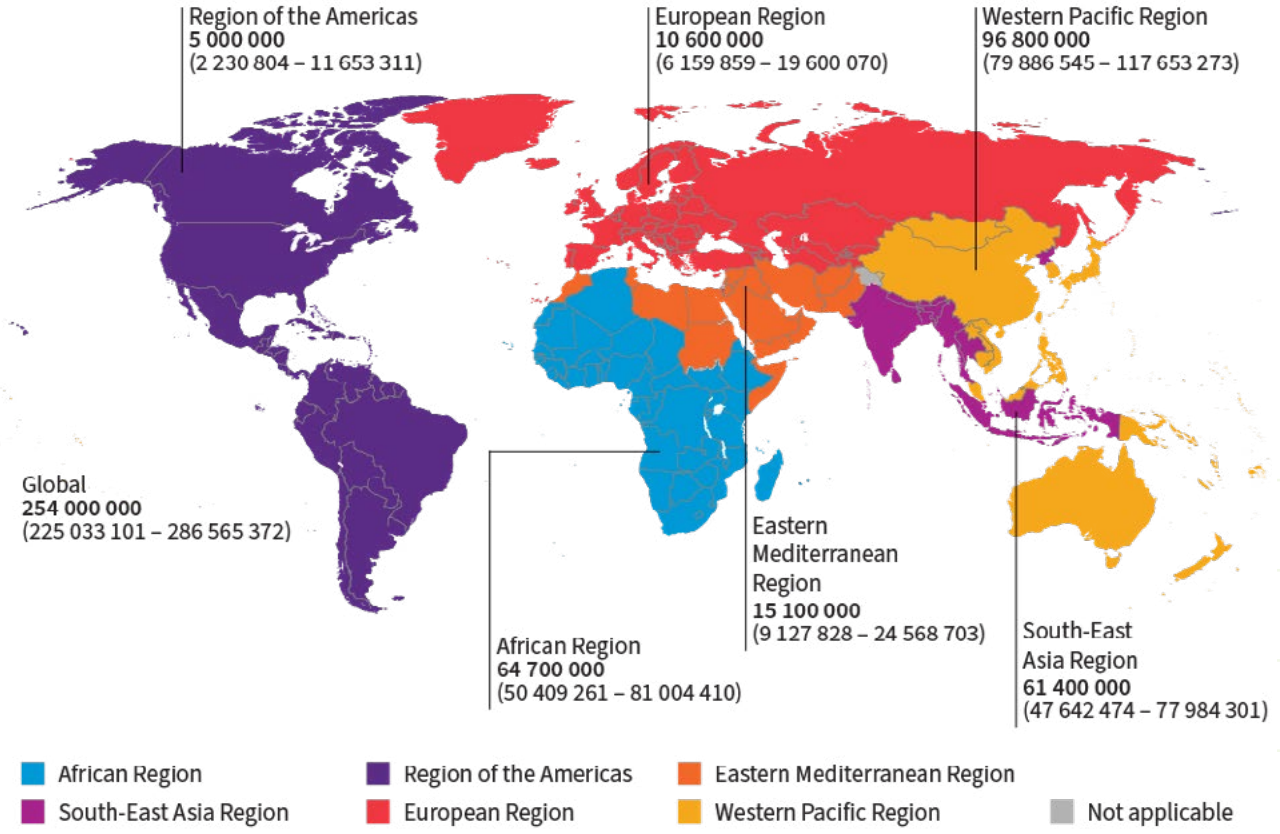
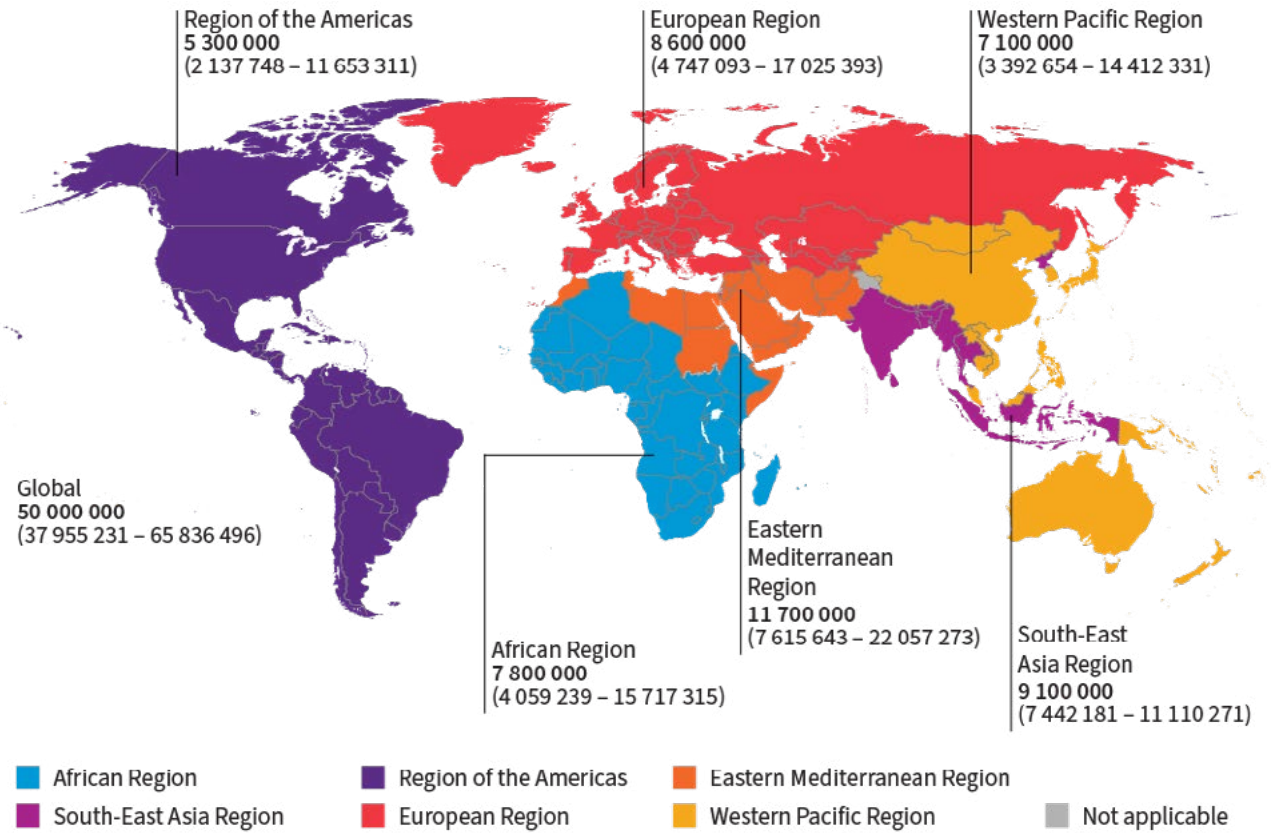


Fig. 2.4 Prevalent cases of chronic hepatitis C by WHO region, 2022



The data also show a concentration of infection in certain WHO regions and countries, which provides opportunities for focused global action. Together, 10 countries represent nearly two thirds of the burden of hepatitis B and C combined (Table 2.6). For hepatitis B, three countries – China, India and Indonesia – represent 50% of the global burden in 2022; and nine countries represent about two thirds of the global burden (Table 2.7). For hepatitis C, six countries – China, India, Indonesia, Pakistan, Russian Federation and United States of America – represent 50% of the global burden; and 15 countries represent about two thirds of the global burden (Table 2.8). Progress in these countries is critical to the global response.

Table 2.6. Countries that represent two thirds of the global disease burden of hepatitis B and C combined, 2022

Country	Total hepatitis B infections (all ages)	Total hepatitis C infections (all ages)	Total hepatitis B + hepatitis C infections (all ages)	Proportion of total hepatitis B + hepatitis C infections(%)
China	79 700 000	4 000 000	83 700 000	27.5
India	29 800 000	5 500 000	35 300 000	11.6
Indonesia	17 500 000	1 400 000	18 900 000	6.2
Nigeria	14 400 000	1 350 000	15 700 000	5.2
Pakistan	3 800 000	8 800 000	12 600 000	4.2
Ethiopia	7 700 000	692 000	8 400 000	2.7
Bangladesh	7 200 000	1 020 000	8 300 000	2.7
Viet Nam	6 500 000	900 000	7 400 000	2.4
Philippines	5 700 000	400 000	6 100 000	2.0
Russian Federation	1 700 000	2 700 000	4 300 000	1.4

Source: Global Hepatitis Reporting System, WHO.

Table 2.7. Countries that represent two-thirds of the global disease burden of hepatitis B, 2022

Country	Total hepatitis B infections (all ages)	Proportion of total hepatitis B infections (%)
China	79 700 000	31.5
India	29 800 000	11.7
Indonesia	17 500 000	6.9
Nigeria	14 400 000	5.7
Ethiopia	7 700 000	3.0
Bangladesh	7 200 000	2.9
Viet Nam	6 500 000	2.6
Philippines	5 700 000	2.2
Pakistan	3 800 000	1.5

Source: Global Hepatitis Reporting System, WHO.

Table 2.8. Countries that represent two thirds of the global disease burden of hepatitis C, 2022

Country	Total hepatitis C infections (all ages)	Proportion of total hepatitis C infections (%)
Pakistan	8 800 000	17.8
India	5 500 000	11.2
China	4 000 000	8.1
Russian Federation	2 700 000	5.4
United States of America	2 400 000	5.0
Indonesia	1 400 000	2.8
Nigeria	1 350 000	2.7
Ukraine	1 250 000	2.5
Uzbekistan	1 070 000	2.2
Bangladesh	1 020 000	2.1
Viet Nam	900 000	1.8
Ethiopia	692 000	1.4
Mexico	678 000	1.4
Brazil	536 000	1.1
Malaysia	517 000	1.0

Source: Global Hepatitis Reporting System, WHO.

Box 2.3. Validation of eliminating viral hepatitis as a public health problem and validation of triple elimination of mother-to-child transmission of HIV, syphilis and HBV

In 2023, WHO published updated guidance for countries and other stakeholders seeking to validate eliminating viral hepatitis as a public health problem *(11)*. The WHO guidance includes criteria for countries to be validated as being on the path to elimination, with a three-tier system (gold, silver and bronze) that recognizes a clear progression in national efforts towards the impact targets of elimination.

Egypt is the first country to achieve the gold tier status on the path to elimination of hepatitis C, based on fulfilling WHO criteria that will set the country up to achieve the reduced incidence and mortality targets of full elimination before 2030. Further, as of December 2023, 16 countries have been validated for eliminating either one or more among HIV, syphilis and HBV.

The updated WHO guidance builds on previous interim guidance and a series of country pilots conducted in 2021–2022 to assess the feasibility of accurately measuring the impact and programmatic targets for viral hepatitis elimination *(12)*. Seven countries across the six WHO regions were included in the pilots: Brazil, Egypt, Georgia, Mongolia, Rwanda, Thailand and the United Kingdom of Great Britain and Northern Ireland. The pilots evaluated national capacity to generate relevant data to measure progress towards elimination, gathered country feedback on the validation tools and provided an important evidence base for refining the criteria for validation and the path to elimination.

The global community has also committed to the “triple elimination” of mother-to-child transmission, also referred to as vertical transmission, of HIV, syphilis and HBV as a public health priority. This initiative focuses on a harmonized approach that builds on a strong maternal and child health platform to eliminate these infections and improve health outcomes for mothers and children. In 2022, WHO published updated global guidance on the criteria and processes for validation of elimination of mother-to-child transmission of HIV, syphilis and HBV *(13)*. The goal of programmes to eliminate mother-to-child transmission is to ensure that mother-to-child transmission of HIV, syphilis and HBV is controlled and incidence is reduced to a very low level, such that these infections cease to be a public health concern.

Although the availability and quality of global viral hepatitis data has improved considerably in this report, uncertainties remain, such as on measuring the incidence of hepatitis B and C. Person-centred monitoring related to viral hepatitis diagnosis, treatment and cure also needs to be further strengthened, to understand gaps in the care cascade and improve retention and outcomes. The 2024 WHO consolidated guidelines on hepatitis strategic information provide improved guidance on priority indicators and action steps to strengthen surveillance and monitoring at the country level *(14)* (Box 2.4).

Box 2.4. Strengthening strategic information for the viral hepatitis response

The 2024 WHO consolidated guidelines on person-centred viral hepatitis strategic information *(14)* provide improved guidance on priority indicators for viral hepatitis and country actions to strengthen surveillance and monitoring. The main recommendations include the following.

1. Use available data. The most important first step to strengthen country data is to use it. Most countries have data available on HBV and HCV burden and treatment. Countries should validate available data, highlight gaps, strengthen measures and use data for planning, developing investment cases and guiding service scale-up.

2. Consolidate measurements of disease burden and the cascade of care. A key component of strengthening viral hepatitis data is implementing a viral hepatitis prevalence survey, either nationally or in specific populations such as antenatal care attendees, blood donors and vulnerable populations, leveraging existing Demographic and Health Surveys and other population-based surveys. Countries should also consolidate measurements along the cascade of care – prevention, care, treatment and cure – and strengthen data analysis to identify gaps and improve linkage. Drug consumption data can also be used to triangulate treatment coverage data and identify gaps.

3. Integrate person-centred viral hepatitis data into routine health information systems. Person-centred data on viral hepatitis diagnosis and treatment should be included in the national health management information systems, such as DHIS-2, for routine use. Other important components of viral hepatitis data systems include data from cancer registries, data on mortality and case surveillance and attributable fraction analysis.

2.2 Testing and treatment coverage

Despite achievements in expanding viral hepatitis testing and treatment in specific countries since 2015, for example in China, Egypt, Mongolia, Rwanda and some high-income countries, global coverage overall is too low and stagnating (Tables 2.9 and 2.10). Many countries have adopted national hepatitis strategies and updated their clinical guidelines to improve access to viral hepatitis prevention, testing and treatment services in recent years, but their implementation has lagged behind.

One reason is the severe impact of COVID-19 on health systems, from which countries are only beginning to recover. In early 2021, a WHO global survey on the continuity of essential health services during the COVID-19 pandemic found that 43% of countries reported disruption in hepatitis B and C testing and treatment services *(15)*. In a repeat survey at the end of 2022, 15% of countries reported increases in service volumes versus pre-pandemic levels *(16)*.

Table 2.9. Coverage of hepatitis B testing and treatment by WHO region, 2022

WHO region	Total number of hepatitis B infections (all ages) in 2022	Number of people with hepatitis B infection diagnosed, end 2022	Number of people receiving hepatitis B treatment, end 2022	Diagnosis coverage, end 2022 (%)	Treatment coverage among all people with hepatitis B, end 2022 (%)	Treatment coverage among all people diagnosed, end 2022 (%)
African Region	64 700 000	2 700 000	150 000	4.2%	0.2%	5.5%
Region of the Americas	5 000 000	1 100 000	220 000	21.2%	4.4%	20.9%
South-East Asia Region	61 400 000	1 800 000	60 000	2.8%	0.1%	3.5%
European Region*	10 600 000	1 700 000	200 000	15.7%	1.9%	12.2%
Eastern Mediterranean Region	15 100 000	2 300 000	300 000	14.7%	2.0%	13.6%
Western Pacific Region	96 800 000	24 700 000	5 720 000	25.5%	5.9%	23.2%
Global	254 000 000	34 100 000	6 650 000	13.4%	2.6%	19.5%

Source: Global Hepatitis Reporting System, WHO.

Table 2.10. Coverage of hepatitis C testing and treatment by WHO region, 2022

WHO region	Total number of hepatitis C infections including cured (all ages) in 2022	Number of people with hepatitis C infection diagnosed (including those cured), end 2022	Number of people receiving hepatitis C treatment, end 2022	Diagnosis coverage, end 2022 (%)	Treatment coverage, end 2022 (%)
African Region	8 000 000	1 000 000	200 000	13%	3%
Region of the Americas	7 000 000	3 100 000	1 800 000	44%	26%
South-East Asia Region	10 600 000	2 700 000	1 600 000	26%	15%
European Region*	7 700 000	2 100 000	1 300 000	29%	9%
Eastern Mediterranean Region	17 700 000	13 000 000	6 300 000	49%	35%
Western Pacific Region	8 300 000	3 800 000	1 300 000	45%	16%
Global	61 200 000	25 700 000	12 500 000	36%	20%

Note: Hepatitis C virus has a cure and those cured are included in the denominator to assess coverage and gaps. For example if 500 out of 1000 people with hepatitis C virus are cured, the coverage is 500/1000. The baseline of 2015 is therefore used here as the denominator.

Source: Global Hepatitis Reporting System, WHO.

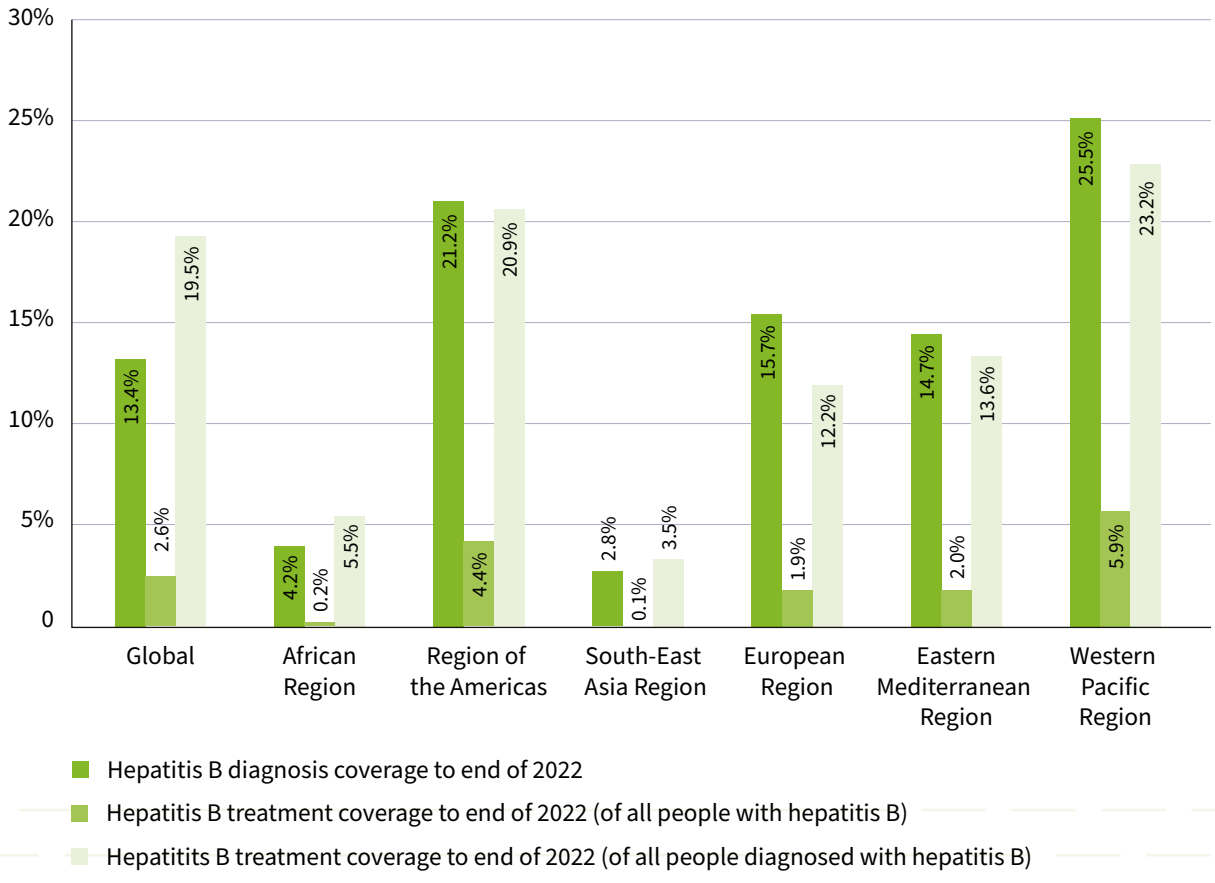
*The data from the European Region in Tables 2.9 and 2.10 reflect significant underreporting from countries. Data from partners were analysed where there were gaps. Coverage can range between 15-22% and 12-20% for hepatitis B diagnosis and treatment respectively, and between 28-32% and 9-11% for hepatitis C diagnosis and treatment initiation respectively. In addition, the percentage of people treated among those diagnosed could range between 59-65% for hepatitis C. This suggests the need to further improve reporting completeness in the European Region. WHO will continue to work with countries to improve and adjust these data for future reporting.

Hepatitis B testing and treatment. Overall, about 7 million people were receiving hepatitis B treatment as of end 2022. Diagnosis and treatment coverage are low. At the end of 2022, of the 254 million people living with chronic hepatitis B infection globally, only 13.4% had been diagnosed. An estimated 2.6% of all people with hepatitis B, and 19.5% of those diagnosed, were receiving treatment. Based on a systematic review conducted in 2018, between 12% and 25% of people with chronic hepatitis B were estimated to meet the treatment eligibility criteria of various professional society guidelines published between 2015 and 2017 *(17)*. Expanded treatment eligibility criteria in the updated 2024 WHO hepatitis B guidelines are likely to expand eligibility to more than 50% of people with chronic hepatitis B infection, but the criteria vary by region *(18)*.

Hepatitis C testing and treatment. Nearly 12.5 million people received the 12-week hepatitis C curative treatment between 2015 and 2022. Diagnosis and treatment coverage remain low for hepatitis C as well. Only 36% of the people living with hepatitis C had been diagnosed, and 20% of people living with hepatitis C have received curative treatment by the end of 2022.

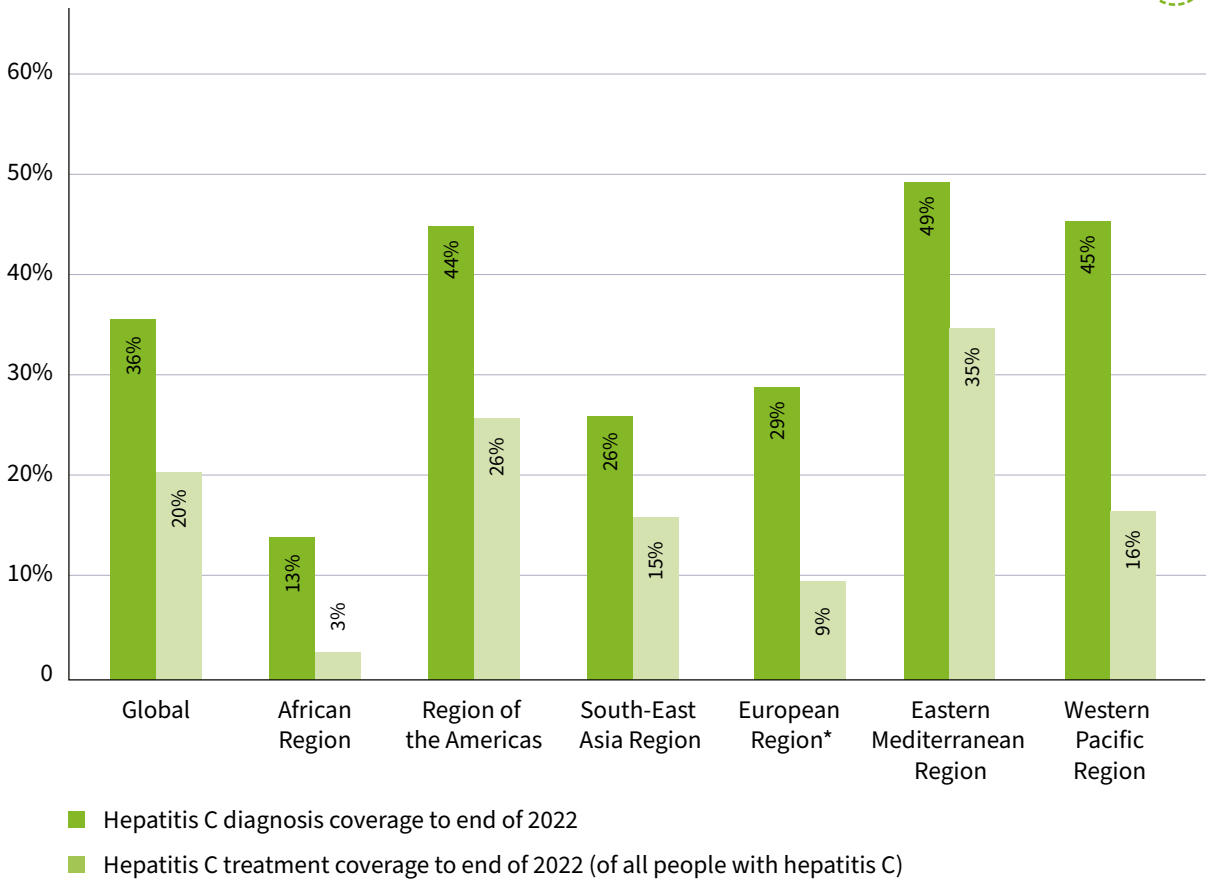
Regional variation. Fig. 2.5 and Fig. 2.6 show the gaps in access to diagnosis and treatment by WHO region. Treatment coverage remains low even among those who are diagnosed, highlighting the urgent need to improve linkages to care.

Fig. 2.5. Coverage of hepatitis B testing and treatment by WHO region, 2022



Source: Global Hepatitis Reporting System, WHO.

Fig. 2.6. Coverage of hepatitis C testing and treatment by WHO region, 2022



Source: Global Hepatitis Reporting System, WHO.

The data show considerable progress in the hepatitis C response in the Eastern Mediterranean Region and in the Region of the Americas. A special effort with additional financing and an investment case is required in the African Region, where hepatitis C diagnosis remains below 15% and treatment coverage below 5%. The Egyptian initiative to provide 1 million courses of hepatitis C curative treatment to countries in sub-Saharan Africa should be expanded to fill the gaps in hepatitis C services in the African Region. Progress in the hepatitis C response in the South-East Asia Region is also critical to reach the Sustainable Development Goals for 2025 and 2030.

The Western Pacific Region has made substantial progress in the hepatitis B response, supported recently by wider treatment eligibility in China. A special focus on the African Region is also required for hepatitis B, where 63% of new global hepatitis B infections occur and hepatitis B diagnosis and treatment coverage remain below 5%. The gaps are also high in the South-East Asia Region.

Table 2.11 presents the disease burden and testing and treatment coverage for the 38 WHO focus countries for the viral hepatitis response. It also presents the most important actions for these countries to advance a public health approach, based on the 10 priority actions of this report (see Chapter 5 for the list of actions).

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
African Region												
Cameroon	1 617 773	14 763	3 505	1.9%	0.2%	157 542	3 725	1 032	17%	11%	Strategic direction 1 Action 3	Strategic direction 1 Actions 1, 2
Côte d'Ivoire	2 155 631	6 986	11 487	1.5%	0.1%	211 114	4 653	892	8%	0%		Strategic direction 2 Actions 4, 5, 7
Democratic Republic of the Congo	2 785 244	105 240	5 185	2.4%	0.4%	432 499	13 104	2 643	13%	0%		Strategic direction 3 Action 8
Ethiopia	7 660 095	32 926	33 867	4.8%	0.0%	691 928	13 490	3 465	8%	1%		
Ghana	2 865 177	10 325	13 910	0.7%	0.0%	442 797	10 714	1 659	5%	0%		
Nigeria	14 384 770	299 334	46 144	0.6%	0.1%	1 349 056	27 596	5 652	5%	1%		
Rwanda	207 232	8 115	706	66.8%	4.0%	62 170	3 352	177	100%	50%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
African Region (continued)												
South Africa	2 741 289	13 339	25 564	23.1%	0.1%	243 978	3 159	2 138	24%	1%	Strategic direction 1 Action 3	Strategic direction 3 Action 8
Uganda	1 123 667	5 549	1 683	35.3%	0.5%	356 043	5 678	723	9%	0%		
United Republic of Tanzania	1 855 605	10 410	8 981	4.5%	0.0%	99 576	1 312	347	7%	0%		
Region of the Americas												
Brazil	1 038 564	642	2 578	34.2%	3.6%	535 868	4 028	2 977	36%	24%		Strategic direction 1 Actions 1, 2
Colombia	307 755	277	54	12.1%	0.9%	309 159	3 646	27	12%	2%		
Mexico	117 412	188	3 927	11.4%	1.0%	678 258	5 736	11 851	16%	4%		
Peru	146 893	361	365	17.0%	1.4%	57 756	814	310	5%	1%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
South-East Asia Region												
Bangladesh	7 237 059	15 947	27 761	0.6%	0.3%	1 020 178	17 008	3 351	26%	8%		Strategic direction 1 Actions 1, 3 Strategic direction 2 Actions 4, 5, 7 Strategic direction 4 Action 9
India	29 750 729	50 083	98 305	2.4%	0.0%	5 507 793	144 187	26 206	28%	21%		
Indonesia	17 544 081	158 563	60 535	3.0%	0.1%	1 392 645	39 134	6 322	14%	1%		
Myanmar	2 618 796	23 878	9 321	0.3%	0.0%	299 482	6 983	1 514	17%	4%		
Thailand	1 837 909	1 104	12 958	11.7%	0.7%	374 514	6 630	2 123	28%	5%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
European Region												
Georgia	78 000	3.3 per 100 000	265	25.7%	0.1%	48 600	1.5 per 100 000	183	100%	65%		Strategic direction 1 Actions 1, 2, 3 Strategic direction 2 Actions 4, 5, 7 Strategic direction 3 Action 8 Strategic direction 4 Action 9
Kyrgyzstan	349 644	730	1 176	15.8%	0.3%	170 824	4 103	605	21%	4%		
Republic of Moldova	294 803	270	1 913	6.8%	0.0%	73 675	1 626	221	30%	4%		
Russian Federation	1 650 951	9 297	8 477	30.1%	0.2%	2 663 597	33 877	4 927	42%	5%		
Ukraine	505 658	990	1 650	12.0%	0.4%	1 250 706	18 031	6 732	11%	4%		
Uzbekistan	713 947	801	1 611	21.2%	2.1%	1 065 843	35 598	1 492	9%	8%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
Eastern Mediterranean Region												
Egypt	952 159	1 778	1 407	3.2%	1.7%	484 523	9 708	7 288	100%	93%		Strategic direction 1 Actions 1, 2 Strategic direction 2 Actions 4, 5, 7 Strategic direction 4 Action 9
Morocco	223 645	187	555	41.1%	2.9%	125 566	3 416	565	24%	7%		
Pakistan	3 796 372	15 068	10 260	29.1%	3.4%	8 790 812	110 000	24 847	36%	20%		
Sudan	2 019 584	15 376	3 299	11.9%	1.7%	511 036	11 876	875	14%	4%		
Yemen	948 579	5 474	2 843	0.4%	0.1%	257 189	4 143	1 361	44%	11%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
Western Pacific Region												
Cambodia	496 539	888	1 310	5.3%	0.3%	183 160	4 625	1 034	23%	12%	Strategic direction 1 Action 3	Strategic direction 1 Actions 1, 2, 3
China	79 741 823	20 914	453 490	24.0%	6.4%	4 012 657	53 383	19 983	45%	12%		Strategic direction 2
Lao People's Democratic Republic	260 495	961	529	4.4%	0.1%	41 888	971	210	17%	4%		Actions 4, 7 Strategic direction 3
Mongolia	193 155	316	677	45.5%	2.4%	128 501	1 939	763	98%	34%		Action 8
Niue	111	1	0	5.7%	0.1%	19	1	0	10%	0%		
Philippines	5 660 072	31 609	18 583	11.2%	0.2%	427 470	8 939	3 001	19%	1%		

Table 2.11 Disease burden, service coverage and priority actions to advance a public health approach in WHO focus countries for the viral hepatitis response, 2023 (continued)

Country	Hepatitis B					Hepatitis C					Priority actions to advance a public health approach (see Chapter 5 for a list of strategic directions and recommended actions)	
	Total hepatitis B infections (all ages) in 2022	Hepatitis B incidence	Number of deaths caused by hepatitis B infection	Diagnosis coverage, end 2022 (of all infected)	Treatment coverage, end 2022 (of all infected)	Total hepatitis C infections (all ages) in 2022	Hepatitis C incidence	Number of deaths caused by hepatitis C infection	Diagnosis coverage (total), end 2022	Treatment coverage, (of all infected), end 2022	Access to hepatitis B Birth-dose vaccine	Access to hepatitis B and C testing and treatment
Western Pacific Region (continued)												
Vanuatu	23 998	120	119	21.3%	0.0%	3 048	85	14	11%	0%		Strategic direction 4 Action 9
Viet Nam	6 520 442	12 605	26 725	41.7%	1.4%	890 997	17 944	3 894	13%	8%		

Note: The data on coverage of diagnosis and treatment in this table are of variable quality, with data quality issues for some countries due to uncertainties in numerators and denominators. Country data are published in this table to support improvements in data quality as part of reporting in subsequent years, and will be updated as improved data are validated.

Testing and treatment coverage among priority populations affected by viral hepatitis

The populations affected by viral hepatitis vary greatly worldwide *(4)*. In many regions, viral hepatitis B and C epidemics affect the general population but also some other people at higher risk who are part of a population with higher prevalence or with a history of exposure and/or high-risk behaviour for infection. Populations that require focused attention in many countries include those at risk of exposure through unsafe blood supplies, unsafe medical injections and other health procedures. In settings with high hepatitis B prevalence, vertical (mother-to-child) transmission of chronic hepatitis B is the major mode of transmission, along with early childhood infection among those who have not been vaccinated.

Depending on the epidemiological context, priority populations also include people who inject drugs, people in prisons and other closed settings, gay men and other men who have sex with men, transgender and other gender-diverse people and sex workers. Viral hepatitis may also disproportionately affect mobile and migrant populations from high- and intermediate-endemic countries. Specific attention must also be given to people with advanced liver disease and people with various comorbidities such as TB, HIV, alcohol and drug use disorders and noncommunicable diseases that may result in higher morbidity and mortality.

Making progress towards eliminating viral hepatitis will require a rapid shift to bring services closer to communities, such as by leveraging opportunities to integrate viral hepatitis services within existing HIV services to reach key populations and other highly affected vulnerable populations, especially those who continue to face the greatest structural barriers to access (Box 2.5). A systematic review to evaluate country, regional and global coverage of HIV and HCV testing and treatment among people who inject drugs found that HIV and hepatitis C testing and treatment uptake among people who inject drugs varied greatly and was suboptimal in most countries *(19)*. Globally, an estimated 47% of people who inject drugs have ever been tested for hepatitis C antibodies. Testing coverage is low (<40%) in 16 countries, moderate (40–75%) in 18 countries and high (>75%) in 15 countries. At the regional level, southern Asia, where 46% of people who inject drugs are living with hepatitis C, has the lowest hepatitis C testing uptake (5%). An estimated 53% of people who inject drugs are exposed to HCV (HCV antibody positive). Treatment coverage is low (<25%) in 14 countries, moderate (25–75%) in eight countries and high (>75%) in one country.

Another review of the status of access to hepatitis C prevention, testing and treatment for people who are incarcerated noted many barriers to the availability of hepatitis C services in prisons, including poor surveillance of hepatitis C in prison settings, lack of screening policies and programmes, limited access to harm-reduction services, poor linkage to hepatitis C confirmatory testing and treatment and pervasive hepatitis C–related stigma and discrimination among people who are incarcerated and among prison staff *(20)*.

A systematic review of viral hepatitis interventions targeting refugee populations globally found that models of hepatitis services for refugee populations remain limited. Across available studies, common challenges included loss to follow-up and uncompleted vaccination series in studies with vaccination. The factors that contributed to the success of programmes targeting refugee populations included community stakeholder participation, language services, the use of cultural mediators and government support *(21)*.

In 2022, WHO published new consolidated guidelines on HIV, viral hepatitis and sexually transmitted infection prevention, diagnosis, treatment and care for key populations, including gay men and other men who have sex with men, sex workers, people in prisons and other closed settings, people who inject drugs and transgender and gender-diverse people *(22)*. The guidelines provide recommendations on how to set priorities for various packages of health interventions and structural enablers to have the greatest impact on HIV, viral hepatitis and sexually transmitted infections for key populations. They include harm reduction, HBV vaccination, preventing vertical transmission, HBV and HCV testing and HBV and HCV treatment as essential viral hepatitis interventions for key populations.

Box 2.5. Supporting community engagement and peer-led service delivery

The active involvement of affected communities plays an important role in designing and delivering services that are tailored to the local epidemiological and social context. Several global organizations support advocacy, community engagement and service delivery for priority populations.

The Coalition for Global Hepatitis Elimination, launched in 2019, works directly with affected communities to elevate their voices and promote advocacy. It supports building the capacity of national viral hepatitis programmes through advocacy, technical assistance, research and generating and disseminating knowledge. The Coalition also compiles national and subnational hepatitis data from various stakeholders in a comprehensive repository of country profiles of progress towards viral hepatitis elimination.

The Treatment Action Group, a community-based research and policy think tank, works in collaboration with affected communities to increase communities' testing and treatment literacy on hepatitis C; provides technical assistance to community-based organizations to build leadership capacity for advancing national elimination campaigns and amplifying community voices in planning and policy development; and supports the delivery of affordable testing and cures for underserved populations.

Médecins du Monde, an international medical humanitarian organization, has supported the delivery of peer-led hepatitis C diagnosis and treatment as part of harm-reduction programmes for people who inject drugs in various countries, including Georgia, Kenya, Myanmar and Viet Nam. With new support from Unitaid, Médecins du Monde will generate evidence on approaches for simplifying hepatitis C service delivery in Armenia, Georgia and the United Republic of Tanzania and pilot new technologies for harm reduction such as long-acting opioid agonist therapy and low dead-space syringes. Two other organisations – Frontline AIDS and PATH – have also received funding from Unitaid to support these efforts. In addition, Médecins du Monde contributes to global advocacy efforts to address intellectual property barriers, such as by opposing patents.

Médecins Sans Frontières, an international medical humanitarian organization, has supported the delivery of hepatitis testing and treatment projects in various countries including Cambodia, India, Malaysia and Pakistan. In 2021, Médecins Sans Frontières launched the Hepatitis C Partnership for Control and Treatment (Hepatitis C PACT), a partnership that includes the Drugs for Neglected Diseases initiative, FIND, Médecins Sans Frontières and the Treatment Action Group, to address key barriers to the low rate of access to testing and treatment for viral hepatitis *(23)*. The Médecins Sans Frontières Access Campaign supports advocacy efforts to address patent-related access barriers to viral hepatitis medicines.

The World Hepatitis Alliance works in partnership with more than 290 member organizations across 94 countries to raise awareness on viral hepatitis, drive policy change and promote access to services by running global public campaigns, convening high-level policy dialogue and building local capacity. As the leading global patient organization for viral hepatitis, the Alliance played a key role in advocating to make the elimination of viral hepatitis by 2030 a global health priority.

2.3 Forecasts for 2025 and 2030

There is a window of opportunity in 2024–2026 to get the global hepatitis B and C response back on track towards achieving the Sustainable Development Goals. A specific focus is required on scaling up the response to hepatitis B and C virus in the African Region as well as rapid scale-up in each of the 10 countries that together represent nearly two thirds of hepatitis B and C infections – China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines and the Russian Federation. If the response is not scaled up, viral hepatitis infections, viral hepatitis–related cancer cases, mortality and costs will increase for the next generation.

Getting back on track to achieve the Sustainable Development Goals requires treating an estimated 40 million people with hepatitis B and administering the curative course of treatment to an estimated 30 million people with hepatitis C by the end of 2026. Fig. 2.7 and 2.8 show projections for hepatitis B and C treatment for 2030 to achieve the goals of the global health sector strategy on viral hepatitis *(24–26)*. The coverage of hepatitis C treatment and cure is projected to increase rapidly to 2028 and then decline, resulting in declining incidence, mortality and costs by 2030. The hepatitis B response is projected to benefit from the success of vaccination programmes in reducing hepatitis B incidence, with declining mortality by 2030 that requires scaling up hepatitis B treatment. Without this expansion in access, the world will face increasing cases of liver cancer in the next generation, with associated increasing care costs and hepatitis-related deaths. The long-term sustainability of the hepatitis B response would also benefit substantially from carefully managing ongoing viral load costs and developing a hepatitis B cure.

Fig. 2.7 Projections in hepatitis C treatment and cure, 2020–2029

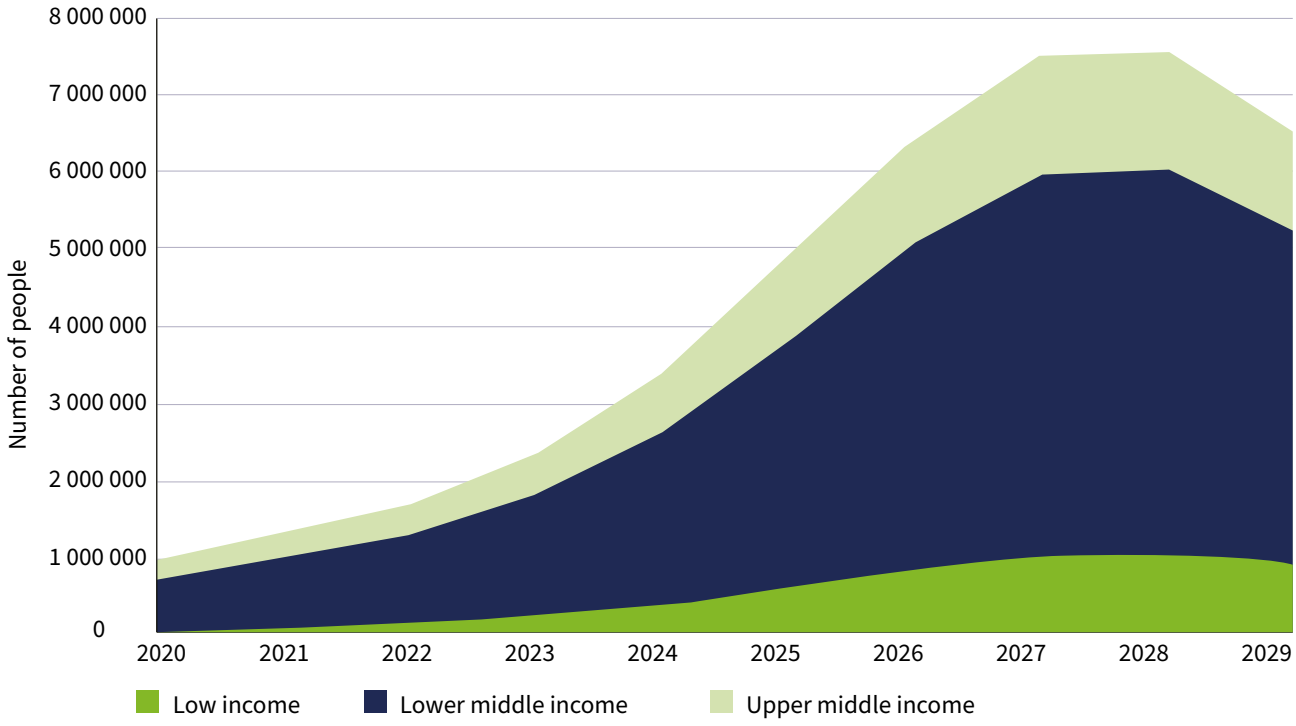
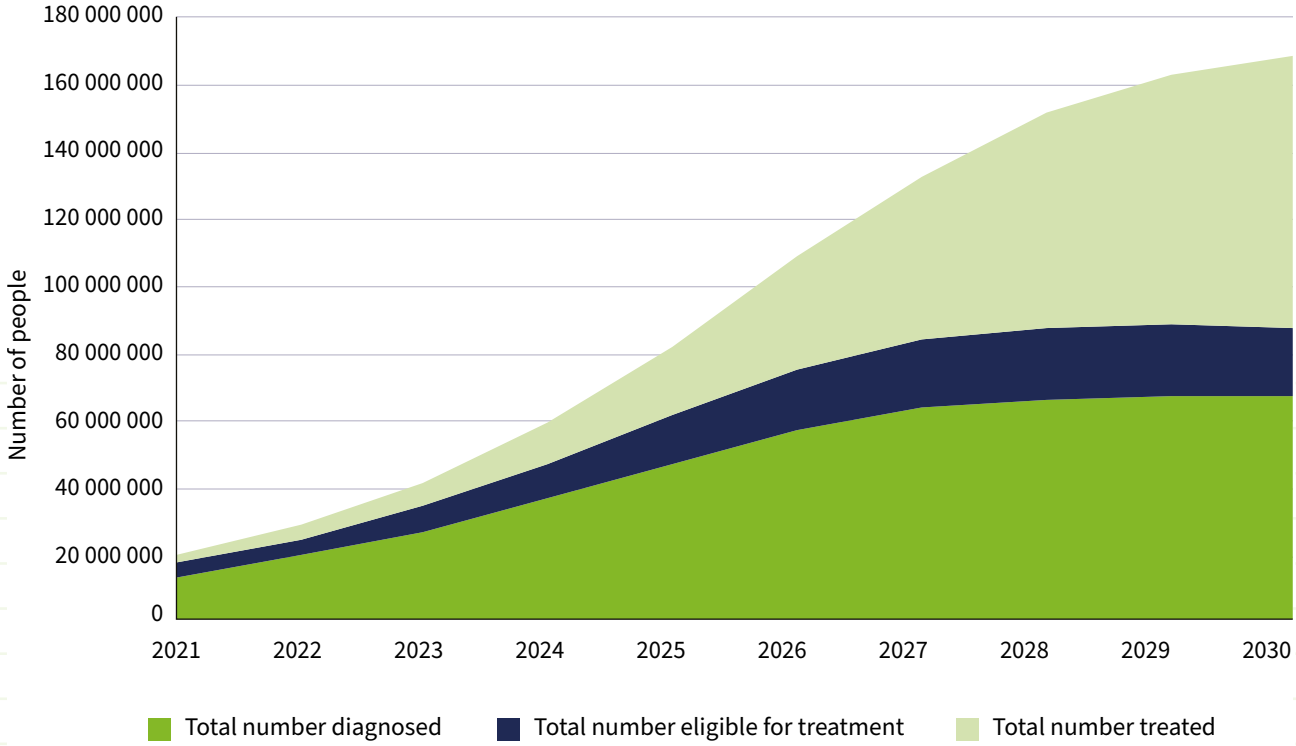


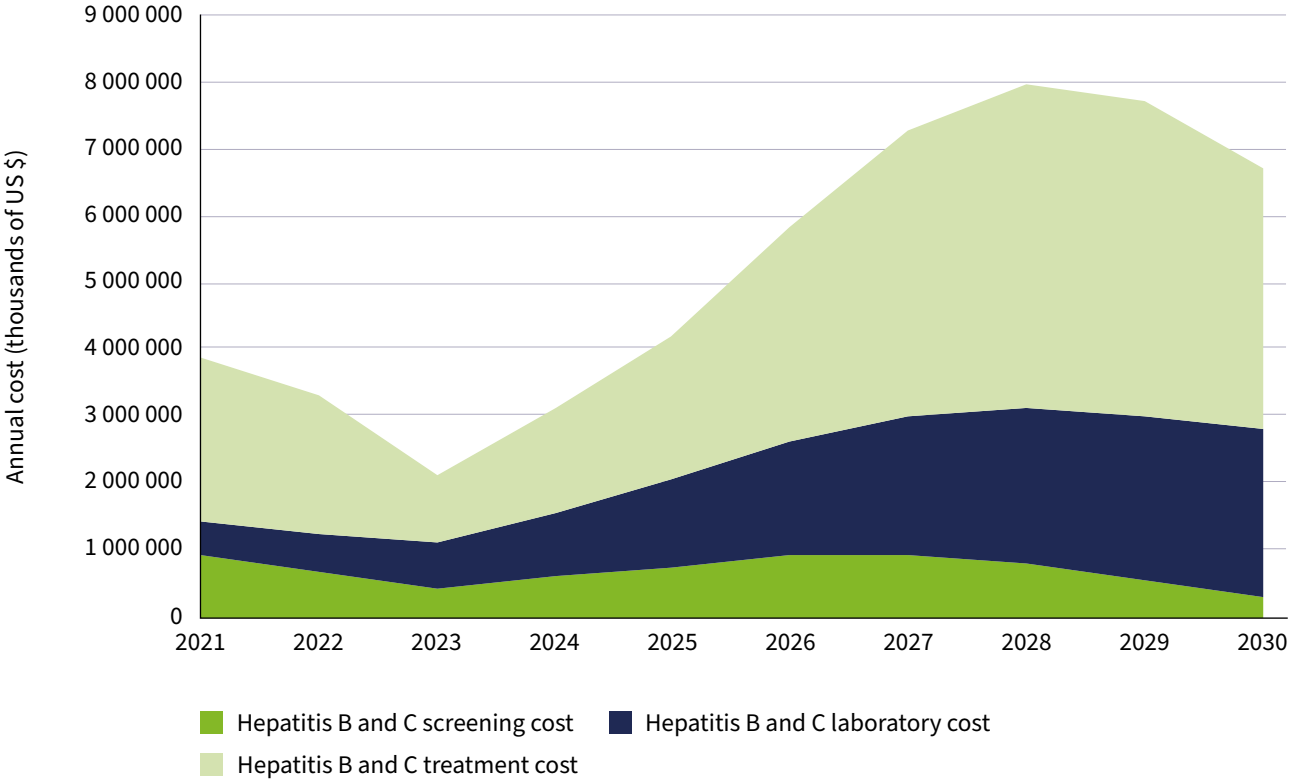
Fig. 2.8 Projections in hepatitis B diagnosis and treatment, 2021–2030



The global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 *(4)* estimate that the costs of the global hepatitis response (Fig. 2.9, Table 2.12) are projected to increase to US$ 8 billion per year by 2028 and then to decline by 15% by 2030. Hepatitis B accounts for 75% of these costs, peaking at US$ 6 billion per year in 2028 and hepatitis C at US$ 2 billion per year. The overall curve has a period of investment until 2028 followed by declining costs and increasing returns in terms of reduced incidence, mortality and cancer, representing a return of US$ 2–3 per dollar invested, based on results from several country investment case studies *(92)*. The returns will improve further as countries take on the increased costs of cancer treatment as part of noncommunicable disease strategies.

The costing assumptions of the global health sector strategies 2022–2030 *(4)* include actions to optimize the response for impact, such as wider access to affordable prices, accelerated treatment uptake and simplified service delivery. The costing also assumes major gains in efficiency in reducing screening, laboratory and treatment costs over time and leveraging primary health care and HIV programmes for service delivery. Screening costs decline over time as more hepatitis B and hepatitis C cases are identified. However, the increasing hepatitis B laboratory costs would be a major barrier to achieving strategy targets. A simplified strategy for service delivery is required, because of the many people with chronic hepatitis B.

Fig. 2.9. Projected costs of the viral hepatitis response, 2021–2030



Note: US$ in constant 2020 US$.

Table 2.12. Costing assumptions of increased efficiency and strategy actions for the hepatitis C response, 2020–2030

	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Target for proportion diagnosed	18%	22%	27%	33%	39%	46%	55%	64%	74%	83%	90%
Target for proportion treated	12%	16%	21%	26%	31%	38%	46%	56%	65%	73%	80%
Average sustained viral response	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%
Mortality change	67%	65%	63%	61%	58%	55%	51%	46%	42%	38%	35%
Mortality rate (all cause)	1.50%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Incidence change	86%	82%	77%	71%	65%	57%	48%	37%	27%	17%	10%
Screening costs (US$ per case)	2.00	2.00	1.07	0.77	0.77	0.73	0.72	0.71	0.69	0.67	0.65
Laboratory costs (US$ per case)	28.0	28.0	18.3	15.2	15.2	14.9	14.8	14.6	14.5	14.3	14.0
Treatment unit cost for for low- and middle-income countries with access to generic direct-acting antiviral drugs (US$)	150	150	95	77	77	75	74	74	73	71	70
Treatment unit cost for low- and middle-income countries without access to generic direct-acting antiviral drugs (US$)	3000	3000	1273	721	721	653	634	611	582	545	500

Note: All US$ figures in constant 2020 US$.

Fig. 2.10. Scenarios showing window of action for 2024–2626 in scaling up viral hepatitis treatment and differences in infections, mortality, cancer cases and lives saved, 2015–2050

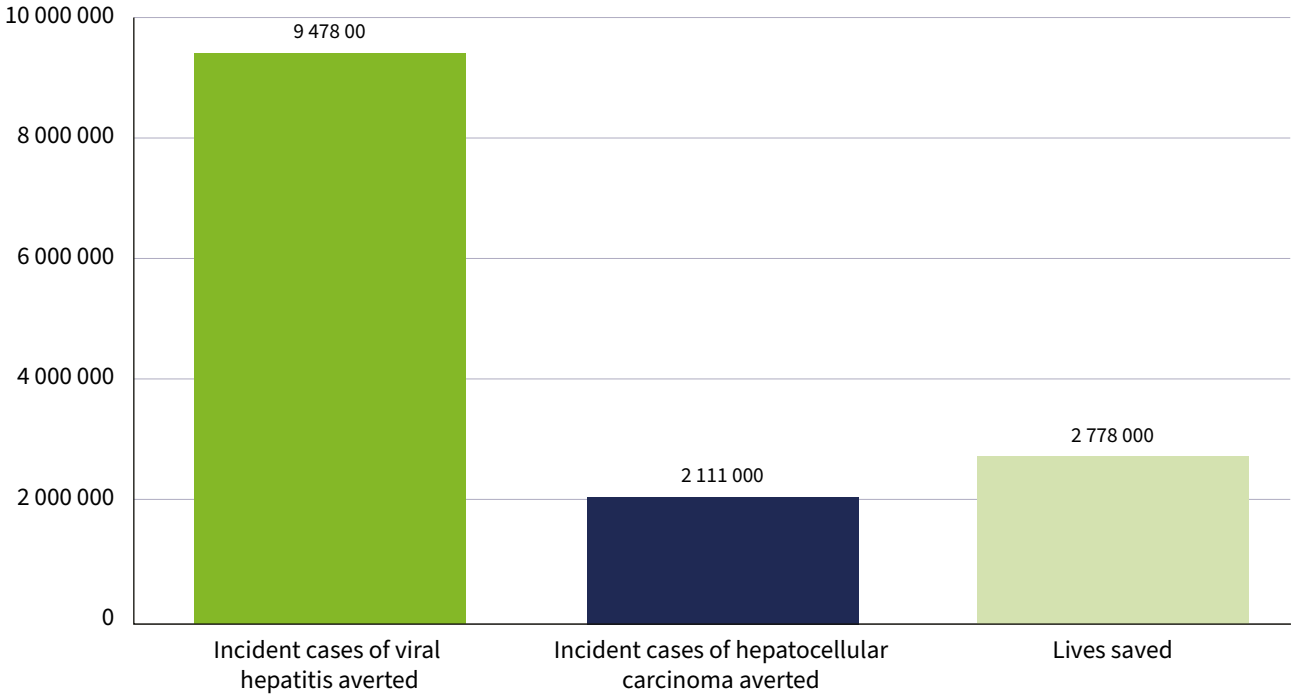


Table 2.13. Scenarios showing window of action for 2024–2026 in scaling up viral hepatitis treatment and differences in infections, mortality, cancer cases and lives saved

Impact	2030	2050
Incident cases of viral hepatitis averted	9 478 000	52 793 000
Incident cases of hepatocellular carcinoma averted	2 111 000	14 690 000
Lives saved	2 778 000	22 854 000

If action is taken now, viral hepatitis incidence, mortality and costs will decline by 2030. This will require rapid scale-up focusing on countries with a high burden of viral hepatitis, with 40 million people living with hepatitis B receiving treatment for HBV, and 30 million people with hepatitis C receiving cure by 2026. If action is not taken, there will be an additional 9.5 million cases of viral hepatitis, 2.1 million cancer cases and 2.8 million deaths by 2030 (Fig. 2.10, Table 2.13). The increased burden of mortality and cancer will be apparent for a generation, with an estimated additional 58 million hepatitis B and C deaths and 45 million cancer cases by 2050. Several country investment case studies suggest that this will result in extensive and increasing health-care costs, with US$ 2–3 lost for every dollar not spent. The window of action in 2024–2026 is critical to contribute to achieving the health-related Sustainable Development Goals for communicable and noncommunicable diseases by 2030.

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3.
Global status of access to health products

3. Global status of access to health products

This chapter presents the global status of access to health products for viral hepatitis. For HBV products, it provides baseline global information for 2023. For HCV products, the chapter provides an update on global progress since the 2020 previous edition of the report *(3)*.

Chapter 4 presents further analysis by WHO region, with country-specific information for the WHO focus countries for the viral hepatitis response.

3.1 Normative guidance

This section summarizes the latest WHO normative guidance on testing, diagnosis, treatment and prevention for viral hepatitis.

Key messages

Normative guidance for HBV

In 2024, WHO updated guidelines on prevention, diagnosis, treatment and care for people with chronic hepatitis B infection. The updated guidelines simplify the clinical algorithm for diagnosis, treatment and monitoring for hepatitis B expand treatment eligibility criteria and provide alternative regimens for treatment. There are also unchanged recommendations from the 2015 guidelines on various aspects of monitoring for treatment response, toxicity monitoring and screening for hepatocellular carcinoma; when to stop and restart antiviral therapy; and using second-line antiviral therapy for managing treatment failure.

For the first time, the updated hepatitis B guidelines include recommendations for hepatitis D, which requires HBV for replicating HDV and is considered to be the most aggressive form of viral hepatitis because of its accelerated progression to liver cirrhosis or liver cancer compared with HBV monoinfection. The guidelines provide recommendations for who to test and how to test, including using laboratory-based reflex viral load testing to promote uptake of testing and to link to treatment.

WHO recommends that all infants should receive their first dose of the hepatitis B vaccine as soon as possible after birth, ideally within 24 hours. The birth dose should be followed by 2 or 3 additional doses to complete the primary series. WHO also recommends that all pregnant women be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible in the pregnancy. In 2020, as an additional measure to prevent mother-to-child transmission of HBV and in settings where HBV DNA or hepatitis B e antigen (HBeAg) testing is available, WHO recommended antiviral prophylaxis with TDF for HBsAg-positive pregnant women with HBV DNA ≥200 000 IU/mL or positive HBeAg. Given the significant challenges in accessing HBV DNA testing among pregnant women who test HBsAg positive to determine eligibility for antiviral prophylaxis, especially in sub-Saharan Africa, the 2024 WHO guidelines provide an option of using antiviral prophylaxis for all HBsAg-positive pregnant women if there is no access to HBV DNA assays.

Normative guidance for HCV

In 2022, WHO released updated recommendations on treatment for adolescents and children with chronic hepatitis C infection. The updated guidelines expanded the treatment recommendations to include all adolescents and children with chronic hepatitis C infection aged three years or older, using the same pangenotypic direct-acting antiviral (DAA) regimens already recommended for adults (sofosbuvir/daclatasvir (SOF/DAC), sofosbuvir/velpatasvir (SOF/VEL) or glecaprevir/pibrentasvir (G/P)).

The guidelines also recommend simplified service delivery, with expanded HCV testing and treatment services, ideally at the same site, by decentralizing care to lower-level facilities; integrating with existing services, such as in primary care, harm reduction, prisons and HIV services; and promoting task sharing. Point-of-care HCV RNA assays are recommended as an additional approach to diagnose viraemic infection, especially among marginalized populations, such as people who inject drugs and hard-to-reach communities with constrained access to health care that have high rates of loss to follow-up. Reflex HCV RNA testing for people with a positive HCV antibody is recommended as an additional strategy to promote linkage to care and treatment.

Since 2021, WHO has recommended offering self-testing for HCV as an additional approach to HCV testing services, especially to reach priority populations that may not otherwise test using existing services and may prefer self-care options. The HCV test must be followed by linkage to appropriate post-test services, including confirming viraemic infection, treatment, care and referral services, according to national standards.

3.1.1 Normative guidance for HBV

Hepatitis B is an infection of the liver caused by HBV. The infection can be acute (short and severe) or chronic (long term). Chronic infection can put people at high risk of death from cirrhosis and liver cancer *(27)*. This section summarizes recent updates in global guidelines, norms and standards for prevention, testing, treatment and service delivery for hepatitis B (Fig. 3.1).

In 2015, WHO issued the first comprehensive guidelines on prevention, care and treatment for people with chronic hepatitis B infection *(28)*, followed in 2017 by guidelines on testing for viral hepatitis B and C *(29)*. In 2020, WHO published guidelines on preventing the mother-to-child transmission of HBV and on antiviral prophylaxis in pregnancy *(30)*.

Several significant developments have occurred since the 2015 guidelines were published. These include new data on the diagnostic performance of non-invasive tests for staging liver disease and cut-off thresholds for diagnosing significant fibrosis or cirrhosis; new studies on antiviral therapy effectiveness according to different HBV DNA and ALT levels and on service delivery models for hepatitis B care and treatment; the introduction of tenofovir alafenamide (TAF), a prodrug of tenofovir with less kidney toxicity, but also the widespread availability of another treatment option – that of dual combination of tenofovir and lamivudine – through HIV programmes, which is effective for treating both HIV and hepatitis B. In addition, there are opportunities to further expand use of antiviral prophylaxis to prevent mother-to-child transmission linked with the global initiative for triple elimination of HIV, hepatitis B and syphilis; and new point-of-care viral load testing technologies to support the scaling up of HBV DNA viral load testing; and testing for hepatitis D coinfection (who to test and how to test), a major contributor to hepatitis B–related morbidity and mortality.

In 2024, WHO updated previous guidelines with new or updated recommendations in 11 key areas *(18)*: using non-invasive tests for staging liver disease; who to treat among people with chronic hepatitis B; first-line antiviral therapy for chronic hepatitis B; preventing mother-to-children transmission using antiviral prophylaxis; treatment for adolescents and children with chronic hepatitis B; measuring HBV DNA to guide treatment and monitoring response; HBV DNA reflex testing; HDV testing – who to test and how to test, including reflex testing; and guiding principles for simplifying service delivery. There are also unchanged recommendations from the 2015 HBV guidelines on various aspects of monitoring for treatment response, toxicity and screening for hepatocellular carcinoma; who to stop and when to restart antiviral therapy; and using second-line antiviral therapy for managing treatment failure.

Testing

Who to test

WHO guidelines recommend offering focused testing to individuals from populations most severely affected by HBV infection (who are either part of a population with higher seroprevalence or have a history of exposure to or high-risk behaviour for HBV infection). In settings with a ≥2% or ≥5% seroprevalence of HBsAg (based on existing published thresholds for intermediate or high seroprevalence, respectively), WHO recommends that all adults have routine access to and be offered testing (a general population testing approach). Routine HBsAg screening of all pregnant women is recommended as part of integrated triple point-of-care screening for syphilis, hepatitis B and HIV in antenatal clinic services. Overall, these different testing approaches should use existing facility-based (such as antenatal clinics, HIV or TB services) or community-based testing opportunities and programmes.

How to test

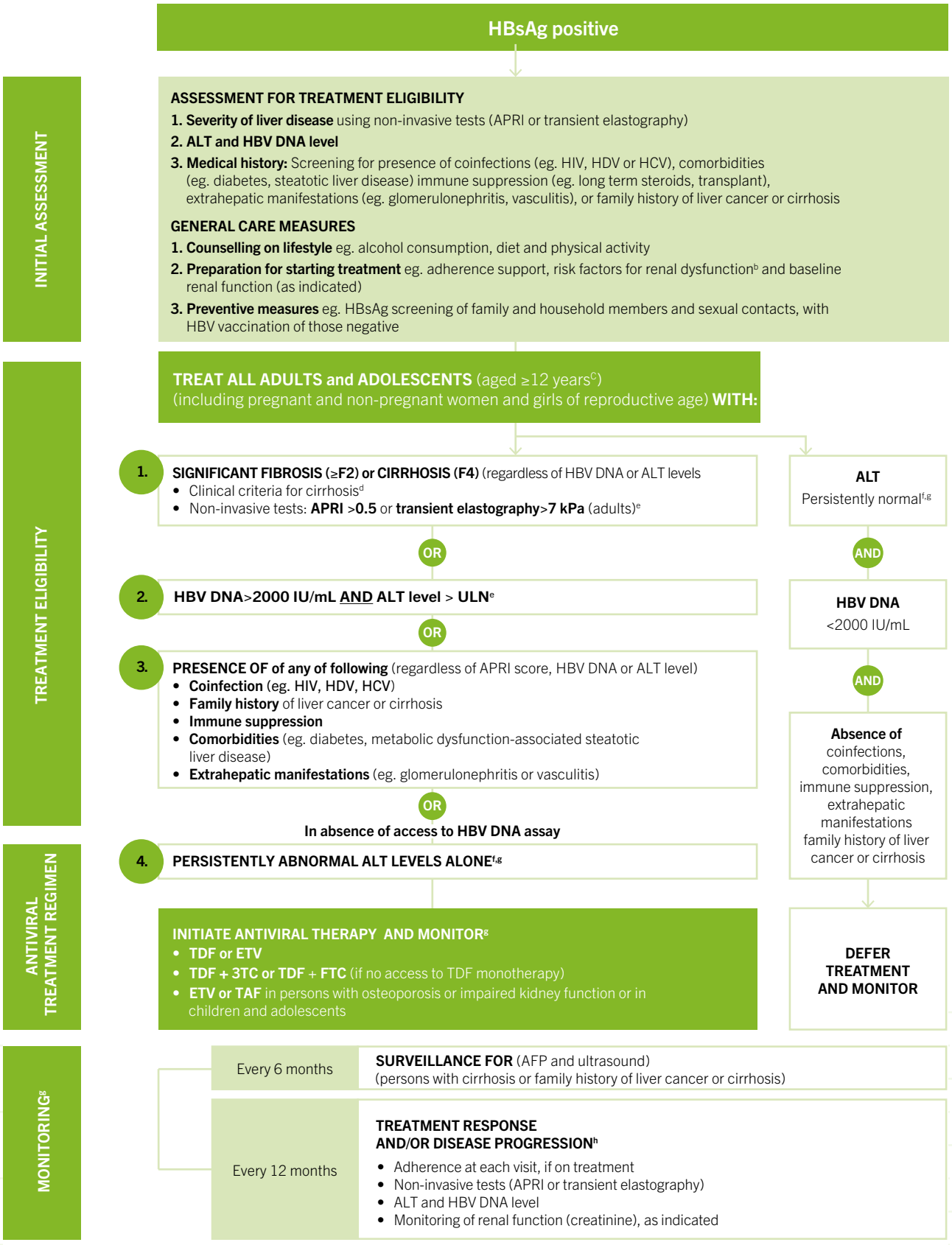
WHO guidelines recommend using a single quality-assured serological in vitro diagnostic test (either a laboratory-based immunoassay (enzyme-linked immunoassay or chemoluminiscence immunoassay) or rapid diagnostic test (RDT)) to detect HBsAg that meets minimum performance standards. Using HBV DNA nucleic acid testing (NAT) following a reactive HBsAg serological test result is recommended to help further guide who to treat and to monitor for treatment response. The use of capillary whole-blood dried blood spot specimens for both serological and NAT technologies for HBV infection may be considered for testing in certain settings. Other recommended interventions to promote the uptake of hepatitis testing and linkage to care include peer and lay health worker support in community-based settings, clinician reminders in facilities and testing as part of integrated services within drug treatment and community-based harm-reduction services.

Treatment and service delivery

The 2024 guidelines also simplify the clinical algorithm for diagnosis, treatment and monitoring for HBV and expand treatment eligibility criteria. The main updates in the new recommendations include the following.

- **Expanded eligibility for treatment**. The updated guidelines recommend four options for meeting treatment eligibility that will capture a much higher proportion (at least 50%) of all HBsAg-positive people versus about 12–25% previously (*18*). They also include options for those without access to HBV DNA testing, which has been a major barrier to accessing treatment. All four recommendations on who to treat now also apply to all age groups (adults and adolescents 12–17 years old and those of reproductive age and pregnant women), which enables a common entry point for assessment and treatment across age groups to promote equity in access to treatment.
- **Alternative antiviral regimens for treatment**. The guidelines maintain the recommendation for TDF or entecavir (ETV) as preferred first-line regimens, with the addition of dual therapy (TDF + XTC) as an alternative regimen (which is widely available at low cost as part of first-line antiretroviral therapy regimens through existing drug procurement through the Global Fund and the United States President's Emergency Plan for AIDS Relief) and the use of TAF reserved for those with existing or at risk of renal impairment or osteoporosis.
- **HBV DNA testing.** The guidelines recommend the use of point-of-care HBV DNA NAT as an additional approach to determining HBV DNA level and eligibility for treatment. Reflex HBV DNA testing for people with a positive HBsAg test result is recommended as an additional approach to promote linkage to care and treatment.
- **HDV coinfection testing**: Chronic hepatitis D coinfection is considered to be the most aggressive form of viral hepatitis because of its accelerated progression to liver cirrhosis or liver cancer compared with hepatitis B monoinfection, and there have been no previous recommendations for testing and treatment. The guidelines now include recommendations for who to test and how to test, including using laboratory-based reflex viral load testing to promote the uptake of testing and to link to treatment.

Fig. 3.1. Algorithm on managing people with chronic hepatitis B infection



Source: *Updated recommendations on prevention, diagnosis, care and treatment for people with chronic hepatitis B infection (18).*

Preventing mother-to-children transmission – hepatitis B immunization and antiviral prophylaxis

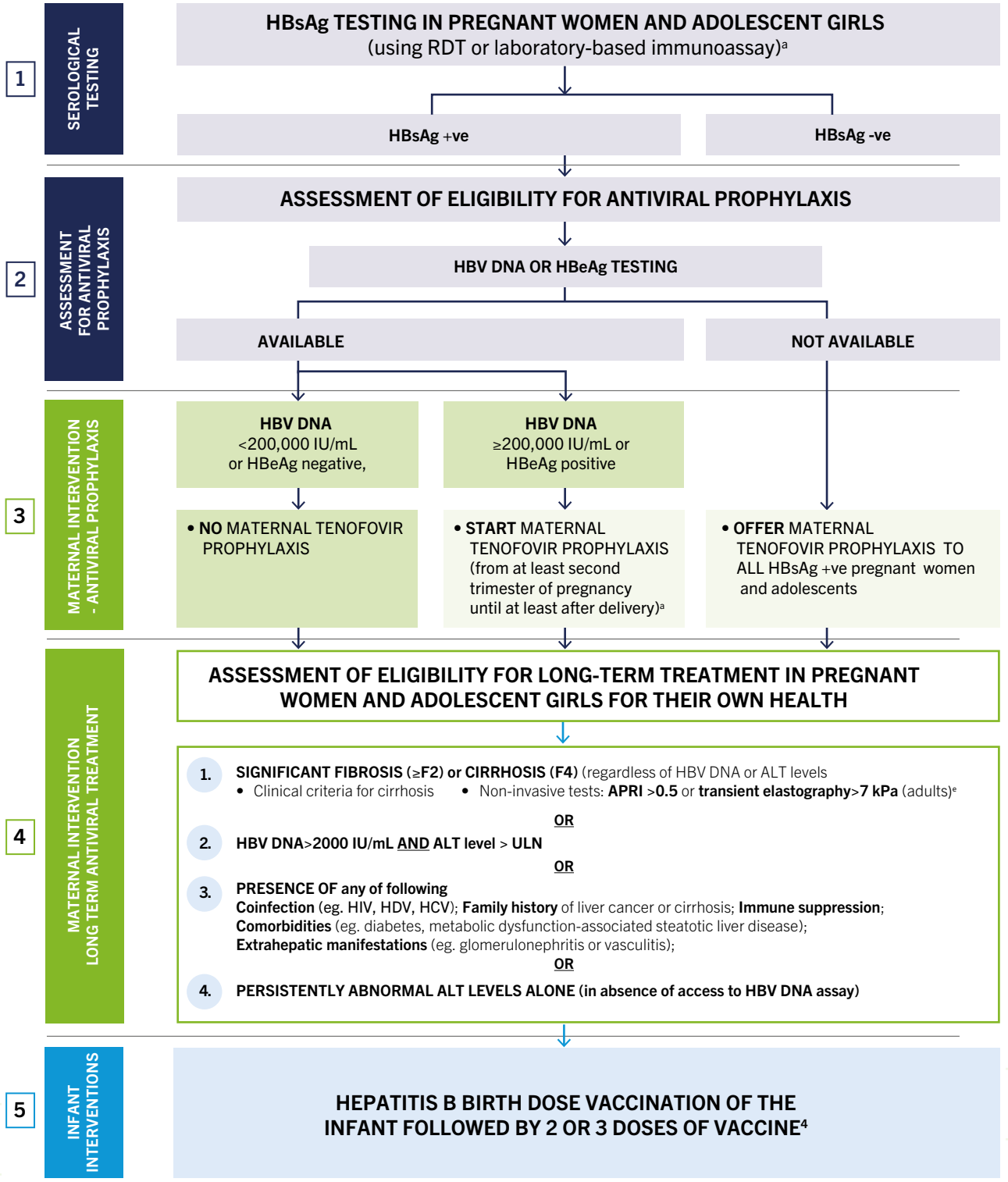
Most of the global burden of chronic hepatitis B can be attributed to vertical mother-to-child transmission of HBV peripartum at the time of or shortly after birth or through horizontal transmission in early childhood from infected children and adults. Such perinatal infections lead to a high rate of chronicity – the risk of developing chronic hepatitis B decreases from about 90% of those infected as neonates to 30% among children infected at 1–4 years old and less than 5% among those infected as adults.

Hepatitis B can be prevented by vaccines that are safe, available and effective. WHO recommends universal immunization of infants, with timely hepatitis B birth dose followed by an additional 2–3 doses in infancy *(31)*. Since 1992, WHO has recommended including the hepatitis B vaccine in the Expanded Programme on Immunization. High coverage of the timely hepatitis B birth dose, given within 24 hours of birth, and completing the infant hepatitis B vaccine series are the most important interventions for reducing vertical transmission of HBV as well as early childhood transmission and achieving the HBV elimination goals *(32)*. WHO 2019 testing guidelines also recommend that all pregnant women be tested for HIV, syphilis and HBsAg, at least once and as early as possible in the pregnancy *(29,33)*.

In 2020, as an additional measure to prevent the mother-to-child transmission of HBV and in settings in which HBV DNA or HBeAg testing is available, WHO recommended using antiviral prophylaxis with TDF for HBsAg-positive pregnant women with HBV DNA ≥200 000 IU/mL or positive HBeAg *(34)*. Given the significant challenges in accessing HBV DNA testing among pregnant women who test HBsAg positive to determine eligibility for antiviral prophylaxis, especially in sub-Saharan Africa, the 2024 WHO guidelines provide an option of using antiviral prophylaxis for all HBsAg-positive pregnant women if there is no access to HBV DNA assays. This is in addition to three-dose hepatitis B vaccination for all infants, including a timely birth dose (Fig. 3.2).

WHO also recommends that high-risk groups be screened for HBsAg and that those at risk and not immune be offered hepatitis B vaccination. These include: household and sexual contacts of people with chronic hepatitis B, people living with HIV, people who inject drugs, gay men and other men who have sex with men, sex workers and other groups such as indigenous peoples, people who are incarcerated and transgender people. Blood and organ donations should also be screened for HBsAg and other bloodborne pathogens in accordance with WHO recommendations to prevent HBV transmission, especially in low- and middle-income countries. Population-based screening is also recommended for migrants from endemic countries *(34)*.

Fig. 3.2. Algorithm on using antiviral prophylaxis for preventing mother-to-child transmission and eligibility for antiviral therapy for pregnant adults and adolescents



Source: *Updated recommendations on prevention, diagnosis, care and treatment for people with chronic hepatitis B infection (18).*

HDV

Hepatitis D is an inflammation of the liver caused by HDV, which requires HBV for replication. HDV infection occurs when people become infected with both HBV and HDV simultaneously (coinfection) or get hepatitis D after first being infected with hepatitis B (superinfection). HDV and HBV coinfection is considered one of the most severe form of chronic viral hepatitis because of more rapid progression towards hepatocellular carcinoma and liver-related death.

The global anti-HDV prevalence among people who are HBsAg positive in the general population is an estimated 4.5%, equivalent to about 12 million people. The prevalence of anti-HDV is significantly higher among populations at increased risk of bloodborne virus infections, including people who inject drugs, sex workers, gay men and other men who have sex with men, haemodialysis recipients and people who are hepatitis C antibody positive or HIV antibody positive versus the general population or asymptomatic HBsAg-positive people, suggesting shared risk factors. The geographical distribution of HDV infection among HBsAg-positive people globally is very heterogeneous, with endemic pockets and high prevalence reported in Mongolia, the Republic of Moldova and countries in western and central Africa, central Asia, eastern Europe, some Pacific Islands and the Amazon Basin, driven by key factors, including migration flow patterns, socioeconomic conditions, timing and coverage of HBV vaccination and differences between HDV genotypes.

Who to test

The 2024 WHO guidelines on people with chronic hepatitis B infection *(18)* recommend serological testing for anti-HDV antibodies for all individuals who are HBsAg positive as the preferred approach to scale up access to HDV diagnosis and linkage to care. In settings in which a universal anti-HDV antibody testing approach is not feasible because laboratory capacity or other resources are limited, testing for anti-HDV may be given priority in specific populations of HBsAg-positive individuals, including the following:

- people born in HDV-endemic countries, regions and areas;
- people with advanced liver disease, those receiving HBV treatment or having features suggesting HDV infection, such as low HBV DNA (if available) with high ALT levels; and
- people considered to have increased risk of HDV infection, such as haemodialysis recipients, people living with hepatitis C or HIV, people who inject drugs, gay men and other men who have sex with men and sex workers.

How to test

For people with chronic hepatitis B (HBsAg positive), HDV infection is diagnosed using a serological assay to detect total anti-HDV followed by an NAT to detect HDV RNA and active (viraemic) infection among those anti-HDV positive. Globally, very few of those HBsAg positive are tested for HDV coinfection (anti-HDV antibody) and then, if positive, promptly tested for HDV RNA to diagnose viraemic HDV infection. As for HCV and HBV, one potential way to promote the uptake of HDV serological testing and confirm HDV RNA viraemic infection is by implementing reflex testing. The 2024 WHO guidelines *(17)* recommend reflex testing for anti-HDV antibody testing following a positive HBsAg test result, and if available, also for HDV RNA testing (if available) following a positive anti-HDV antibody test result as an additional strategy to promote diagnosis (see Box 3.1).

Box 3.1 Laboratory-based reflex HDV testing

Laboratory-based reflex HDV testing refers to a testing algorithm in which individuals have only a single clinical encounter and one blood draw or specimen for an initial laboratory-based anti-HDV antibody test. If the individual's sample for HBsAg screening in the laboratory is positive, then the same or a duplicate specimen is automatically used for a prompt reflex laboratory-based anti-HDV test. The results returned to the individual and health-care worker therefore include both the HBsAg result and, if positive, the anti-HDV result. Further reflex testing for the presence of HDV RNA may also be performed at the laboratory level for individuals testing positive for anti-HDV. Currently, reflex testing for anti-HDV can only be implemented through a laboratory-based testing strategy since HDV RDTs are not commercially available to enable clinic-based reflex testing.

Although WHO has no specific recommendations on HDV, preventing HBV transmission through hepatitis B immunization, including a timely birth dose followed by an additional 2–3 doses in infancy, additional antiviral prophylaxis for eligible pregnant women, blood safety, safe injection practices in health-care settings and harm-reduction services with clean needles and syringes are effective in preventing HDV transmission.

Until recently, pegylated interferon-alpha was the only treatment option for HDV. However, its use has been limited by a series of contraindications and poor treatment outcomes and side-effect profile. In 2020, bulevirtide received conditional approval and subsequently full approval in 2023 from the European Medicines Agency for chronic hepatitis D among adults testing positive for HDV RNA with compensated liver disease. More efforts are needed to reduce the global burden of chronic hepatitis B, standardize testing and develop more IVDs for HDV and develop medicines that are safe and effective against HDV and are affordable enough to be deployed on a large scale to those who are most in need.

3.1.2 Normative guidance for HCV

Hepatitis C is an infection of the liver caused by HCV. It can cause both acute (short-term) and chronic (long-term) illness, ranging in severity from mild illness to serious, lifelong illness including liver cirrhosis and cancer. This section summarizes the global guidelines, norms and standards for prevention, diagnosis and treatment for HCV (Fig. 3.3).

Since DAAs were introduced for HCV infection in 2014, there has been progressive and continued evolution in global guidelines towards simplifying HCV testing, treatment and service delivery in a public health approach.

Testing

In 2017, the first WHO guidelines on testing for hepatitis B and C infection made recommendations on who to test and how to test for chronic hepatitis C infection *(29)*.

Who to test

The guidelines recommend offering focused testing to individuals from populations most severely affected by hepatitis C (who are either part of a population with higher seroprevalence or who have a history of exposure to or high-risk behaviour for HCV infection). In settings with a ≥2% or ≥5% seroprevalence of HBsAg or HCV antibody (anti-HCV) (based on existing published thresholds for intermediate or high seroprevalence, respectively), WHO recommends that all adults have routine access to and be offered testing (a general population testing approach) or use birth cohort testing for specific age groups with higher anti-HCV seroprevalence. However, the threshold a country uses depends on other country considerations and the epidemiological context. Overall, these different testing approaches should use existing facility-based (such as antenatal clinics, HIV or TB services) or community-based testing opportunities and programmes.

How to test

Overall, the guidelines recommend a single quality-assured serological in vitro diagnostic test (either a laboratory-based immunoassay [enzyme linked immunoassay or chemoluminiscence immunoassay] or RDT) to detect HCV antibody. The RDTs should meet minimum performance standards and be delivered at the point of care to improve access and linkage to care and treatment.

Self-testing

In 2021, WHO published new guidelines that recommend offering self-testing for HCV as an additional approach to HCV testing services (Box 3.2), especially to reach priority populations that may not otherwise test using existing services and may prefer self-care options *(35)*.

Box 3.2. Hepatitis C self-testing

Since 2021, WHO has recommended offering self-testing for HCV as an additional approach to HCV testing services, especially to reach priority populations that may not otherwise test using existing services and may prefer self-care options. These populations may include key populations and other vulnerable populations as well as those with a high burden of HCV infection, such as men and migrant populations from setting with a high burden of hepatitis C.

Building on the experience of self-testing approaches in other health programme areas, including HIV and COVID-19, these guidelines provide key considerations for policy-makers, national programmes and service providers to design appropriate messages, service delivery models and tools to make HCV self-testing available in various contexts. The guidelines indicate that the HCV testing must be followed by linkage to appropriate post-test services, including confirming viraemic infection and treatment, care and referral services, according to national standards. Communities, including networks of key and vulnerable populations and peer-led organizations, need to be meaningfully and effectively engaged in developing, adapting, implementing and monitoring HCV self-testing programmes. Countries introducing HCV self-testing need to adapt national testing policies and update product regulation, registration and related policies to ensure the availability of affordable quality-assured test kits.

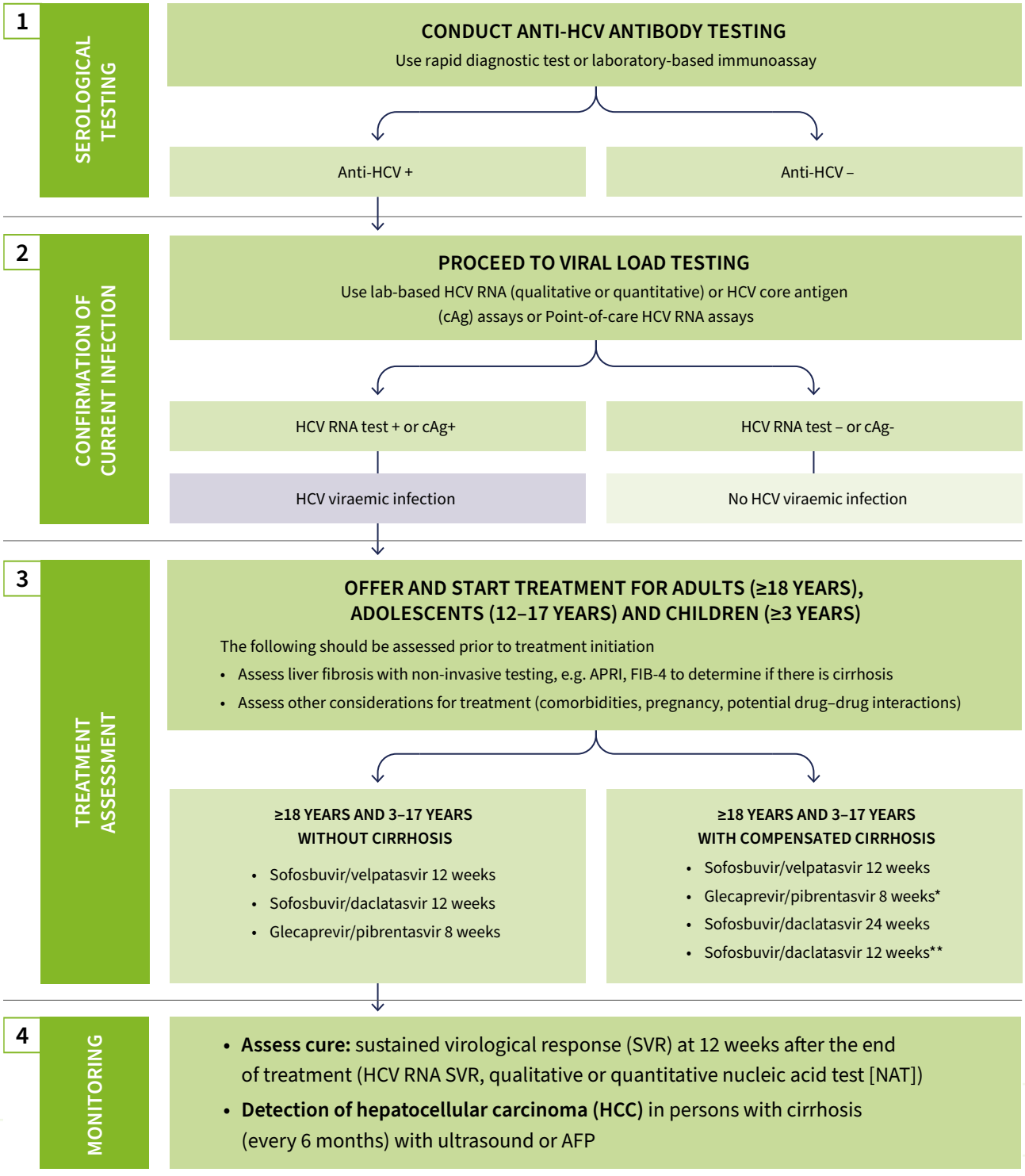
Treatment and service delivery

The 2018 updated guidelines for care and treatment for people diagnosed with chronic hepatitis C introduced further simplifications for delivering diagnosis and treatment, with a "treat-all" approach that recommended that all people living with chronic hepatitis C (except pregnant women and children younger than 12 years) start treatment with DAAs immediately, regardless of disease stage *(36)*.

In 2022, WHO released updated recommendations on treatment for adolescents and children with chronic hepatitis C infection, service delivery and IVDs *(37)*. The main features were as follows.

- **Treatment for adolescents and children**. The 2018 "treat-all" recommendation for all adults was expanded to now include all adolescents and children with chronic hepatitis C three years or older, with the same pangenotypic DAA regimens already recommended for adults (SOF/DAC, SOF/VEL and G/P).
- **Simplified service delivery**. HCV testing and treatment services should be expanded, ideally at the same site, by decentralizing care to lower-level facilities; integrating with existing services, such as in primary care, harm reduction, prisons and HIV services; and promoting task sharing by trained but non-specialist doctors and nurses delivering HCV testing, care and treatment.
- **HCV RNA testing.** Point-of-care HCV RNA assays are now recommended as an additional approach to diagnose viraemic infection, especially among marginalized populations, such as people who inject drugs and hard-to-reach communities with constrained access to health care that have high rates of loss to follow-up. Reflex HCV RNA testing for those with a positive HCV antibody is recommended as an additional strategy to promote linkage to care and treatment. This can be achieved either through laboratory-based reflex HCV RNA testing using a sample already held in the laboratory or clinic-based reflex testing in a health facility through immediate sample collection for HCV RNA testing following a positive rapid HCV antibody test.

Fig. 3.3. Algorithm for testing and treatment of HCV



Source: *Updated recommendations on treatment of adolescents and children with chronic hepatitis C infection, and HCV simplified service delivery and diagnostics (37).*

Prevention

There is currently no effective vaccine against HCV. Hepatitis C can be prevented by adequately screening all donated blood, ensuring safe injection practices in health-care settings, at home and especially among people who inject drugs.

3.2 Access to diagnostics

This section presents the global status of access to viral hepatitis diagnostics used in testing services. It covers the various dimensions of product access, including product selection, quality, regulatory status, intellectual property, pricing and procurement.

Key findings

1 Countries have developed national plans and adopted WHO guidelines to scale up viral hepatitis testing in the public health sector, but implementation varies. More than 70% of the reporting WHO focus countries have a national viral hepatitis testing strategy or policy, and 60% of the reporting focus countries have or are developing a costed testing approach or investment case for scaling up access to viral hepatitis testing. Nearly all reporting countries have a national viral hepatitis screening strategy for priority population groups, with three reporting countries targeting the entire adult population.

2 Incorporating viral hepatitis IVDs into national lists of essential IVDs is limited but increasing; 50% of the reporting focus countries have added or are planning to add viral hepatitis IVDs to their national list of essential IVDs.

3 Access to high-quality viral hepatitis testing services is expanding as national hepatitis programmes mature. More than 50% of the reporting focus countries apply reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval. Nearly 60% of reporting focus countries implement post-market surveillance activities to ensure high-quality viral hepatitis diagnostic testing.

4 Implementation of testing policies remains low, and the lack of funding for viral hepatitis programmes, including for IVDs, has restricted the scale-up of testing; 75% of reporting focus countries rely primarily on government funding or out-of-pocket funding for viral hepatitis testing.

5 The decentralization of testing services is limited. Shortages in funding, policies and human resources have limited the uptake of hepatitis testing overall, including approaches such as self-testing, NAT at- or near-to point-of-care, dried blood spot specimen implementation and community-based case-finding and screening approaches. There is limited use of RDTs in primary care and community settings.

6 Although viral hepatitis testing remains largely centralized, countries report implementing diagnostic integration across diseases and testing services. About 60% of the reporting focus countries share NAT platforms with other disease programmes, and 80% of reporting countries share other related services, such as human resources for testing services.

7 Clear case-finding strategies with simplified testing algorithms and IVDs could lead to wider access, reduced costs and better linkage to care, if accompanied by increased testing uptake and fundings.

3.2.1 Hepatitis B IVDs

Table 3.1 provides an overview of the global landscape of hepatitis B testing and the IVDs required. It summarizes the algorithm for WHO recommendations for diagnosing hepatitis B infection, detection of viraemia for treatment eligibility, and monitoring treatment response and disease progression. In relation to these steps, it presents the respective IVDs that are included in the WHO Model List of Essential In Vitro Diagnostics, the specific products that are WHO prequalified or determined acceptable for procurement and listed by the Expert Review Panel for Diagnostics and benchmark prices.

As of December 2023, two RDTs for use in non-laboratory settings and two immunoassays for use in clinical laboratories have been WHO prequalified for detecting HBsAg. No products for detecting HBV DNA NAT are currently WHO prequalified and none have been submitted for assessment. Suppliers of HBV DNA NAT products should ideally prepare dossiers and apply for WHO prequalification to better support country uptake, implementation and use of high-quality viral hepatitis IVDs. Products for detecting HBeAg (RDTs or immunoassays) are not currently within the scope of prequalification. The sections below provide further details.

Table 3.1. Global overview of hepatitis B IVDs

	Serological testing to screen for HBV infection and diagnose acute and chronic HBV infection	Determining HBV DNA for treatment eligibility, and monitoring treatment response and disease progression
WHO guidelines[a]	HBsAg – RDT or laboratory-based immunoassay	HBV viral load HBeAg – laboratory-based immunoassay
Assay types listed in WHO Model List of Essential In Vitro Diagnostics	***Community settings and health facilities without laboratories:***	
	HBsAg RDT	HBeAg RDT
	Clinical laboratories	
	HBsAg RDT (with particle agglutination additionally listed for use in blood screening) HBsAg immunoassay	Quantitative HBV NAT HBeAg immunoassay IgM anti-hepatitis B core antigen immunoassay
Products with WHO prequalification[b]	**HBsAg RDT** 1) Bioline HBsAg WB (Abbott Diagnostics Korea) 2) Determine HBsAg 2 (Abbott Diagnostics Medical Company) **HBsAg immunoassay** 1) Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3 (DiaSorin S.p.A, UK Branch) 2) DS-EIA-HBsAg-0,01 (RPC Diagnostics Systems)	**HBV DNA** None submitted to date **HBeAg RDT, HBeAg immunoassay** Product category currently not eligible for WHO prequalification
Products with Expert Review Panel-listing[b]	**HBsAg RDT** 1) Standard Q HbsAg (SD Biosensor, Inc.) – 2022 and 2023-Extension 1 2) HBsAg RDT available on request to the Global Fund[c]	**HBV DNA** None **HBeAg RDT, HBeAg immunoassay** None
Benchmark prices	**HBsAg RDT prices paid by countries:** about US$ 1 per test **Benchmark price**: global prices for HBsAg RDTs are generally comparable with those of RDTs across other disease areas	**HBV viral load prices paid by countries**: US$ 9.36–62.00 **Benchmark price:** several HBV viral load suppliers offer global access pricing at US$ 9–16

Source for information on prices: *Hepatitis B market report (38)*.

[a] *Updated recommendations on prevention, diagnosis, care and treatment for people with chronic hepatitis B infection (18)*.
[b] As of December 2023. For details on products prequalified and Expert Review Panel listed, see subsection 3.1.2.2.
[c] The list of products eligible for Global Fund procurement is available at https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf.
Note: Updated WHO guidelines also provide options for clinical criteria and other non-invasive tests to be used for assessing eligibility for treatment. Since these tests are not specific to hepatitis B, they are outside the scope of the current report.

3.2.1.1 Product selection

The WHO Model List of Essential In Vitro Diagnostics provides countries with a reference for the development and update of national lists of essential IVDs. Essential IVDs are those that satisfy the priority health-care needs of the population and are selected with due regard to disease prevalence, public health relevance, evidence of efficacy and accuracy and comparative cost–effectiveness. IVDs in the WHO Model List of Essential In Vitro Diagnostics are intended to be available in the context of functioning health systems, always performed with assured quality and adequate information *(39)*.

Table 3.2 presents the IVDs for HBV that are included in the 2023 WHO Model List of Essential In Vitro Diagnostics.

Table 3.2. IVDs for HBV included in the 2023 WHO Model List of Essential In Vitro Diagnostics

IVD test	Test purpose	Assay format	Specimen type
Disease-specific IVDs recommended for use in community settings and health facilities without laboratories			
HBsAg	To screen for HBV infection and to aid in diagnosing chronic and acute HBV infection: infants > 12 months of age, children, adolescents and adults. (For acute infection, IgM-specific antibodies to hepatitis B core antigen (IgM anti-HBc) are needed in addition to HBsAg.)	RDT	Capillary whole blood, venous whole blood
HBeAg	Staging to assess the need for hepatitis B treatment in chronic hepatitis B infection together with ALT measurement and as a criterion for antiviral therapy for the mother to prevent mother-to- child transmission (used only when an HBV DNA test is not available).	RDT	Capillary whole blood, venous whole blood
Disease-specific IVDs recommended for use in clinical laboratories			
HBsAg	To screen for HBV infection and to aid in diagnosing chronic and acute HBV infection: infants > 12 months of age, children, adolescents and adults	RDT	Venous whole blood, capillary whole blood, plasma, serum
	(For acute infection, IgM-specific antibodies to hepatitis B core antigen are needed in addition to HBsAg.)	Immunoassay	Plasma, serum
Quantitative HBV NAT	To stage chronic HBV infection, to determine the need for treatment (including antiviral therapy for the mother to prevent mother-to-child transmission) and to monitor response to treatment	NAT	Serum, plasma
HBeAg	Staging to assess the need for HBV treatment in chronic HBV infection together with ALT measurement and as a criterion for using antiviral therapy for the mother to prevent mother-to-child transmission (used only when HBV DNA test is not available).	Immunoassay	Serum, plasma
IgM-specific antibodies to hepatitis B core antigen	To aid in diagnosing acute HBV infection in the context of outbreak investigation	Immunoassay	Serum, plasma
Antibodies to HBsAg	To determine immune status resulting from HBV immunization	Immunoassay	Serum, plasma
Disease-specific IVDs recommended for use in blood screening laboratories			
HBsAg	To screen blood donations for HBV	RDT	Capillary whole blood, venous whole blood, plasma, serum
		Particle agglutination assay	Plasma, serum
		Immunoassay	Plasma, serum

Source: *The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022 (including the fourth WHO model list of essential in vitro diagnostics)* (41).

3.2.1.2 Product quality, safety and performance

The availability of quality-assured IVDs is essential to ensure that everyone can access testing services that are reliable and effective. As of December 2023, four HBsAg assays (two RDTs and two enzyme immunoassays) were WHO prequalified (Table 3.3). Table 3.4 presents the additional hepatitis B IVD products listed under the Expert Review Panel as of December 2023.

WHO encourages manufacturers of HBsAg RDTs to apply for WHO prequalification. For HBV DNA NAT, manufacturers who already have NAT platforms with other WHO-prequalified IVDs are encouraged to apply for WHO prequalification as are others who are new to prequalification. Doing so may expedite national regulatory approval, uptake and implementation of IVDs since many countries rely on WHO prequalification, as do international implementing partners that might be supporting national viral hepatitis programmes.

Table 3.3. Status of IVD products for HBV prequalified by WHO, 2023

Type of assay	Product name	Manufacturer	Date product prequalified
HBsAg RDT	Bioline HBsAg WB	Abbott Diagnostics Korea Inc.	2017
	Determine HBsAg 2	Abbott Diagnostics Medical Co. Ltd	2019
HBsAg immunoassay	Murex HBsAg Version 3 with Murex HBsAg Confirmatory Version 3	DiaSorin S.p.A UK Branch	2014
	DS-EIA-HBsAg-0,01	RPC Diagnostics Systems	2016

Table 3.4 Status of IVD products for HBV listed under the Expert Review Panel for Diagnostics, 2023

Type of assay	Product name	Manufacturer	Risk category	Year of review
HBsAg RDT	Standard Q HBsAg Test	SD Biosensor, Inc.	2	2023-Extension 1

The WHO Technical Specifications Series, intended to support submission for WHO prequalification specifically intended for IVDs used to detect HBV DNA, was published on the WHO website in 2022 *(40)*.

3.2.1.3 Product availability and implementation

Access to quality-assured hepatitis B IVDs varies across countries and regions (Table 3.5). Several countries have many products available for HBsAg RDTs and laboratory-based HBsAg testing. In contrast, a limited number of products are typically available for HBeAg and HBV NAT in all countries. Of the 22 reporting WHO focus countries, the median number of hepatitis B diagnostic products per country was eight. This number of products per country is likely reasonable in relation to needs and supply chain management. Some countries have many options available for procurement (10 or more products). Although this may provide a variety of options for implementation and pricing negotiation, overall system management will be critical to ensure consistent availability, adequate training, clear guidance and education for each product and support for product selection, if left to regional authorities or health-care facilities.

Nearly all countries surveyed implement RDTs at least to the primary care level. NAT was generally conducted at the secondary and/or tertiary health-care levels only and should be further decentralized.

Table 3.5. Number of viral hepatitis B IVDs available per country per assay category, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (in parantheses: number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Laboratory-based HBsAg**	**Laboratory - based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
African Region					
Ethiopia	1			1	
Ghana	10 **(2)**			1	
Uganda	1 **(1)**		1	1	
Region of the Americas					
Brazil	1			2	1
Colombia	5	25	7	5	
Mexico	2	19	1	2	2
South-East Asia Region					
Indonesia	41 **(2)**	12	3	3	1
Myanmar	1 **(1)**				
Thailand	16 **(2)**	4	4	4	
European Region					
Georgia	4	9	1	4	
Republic of Moldova	1	1	1		1
Russian Federation	3	3	3	3	
Ukraine	3 **(1)**			1	
Uzbekistan	1	4	1	1	1
Eastern Mediterranean Region					
Egypt		3		2	
Pakistan	1			1	
Yemen	6	4		3	
Western Pacific Region					
Cambodia	1 **(1)**			1	1
China	4	4	3	5	
Lao People's Democratic Republic	5			1	
Mongolia	14	6	2	1	1
Vanuatu	1 **(1)**			1	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

More than 70% of the reporting WHO focus countries (17 of 23) had a national hepatitis B testing strategy or policy that has been adopted and is being implemented. The hepatitis testing strategy for 76% of these countries included at least one serology test before following up with NAT – in accordance with WHO guidelines. In addition, some countries require several serological assays within the national testing algorithm (n = 3) or add an additional test type within the testing algorithm (n = 4). Implementing more and/or multiple tests within the testing strategy may not provide considerable return on investment. Although it could, slightly, improve the overall positive or negative predictive value of the testing strategy, it may potentially lead to confusion in interpretation and is likely to delay linkage to treatment. For several countries, specific products or brands are not identified within the hepatitis B testing algorithm, which could challenge implementation in the countries with considerable numbers of options available for procurement – leaving product selection to decentralization (county or province or health-care facility). Simplification and clarity within the national hepatitis B testing algorithm is likely to support increase uptake and linkage to treatment and care.

Ninety per cent of the reporting countries (21 of 23) offer focused testing to individuals from the most severely affected populations as part of the national testing approach for hepatitis B. The populations covered vary considerably across countries. Three countries (Georgia, Mongolia and Uzbekistan) target the entire adult population. The populations mentioned by other reporting countries include pregnant women (14 reporting countries), people who use drugs (13 reporting countries), female sex workers (11 reporting countries), men who have sex with men (11 reporting countries), health-care workers (10 reporting countries), people living with HIV (nine reporting countries), transgender people (eight reporting countries), blood donors (seven reporting countries), people in prisons and other closed settings (seven reporting countries) and household and/or sexual contacts (seven reporting countries). Some countries also include homeless people and children of parents with hepatitis B, but this was fewer than seven reporting countries.

Facility-based testing was the primary way of finding people with hepatitis B. Inpatient and outpatient hospital settings (21 of 23 reporting countries), routine testing in antenatal care settings (17 reporting countries), HIV service delivery points (17 reporting countries), primary clinics (14 reporting countries) and harm-reduction services for people who inject drugs (12 reporting countries) were the primary facility-based settings used to identify people with hepatitis. About 50% of reporting countries (12 of 23) indicated that community-based viral hepatitis B testing approaches were being implemented.

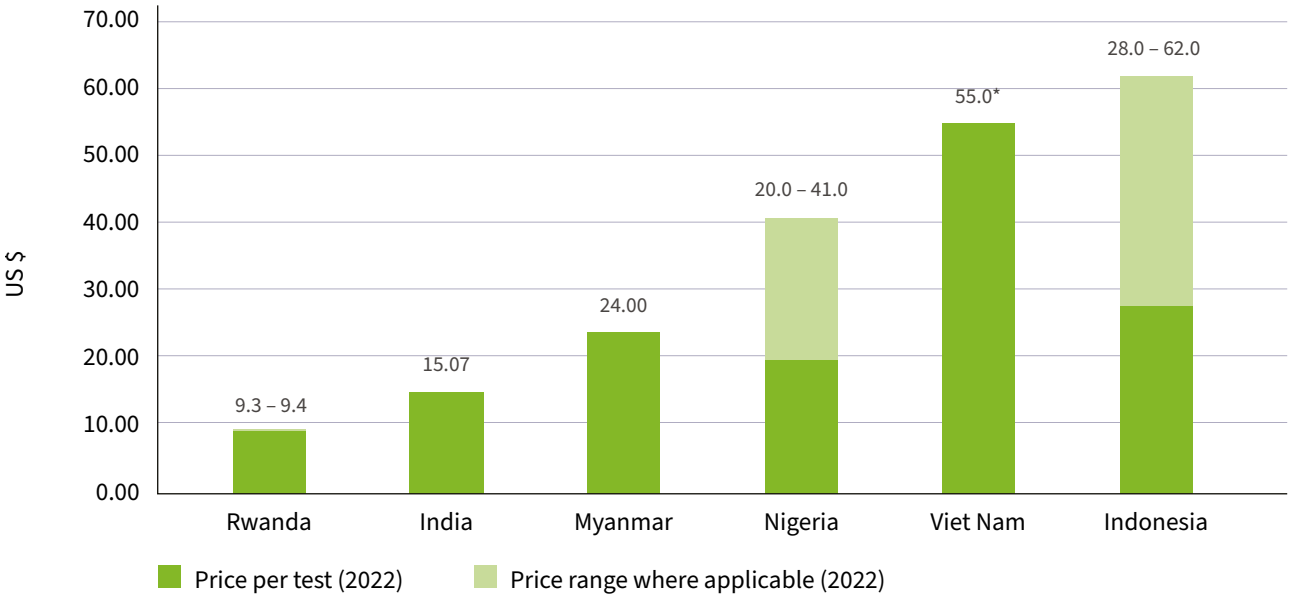
3.2.1.4 Product pricing

The *Hepatitis B market report 2022* from the Clinton Health Access Initiative (Box 3.3) reported data on market trends and prices of hepatitis B IVDs *(38)*. For RDTs, most countries with a high burden of hepatitis B were procuring the HBsAg RDT at about US$ 1 per test in the public sector in 2022, ranging from US$ 0.09 in India to US$ 2.40 in Nigeria, which was generally comparable with the price of RDTs across other disease areas. Differences, higher or lower, were based on procurement modalities used and/or whether procuring locally manufactured products was given priority.

The total cost paid by countries for HBV DNA NAT in selected hepatitis programmes supported by the Clinton Health Access Initiative in 2022 varied between US$ 9.36 and US$ 62.00 (Fig. 3.4). However, the prices for the same tests when procured using domestic funds and other pathways may not be the same.

With support from Unitaid, the Clinton Health Access Initiative led the development of a Diagnostic Pricing Database to provide and compare supplier pricing and offering across components of test procurement, including commodities, logistics, service and key product features *(42)*. In 2022, several HBV DNA NAT suppliers, especially those who supply multi-disease platforms, offered global access pricing from US$ 9.00 to US$ 16.00. It was estimated that 145 countries were eligible for global access pricing agreements with at least one supplier. However, although many hepatitis B NATs are relatively inexpensive and comparable to higher-volume assays, such as HIV viral load and human papillomavirus testing, the consistency of these prices can vary based on how they are procured. For example, the number of platform or device placements, test volumes, service and maintenance conditions and distributor conditions can affect the final price.

Fig. 3.4. Price of HBV viral load assays paid by selected country programmes supported by the Clinton Health Access Initiative in low- and middle-income countries, US$, 2022



*According to the National Social Health Insurance (SHI) scheme, the price of HBV tests is covered 80 percent by the policy and patients pay the remaining 20 percent out of pocket.

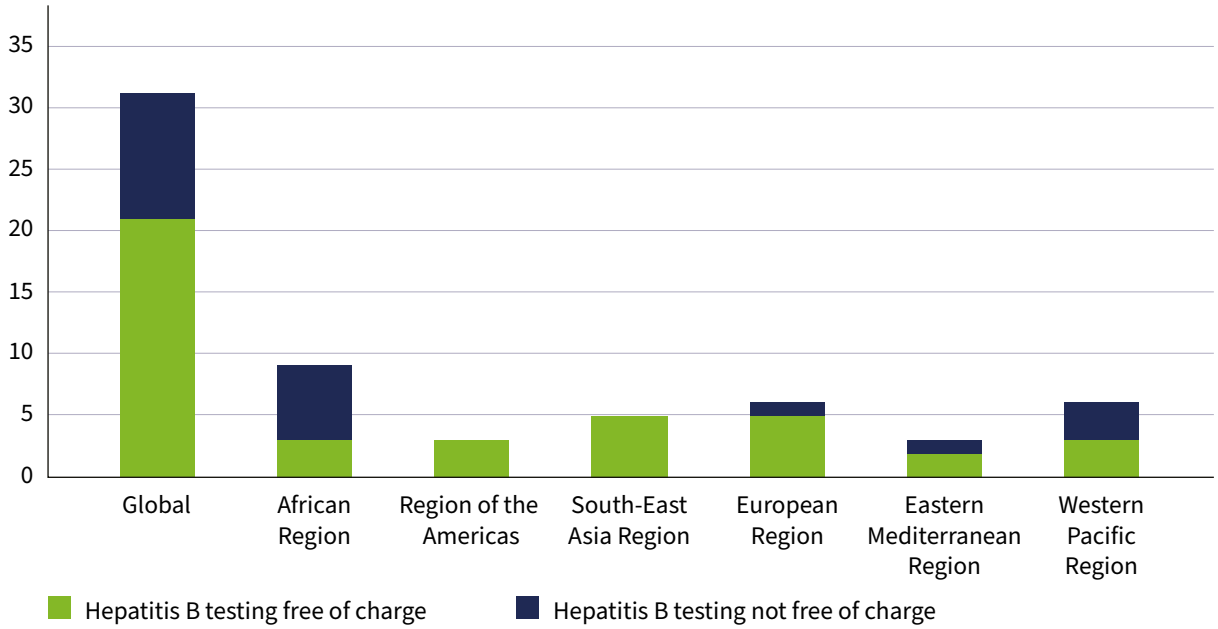
Source: *Hepatitis B market report 2022 (38).*

Box 3.3. Clinton Health Access Initiative

The Clinton Health Access Initiative supports low- and middle-income countries in scaling up access to viral hepatitis commodities through market shaping and price negotiations. In May 2023, the Clinton Health Access Initiative and The Hepatitis Fund signed two new memoranda of understanding with generic manufacturers Viatris and Hetero to make treatment for hepatitis B and C virus available at lower cost to low- and middle-income countries *(43)*. The Clinton Health Access Initiative has also provided support to various countries, including Cambodia, India, Indonesia, Myanmar, Nigeria, Rwanda and Viet Nam, for resource mobilization, pricing negotiations with suppliers, policy development, fast-track registration of quality-assured generics, implementation of simplified service delivery models, and advocacy support *(44)*.

Since 2020, the Clinton Health Access Initiative has published regular market reports with a detailed overview of the supplier landscape, prices and volume trends for WHO-recommended health products for viral hepatitis. Information from the Hepatitis B market report 2022 *(38)* and the Hepatitis C market intelligence report 2023 *(45)* is presented in this report as relevant. These reports complement the WHO global progress reports by providing comprehensive supplier-side and market information.

Fig. 3.5. Availability of hepatitis B testing free of charge in the public sector, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.2.1.5 Out-of-pocket expenditure

Financial protection is at the core of universal health coverage. It is achieved when direct payments made to obtain health services do not expose people to financial hardship and do not threaten living standards. Key to protecting people is to ensure prepayment and pooling of resources for health rather than relying on people paying for health services out of pocket at the time of use *(46)*.

Of the 31 WHO focus countries for which information on out-of-pocket expenditure was available, 21 reported that hepatitis B testing is available free of charge in the public sector, either fully or for specific subpopulations or geographical areas, such as for pregnant women, key populations and inpatients in Myanmar; for people who have compulsory health insurance in the Republic of Moldova; and variable access by administrative region in the Russian Federation (Fig. 3.5). Chapter 4 provides details by focus country.

3.2.1.6 Procurement, local production and technology transfer

Many low- and middle-income countries have limited access to the resources, technologies and specialized staff for hepatitis B diagnosis. Domestic manufacturing of hepatitis B IVDs may help to meet country-specific demand *(47)*. The African Region, which accounts for 63% of new hepatitis B infections, currently has the most limited capacity for local production of hepatitis B IVDs. It relies almost entirely on imports from countries in other regions, such as China, India and Malaysia, which account for 84% of the products imported *(48)*.

Local manufacturing capacity exists in countries such as Brazil and Canada in the Region of the Americas; France, Germany and Spain in the European Region; Bangladesh and India in the South-East Asia Region; and China, Malaysia and the Republic of Korea in the Western Pacific Region.

Of the 20 reporting WHO focus countries that provided this information, 11 had experienced no challenges in procuring and supplying quality-assured viral hepatitis B IVDs in recent years. Of those that experienced challenges, common issues were stock-outs, low testing volumes, commodity expiry, high error rates and broken-down platforms.

3.2.2 Hepatitis C IVDs

This section provides information on the global status of access to hepatitis C IVDs. It covers the various dimensions of product access, including product selection, quality, regulatory status, intellectual property, pricing and procurement.

Table 3.6 provides an overview of the global landscape of hepatitis C IVDs. It summarizes the algorithm of WHO recommendations for diagnosing chronic hepatitis C infection, confirming infection for treatment and monitoring treatment response and disease progression. In relation to these steps, it presents the respective diagnostic products included in the WHO Model List of Essential In Vitro Diagnostics, the specific products that are WHO prequalified or determined acceptable for procurement and listed by the Expert Review Panel for Diagnostics and benchmark prices.

As of December 2023, six RDTs for use in non-laboratory settings and three immunoassays for use in clinical laboratories have been WHO prequalified for detecting hepatitis C antibodies. Five products for detecting HCV RNA are currently WHO prequalified. One product for detecting HCV core antigen has been WHO prequalified. The sections below provide further details.

Table 3.6. Global overview of the landscape of access to hepatitis C IVDs

	Serological testing to screen for HCV antibodies and to aid in diagnosing viraemic HCV infection	**Confirming HCV viraemia to initiate treatment and monitoring sustained virological response at 12 weeks after the end of treatment**
WHO guidelines	RDT or laboratory-based immunoassay Self-testing	**HCV viral load:** Laboratory-based HCV RNA (qualitative or quantitative) NAT or HCV core antigen assays or point-of-care HCV RNA NAT
Assay types listed in WHO Model List of Essential In Vitro Diagnostics	***Community settings and health facilities without laboratories***	
	anti-HCV RDT	HBeAg RDT
	Clinical laboratories	
	anti-HCV RDT anti-HCV immunoassay combined anti-HCV and HCVcAg anti-HCV and combined anti-HCV and HCVcAg for use in blood screening	HCVcAg qualitative or quantitative HCV NAT
Products with WHO prequalification[b]	**Anti-HCV RDT** 1. Bioline HCV (Abbott Diagnostics Korea Inc.) 2. OraQuick HCV Rapid Antibody Test Kit (OraSure Technologies, Inc.) 3. Rapid Anti-HCV Test (InTec Products, Inc.) 4. STANDARD Q HCV Ab Test (SD Biosensor, Inc.) 5. First Response HCV Card Test (Premier Medical Corporation Pvt Ltd) 6. HCV Hepatitis C Virus Rapid Test Device (ABON Biopharm) **Anti-HCV immunoassay** 1. INNO-LIA HCV Score (Fujirebio Europe NV)a 2. INNOTEST HCV Ab IV (Fujirebio Europe NV) 3. Monolisa HCV Ag-Ab ULTRA V2 (Bio-Rad)	**HCV viral load** 1. Xpert HCV Viral Load (Cepheid AB) 2. Abbott RealTime HCV (Abbott Molecular Inc) 3. Alinity m HCV (Abbott Molecular Inc) 4. cobas HCV (Quantitative NAT for use on cobas 5800/6800/8800 Systems) (Roche Diagnostics GmbH) 5. Xpert HCV VL Fingerstick (Cepheid AB) – the only assay that can be used at- or near-to point-of-care **HCVcAg** 6. ARCHITECT HCV Ag assay (Denka Seiken Co., Ltd, Kagamida Factory)
Products with Expert Review Panel-listing[b]	**Anti-HCV RDT:** None **Anti-HCV Immunoassay:** None **Self-testing:** None	**HCV viral load:** None **HCVcAg:** None
Benchmark prices	**HCV RDT prices paid by countries**: US$ 0.21 to US$ 2.42 per test **Benchmark price**: US$ 0.80–1.10 ex works (Global Fund Pooled Procurement Mechanism)	**HCV viral load test prices paid by countries**: US$ 6.12 to US$ 56.40 **Benchmark price**: several HCV viral load suppliers offer global access pricing at US$ 8 - 15

Source for information on prices: *Hepatitis C market intelligence report (45)*.
[a]The product was prequalified before WHO guidelines for hepatitis C diagnosis were updated.
[b]As of December 2023. For details on products prequalified and listed by the Expert Review Panel, see subsection 3.2.2.2.
The list of products eligible for Global Fund procurement is available at https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf.

3.2.2.1 Product selection

As noted in subsection 3.1.2.1, the WHO Model List of Essential In Vitro Diagnostics provides countries with a reference for developing and updating national essential lists of essential IVDs. Table 3.7 presents the IVDs for HCV included in the 2023 WHO Model List of Essential In Vitro Diagnostics.

Table 3.7. IVDs for HCV included in the 2023 WHO Model List of Essential In Vitro Diagnostics

IVD test	Test purpose	Assay format	Specimen type
Disease-specific IVDs recommended for use in community settings and health facilities without laboratories			
Antibodies to HCV (anti-HCV)	To screen for and to aid in the diagnosis of viraemic HCV infection: infants >18 months of age, children, adolescents and adults	RDT	Oral fluid Capillary whole blood Venous whole blood
Disease-specific IVDs recommended for use in clinical laboratories			
Antibodies to HCV (anti-HCV)	To screen for and to aid in the diagnosis of viraemic HCV infection: infants >18 months of age, children, adolescents and adults	RDT	Capillary whole blood Venous whole blood Plasma Serum
		Immunoassay	Serum Plasma
Combined antibodies to HCV (anti-HCV) and HCVcAg	To screen for HCV infection, and to aid in the diagnosis of viraemic HCV infection: infants >18 months of age, children, adolescents and adults	Immunoassay	Serum Plasma
HCVcAg	To aid in the diagnosis of viraemic HCV infection	Immunoassay	Serum Plasma
Qualitative or quantitative HCV NAT	To diagnose viraemic HCV and as a test of cure	NAT	Capillary whole blood Venous whole blood Serum Plasma dried blood spots
Disease-specific IVDs recommended for use in blood screening laboratories			
Antibodies to HCV (anti-HCV)	To screen blood donations for HCV	RDT	Capillary whole blood Venous whole blood Plasma Serum
		Immunoassay	Serum Plasma
Combined antibodies to HCV (anti-HCV) and HCVcAg	To screen blood donations for HCV	Immunoassay	Serum Plasma

Source: *The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022 (including the fourth WHO model list of essential in vitro diagnostics) (41).*

3.2.2.2 Product quality, safety and performance

As noted in subsection 3.1.2.3, the availability of quality-assured IVDs is essential to ensure that everyone can access testing services that are reliable and effective. As of December 2023, 15 IVD products for HCV were WHO prequalified (Table 3.8). Another two HCV RDTs and one HCV RNA NAT were undergoing prequalification assessment. As of December 2023, no products had Expert Review Panel listing.

Table 3.8. Status of IVD products for HCV that are prequalified by WHO, 2023

Type of assay	Product name	Manufacturer	Date product prequalified
Anti-HCV RDT	Bioline HCV (formerly SD BIOLINE HCV)	Abbott Diagnostics Korea Inc. (formerly Standard Diagnostics, Inc.)	2016
	OraQuick HCV rapid antibody test kit	OraSure Technologies, Inc.	2017
	Rapid anti-HCV test	InTec Products, Inc.	2019
	STANDARD Q HCV Ab test	SD Biosensor, Inc.	2020
	First Response HCV Card Test	Premier Medical Corporation Private Limited	2023
	HCV Hepatitis C Virus Rapid Test Device (whole blood/serum/plasma)	ABON Biopharm (Hangzhou) CO., LTD	2023
Anti-HCV immunoassay	INNO-Lia HCV Score	Fujirebio Europe NV	2015
	INNOTEST HCV Ab IV	Fujirebio Europe NV	2018
	Monolisa HCV Ag-Ab ULTRA V2	Bio-Rad	2020
HCV viral load	Xpert HCV Viral Load with GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80	Cepheid AB	2017
	Abbott RealTime HCV	Abbott Molecular Inc.	2019
	Alinity m HCV	Abbott Molecular Inc.	2020
	Cobas HCV (Quantitative NAT for use on cobas 6800/8800 Systems)[a]	Roche Diagnostics GmbH	2021
	Xpert HCV VL Fingerstick[a]	Cepheid AB	2022
HCVcAg	ARCHITECT HCV Ag assay	Denka Seiken Co., Ltd, Kagamida Factory	2019

The product Murex anti-HCV (version 4.0), manufacturer DiaSorin South Africa (Pty) Ltd, prequalified in 2015, was withdrawn from prequalification listing in 2019 at the request of the manufacturer.

The product Genedrive HCV ID Kit, manufacturer Genedrive Diagnostics Ltd, prequalified in 2020, was delisted from prequalification listing in 2020 because the manufacturer was unable to verify the claimed analytical limit of detection as a post-prequalification commitment.

[a]Additional IVDs for HCV that are prequalified by WHO versus the 2021 edition of this report *(3)*.

3.2.2.3 Product availability and implementation

Access to quality-assured hepatitis C IVDs varies across countries and regions (Table 3.9). Only one country noted that IVDs are available for HCV self-testing. All countries had anti-HCV RDTs available. All but three countries also had HCV RNA NAT available. Several countries have many products available for anti-HCV RDTs. Of the 22 reporting countries, the median number of hepatitis C products per country was seven. This number of products per country is likely reasonable in relation to needs and supply chain management. Some countries have many options available for procurement (10 or more products). Although this may provide a variety of options for implementation and pricing negotiation, overall system management will be critical to ensure consistent availability, adequate training, clear guidance and education for each product and support for product selection if left to regional authorities or health-care facilities.

In addition to IVDs for HCV self-testing, there is limited use of laboratory-based HCVcAg and HCV Ag/Ab assays as well as multiplex RDTs that test for anti-HCV and any other pathogen such as HIV or HBsAg. Nearly all countries surveyed implement RDTs at least to the primary care level. However, NAT was generally only conducted at the secondary and/or tertiary health-care levels, with some consideration for NAT at- or near-to point-of-care.

Table 3.9. Number of viral hepatitis C IVDs available per country per assay category, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses**: number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
African Region								
Ethiopia		1				1 **(1)**		
Ghana		4	2					
Region of the Americas								
Brazil		2 **(1)**				2 **(2)**	1 **(1)**	
Colombia		12 **(3)**	25 **(2)**	2	1	16 **(4)**		
Mexico		2	5		5 **(1)**	2 **(2)**		
South-East Asia Region								
Indonesia		25 **(3)**	8 **(1)**			4 **(2)**	3 **(2)**	
Myanmar		1 **(1)**	1			1 **(1)**		
Thailand		14 **(4)**	4	1	1	3 **(2)**	1 **(1)**	
European Region								
Georgia		4	7 **(1)**	1		3 **(1)**	1 **(1)**	
Republic of Moldova		1	3				1 **(1)**	
Russian Federation	1	1	2	1	1	3		1
Ukraine		2				2 **(2)**		
Uzbekistan		1	2			2	2	
Eastern Mediterranean Region								
Egypt		2	3			2 **(1)**		
Morocco		1				1		
Pakistan		2		1		1		
Yemen		6	4			3 **(1)**		
Western Pacific Region								
Cambodia		1 **(1)**				1 **(1)**	1 **(1)**	
China		2	5	4	3	2		2
Lao People's Democratic Republic		6 **(1)**				1 **(1)**		
Mongolia		14	4			1	1 **(1)**	
Vanuatu		1 **(1)**						

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

More than 75% of reporting countries (18 of 23) had a national hepatitis C testing strategy or policy that has been adopted and is being implemented. The hepatitis testing strategy for all but one of these countries included at least one serology test before following up with one NAT – in accordance with WHO guidelines. In addition, some countries require several serological assays within the national testing algorithm (n = 3), both quantitative and qualitative NAT (n = 2) or add an additional test type (immunoassay) within the testing algorithm (n = 1). Implementing more and/or multiple assays may not provide considerable return on investment. Although it could, slightly, improve the overall positive or negative predictive value of the testing algorithm, it may potentially lead to confusion in interpretation and is likely to delay linkage to treatment. For several countries, specific products or brands are not identified within the hepatitis C testing algorithm, which could challenge implementation in these countries with considerable numbers of options available. Simplification and clarity within the national viral hepatitis C testing algorithm are likely to support increase uptake and linkage to treatment and care.

Ninety per cent of reporting countries (21 of 23) offer focused testing to individuals from most severely affected populations as part of the national testing approach for hepatitis C. The populations covered considerably across countries. Three countries (Georgia, Mongolia and Uzbekistan) prioritize the entire adult population for screening. The populations mentioned by other countries include people who use drugs (15 reporting countries), people living with HIV (12 reporting countries), men who have sex with men (12 reporting countries), people in prisons and other closed settings (11 reporting countries), health-care workers (nine reporting countries), female sex workers (nine reporting countries), people receiving haemodialysis (eight reporting countries), people suspected of being or exposed to hepatitis C (seven reporting countries), pregnant women (six reporting countries), household and/or sexual contacts (six reporting countries), blood donors (six reporting countries), and transgender people (six reporting countries). Some countries also include other populations in their focused testing approach, such as migrants, homeless people and the children of parents with hepatitis C, but each were reported in less than six reporting countries.

Facility-based testing was the primary mode for case finding of people with hepatitis. Inpatient and outpatient hospital settings (21 of 23 reporting countries), routine testing in antenatal care settings (17 reporting countries), HIV service delivery points (17 reporting countries), primary clinics (14 reporting countries) and harm-reduction services for people who infect drugs (12 reporting countries) were the primary facility-based settings used to identify people with hepatitis. Nearly 50% of reporting countries (11 of 23) indicated that community-based viral hepatitis C testing approaches were being implemented.

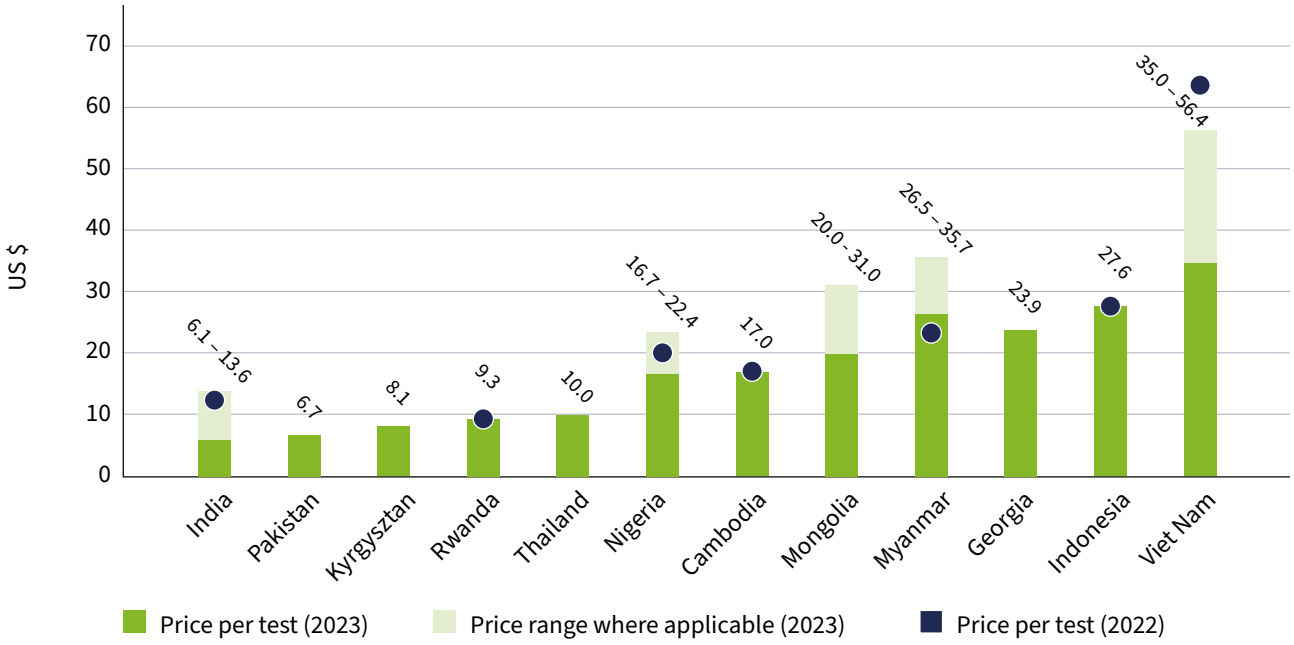
3.2.2.4 Product pricing

The *Hepatitis C market intelligence report* reported data on market trends and prices for hepatitis C IVDs *(45)*. The report indicated that in 2023, the price of hepatitis C RDTs in the public sector ranged between US$ 0.21 per test in India to US$ 2.42 per test in Kyrgyzstan. Differences, higher or lower, were based on how they were procured and/or whether procurement of locally manufactured products was given priority.

The total cost paid by countries for HCV RNA NAT in selected country programmes supported by the Clinton Health Access Initiative in 2023 ranged from US$ 6.12–13.67 in India to US$ 35.00–56.40 in Viet Nam (Fig. 3.6). Several countries accessed prices of US$ 10 or less. Similar to hepatitis B NAT, the prices for the same tests may not be same when procured using domestic funds or other pathways.

Similar to hepatitis B IVDs, the Diagnostic Pricing Database provides and compares supplier pricing and offers across components of test procurement, including commodities, logistics, service and key product features *(42)*. In 2022, several HCV viral load suppliers offered global access pricing from US$ 8.00 to US$ 15.00, with varying terms and conditions. Global access pricing mechanisms for NAT have enabled more affordable baseline tests across several infectious diseases, including and especially with suppliers that have multi-disease platforms. However, although many hepatitis C RNA NATs are relatively inexpensive and comparable to higher-volume assays, such as HIV viral load and human papillomavirus testing, the consistency of the prices can vary based on how they are procured. For example, the number of platforms and device placements, test volumes, service and maintenance conditions and distributor conditions can affect the final price.

Fig. 3.6. Price of HCV RNA NAT paid by selected programmes supported by the Clinton Health Access Initiative in low- and middle-income countries, US$, 2023

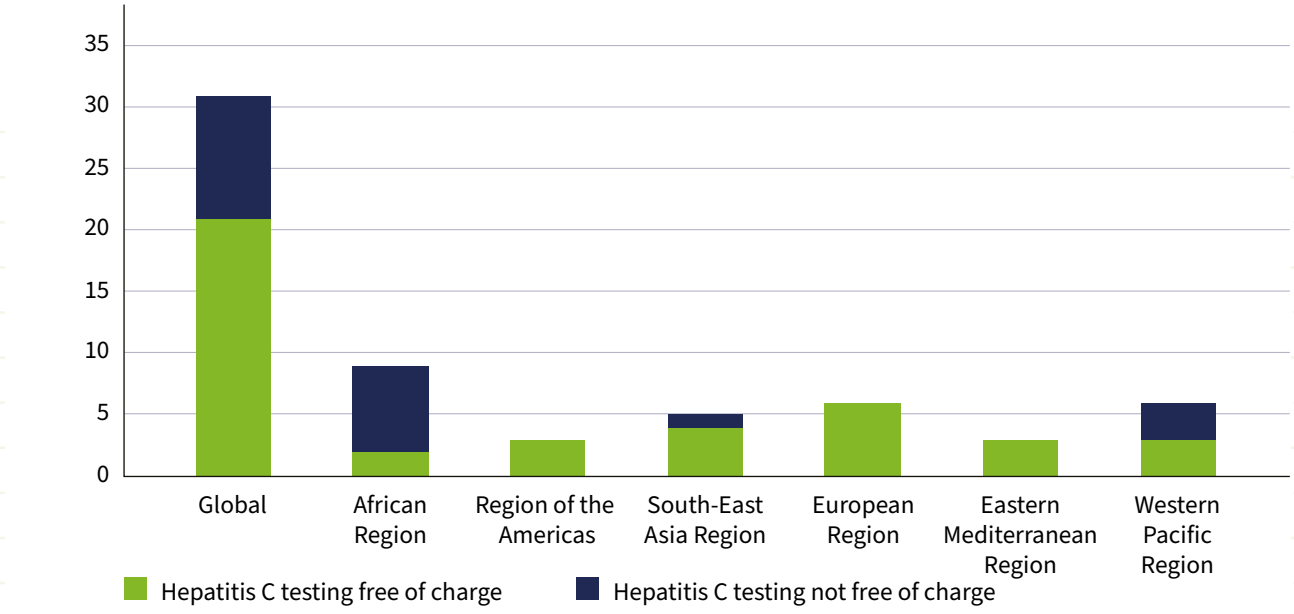


Source: *Hepatitis C market intelligence report (45)*.

3.2.2.5 Out-of-pocket expenditure

As noted for hepatitis B IVDs, financial protection is at the core of universal health coverage. Of the 31 WHO focus countries for which information on out-of-pocket expenditure was available, 21 reported that hepatitis C testing is available free of charge in the public sector, either fully or for specific subpopulations or geographical areas, or with co-payment (Fig. 3.7). Examples include partial reimbursement of the cost of testing in Ghana, free access for pregnant women, key populations and inpatients in Myanmar, free access for people with a compulsory health insurance policy in the Republic of Moldova or free of charge in national and selected provincial hospitals in Viet Nam. Two countries – Mexico and Uzbekistan – reported that HCV self-testing was available free of charge in the public sector. Chapter 4 provides details by focus country.

Fig. 3.7. Availability of hepatitis C testing free of charge in the public sector, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.2.2.6 Procurement, local production and technology transfer

Low- and middle-income countries with high HCV and HIV coinfection prevalence may be eligible for external support, such as through the Global Fund, to improve access to HCV testing. A Global Fund list *(49)* shows that manufacturers of HCV IVDs supplying low- and middle-income countries under this policy are mostly based in high-income countries, except for one manufacturer from India and one from South Africa. It is unclear whether production capacity is adequate locally or regionally to provide timely supply of high-quality HCV IVDs to countries that are not eligible under this policy and/or have high HCV prevalence without HIV coinfection.

Of the 19 reporting WHO focus countries that provided this information, nine had experienced no challenges in procuring and supplying quality-assured viral hepatitis C IVDs in recent years. Of those that experienced challenges, common issues were stock-outs, low testing volumes, commodity expiry, high error rates and broken-down platforms or equipment.

3.2.3 Cross-cutting considerations for viral hepatitis testing

3.2.3.1 National diagnostic planning and financing

Political will, advocacy and developing and implementing policies for hepatitis testing are critical to support access to testing services. In 2023, less than half the reporting WHO focus countries indicated having a national list of essential IVDs (nine of 24). Of those with a national list of essential IVDs, six had incorporated hepatitis B IVDs and five had incorporated hepatitis C IVDs into the national list of essential IVDs. Four reporting countries indicated that a national list of essential IVDs was being developed or forthcoming.

More than 70% of the reporting focus countries have a national viral hepatitis strategy or policy, and nearly 60% of reporting countries (12 of 21) indicated the presence of or development of a costed national viral hepatitis testing approach or an investment case for scaling up access to testing for viral hepatitis. The primary cost drivers of these national costed plans were the commodities (platforms and reagents and tests) and training. In addition, reporting focus countries mentioned the following barriers to expanding access to viral hepatitis testing at affordable prices:

- the lack of available funding
- limited national policies for decentralization
- the high cost of reagents of certain IVDs
- limited human resource and testing capacity outside centralized laboratories
- lack of local production of IVDs.

The main sources of financing for viral hepatitis testing, both commodities and programmes, were government funding (20 of 22 reporting countries), out-of-pocket payments (11 of 22 reporting countries) and bilateral or multilateral support (the Global Fund and WHO) (four of 20 reporting countries). The majority (75%) of reporting countries rely primarily on government funding or out-of-pocket funding for viral hepatitis testing.

Scaling up and expanding viral hepatitis programmes, especially in high-burden countries, requires significant consideration for additional funding and funding sources. Some possibilities for doing so include allocating additional government funding; seeking support from and leveraging national, regional and international donors or bilateral and multilateral agencies; leveraging diagnostic integration to reduce overall viral hepatitis testing programmatic costs and maximize hepatitis-specific funding by improving efficiency; new initiatives, such as The Hepatitis Fund; and further enhancing public–private partnerships.

Box 3.4. Unitaid

Unitaid is a global health agency supporting the development and adoption of innovative solutions for more effective disease prevention, diagnosis and treatment in low- and middle-income countries. Since 2015, Unitaid has invested more than US$ 45 million to support projects to improve access to care for people with hepatitis C. With these investments, Unitaid has driven efforts to develop simpler diagnostic tests that can be used at decentralized levels by non-specialist staff. Further, with the MPP, Médecins Sans Frontières and Coalition PLUS, Unitaid has contributed to securing more affordable prices for hepatitis B and C medicines and facilitating scale-up by identifying cost-effective ways to deliver these medicines.

Through support for the five-year Longevity Project, led by the University of Liverpool, Unitaid is contributing to research into developing a single-injection cure for hepatitis C. With Coalition PLUS, Unitaid has supported advocacy efforts at the government level and awareness raising at the community level to increase diagnosis, combat stigma and generate demand for treatment.

In 2023, Unitaid announced a new investment of US$ 31 million in harm reduction to prevent hepatitis C among people who inject drugs and others at high risk, including by piloting the use of novel or underused products aimed at reducing risks associated with injecting drugs such as low dead-space syringes and new, long-acting formulations of buprenorphine, a medicine used in opioid agonist therapy. Frontline AIDS, Médecins du Monde and PATH will lead the work in 10 countries to assess demand and generate evidence needed to trigger broader scale-up of hepatitis C treatment and prevention through these complementary projects.

3.2.3.2 Product registration and availability

Regulatory gaps, including under-resourced national regulatory authorities, can delay the registration, implementation, access and scaling up of testing. Reliance and collaboration with global, regional or other national regulatory authorities, conformity assessment bodies or other entities can expedite national regulatory approvals. This includes IVDs for viral hepatitis. Nearly 60% of reporting countries (14 of 25) reported applying reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval of viral hepatitis IVDs. The primary conformity assessment bodies or regulatory authorities on which countries relied were WHO prequalification (n = 12), United States Food and Drug Administration (n = 7), European Union, In Vitro Diagnostic Medical Device Directive (soon to be replaced by the In Vitro Diagnostic Medical Devices Regulation) (n = 6), Health Canada (n = 4), Australia, Therapeutic Goods Administration (n = 4) and Japan, Ministry of Health, Labour and Welfare (n = 4). Applying reliance principles can support all countries, even those with strong and developed national regulatory authorities, by sharing and expediting national regulatory approvals, which in turn will support more rapid uptake and implementation of essential IVDs. The collaborative registration procedure enables WHO prequalification assessment reports to be shared with national regulatory authorities based on an agreement with the manufacturer and to facilitate in-country registration of prequalified in vitro diagnostics.

Conducting or ensuring the implementation of post-market surveillance for IVDs is critical to maintaining access to high-quality testing. Nearly 60% of reporting countries (14 of 24) reported conducting post-market surveillance activities for all or some products. The primary activities included incident reporting (13 reporting countries), field safety correction action reporting (11 reporting countries) and annual reporting (five reporting countries). Post-market surveillance activities are critical to ensuring consistent high-quality testing and should be implemented regularly across countries and products.

The use of innovative IVDs across other diseases, primarily community-based testing, testing at- or near-to point-of-care and self-testing remain relatively low within the viral hepatitis programmes of the countries surveyed. There was also limited use of RDTs at the primary care level and in community settings. Further, dried blood spot specimens to support broader access to NAT for viral hepatitis were only used in one country (Ethiopia) of the 20 countries that reported. The primary reasons for the lack of implementation of these innovations were financial constraints, lack of necessary policies and/or limited human resource capacity for implementation. Consideration for innovations, especially those that support the decentralization of access to viral hepatitis testing, will improve both individual and public health and support programme goals.

A report by the Coalition for Global Hepatitis Elimination noted that, although accurate and affordable viral hepatitis IVDs are available, testing is poorly integrated with primary care and is more commonly accessible in specialist care *(50)*. The report encourages countries to adopt advances in telemedicine, self-testing and community-based service delivery models, which were brought into routine practice as part of the COVID-19 response, to strengthen the delivery of viral hepatitis services. Equally, by investing in infrastructure and integrated hepatitis surveillance, countries will strengthen the response to new and emerging infectious diseases overall.

3.2.3.3 Multi-disease platforms and integrating viral hepatitis testing across critical services

Multi-disease platforms and integrating testing can lead to significant gains for national programmes, primarily wider access to testing, lower programmatic and commodity costs and increased efficiency of testing and services. Many countries have begun to pilot or implement the integration of testing, including sharing platforms capable of multi-disease testing and sharing services across diseases and/or programmes. Of the reporting countries, 64% (14 of 22) reported sharing NAT platforms capable of multi-disease testing across programmes. The multi-disease platforms were primarily shared with assays for HIV viral load (12 reporting countries), COVID-19 (12 reporting countries), TB (nine reporting countries), HIV infant diagnosis (seven reporting countries) and human papillomavirus (four reporting countries).

Testing services can be similar and sometimes duplicative across disease programmes. These can include human resources and quality assurance. Integrating diagnostic services can create efficiency for national programmes. Eighty-two per cent of reporting countries (18 of 22) share viral hepatitis diagnostic services with other disease programmes. The key services shared across disease programmes include human resources (17 reporting countries), specimen transport (15 reporting countries), quality assurance (14 reporting countries), waste management (14 reporting countries), training (13 reporting countries), supply chain (10 reporting countries) and data connectivity (nine reporting countries). The diagnostic services were primarily shared with national programmes on HIV (17 reporting countries), TB (10 reporting countries), COVID-19 (eight reporting countries), influenza (five reporting countries) and cervical cancer (four reporting countries).

Molecular testing capacity using NAT dramatically expanded during the COVID-19 pandemic. National programmes should use the gains made during COVID-19 and the considerable international support available for HIV, TB, and malaria disease programmes to implement diagnostic integration by sharing molecular platforms and devices and/or sharing services, such as human resources, specimen transport, supply chain, quality assurance, data connectivity, waste management and training. Doing so will support cost-sharing efforts, reduce overall programmatic costs for all disease programmes, create efficiency in the diagnostic network and result in developing a more optimized, integrated diagnostic network fit to support the needs of the national population.

At the Seventy-sixth World Health Assembly in 2023, WHO Member States adopted a resolution to strengthen diagnostics capacity in countries and to improve access to diagnostic services *(51)*. The resolution urges Member States to take specific steps to strengthen diagnostics capacity, including both IVDs such as RDTs and NAT and other diagnostics, such as imaging or blood pressure measurement devices. It covers actions related to developing testing strategies and algorithms; product regulation, selection and procurement; a skilled workforce; manufacturing (including local production and technology transfer), research and development; and policy measures for equitable and timely access to diagnostics and other health technologies for all.

3.2.3.4 Intellectual property

The role of patent protection is often more complex for IVDs than it is for medicines. This is because many different parts of an IVD and the technique may be patented, and thus the number of relevant patents can often be greater than those for a medicine. For example, a patent landscape analysis by Médecins Sans Frontières on IVDs noted that major IVD manufacturers hold many patents, often bundled into thickets for various instrumentation, assays, methods and software related to different aspects of the technologies, methods and devices *(52)*. More effort is needed to understand patent landscapes and identify key actions to promote access to affordable IVDs.

In January 2024, WHO announced the WHO Health Technology Access Pool (H-TAP), the successor to the COVID-19 Technology Access Pool (C-TAP). The H-TAP provides a structure and process for securing the intellectual property and manufacturing know-how of health technologies that address important health access gaps, and supporting their diversified production *(53)*. H-TAP actively targets technologies relevant to pandemic preparedness and response as well as health products that respond to other public health priorities. In parallel, WHO and the MPP signed a new licensing agreement with SD Biosensor, Inc., to provide sublicensees the right, know-how and material to manufacture SD Biosensor's RDTs, including viral hepatitis RDTs, with the goal of expanding the production base in low- and middle-income countries *(54)*. This recent development has the potential to facilitate the expansion of access to viral hepatitis testing in these countries.

3.3 Access to medicines

Key findings

1 The prices of generic viral hepatitis medicines continue to be low, but many countries are still not accessing generic medicines at these low prices because of policy and access barriers. The prices paid across and within WHO regions vary greatly, and many countries pay higher prices than global benchmarks, even if drugs are off patent or if the countries are included in voluntary licensing agreements or manufacture generic products locally.

Hepatitis B: although TDF for hepatitis B treatment is off patent and available at a global benchmark price of US$ 2.40 per month, less than one third of reporting countries (seven of 26 countries – Burkina Faso, China, India, South Africa, Ukraine, United Republic of Tanzania and Viet Nam) paid prices at or below the benchmark. The lowest reported price paid for a generic monthly treatment of TDF ranges between US$ 1.20 in China and India and US$ 31.90 in the Russian Federation. Where countries report prices of multiple products, the range of prices paid can be much higher. In Viet Nam, the reported prices range between US$ 2.10 and US$ 1849.60 for a monthly supply of a generic product. The Democratic Republic of the Congo reports US$ 108 for a monthly supply of the originator product.

Hepatitis C: Between 2016 and 2023, the lowest reported prices of generic formulations of DAC, SOF and SOF/LED in public sector procurement have declined by 93%, 82% and 92%, respectively. The prices of SOF and DAC have fallen to as low as US$ 10 and US$ 1, respectively, for a monthly supply. Similarly, a monthly supply of SOF/VEL is available for US$ 25. Despite downward trends, many countries are still paying higher prices. Although a 12-week course of a pangenotypic regimen to cure hepatitis C is available for US$ 60 through a global pricing agreement, only four of 24 reporting countries (Egypt, India, Nigeria and Pakistan) are paying prices at or below this benchmark.

The lowest reported price of SOF and DAC combined for a 12-week course of treatment was from Pakistan at about US$ 33 for a generic course of treatment; the highest reported price was from China, at about US$ 10 000, with similar prices for generic and originator products. The lowest reported price of the SOF/DAC fixed-dose combination was from Nigeria, at US$ 60 for the 12-week course of treatment. Low-income countries continue to pay prices much higher than the benchmark price, such as US$ 1050 in the Democratic Republic of the Congo and US$ 481 in Cameroon for the SOF/DAC fixed-dose combination.

2 Countries have adopted WHO treatment guidelines; however, these guidelines are not yet being implemented with a public health approach.

Hepatitis B: 94% of reporting focus countries have included TDF in their national viral hepatitis guidelines, and 79% have included it in national essential medicines lists. Only 45% of reporting countries have TDF available for use in primary health care.

Hepatitis C: 88% of reporting focus countries have included SOF and DAC in their national viral hepatitis guidelines and 57% have included it in national essential medicines lists (both or as co-blistered or fixed-dose combination). Only 30% have SOF and DAC available for use in primary health care.

3 Product registration varies and lags behind for medicines for children.

Hepatitis B: 28 countries (85% of 33 reporting focus countries) have registered at least one originator or generic product for TDF. For ETV, 76% of the reporting countries have registered at least one product for adults; but only 40% of the reporting countries have registered at least one product for children.

Hepatitis C: 24 countries (73% of 33 reporting focus countries) have registered either originator or generic products of SOF and DAC (both or as co-blistered or fixed-dose combinations) for adult use. Of the 24 countries, only four – Cambodia, Myanmar, Nigeria and Uganda – reported having registered the SOF/DAC fixed-dose combination. Only 36% of countries have registered these for children.

4 Among the countries that have registered TDF, and SOF and DAC, in the country, about two thirds have registered either the originator or at least one WHO-prequalified generic product of these medicines.

5 About 60% of reporting WHO focus countries offer viral hepatitis testing and treatment free of charge, either fully or partly, in the public sector. Financial protection is lower in the African Region, with only 33% of the reporting countries providing viral hepatitis services free of charge. As a result, many affected populations need pay out of pocket for viral hepatitis services, which is a financial barrier to access.

6 Of the 31 WHO focus countries for which this information was available, 14 manufacture TDF locally and eight manufacture SOF and/or DAC locally. In some countries with comparable data, such as Colombia and Viet Nam, locally produced generic medicines are less expensive than equivalent imported generic products. In other countries, such as Brazil, China and Morocco, locally produced generic medicines and equivalent imported generic products remain more expensive than global benchmark prices.

3.3.1 Hepatitis B medicines

Table 3.10 provides an overview of the global landscape for hepatitis B medicines. It summarizes the WHO treatment recommendations for hepatitis B and presents the respective medicines included in the WHO Model List of Essential Medicines, the specific products that are WHO prequalified and benchmark prices.

As of December 2023, six generic products for TDF and one generic product for ETV have been WHO prequalified. No TAF product is WHO prequalified. Countries report public procurement prices that exceed available global price benchmarks. The following sections provide further details.

Table 3.10. Global overview of hepatitis B medicines

	First-line antiviral therapies for chronic hepatitis B		
WHO guidelines[a]	*For all adults, adolescents and children (two years or older) for whom antiviral therapy is indicated:* Tenofovir (TDF) or ETV as preferred regimens; and Tenofovir (TDF) + lamivudine, tenofovir + FTC as alternative regimens ETV or TAF should be considered for people with established osteoporosis and/or impaired kidney function or on dialysis and also for children or adolescents (aged two years or older for ETV and aged 12 years or older for TAF).		
WHO Model List of Essential Medicines	TDF: Tablet: 300-mg tablet equivalent to 245 mg of tenofovir disoproxil	ETV: Oral liquid: 0.05 mg /mL Tablet: 0.5 mg ; 1 mg	TAF: Not included
WHO prequalification products[b]	TDF: Aurobindo Pharma Ltd Cipla Ltd Mylan Laboratories Ltd (Viatris) Macleods Pharmaceuticals Ltd Strides Pharma Science Ltd Laurus Labs Ltd	ETV: BrightGene Bio-Medical Technology Co., Ltd	TAF: None
Prices	TDF: **Reported public procurement prices, 2023** range US$ 1.22 (generic) US$ 1849.50 (generic) for 30 tablets, 300 mg (WHO survey, focus countries, 2023) **Benchmark** Global Fund and Pan American Health Organization pooled procurement offer, 2023: US$ 2.40 per 30 tablets, 300 mg Global pricing agreement of the Clinton Health Access Initiative and The Hepatitis Fund, 2023: US$ 2.40 per 30 tablets, 300 mg (under the memorandum of understanding of the Clinton Health Access Initiative and The Hepatitis Fund with Viatris and Hetero)	ETV: **Reported public procurement prices, 2023** range US$ 0.77 (generic) US$ 143.70 (originator) for 30 tablets, 0.5 mg (WHO survey, focus countries, 2023) **Benchmark** Global Fund pooled procurement offer, 2023: US$ 8.50 per 30 tablets, 0.5 mg or US$ 22.50 per 90 tablets (US$ 7.50 per 30 tablets), 0.5 mg	TAF: **Reported public procurement prices, 2023** range US$ 1.34 (generic) US$ 96 (originator) for 30 tablets, 25 mg (WHO survey, focus countries, 2023)

[a] *Updated recommendations on prevention, diagnosis, care and treatment for people with chronic hepatitis B infection (18).*
[b] As of December 2023.

Table 3.11. Medicines for hepatitis B included in the 2023 WHO Model List of Essential Medicines

Medicine INN	Indications	Formulations
TDF	Chronic hepatitis B	Tablet: 300-mg tablet – equivalent to 245 mg of tenofovir disoproxil
ETV	Chronic hepatitis B	Oral liquid: 0.05 mg /mL Tablet: 0.5 mg ; 1 mg

Source: *The selection and use of essential medicines 2023: Web Annex A: World Health Organization model list of essential medicines: 23rd list* (2023) (56).

Table 3.12. Medicines for hepatitis B included in the 2023 WHO Model List of Essential Medicines for Children

Medicine INN	Indications	Formulations
ETV	Chronic hepatitis B	Oral liquid: 0.05 mg /mL Tablet: 0.5 mg ; 1 mg

Source: *The selection and use of essential medicines 2023: Web Annex B: World Health Organization model list of essential medicines for children: 9th list* (2023) (57).

3.3.1.1 Product selection

The WHO Model List of Essential Medicines provides countries with a reference to select medicines for national essential medicines lists that satisfy the priority health care needs of the population, with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost–effectiveness. Essential medicines are intended to be available in functioning health systems at all times in appropriate dosage forms, of assured quality and at prices that individuals and the community can afford (55).

Tables 3.11 and 3.12 present the medicines for hepatitis B included in the 2023 WHO Model List of Essential Medicines and Model List of Essential Medicines for Children.

TAF is included in the 2024 WHO updated recommendations on chronic hepatitis B infection (17), which were updated after the 2023 WHO Model List of Essential Medicines had been published. An application considering adding TAF to the WHO Model List will be presented as part of the 2025 update.

3.3.1.2 Product quality, safety and performance:

The fifth invitation for submission of applications for prequalification of medicines issued in October 2022 includes three medicines, including one formulation for children, for hepatitis B treatment. To support the development of generic formations of the invited medicines, the WHO Prequalification Unit – Medicines Assessment Team has issued nine new or updated notes on the design of bioequivalence study for invited medicines.

The following hepatitis B medicines are WHO prequalified as of December 2023 (Table 3.13):

TDF generic products (300-mg film-coated tablet): six manufacturers; and

ETV generic products (0.5.mg and 1-mg film-coated tablets): one manufacturer.

As of December 2023, one TDF product is under assessment. Also, as of December 2023, TAF has not been invited for WHO prequalification. No hepatitis B medicines are reviewed by the Expert Review Panel.

In 2023, Clinton Health Access Initiative and The Hepatitis Fund signed a memorandum of understanding with two generic manufacturers, Hetero and Viatris, to offer WHO-prequalified and/or United States Food and Drug Administration–approved TDF 300 mg at a ceiling price of US$ 2.40 per 30 tablets (or US$ 2.20 per 28 tablets) (43). The product from Viatris is WHO prequalified. The product from Hetero was prequalified for its HIV indication until the company withdrew it in 2019 for market reasons.

Table 3.13. Status of hepatitis B medicines prequalified by WHO

Medicine INN	Applicant	Dosage form and strength	Date of prequalification
TDF	Aurobindo Pharma Ltd	Tablet 300 mg	Basis of listing: United States Food and Drug Administration
	Cipla Ltd	Tablet, film-coated 300 mg	30 June 2009
	Mylan Laboratories Ltd (Viatris)	Tablet, film-coated 300 mg	27 Oct 2009
	Macleods Pharmaceuticals Ltd	Tablet, film-coated 300 mg	23 May 2013
	Strides Pharma Science Limited	Tablet, film-coated 300 mg	21 Oct 2013
	Laurus Labs Limited	Tablet, film-coated 300 mg	12 Dec 2017
ETV	BrightGene Bio-Medical Technology Co., Ltd	Tablet, film-coated 0.5 mg Tablet, film-coated 1 mg	22 March 2022
TAF	(none)		

In total, since 2016, 13 hepatitis B medicines have been prequalified (four ETV and nine TDF products prequalified under the HIV/AIDS expression of interest). Of these, manufacturers have withdrawn two ETV products and five TDF products for market reasons.

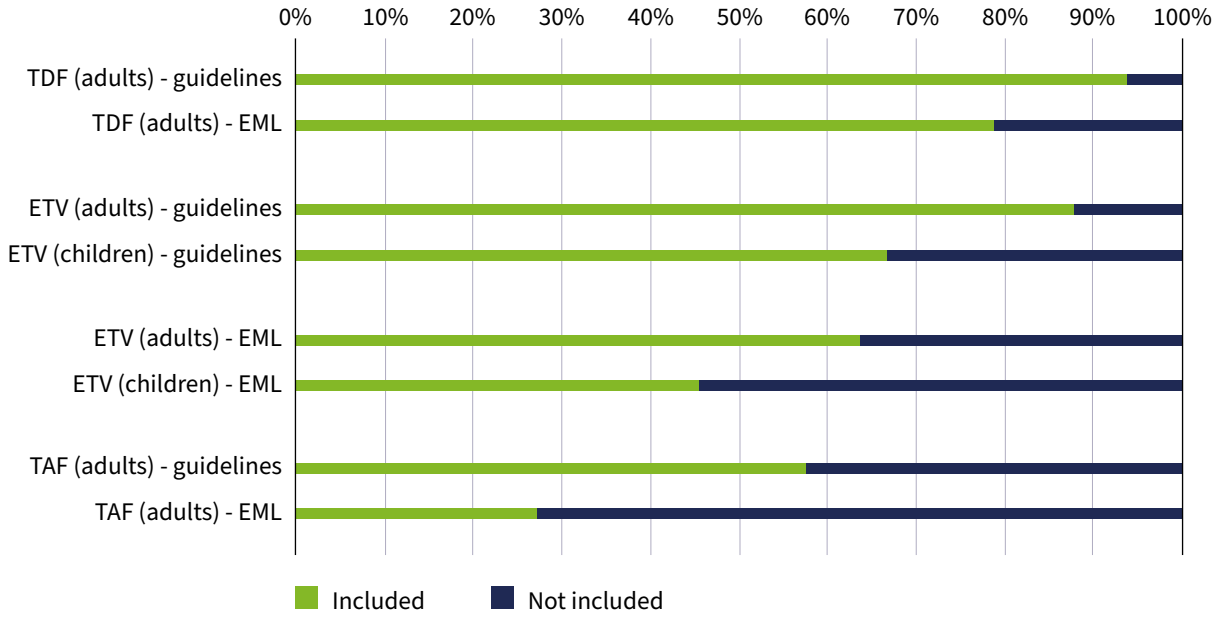
3.3.1.3 Product availability and implementation

Of the 33 WHO focus countries for which this information was available, most countries have included TDF and ETV in their national viral hepatitis guidelines, in accordance with WHO normative guidance. Fewer countries have also included these in national essential medicines lists, which are often updated less frequently, and for which there must often be financial coverage as well (Fig. 3.8).

- 94% of countries include TDF in their national viral hepatitis guidelines, and 79% include it in the essential medicines list.
- ETV, which is recommended for both adults and children, is included in national viral hepatitis guidelines for adults in 88% of reporting countries and for children in 67% of reporting countries and in the essential medicines lists in 64% and 45% of reporting countries, respectively.
- TAF, which is newly recommended in the 2024 WHO updated recommendations for chronic hepatitis B in special circumstances, is included in national viral hepatitis guidelines in 58% of reporting countries and in the essential medicines list in 27% (Fig. 3.8).

Dual therapy (TDF + XTC), which is recommended in the 2024 updated WHO guidelines for chronic hepatitis B (see subsection 3.1.1) was not included in the 2023 WHO country questionnaire for this report.

Fig. 3.8. Inclusion of hepatitis B medicines in national hepatitis B guidelines and essential medicines lists, WHO focus countries for the viral hepatitis response, 2023 (percentage of reporting countries)



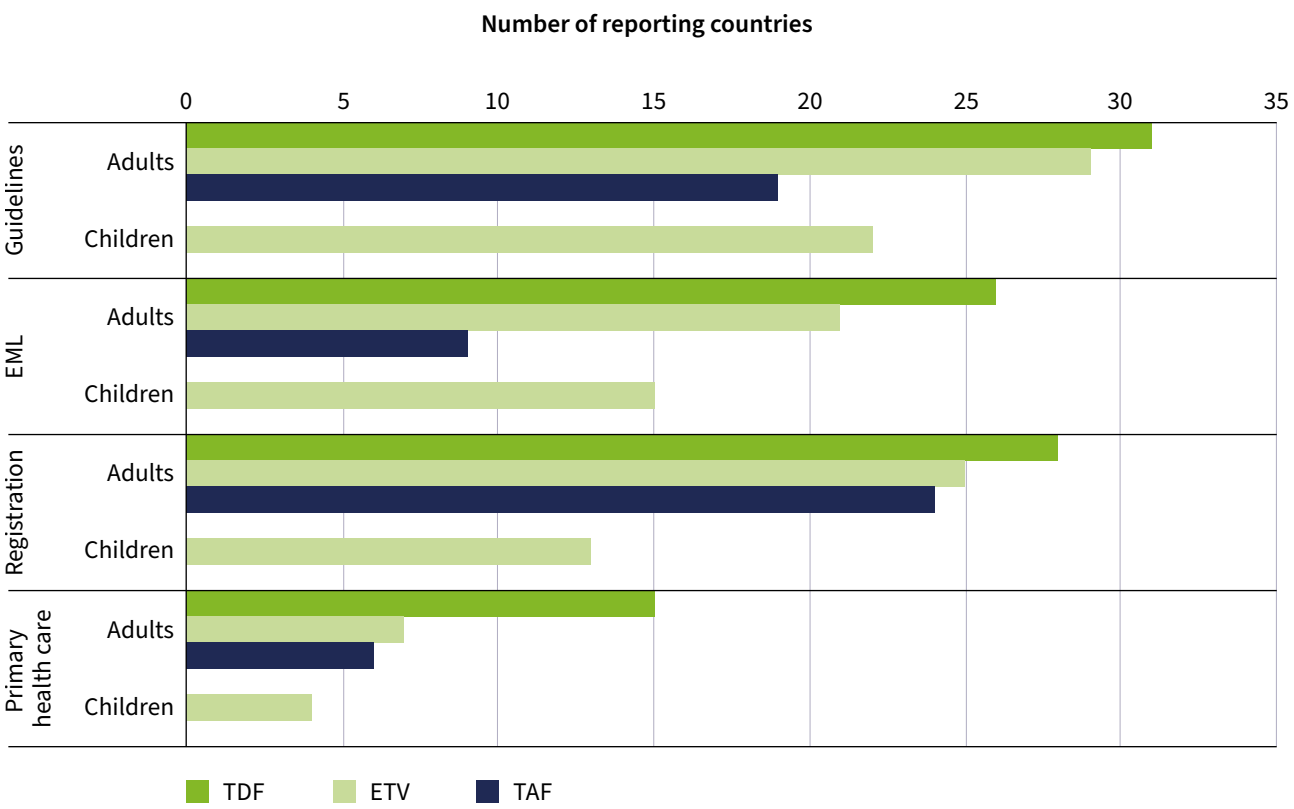
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product registration and product availability in primary health care are more limited.

- Of the 33 focus countries for which this information was available, 28 (85%) had registered at least one originator or generic TDF product in the country. Only 15 countries (45%) had TDF available in primary health care.
- For ETV, 22 countries (67%) had registered at least one originator or generic product in the country for adults, and 13 countries (39%) had registered it for children. Only seven countries reported having ETV available in primary health care for adults and four for children.
- TAF was registered in 24 countries, and six reported that it was available in primary health care.

Fig. 3.9 shows the status of hepatitis B medicines across the key components of availability – inclusion in national guidelines, inclusion in essential medicines lists, registration of the product in the country and availability in primary health care. Although viral hepatitis treatment services may not be available in primary health care in many countries, they may be available at tertiary levels and in specialized care.

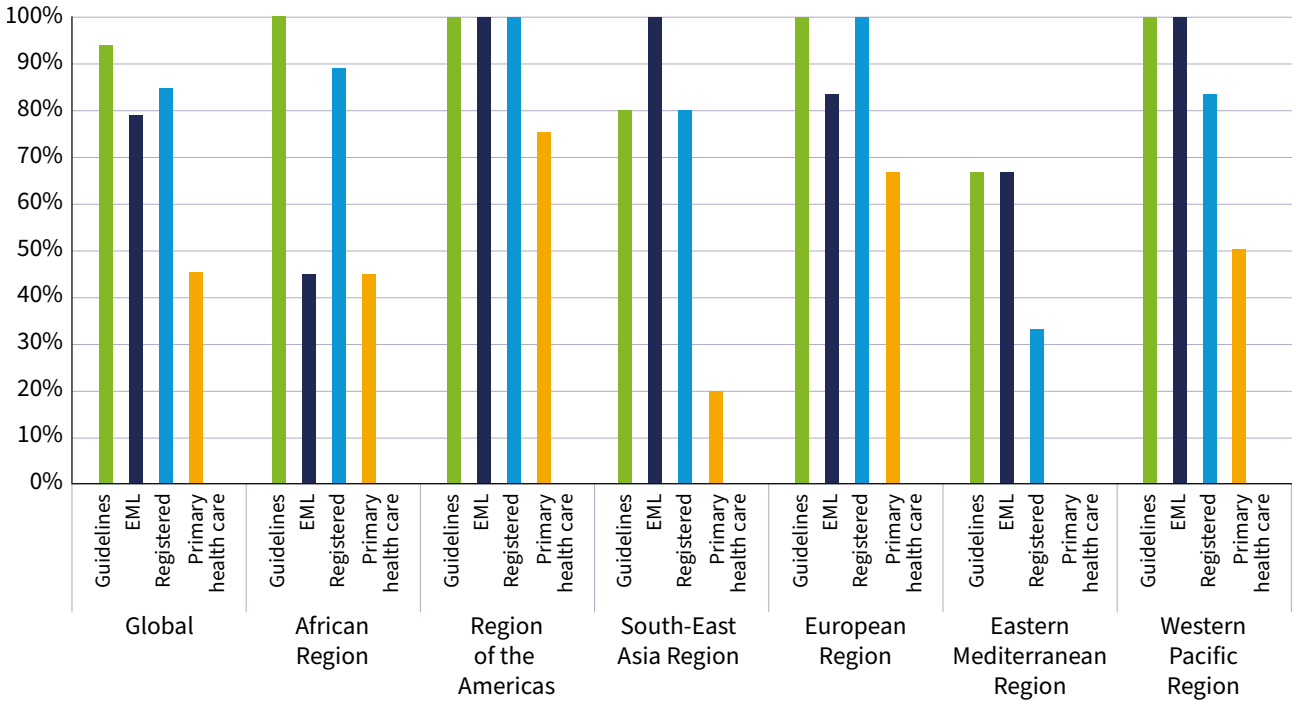
Fig. 3.9. Hepatitis B medicines in national programmes: inclusion in treatment guidelines and essential medicines lists, product registration in-country and availability in primary health care – adults and children, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

There is regional variation in the availability of hepatitis B medicines (Fig. 3.10). In the African Region, which accounts for 63% of hepatitis B infections, all reporting countries had included TDF in the national guidelines. Less than half the countries (44%) had included it in the national essential medicines list and made it available in primary health care.

Fig. 3.10. Inclusion of TDF in national essential medicines lists and national hepatitis B guidelines and availability in primary health care, by WHO region among WHO focus countries for the viral hepatitis response, 2023 (percentage of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.3.1.4 Application and management of intellectual property

A country's ability to access generic medicines depends, among other aspects, on whether patents are filed or granted in the country or whether other market exclusivities are granted in the country (such as data exclusivity protection) and – if patents are filed or granted – whether the country in question is included in the geographical scope of the respective voluntary licensing agreements of the originator company (Box 3.5). Under voluntary licensing agreements, a patent holder normally permits a generic company to manufacture and sell the patented product in a defined number of countries. Other countries not included in such voluntary licensing agreements can pursue alternative strategies to reduce prices, such as using flexibilities contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights to issue a government-use or compulsory licence, which enables a local company to manufacture the patented product or import it under specific conditions without the authorization of the patentholder. Some countries also engage directly in price–volume negotiations with manufacturers, but transparency in pricing is indispensable to achieve the objective of effective price reductions.

Box 3.5. Medicines Patent Pool

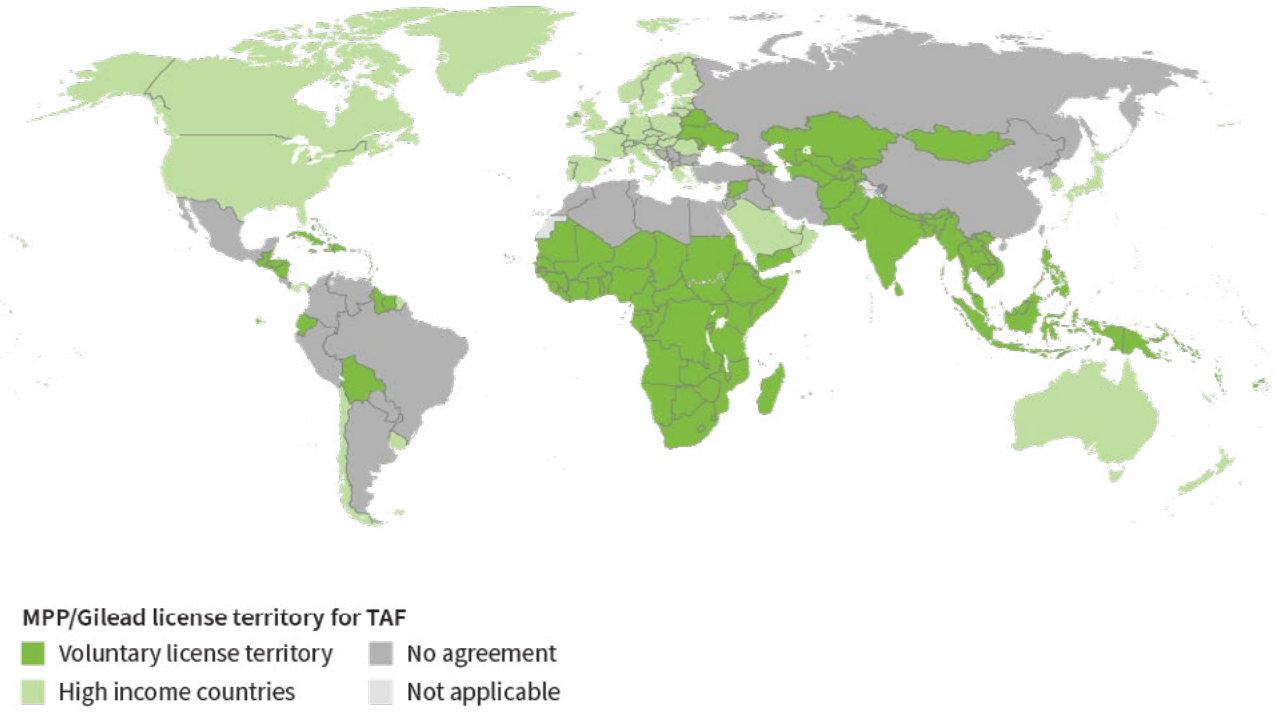
The Medicines Patent Pool (MPP) is a public health organization created and financially supported by Unitaid. MPP collaborates with WHO and is supported by the United Nations General Assembly to improve and accelerate access to essential affordable medicines and health technologies in low- and middle-income countries. The MPP mechanism is based on public health–oriented licensing of patented health products from originator manufacturers and sublicensing generic manufactures for them to develop, manufacture and supply quality-assured generic treatments to low- and middle-income countries. For viral hepatitis, MPP holds licences for some key WHO-recommended medicines for hepatitis B and C treatment, for countries included in their territory and countries with no patent infringements. For hepatitis B, MPP holds a licence for TAF, a prodrug of TDF, with Gilead Sciences. MPP also previously held a licence for TDF, which is now off-patent, i.e. in the public domain. For hepatitis C, MPP holds licences for DAC with Bristol-Myers Squibb that allows sublicensees to develop, manufacture and supply DAC and DAC/SOF; for G/P with AbbVie; and for ravidasvir, an investigational pangenotypic DAA, with Pharco Pharmaceuticals.

The intellectual property status of hepatitis B medicines is summarized below (Table 3.14).

- **TDF: off patent**
  TDF (300 mg), which has been used extensively for HIV and hepatitis B treatment, is now off patent and should be available worldwide. Countries anywhere in the world should be now able to procure generic TDF not only for HIV but also for hepatitis B.
- **TAF: patented and licensed to generic manufacturers via MPP**
  In 2014, MPP signed a licensing agreement with Gilead Sciences for TAF and as of September 2019, 117 countries and territories were included in this licensing agreement (Fig. 3.11). Of these, 51 countries have patents or patent applications, and in these countries, the licensing agreement would enable the country to produce generic TAF and supply it to the countries covered by the respective license, or to import generic TAF.

  In some of these countries, secondary patent applications or patents are expected to expire in 2032–2033 or, in other cases, the main patent has only been extended until 2026–2027. As of mid-2023, MPP has signed sub-licensing agreements with 12 generic manufacturers, of which two have developed the TAF 25-mg formulation and were ready to commercialize the product as of December 2023. Countries have already started procuring TAF 25 mg from MPP licensees, and as of June 2023, MPP licensees have supplied 1.6 million packs (of 30 tablets each) to 17 countries.
- **ETV: off patent**
  ETV is off patent and should be available worldwide: any country in the world should be able to procure generic ETV.

Fig. 3.11. MPP/Gilead licence territory for TAF



Source: MPP.

Table 3.14. Licensing status of hepatitis B medicines

Originator company	Voluntary licensing agreement	Medicine	Number of countries included in the licensing or sublicensing agreement and Number of countries with patents or patent applications	Number of generic sublicensee manufacturers and Number of generic sublicensee manufacturers that have WHO prequalification approval
Gilead Sciences	MPP-Gilead Sciences (signed 2019)	TAF	117 countries included in the licensing agreement Of these, 51 have patents or patent applications in the country	*Generic sublicensees that are commercializing the product as of December 2023* Laurus Labs Lupin *Other generic sublicensees* Adcock Ingram Anhui Biochem Pharmaceutical Co. Ltd Arene Lifesciences Limited Aurobindo Desano Emcure Langhua Macleods Micro Labs Ltd Natco *WHO prequalified as of December 2023* none

Source: MPP and WHO.

Of the 38 WHO focus countries for the viral hepatitis response, nine – Brazil, Colombia, Mexico and Peru in the Region of the Americas; Russian Federation in the European Region; Egypt and Morocco in the Eastern Mediterranean Region; and China and Niue in the Western Pacific Region are not included in the MPP-Gilead licensing agreement for TAF, as of December 2023. Fig. 3.12 provides a roadmap of alternatives for improving access for countries that are not included in a patent licence on key hepatitis B or hepatitis C medicines.

Fig. 3.12. Roadmap of alternatives for countries to access key hepatitis medicines

Source: adapted from: Unitaid & WHO (58).

3.3.1.5 Product pricing

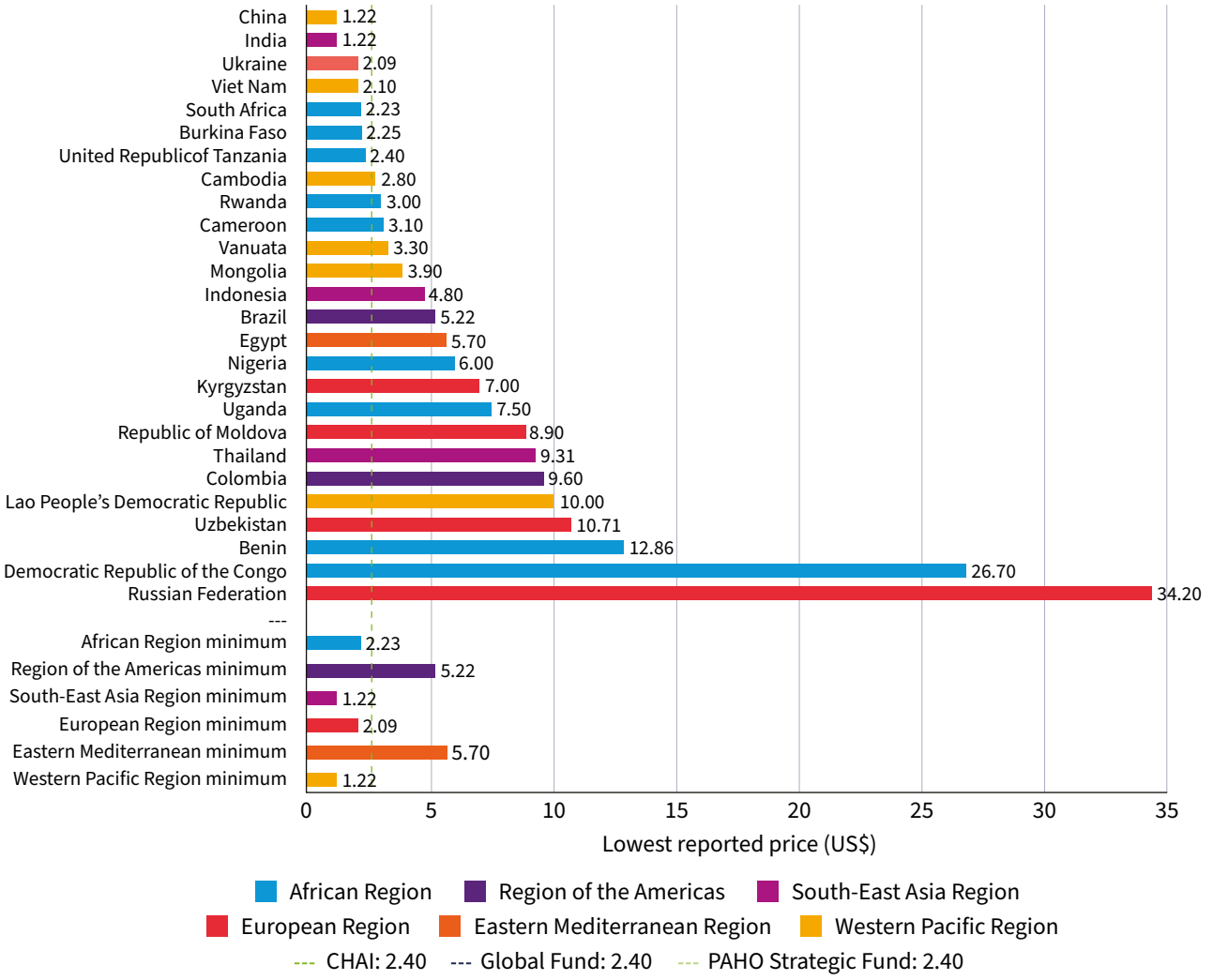
The data reported by the WHO focus countries for the viral hepatitis response show that most reporting countries are paying prices at or above the benchmark prices that are available through global access pricing agreements or pooled procurement mechanisms for these medicines. Further, the price of hepatitis B medicines varies widely across WHO regions and country income groupings. Such differences highlight the different dimensions of product access as they may be related to price negotiations, registration issues, procurement rules or purchase volumes. In countries with local production, locally produced hepatitis B medicines are less expensive than imported counterparts. Substantial cost savings for hepatitis B treatment could be realized if procurement strategies could be optimized such that all countries can access generic medicines at the lowest available prices.

TDF

As mentioned in subsection 3.3.1.4, TDF, which has been used extensively for HIV and hepatitis B treatment, is now off patent and all countries should be able to procure generic TDF at accessible prices using generic competition. In 2023, the Clinton Health Access Initiative and The Hepatitis Fund signed a memorandum of understanding with two generic manufacturers, Hetero and Viatris, to offer WHO-prequalified and/or United States Food and Drug Administration–approved TDF 300 mg at a ceiling price of US$ 2.40 per 30 tablets (or US$ 2.20 per 28 tablets) *(43)*. Further, international and regional pooled procurement mechanisms have also implemented central mechanisms to pool procurement orders to help to negotiate lower prices with suppliers for low- and middle-income countries. For example, the Global Fund and the Pan American Health Organization's Strategic Fund also offer procurement of WHO-prequalified TDF at this benchmark price of US$ 2.40 per 30 tablets.

Data on public procurement prices reported by the WHO focus countries for the viral hepatitis response show great variation in the prices countries pay for TDF, even though it is off patent (Fig. 3.13). Of the 26 WHO focus countries that provided this information (including two additional countries, Benin and Burkina Faso, that also reported data), only seven countries – Burkina Faso, China, India, South Africa, Ukraine, United Republic of Tanzania and Viet Nam – are paying prices at or below the benchmark of US$ 2.40 per 30 tablets. The reported monthly treatment prices reported by countries ranged from US$ 1.22 for 30 tablets in China and India to US$ 34.20 for 30 tablets in the Russian Federation. Analysis by World Bank income group showed that upper-middle-income countries are paying lower prices than low-income and lower-middle-income countries. For example, the Democratic Republic of the Congo, a low-income country, is paying 21 times as much for TDF as the price paid by China, an upper-middle-income country.

Fig. 3.13. Lowest reported monthly treatment price of TDF 300 mg (30 tablets), WHO focus countries for the viral hepatitis response, 2023



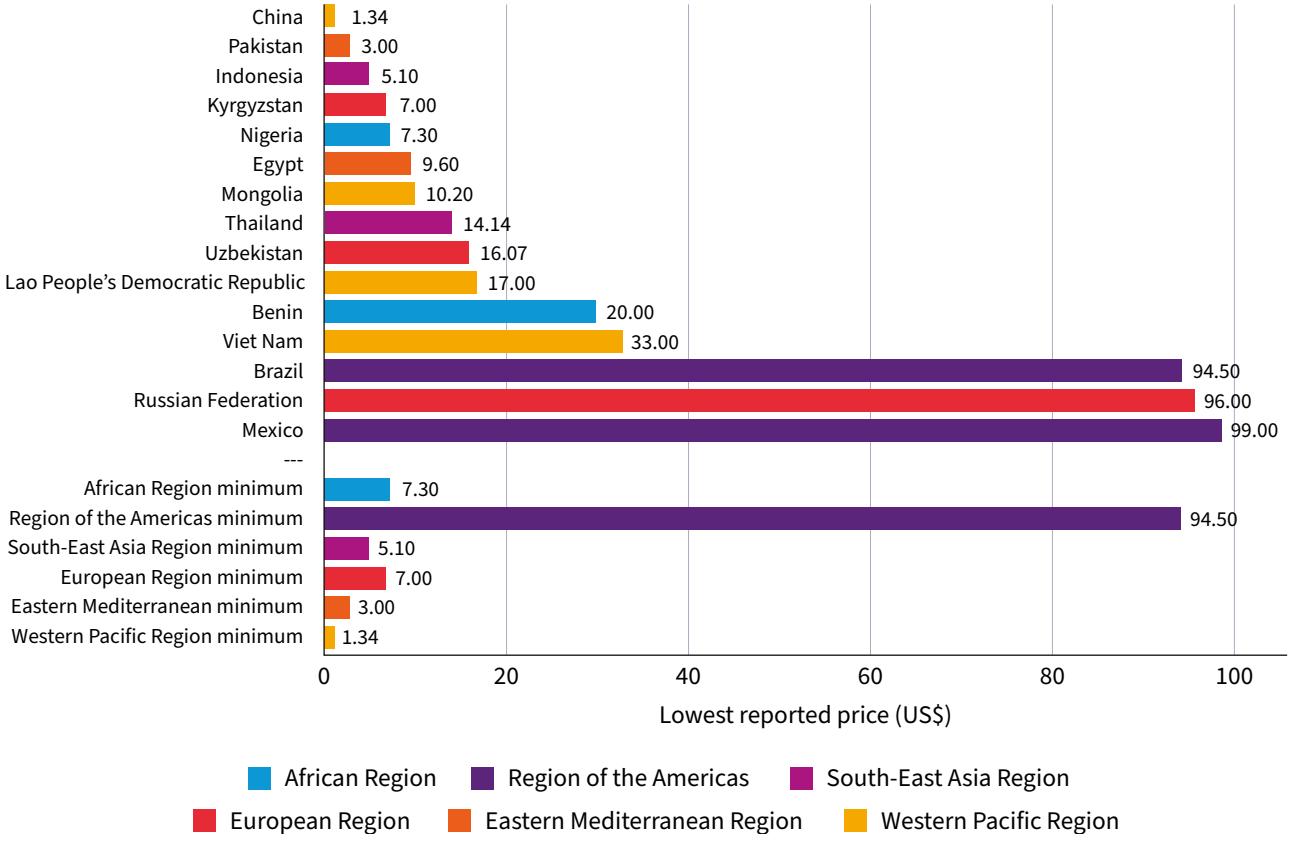
Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

TAF

The reported public procurement price of TAF, which is a patented medicine, also varies widely between reporting countries across WHO regions and within the same WHO region or the same income group (Fig. 3.14 and 3.15). For example, countries from the Region of the Americas pay up to 70 times more for TAF than countries in the Western Pacific Region.

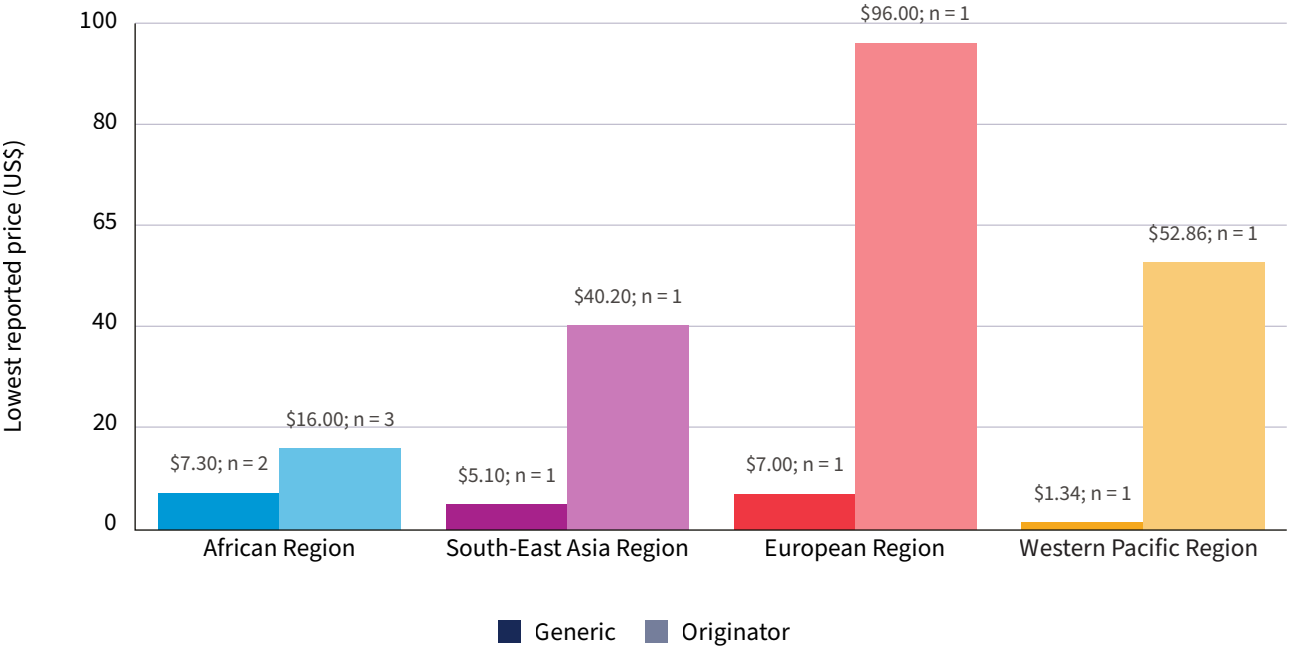
There are also large differences between the price of originator and generic products. For example, Brazil, which is excluded from the MPP-Gilead voluntary licensing agreement for TAF, pays US$ 94.5 for 30 tablets of the originator product. IN contrast, China, which is also excluded from the voluntary licensing agreement but has local production of TAF, is paying US$ 1.3 for 30 tablets of the generic product.

Fig. 3.14. Lowest reported monthly treatment price of TAF 25 mg (30 tablets), WHO focus countries for the viral hepatitis response, 2023



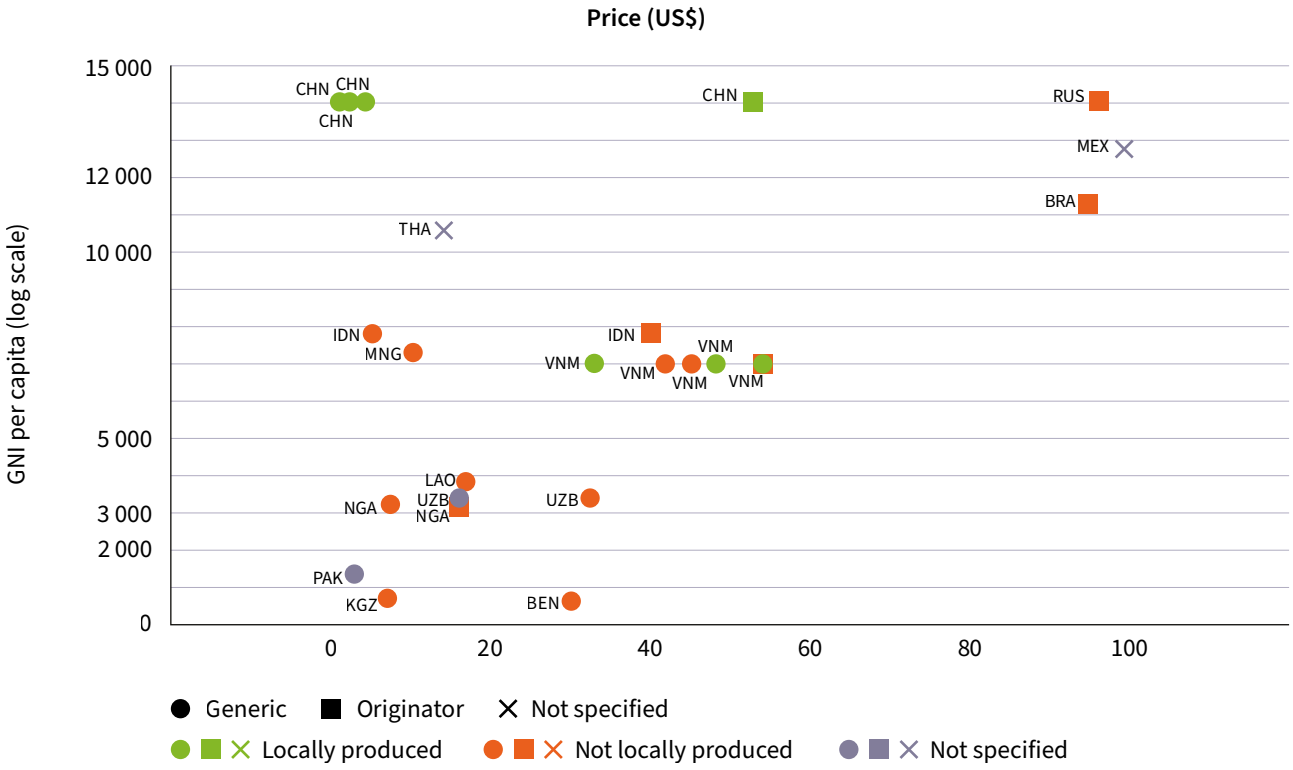
Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Fig. 3.15. Lowest reported generic and originator price comparison for TAF 25 mg (30 tablets), WHO focus countries for the viral hepatitis response, 2023



Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Fig. 3.16. Price of TAF 25 mg (30 tablets) in relation to country gross national income per capita, WHO focus countries for the viral hepatitis response, 2023



BEN: Benin, BRA: Brazil, CHN: China, IDN: Indonesia, KGZ: Kyrgyzstan, LAO: Lao People's Democratic Republic, MNG: Mongolia, NGA: Nigeria, MEX: Mexico, PAK: Pakistan,RUS: Russian Federation, THA: Thailand, UZB: Uzbekistan, VNM: Viet Nam.

Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

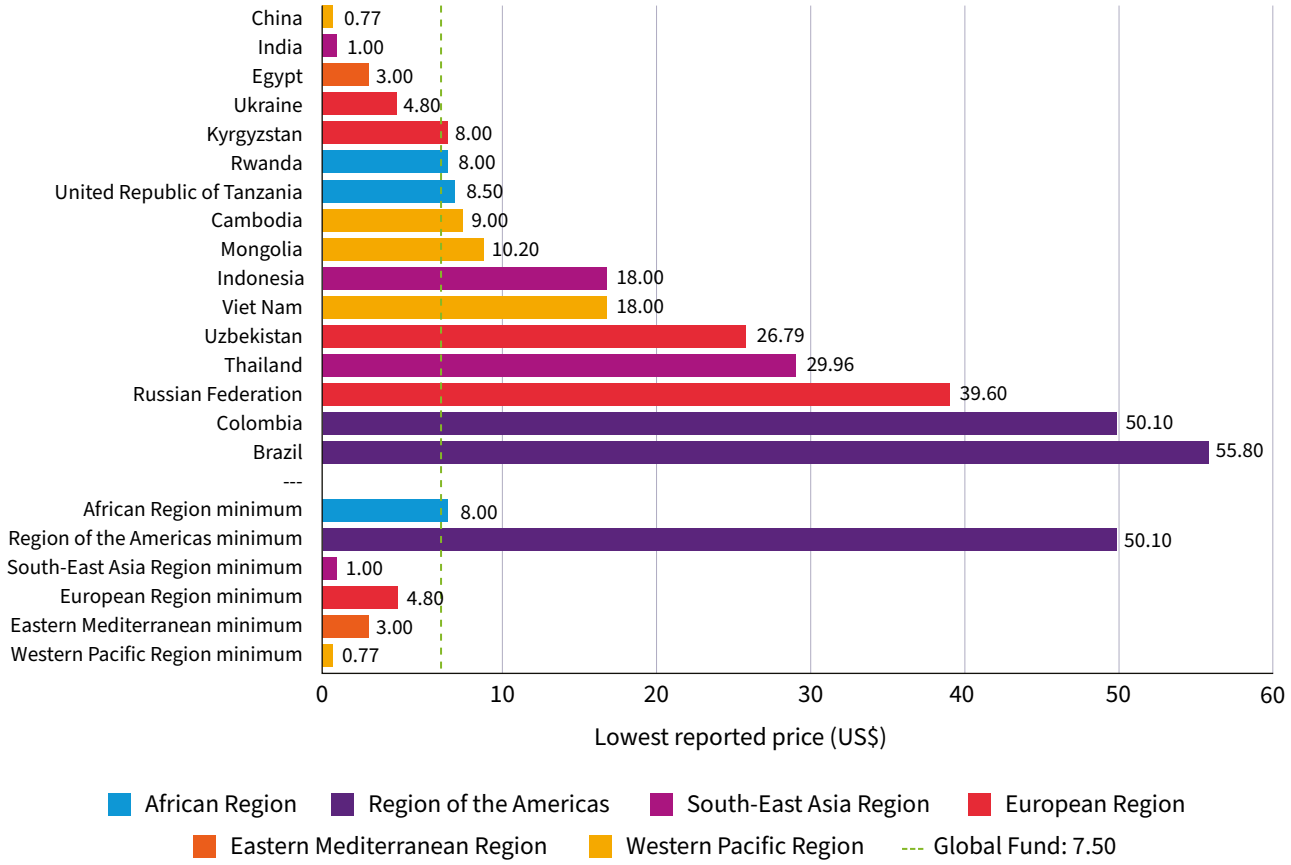
A comparison of all reported public procurement prices of TAF against their income level shows variation between the price paid and the gross national income per capita (Fig. 3.16). For example, Benin pays more for TAF than more than half of all reporting countries, despite having the lowest gross national income per capita. The Russian Federation pays 78 times as much as China despite minimal differences gross national income per capita between these countries.

ETV

The Global Fund's pooled procurement mechanism offers multiple procurement options of ETV 0.5 mg at a price of US$ 8.50 for 30 tablets or ETV 0.5 mg at a price of US$ 22.50 for 90 tablets (US$ 7.50 per 30 tablets). It also offers ETV 1 mg at a price of US$ 15 for 30 tablets *(59)*. Similar to TDF and TAF, the prices paid for ETV also vary greatly across countries.

Data on the public procurement prices reported by the WHO focus countries for the viral hepatitis response show large disparities in the prices countries pay for ETV, even though it is also off patent (Fig. 3.17). Of the 16 WHO focus countries that provided this information, four – China, India, Egypt and Ukraine – are paying prices at or below the lowest global pooled procurement benchmark of US$ 7.50 for 30 tablets of ETV 0.5 mg. Kyrgyzstan, Rwanda and the United Republic of Tanzania are paying prices at or below the Global Fund's second reference price of US$ 8.50 per 30 tablets. The remaining countries are still paying higher prices. Further, Brazil, an upper-middle-income country, pays 72 times more than China, which is also an upper-middle-income country; and Rwanda, a low-income country, pays 10 times as much as China. Similar results were found for ETV 1 mg, with Egypt, India, Pakistan, and Ukraine paying lower prices than the global pooled procurement benchmark of US$ 15 for 30 tablets. Viet Nam, a lower-middle-income country, pays 55 times as much as Pakistan, another lower-middle-income country; and Colombia, an upper-middle-income country, pays 114 times as much as Pakistan.

Fig. 3.17. Lowest reported monthly treatment price of ETV 0.5 mg (30 tablets), WHO focus countries for the viral hepatitis response, 2023

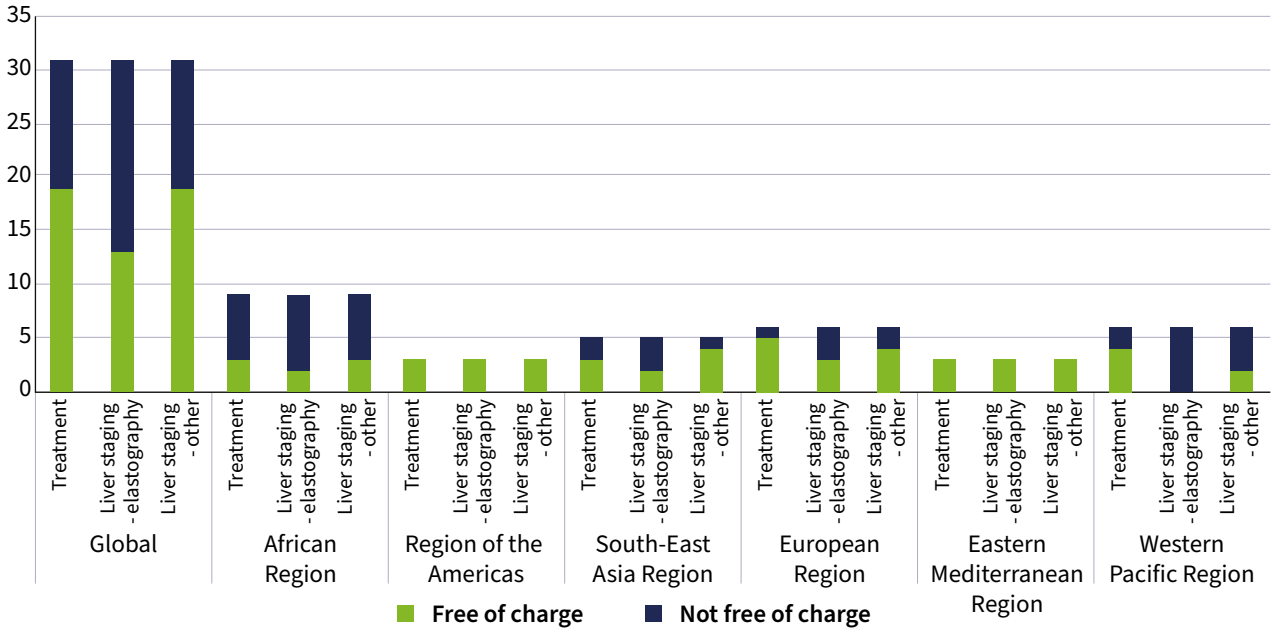


Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.3.1.6 Out-of-pocket expenditure

Of the 31 WHO focus countries for which information on out-of-pocket expenditure for hepatitis B treatment and follow-up was available, 19 provided hepatitis B treatment, 13 provided liver staging by elastography and 19 provided liver staging by other methods free of charge in the public sector, either fully or partly for specific subpopulations or geographical areas or with co-payment (Fig. 3.18). For example, liver staging is partly reimbursed in Rwanda, subsidized in Bangladesh or available free of charge for people with compulsory health insurance in the Republic of Moldova (Fig. 3.18). Chapter 4 provides details by focus country.

Fig. 3.18. Availability of hepatitis B treatment and follow-up free of charge in the public sector, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.3.1.7 Procurement, local production and technology transfer

Manufacturers are producing generic versions of hepatitis B medicines in several countries. Of the 31 WHO focus countries for which information on local production was available, 14 countries reported locally producing generic TDF; six countries reported locally producing generic TAF; and 11 countries reported locally producing generic ETV (Table 3.15).

Table 3.15. Local production of generic hepatitis B medicines, WHO focus countries for the viral hepatitis response, 2023

Number of countries with local production	African Region	Region of the Americas	South-East Asia Region	European Region	Eastern Mediterranean Region	Western Pacific Region
TDF **(14)**	South Africa	Brazil, Colombia, Peru	Bangladesh, India, Indonesia, Myanmar, Thailand	Russian Federation, Uzbekistan	Egypt	China, Viet Nam
TAF **(6)**			Bangladesh		Egypt, Pakistan	China, Lao People's Democratic Republic, Viet Nam
ETV **(11)**		Brazil, Colombia	Bangladesh, India, Indonesia, Thailand		Egypt, Pakistan	China, Viet Nam

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

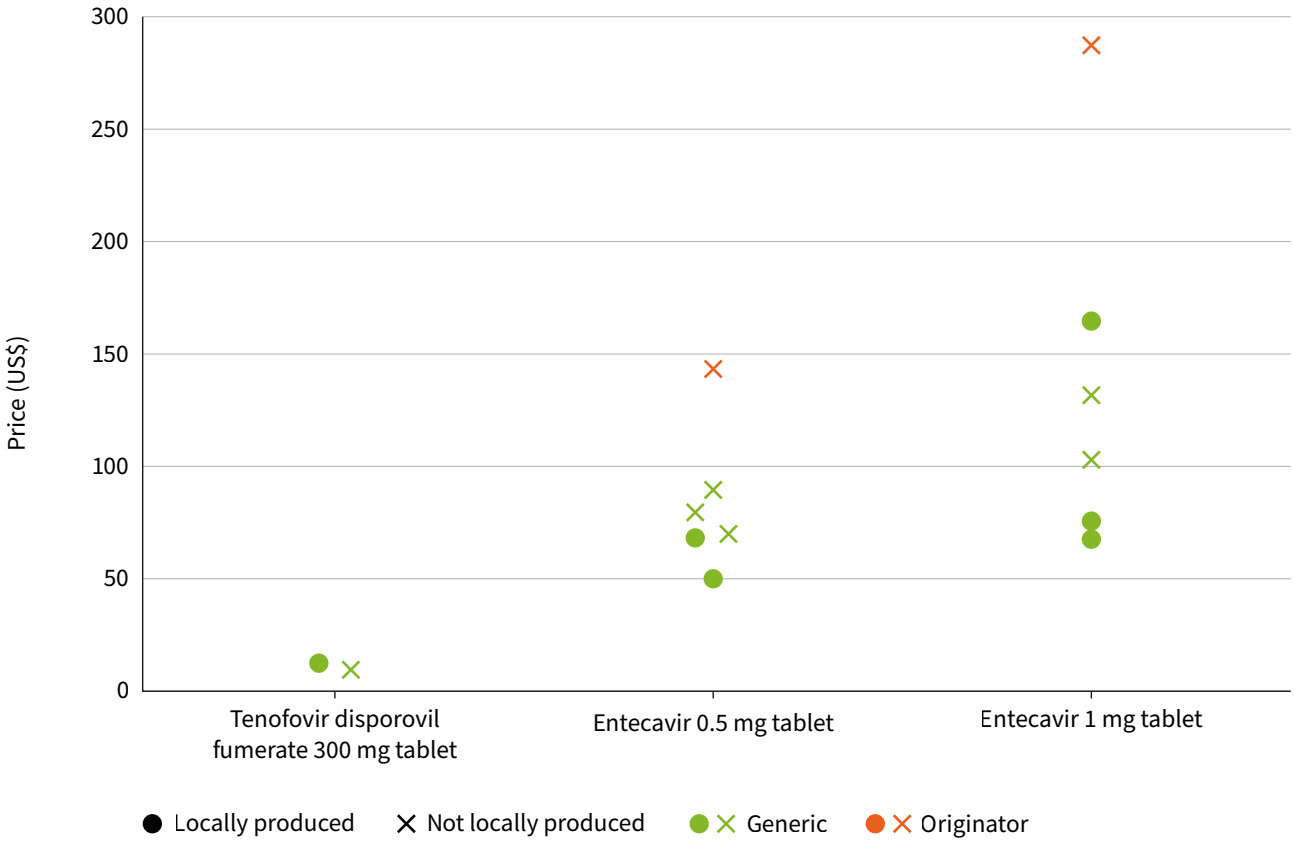
In countries where comparable data on public procurement prices were available, locally produced generic hepatitis B medicines were less expensive than imported generic medicines. For example, in Colombia, locally produced TDF and ETV were less expensive than imported counterparts (Fig. 3.19). Similar results were found in Viet Nam, where locally produced TDF, TAF and ETV were less expensive than their imported counterparts. Local production is becoming an important approach to implement the global health sector strategy on viral hepatitis 2022–2030.

3.3.2 Hepatitis C medicines

Table 3.16 provides an overview of the global landscape of hepatitis C medicines. It summarizes the WHO treatment recommendations for hepatitis C and presents the respective medicines included in the WHO Model List of Essential Medicines, the specific products that are WHO prequalified and benchmark prices.

As of December 2023, four generic products for SOF, five generic products for DAC, one SOF/DAC fixed-dose combination and two generic products for SOF/VEL were WHO prequalified. Countries report public procurement prices above the available global benchmark prices. The following sections provide further details.

Fig. 3.19. Variation in treatment prices of generic and originator medicines for hepatitis B based on local production status in Colombia, 2023



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 3.16. Global overview of the landscape of access to hepatitis C medicines

	First-line antiviral therapies for chronic hepatitis C				
WHO guidelines	***Pangenotypic DAA regimens recommended for all adults, adolescents and children three years and older with chronic hepatitis C, regardless of stage of disease***			***Non-pangenotypic DAA regimen (in settings with minimal GT3 infection):***	***Other***
	SOF/DAC: 12 weeks	**SOF/VEL:** 12 weeks	**G/P:** 8 weeks	**SOF/LED:** 12 weeks	
WHO Model List of Essential Medicines	**SOF:** Tablet: 200 mg ; 400 mg Pangenotypic when used in combination with DAC or ravidasvir **DAC:** Tablet: 30 mg ; 60 mg (as hydrochloride) Pangenotypic when used in combination with SOF **DAC/SOF:** Tablet: 60 mg + 400 mg	**SOF + VEL:** Tablet: 200 mg + 50 mg ; 400 mg + 100 mg	**G/P:** Tablet: 100 mg + 40 mg Granules: 50 mg + 20 mg in sachet	**SOF/LED:** Tablet: 90 mg + 400 mg	**Ravidasvir:** Tablet: 200 mg **Ribavirin:** Injection for intravenous administration: 800 mg and 1000 mg in 10 mL phosphate buffer solution Solid oral dosage form: 200 mg ; 400 mg; 600 mg
WHO prequalification products[a]	**SOF:** Mylan Laboratories Ltd (Viatris) Hetero Labs Ltd European Egyptian Pharmaceuticals Industries Co. Strides Pharma Science Limited **DAC:** Bristol-Myers Squibb Company Laurus Labs Ltd Hetero Labs Ltd Mylan Laboratories Ltd (Viatris) Cipla Ltd Zydus Lifesciences Ltd **SOF/DAC:** Mylan Laboratories Ltd (Viatris)	**SOF/VEL:** Gilead Sciences Ireland UC Mylan Laboratories Ltd (Viatris)	**G/P:** None	**SOF/LED:** None	**Other:** None
Expert Review Panel-reviewed[a]	There are no products with valid Expert Review Panel status.				

[a]As of December 2023.

Table 3.16. Global overview of the landscape of access to hepatitis C medicines (continued)

	First-line antiviral therapies for chronic hepatitis C			
Prices (benchmarks)	**SOF:** Reported public procurement prices range US$ 30 (generic) US$ 8257 (originator) for 12-week treatment course **DAC:** Reported public procurement prices range US$ 3.36 (generic) US$ 2203 (originator) for 12-week treatment course **SOF/DAC:** Reported public procurement prices range US$ 60 (generic) US$ 1050 (originator) for 12-week treatment course *(WHO survey, focus countries, 2023)* **Benchmark:** Global pricing agreement, 2023: US$ 60 for SOF/DAC generic 12-week treatment course (under the memorandum of understanding of Clinton Health Access Initiative and The Hepatitis Fund with Viatris and Hetero)	**SOF/VEL:** Reported public procurement prices range US$ 75 (generic) – US$ 8652 (originator) for 12-week treatment course *(WHO survey, focus countries, 2023)* **Benchmark:** Global Fund pooled procurement and Pan American Health Organization Strategic Fund offer, 2023: US$ 174 for a generic 12-week treatment course	**G/P:** Reported public procurement prices range US$ 5680 (originator) – US$ 15 780 (originator) for 8-week treatment course *(WHO survey, focus countries, 2023)*	**SOF/LED:** Reported public sector procurement prices range US$ 60.48 (generic)– US$ 4492 (originator) for 12-week treatment course *(WHO survey, focus countries, 2023)* **Benchmark:** United Nations Development Programme pooled procurement offer, 2023: US$ 450 for 12-week treatment course

3.3.2.1 Product selection:

As noted in subsection 3.3.1.1, the WHO Model List of Essential Medicines provides countries with a reference to select medicines for national essential medicines lists that satisfy the priority health care needs of the population, with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost–effectiveness. Tables 3.17 and 3.18 present the medicines for hepatitis C that are included in the 2023 Model List of Essential Medicines and Model List of Essential Medicines for Children.

Table 3.17. Medicines for hepatitis C included in the 2023 WHO Model List of Essential Medicines for adults

	Medicine INN	Formulations
Pangenotypic DAA combinations	DAC Pangenotypic when used in combination with SOF	Tablet: 30 mg ; 60 mg (as hydrochloride)
	DAC/SOF	Tablet: 60 mg + 400 mg
	G/P	Tablet: 100 mg + 40 mg Granules: 50 mg + 20 mg in sachet
	Ravidasvir[a] Pangenotypic when used in combination with SOF	Tablet: 200 mg
	SOF Pangenotypic when used in combination with DAC or ravidasvir	Tablet: 200 mg ; 400 mg
	SOF/VEL	Tablet: 200 mg + 50 mg ; 400 mg + 100 mg
Non-pangenotypic DAA combinations	LED + SOF	Tablet: 90 mg + 400 mg
Other antiviral drugs for hepatitis C	Ribavirin	Injection for intravenous administration: 800 mg and 1000 mg in 10 mL phosphate buffer solution Solid oral dosage form: 200 mg ; 400 mg ; 600 mg

[a]Ravidasvir (for use in combination with SOF) was added to the WHO Model List of Essential Medicines in 2023.
Source: *The selection and use of essential medicines 2023: Web Annex A: World Health Organization model list of essential medicines: 23rd list* (2023) (56).

Table 3.18. Medicines for hepatitis C included in the 2023 WHO Model List of Essential Medicines for Children

Medicine INN	Formulations
DAC Pangenotypic when used in combination with SOF	Tablet: 30 mg ; 60 mg (as hydrochloride)
DAC/SOF	Tablet: 60 mg + 400 mg
G/P	Granules: 50 mg + 20 mg in sachet Tablet: 100 mg + 40 mg
SOF Pangenotypic when used in combination with DAC	Table: 200 mg ; 400 mg
SOF/VEL	Table: 200 mg + 50 mg ; 400 mg + 100 mg

Source: *The selection and use of essential medicines 2023: Web Annex B: World Health Organization model list of essential medicines for children: 9th list* (2023) (57).

The following hepatitis C medicines were removed from the 2023 WHO Model List of Essential Medicines – dasabuvir; ombitasvir + paritaprevir + ritonavir; pegylated interferon alpha (2a); and pegylated interferon alpha (2b) (60).

3.3.2.2 Product quality, safety and performance

Since 2016, WHO has prequalified 20 hepatitis C products. Of these, four have been withdrawn for market reasons. Manufacturers do not provide details, but this may be related to a limited market, reduced margins or preference for a fixed-dose product over a co-packaged product.

The fifth invitation for submitting applications for prequalification issued in October 2022 added G/P, tablet 100 mg /40 mg for adults and DAC tablet 30 mg (preferably dispersible) and SOF tablet 100 mg (preferably dispersible) for children. Overall, the invitation includes 13 single or fixed-dose combination medicines, including three formulations for children, for treatment for HCV.

The following HCV medicines are WHO prequalified as of December 2023 (Table 3.19):

SOF 400-mg film-coated tablets: four generic products, total four manufacturers;

DAC 30- and 60-mg film-coated tablets: five generic products, one innovator product, total six manufacturers;

DAC/SOF 60 mg /400 mg film-coated tablets: one generic product, one manufacturer; and

SOF/VEL 400 mg /100 mg film-coated tablets: one generic product and one innovator product, total two manufacturers.

Two DAC products (30 and 60 mg) and one SOF/VEL fixed-dose combination tablet are under assessment as of December 2023.

Since 2021, one SOF/VEL fixed-dose combination tablet product received “no objection” to temporary procurement from the Expert Review Panel, but the Expert Review Panel status was not extended. All other products that had received Expert Review Panel’s “no objection” before 2021 have since been prequalified by WHO.

Table 3.19. Status of hepatitis C medicines prequalified by WHO

Medicine INN	Applicant	Dosage form and strength	Date of prequalification
SOF	Mylan Laboratories Ltd (Viatris)	Tablet, film-coated 400 mg	20 Jul 2017
	Hetero Labs Ltd	Tablet, film-coated 400 mg	7 Feb 2018
	European Egyptian Pharmaceuticals Industries Co	Tablet, film-coated 400 mg	18 Dec 2018
	Strides Pharma Science Limited	Tablet, film-coated 400 mg	3 Mar 2020
DAC (dihydrochloride)	Bristol-Myers Squibb Company	Tablet, film-coated 30 mg Tablet, film-coated 60 mg	14 Oct 2016
	Laurus Labs Limited	Tablet, film-coated 30 mg Tablet, film-coated 60 mg	18 Dec 2020
	Hetero Labs Ltd	Tablet, film-coated 30 mg Tablet, film-coated 60 mg	17 Dec 2019
	Mylan Laboratories Ltd (Viatris)	Tablet, film-coated 60 mg	15 May 2019
	Cipla Ltd	Tablet, film-coated 30 mg Tablet, film-coated 60 mg	17 Dec 2019
	Zydus Lifesciences Limited	Tablet, film-coated 30 mg Tablet, film-coated 60 mg	22 Dec 2023
DAC (dihydrochloride)/ SOF	Mylan Laboratories Ltd (Viatris)	Tablet, film-coated 60 mg /400 mg	27 Oct 2020
SOF/VEL	Gilead Sciences Ireland UC	Tablet, film-coated 400 mg /100 mg	6 Feb 2019
	Mylan Laboratories Ltd (Viatris)	Tablet, film-coated 400 mg /100 mg	27 Oct 2020

Since the previous edition of this report in 2021, the manufacturers withdrew the prequalification status of the following for market reasons:

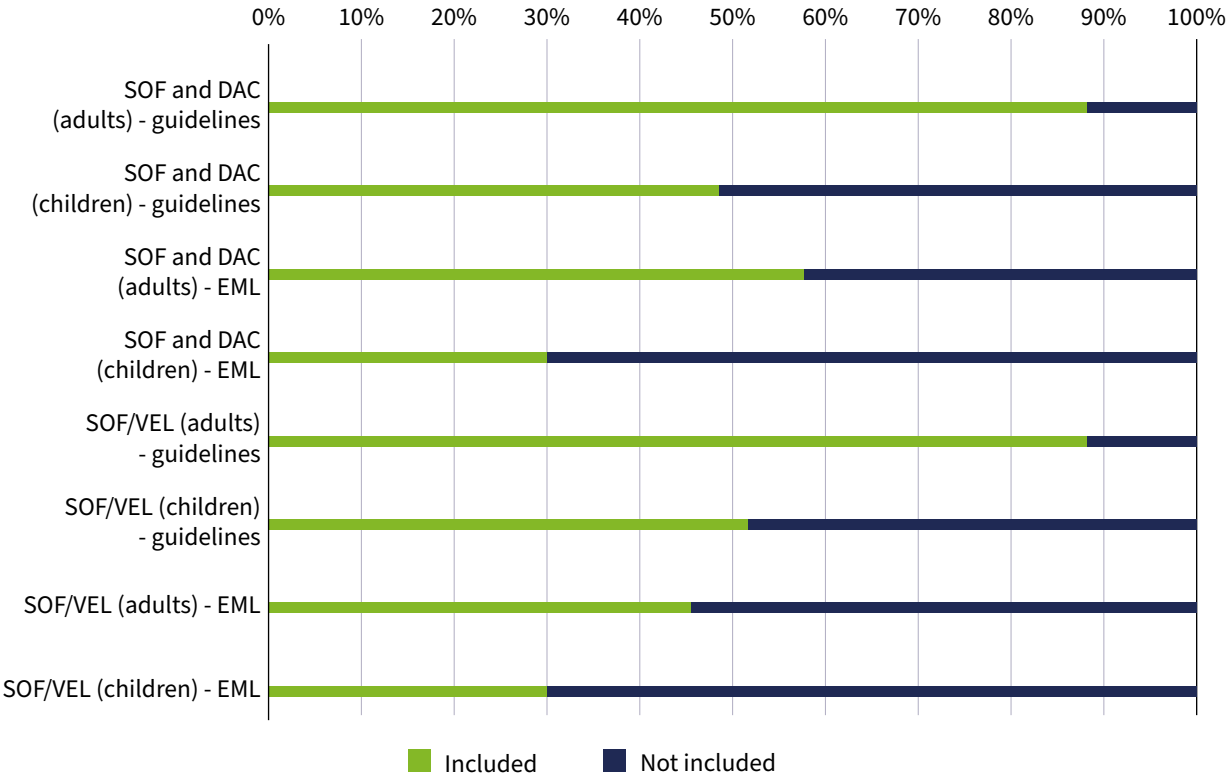
- SOF from Cipla
- SOF + DAC (co-blistered) from Cipla
- SOF/LED from Mylan.

3.3.2.3 Product availability and implementation

Of the 33 WHO focus countries for which this information was available, most countries have included viral hepatitis medicines in their national viral hepatitis guidelines, in accordance with WHO normative guidance (Fig. 3.20).

- About 88% of reporting focus countries have included the WHO-preferred treatment regimen of SOF and DAC in their national viral hepatitis guidelines for adults. However, only 48% have included these in their national guidelines for children.
- About 57% of reporting countries have included these in their national essential medicines lists for adults (either SOF and DAC both or SOF/DAC fixed-dose combination or SOF+DAC co-blistered), and only 30% in national essential medicines lists for children.
- About 88% of reporting focus countries have included SOF/VEL in the national guidelines for adults, and half the countries (52%) have included it for children. Half the reporting countries have included these in national essential medicines lists.
- About 42% of reporting focus countries have included G/P in national guidelines for adults, and 25% have included G/P in national guidelines for children. Less than one third of countries include G/P in the essential medicines lists.

Fig. 3.20. Inclusion of hepatitis C medicines in national hepatitis C guidelines and essential medicines lists, WHO focus countries for the viral hepatitis response, 2023 (percentage of reporting countries)



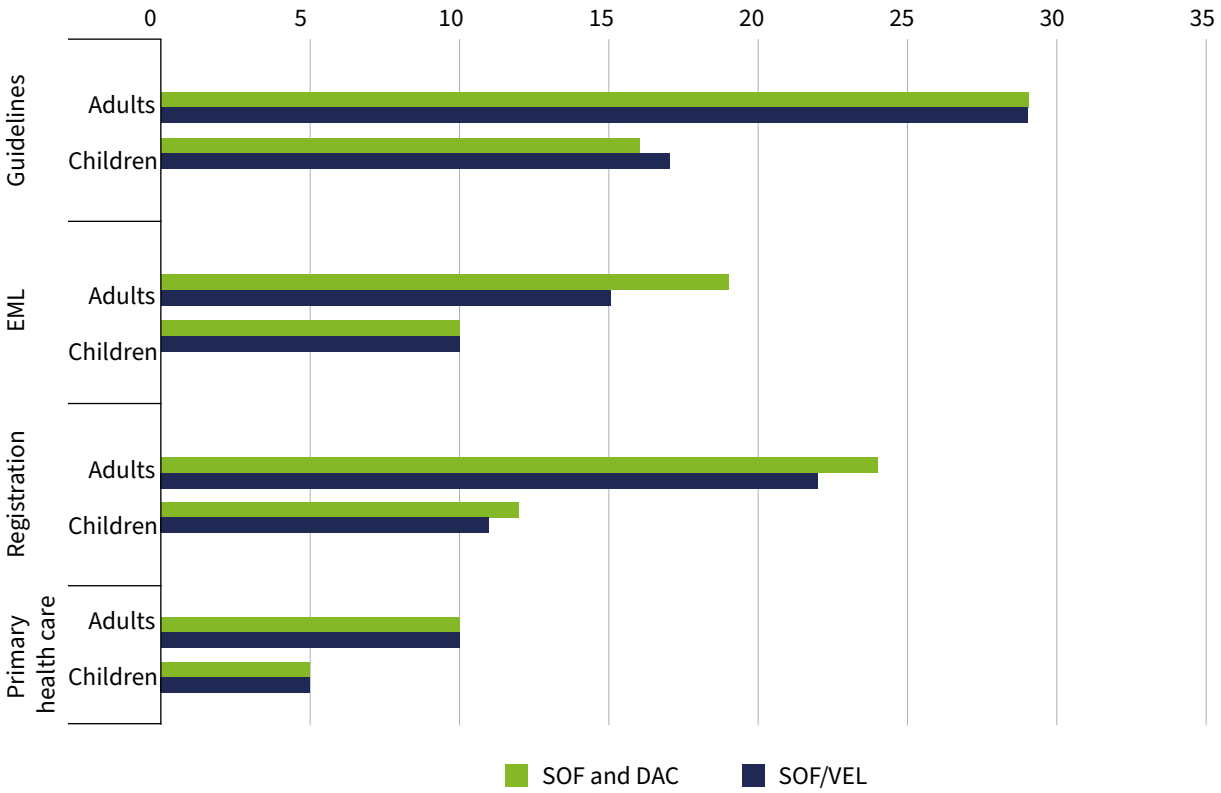
*SOF and DAC include either SOF and DAC both or SOF/DAC fixed-dose combination or SOF+DAC co-blistered.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

However, product registration and product availability in primary health care are more limited, slowing down treatment uptake and decentralization of services (Fig. 3.21).

- Of the 33 WHO focus countries for which this information was available, only 24 (72%) had registered at least one originator or generic product of SOF and DAC (both or fixed-dose combination or co-blistered) in the country for adults. Of these 24 countries, only four – China, Myanmar, Nigeria and Uganda – reported having registered the SOF/DAC fixed-dose combination. Only 12 countries (36%) had registered these medicines for children.
- Of the 24 countries that had registered at least one SOF and DAC product for adults, 16 had registered either the originator or at least one WHO-prequalified product.
- The medicines were available in primary health care in 10 countries (30%) for adults and in only five countries (15%) for children.

Although viral hepatitis treatment services may not be available in primary health care in many countries, they may be available at tertiary levels and in specialized care.

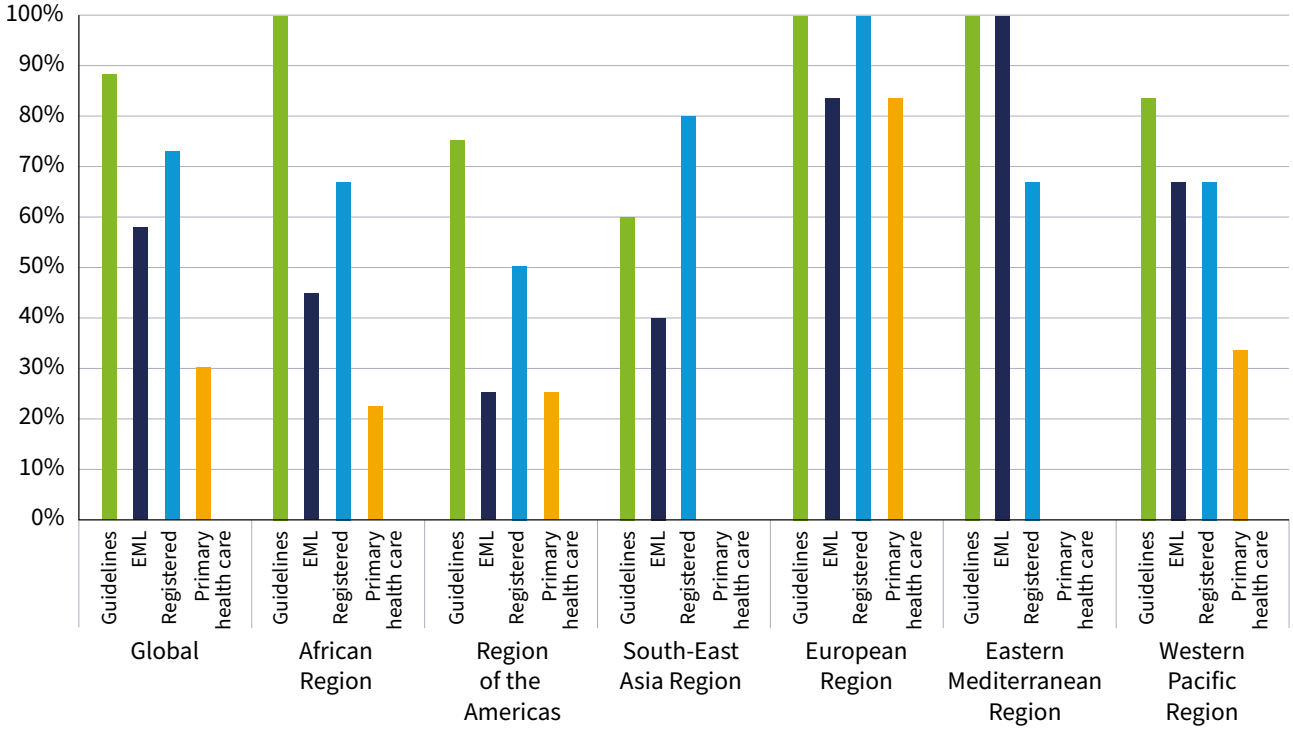
Fig. 3.21. Hepatitis C medicines in national programmes (inclusion in treatment guidelines and essential medicines lists, product registration in-country and availability in primary health care) – adults and children, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



SOF and DAC: refers to either SOF and DAC both or SOF/DAC fixed-dose combination or SOF+DAC co-blistered.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

There is regional variation in the availability of hepatitis C medicines (Fig. 3.22). In the African Region, for example, all reporting countries have included SOF and DAC in the national guidelines. Four countries had included them in the national essential medicines list, and six countries had registered at least one product for adults – lower than the global average. Only one country – Rwanda – reported having these medicines available for adults in primary health care.

Fig. 3.22. Inclusion of SOF and DAC[a] in national essential medicines lists and national hepatitis C guidelines and availability in primary health care, by WHO region, among WHO focus countries for the viral hepatitis response, 2023 (percentage of reporting countries)



[a]SOF and DAC include either SOF and DAC both or SOF/DAC fixed-dose combination or SOF+DAC co-blistered.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

3.3.2.4 Application and management of intellectual property

As noted in subsection 3.1.3.5, a country's ability to access generic medicines depends, among other aspects, on whether patents are filed or granted in the country or whether other market exclusivities are granted in the country (such as data exclusivity protection) and – if patents are filed or granted – whether the country in question is included in the geographical scope of the respective voluntary licensing agreements – either bilateral, i.e. between originator and generic companies, or through the MPP.

Most DAA drugs are still under patent, with the exception of DAC, for which most patents have been withdrawn by the innovator. Generic products are available through voluntary or compulsory licensing, and most low- and middle-income countries are covered by voluntary licences (Fig. 3.23 and Table 3.20). However, the uptake of these medicines remains low and many countries are still not accessing medicines at global benchmark prices, even though they may be covered under voluntary licensing agreements.

The intellectual property status of hepatitis C medicines is summarized below.

- **SOF, LED, VEL: patented and licensed to generic manufacturers**
  In 2018, the originator company Gilead signed voluntary licensing agreements with 11 India-based generic manufacturers to produce and/or sell generic versions of SOF, LED and VEL for distribution in 105 countries. Of the 105 countries, 59 have patents or patent applications in the country, and in these countries, the licensing agreement would enable the country to produce or import generic products for these medicines. Many upper-middle-income countries, such as Brazil, China, Mexico and the Russian Federation, remain excluded from the licensing agreement, and are therefore unable to import or locally manufacture these medicines. In 2017, Malaysia was the first country to issue a government use or compulsory licence to enable local companies to manufacture SOF or import generic SOF into the country under certain conditions (*61*). There are also several pre- or post-grant opposition processes in various jurisdictions.

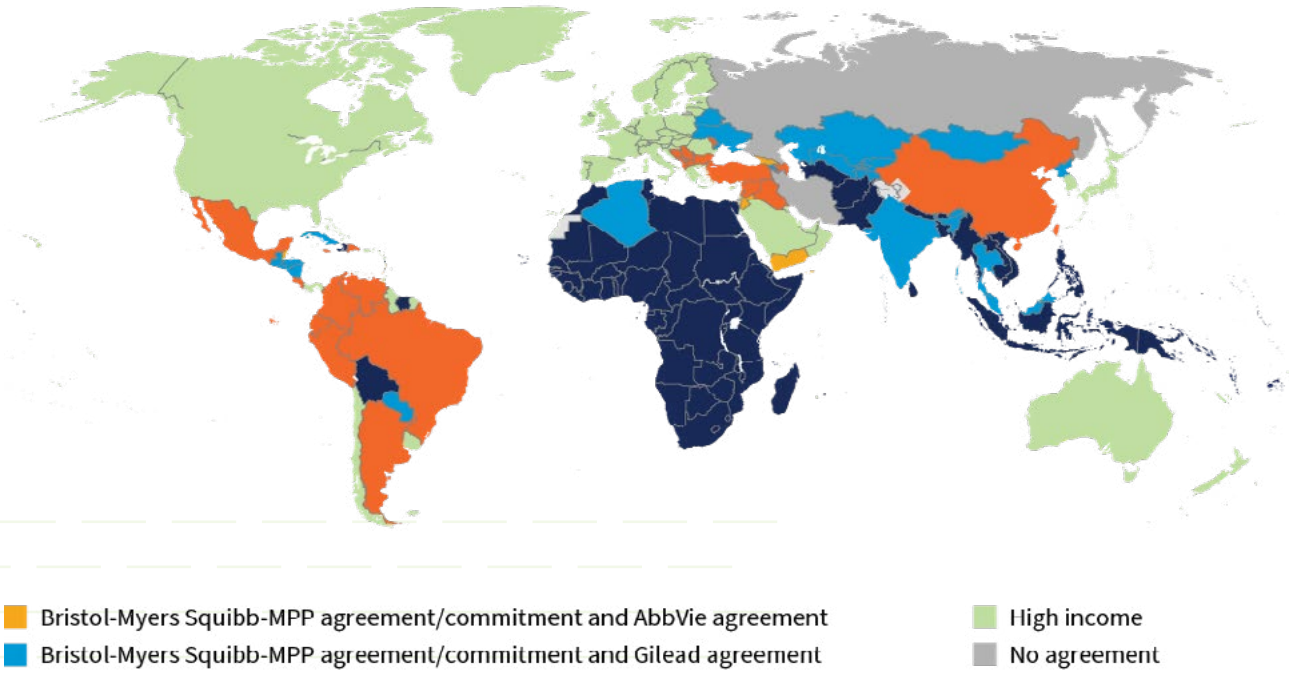
- **DAC: patented, licensed to generic manufacturers via MPP, patents subsequently withdrawn by innovator**
  In 2015, the originator company Bristol-Myers Squibb signed a voluntary royalty-free licensing agreement with MPP to allow generic companies to develop, manufacture and sell DAC and its combinations in 112 countries. Of these, seven countries had patents or patent applications on DAC – including India, which is home to all the generic manufacturers who have obtained WHO prequalification for the product and who therefore needed a licence to be able to manufacture the product and supply it in the territory of the license. In 2020, following the Bristol-Myers Squibb announcement of the withdrawal of its patents and market authorizations in several countries, including all low- and middle-income countries with the exception of the Russian Federation, generic DAC can now be supplied in all such countries. The practical effect of the withdrawal of the patents was to enable the generic manufacturers who had developed the product to supply it to additional countries, which was effectively equivalent to a licence expansion.

  MPP has sublicensee agreements with seven generic manufacturers who are developing, manufacturing and/or supplying DAC and the DAC/SOF combination to low- and middle-income countries. In the case of the Russian Federation, there is an exclusive bilateral agreement between Bristol-Myers Squibb and Pharmstandard *(64,65)*. As of September 2023, DAC 30 mg and 60 mg sales had been supplied by MPP licensees to 38 countries (4.2 million packs of 28 tablets, equivalent to 1.4 million courses of treatment). In addition, 19 countries have procured DAC/SOF from MPP licensees (365 000 packs of 28 tablets).

- **G/P: patented and licensed to generic manufacturers via MPP**
  In 2018, the originator company AbbVie signed a voluntary licensing agreement with MPP to enable quality-assured generic manufacturers to develop, manufacture and sell generic WHO-prequalified medicines containing G/P in 96 low- and middle-income countries and areas. Specifically, the license is enabling manufacturers in countries where G/P has patents pending or granted (India and Pakistan) to develop the product, and once registered, to supply it in the 96 countries covered by the license – including eight in which the product also has patents granted or pending. As of December 2023, MPP has four sublicensing agreements with generic manufacturers, which are required to get WHO prequalification approval to meet MPP quality criteria. WHO announced the expression of interest for generic companies to apply for WHO prequalification in October 2022.

  Some middle-income countries are currently not included in this licence. In 2021, the Médecins Sans Frontières Access Campaign sent an open letter to AbbVie, urging them to expedite the registration of G/P in low- and middle-income countries and to expand the voluntary licensing agreement territory to make generic G/P accessible to more countries *(62)*. Also in August 2022, the Treatment Action Group called on AbbVie to expand the MPP G/P voluntary licence to include marketing and sales in India to avoid the situation in which generic developers in India manufacture and commercialize generic G/P for markets outside India while people in India need the same medicine. They also urged AbbVie to immediately register G/P in low- and middle-income countries to enable the manufacture and sale of generic formulations, to increase competition and reduce prices *(63)*.

Fig. 3.23. Territories licensed through Gilead, Bristol-Myers Squibb, AbbVie and MPP, 2023



Note: In addition to the countries in the territory of the Bristol-Myers Squibb-MPP licensing agreement, DAC can be supplied into these additional countries and territories: Albania, Argentina, Armenia, Belarus, Bosnia and Herzegovina, Brazil, Bulgaria, Chile, China, Colombia, Egypt, Jordan, Kazakhstan, Kosovo (in accordance with United Nations Security Council resolution 1244 *(1999)*), Kyrgyzstan, Lebanon, Malaysia, Mexico, Montenegro, North Macedonia, Peru, Republic of Moldova, Romania, Serbia, Tajikistan, Thailand, Türkiye, Ukraine, United Arab Emirates, Uruguay and Venezuela (Bolivarian Republic of).

Source: MPP.

Table 3.20. Licensing status of hepatitis C medicines, 2023

Originator company	Voluntary licensing agreement	Medicine	Number of countries included in the licensing or sublicensing agreement or benefitting from non-enforcement commitment and Number of countries with patents or patent applications	Number of generic sublicensee manufacturers and Number of generic sublicensee manufacturers that have WHO prequalification approval
Gilead	Bilateral (2018)	SOF SOF/LED SOF/VEL SOF/VEL/ voxilaprevir (VOX)	105 countries Of these, 59 have patents or patent applications	*International licences (India)* Aurobindo Pharma Ltd. Biocon Limited Cadila Healthcare Ltd. Cipla Ltd. Hetero Labs Ltd. Laurus Labs Pvt. Ltd. Mylan Laboratories Ltd. Natco Pharma Ltd. SeQuent Scientific Ltd. Strides Shasun Ltd. Sun Pharmaceuticals Industries Ltd. *In-country licensees* Ferozsons Laboratories Ltd. Magic Pharma Pharmed Healthcare *WHO prequalified as of December 2023* Hetero Labs Ltd. Mylan Laboratories Ltd. Strides Shasun Ltd.
AbbVie	MPP-AbbVie licensing agreement (2018)	G/P	96 countries Of these, eight have patents or patent applications	*Generic sublicensees* Arene Lifesciences Mylan Remington USV *Generic sublicensees that are commercializing the product as of December 2023* none *WHO prequalified as of December 2023* none

Table 3.20. Licensing status of hepatitis C medicines, 2023 (continued)

Originator company	Voluntary licensing agreement	Medicine	Number of countries included in the licensing or sublicensing agreement or benefitting from non-enforcement commitment and Number of countries with patents or patent applications	Number of generic sublicensee manufacturers and Number of generic sublicensee manufacturers that have WHO prequalification approval
Bristol-Myers Squib	MPP-Bristol-Myers Squibb licensing agreement (2015) Announcement of withdrawal of market authorization in certain countries (2020)	DAC	144 countries (including the Russian Federation, which has a bilateral licence) Of these, 7+1 have patents or patent applications	*Generic sublicensees that are commercializing the product as of December 2023* Cipla Hetero Laurus Labs Mylan (Viatris) *Other generic sublicensees* Beximco Pharma Natco Zydus Cadila *WHO prequalified as of December 2023* Cipla Hetero Laurus Labs Mylan (Viatris) Zydus Lifesciences

Source: MPP and Gilead.

Of the 38 WHO focus countries for the viral hepatitis response, large upper-middle-income countries such as Brazil, China and Mexico are excluded from these voluntary licences. Table 3.21 presents the WHO focus countries that are not included in the licensing agreements as of December 2023.

As described in subsection 3.3.1.4, countries that are not inluded in a patent licence on viral medicines can refer to a roadmap of alternatives for improving access to these medicines.

Table 3.21. WHO focus countries for the viral hepatitis response not included in licensing agreements for hepatitis C medicines, 2023

Focus countries not included	African Region	Region of the Americas	South-East Asia Region	European Region	Eastern Mediterranean Region	Western Pacific Region
Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX		Brazil Colombia Mexico Peru		Georgia Republic of Moldova Russian Federation	Yemen	China Niue
Bristol-Myers Squibb and MPP licensing agreement or patent withdrawal or lapse for DAC						
AbbVie and MPP licensing agreement for G/P		Brazil Colombia Mexico Peru	India			China Mongolia

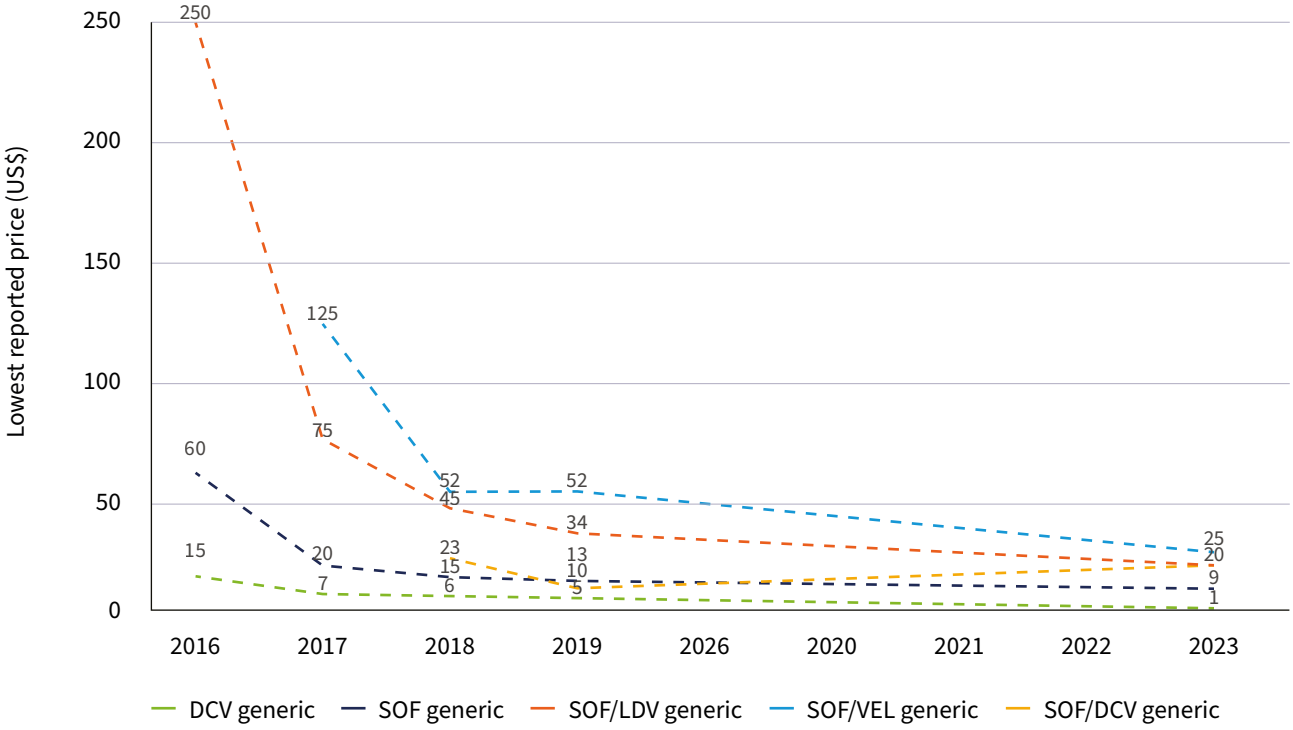
Source: MPP and Gilead.

3.3.2.5 Product pricing

Comparison with data gathered for previous editions of this report indicates that the prices of generic hepatitis C treatment have continued to decline (Fig. 3.24). Between 2016 and 2023, the lowest reported prices of generic DAC 60-mg tablet, SOF 400-mg tablet and SOF/LED 400- + 90-mg tablet in public sector procurement have decreased by 93%, 82% and 92%, respectively. A 12-week curative treatment for hepatitis C can be accessed for as low as US$ 34 if SOF and DAC are purchased separately: for example, in Pakistan from local manufacturers. Other cost savings may be obtained if countries can access SOF and DAC at the ceiling price of US$ 60 per person-course of treatment that is offered through the memorandum of understanding signed by the Clinton Health Access Initiative and The Hepatitis Fund with two generic manufacturers, Hetero and Viatris.

A comparison of the lowest reported originator price for each DAA with the lowest reported price of its generic equivalent shows that the prices of originator medicines are much higher than the price of generic medicines. Originator SOF was nearly 50 times more expensive than its generic counterpart; originator DAC was 449 times more expensive than its generic counterpart. For example, in the WHO Western Pacific Region, the lowest reported price of generic SOF was US$ 99.10 for the 12-week course of treatment versus the lowest reported price of originator SOF of US$ 8257. In the European Region, the lowest reported price of generic DAC was US$ 14.28 for the 12-week course of treatment versus the lowest reported price for originator DAC of US$ 1508.60. Similarly, originator products for SOF/LED and SOF/VEL are 20 times and 19 times (respectively) more expensive than their generic counterparts.

Fig. 3.24. Trends in the lowest reported public procurement price of generic DAAs for hepatitis C for a month's supply, WHO focus countries for the viral hepatitis response, 2016–2023



Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

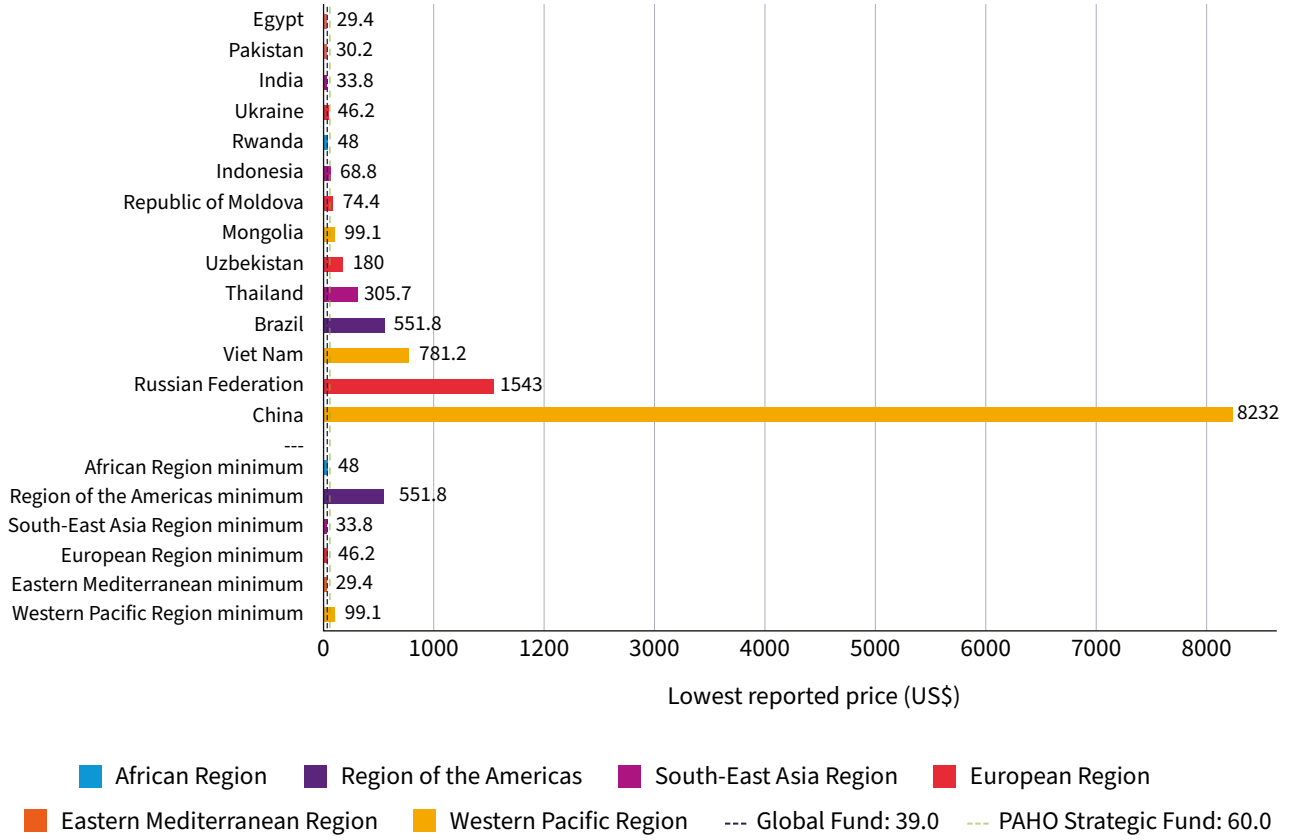
Despite downward trends in the price of generic hepatitis C medicines, many reporting countries are still paying higher prices than the benchmark prices available through global access pricing agreements. Further, the price of hepatitis C medicines also varies widely across WHO regions and country income groupings. These differences may be related to many factors, such as patent status, inclusion in voluntary licensing agreements, pooled procurement, local production, price negotiations or purchase volumes. Substantial cost savings for hepatitis C treatment could be realized if all countries were able to access generic medicines at the lowest available prices.

Rwanda, a low-income country, is paying more for SOF than Pakistan, a lower-middle-income country. Brazil, despite being an eligible member of the Pan American Health Organization's Strategic Fund, is paying nine times more for SOF than the Strategic Fund access price.

SOF and DAC

SOF: As mentioned in subsection 3.3.2.4, SOF is a patented medicine, and many upper-middle-income countries remain excluded from the voluntary licensing agreement of the originator company Gilead. The reported public procurement price of SOF varies widely across WHO regions and country income groupings (Fig. 3.25). The lowest reported price was from Egypt, at US$ 29.49 for a 12-week generic course of treatment. The highest reported price was from China at US$ 8257.2 for a 12-week generic course of treatment, although the price difference with the originator product in China was minimal.

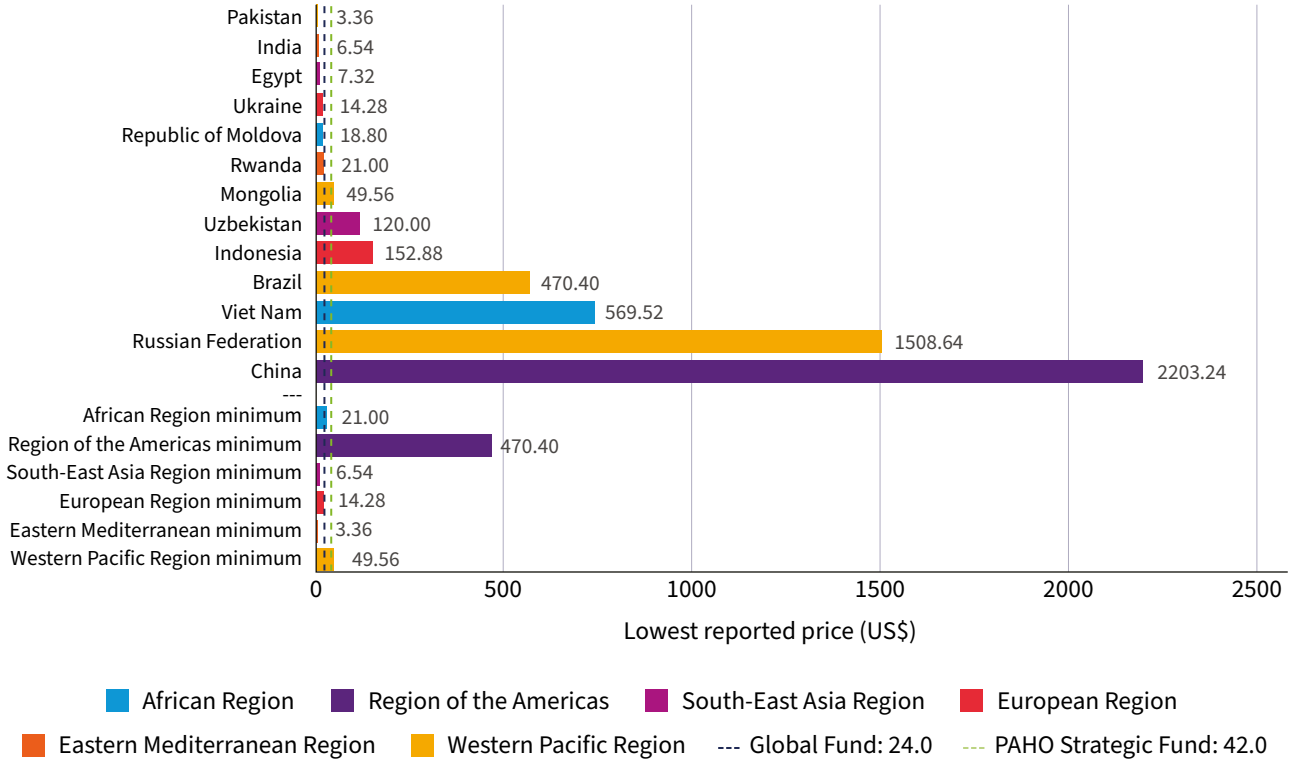
Fig. 3.25. Lowest reported curative treatment price of SOF 400 mg (12 weeks), WHO focus countries for the viral hepatitis response, 2023



Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

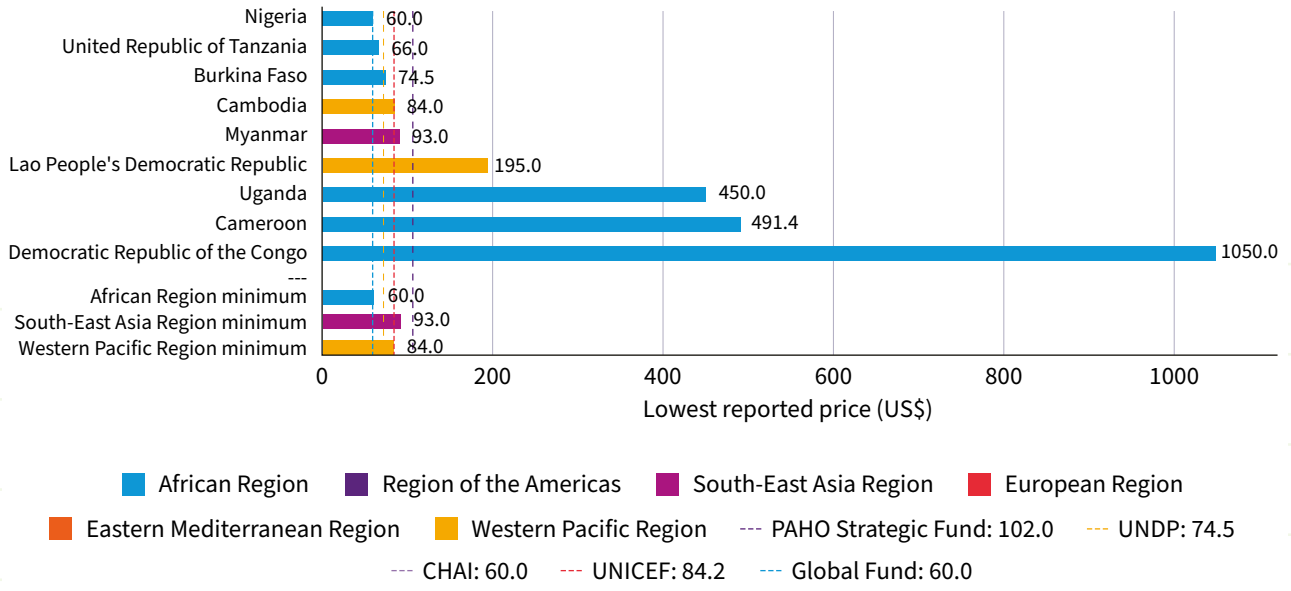
DAC: After Bristol-Myers Squibb announced in 2020 the withdrawal of market authorization for DAC, 143 countries and territories should be able to procure generic DAC. However, the prices countries pay continue to vary greatly. The lowest reported price was from Pakistan, at US$ 3.36 per 12-week course of treatment, and the highest reported price was from China, at US$ 2203 per 12-week course of treatment. Brazil, despite being an eligible member of the Pan American Health Organization's Strategic Fund, is paying 11 times more for DAC than the Strategic Fund access price (Fig. 3.26).

Fig. 3.26. Lowest reported curative treatment price of DAC 60 mg (12 weeks), WHO focus countries for the viral hepatitis response, 2023



Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Fig. 3.27. Lowest reported curative treatment price of SOF 400 mg /DAC 60 mg (12 weeks), WHO focus countries for the viral hepatitis response, 2023



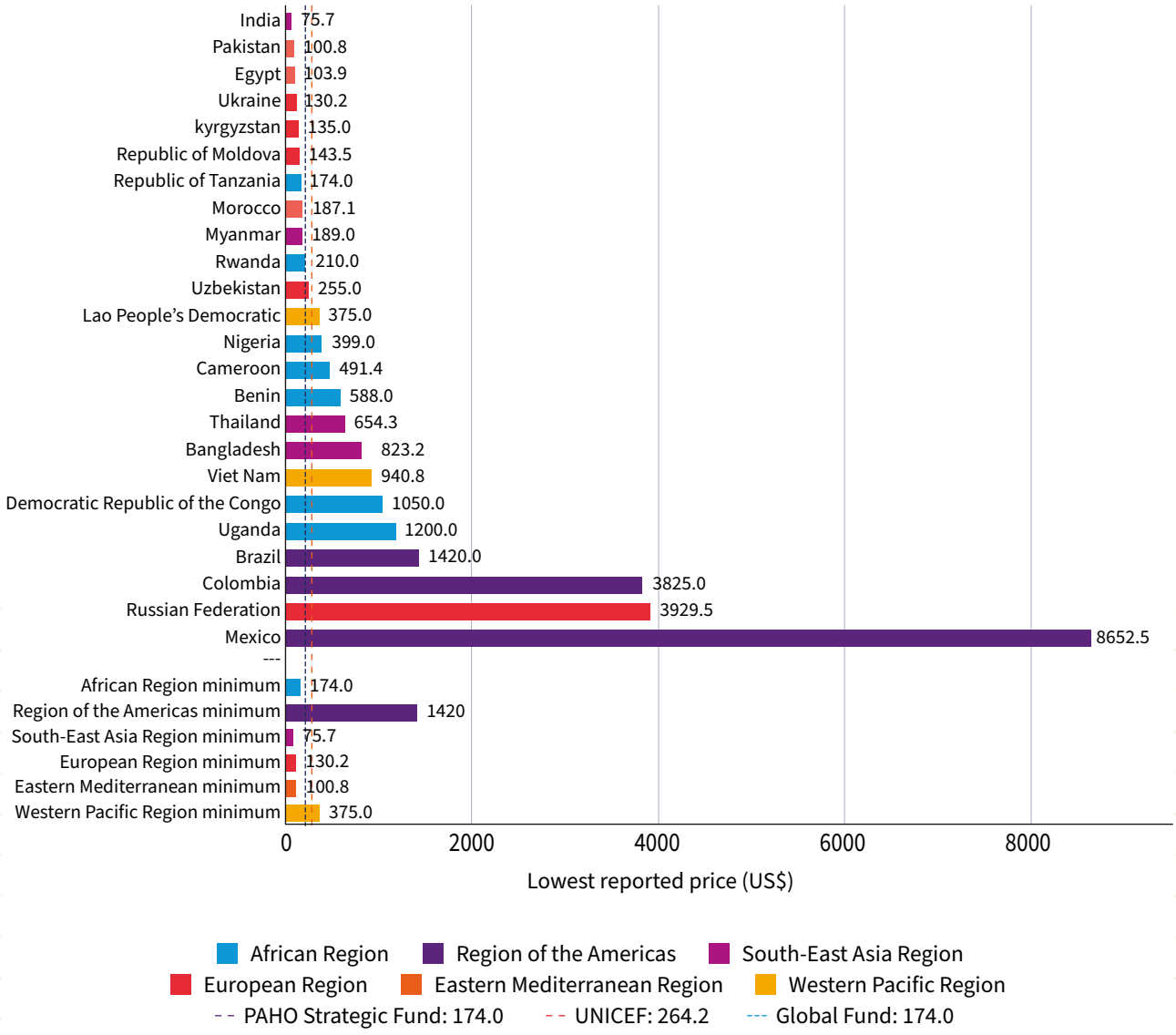
Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

SOF/DAC: The reported public procurement price of the SOF/DAC fixed-dose combination varied between US$ 60 for a 12-week course of treatment in Nigeria and US$ 1050 for a 12-week course of treatment in the Democratic Republic of the Congo. Only Nigeria accessed SOF/DAC at or below the global benchmark price of US$ 60 for a 12-week course of treatment. Cameroon pays seven times more for SOF/DCV than the United Republic of Tanzania, despite having only US$ 460 higher gross national income per capita. Burkina Faso, a low-income country, pays more than United Republic of Tanzania, a lower-middle-income country (Fig. 3.27).

SOF/VEL

International and regional pooled procurement mechanisms provide access pricing through pooled procurement orders for SOF/VEL in low- and middle-income countries. The Global Fund and the Pan American Health Organization Strategic Fund offer generic SOF/VEL at US$ 174 for a 12-week course of treatment. The Strategic Fund also offers originator SOF/VEL at US$ 4050 for a 12-week course of treatment. However, of the 22 reporting countries that provided data on public procurement of SOF/VEL, only seven – Egypt, India, Kyrgyzstan, Pakistan, Republic of Moldova, United Republic of Tanzania and Ukraine – reported prices at or below the lowest available benchmark price (Fig. 3.28). The highest prices were reported from the reporting countries in the Region of the Americas and from the Russian Federation, all of which are excluded from the Gilead voluntary licensing agreement. In addition, Mexico, despite being an eligible member of the Strategic Fund, is paying 50 times more than the Strategic Fund access price. Colombia pays more than Brazil despite having a lower gross national income per capita. In the African Region, low-income countries such as the Democratic Republic of the Congo are paying more for SOF/VEL than other low-income countries in the Region or other lower-middle-income countries in other regions.

Fig. 3.28. Lowest reported curative treatment price of SOF 400 mg /VEL 100 mg (12 weeks), WHO focus countries for the viral hepatitis response, 2023



Note: Countries self-report procurement prices. Data on procurement volumes are not captured.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

SOF/LED

No international or regional pooled procurement mechanism offers procurement of SOF/LED. Similar to other hepatitis C medicines, the price varies across countries. Among the 10 countries that reported public procurement data on SOF/LED, the lowest price was reported by Mongolia, at US$ 60.40 for a 12-week generic course of treatment. The highest price was reported by the Russian Federation, at US$ 4492.30 for a 12-week originator course of treatment. The lowest reported price in Viet Nam was still 10 times more expensive than the price reported in Mongolia, despite similarities in income levels.

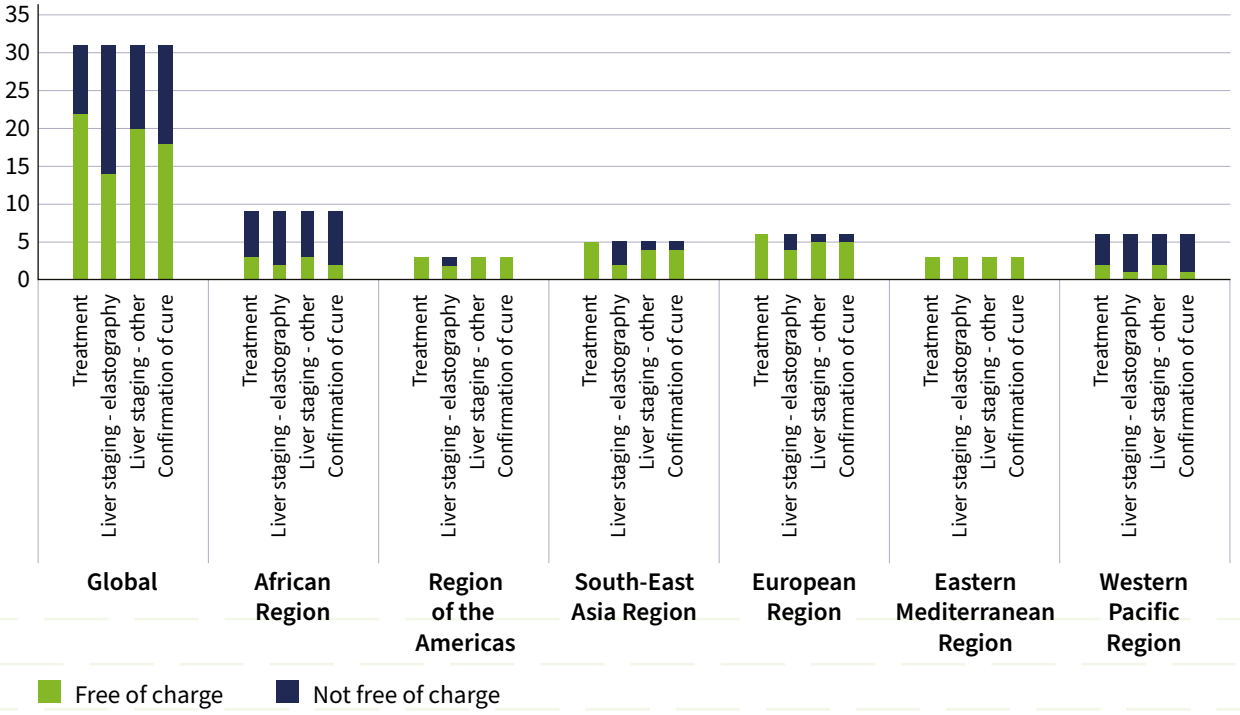
G/P

No international or regional pooled procurement mechanism offers procurement of G/P, and as of among the four countries that reported public procurement data on G/P, the price for the eight-week regimen from the originator company varied from US$ 5681 in Brazil, US$ 7859 in the Russian Federation, US$ 13 020 in Mexico and US$ 15 780 in China. The Russian Federation paid a lower price than Mexico despite having a higher gross national income.

3.3.2.6 Out-of-pocket expenditure

Universal health coverage means that all people have access to the full range of high-quality health services they need, when and where they need them, without financial hardship. Of the 29 WHO focus countries for which information on out-of-pocket expenditure for hepatitis C treatment and follow-up was available, 20 provided hepatitis C treatment, 13 provided liver staging by elastography and 17 provided liver staging by other methods, free of charge in the public sector (Fig. 3.29). Among reporting countries, only two countries – Mexico and Uzbekistan – reported hepatitis C self-testing being available free of charge in the public sector. Chapter 4 provides details by focus country.

Fig. 3.29. Availability of hepatitis C treatment and follow-up free of charge in the public sector, WHO focus countries for the viral hepatitis response, 2023 (number of reporting countries)



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

A recent review of the global status of registration, reimbursement and restrictions related to DAAs for hepatitis C, conducted by the Kirby Institute in Australia, assessed whether people with hepatitis C had access to reimbursement of DAAs (through government reimbursement, subsidized treatment or fee-free policies) and whether there were restrictions on reimbursement. Of the 160 countries, 109 reimbursed at least one DAA combination therapy. Among these, of the 102 low- and middle-income countries for which information was available, 89 had registered at least one pangenotypic DAA, and 53 reimbursed at least one DAA combination therapy. However, among the 109 countries providing reimbursement, 66 required prescription by a specialist, eight had retreatment restrictions, seven had an illicit drug use restriction, five had an alcohol use restriction and three had restrictions related to liver disease stage (*66*).

3.3.2.7 Procurement, local production and technology transfer

Of the 31 WHO focus countries for which information on local production was available, seven reported local production of generic SOF, eight generic DAC, three generic SOF/LED and five generic SOF/VEL. No country reported local production of generic G/P (Table 3.22). Local production is an increasingly important action to implement the global health sector strategy on viral hepatitis, 2022–2030.

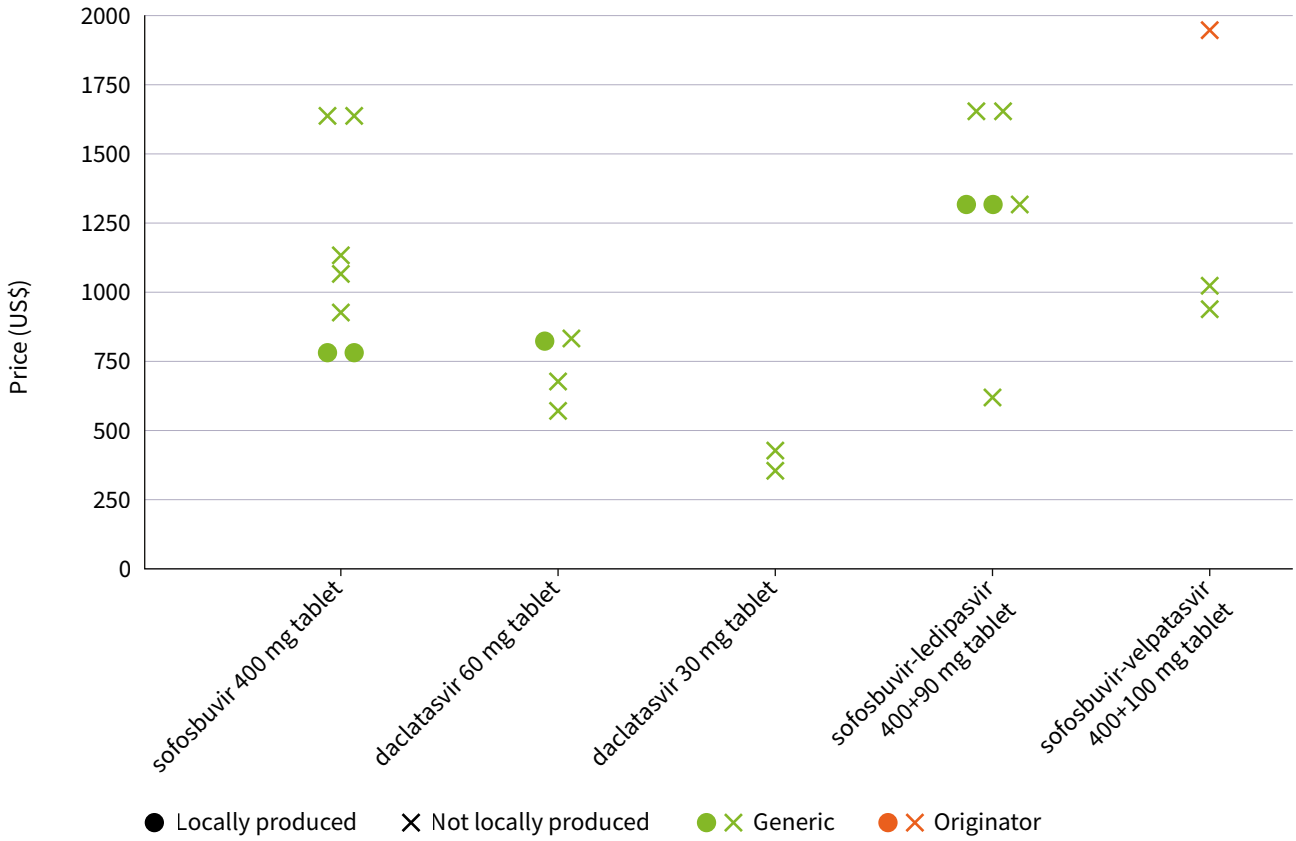
Table 3.22. WHO focus countries for the viral hepatitis response with local production of generic hepatitis C medicines, 2023

Number of countries with local production	**African Region**	**Region of the Americas**	**South-East Asia Region**	**European Region**	**Eastern Mediterranean Region**	**Western Pacific Region**
SOF **(7)**		Brazil	Bangladesh, India		Egypt, Pakistan	China, Viet Nam
DAC **(8)**		Brazil	Bangladesh, India	Russian Federation	Egypt, Pakistan	China, Viet Nam
SOF/DAC, SOF+DAC **(1)**			Bangladesh			
G/P						
SOF/LED **(3)**					Egypt, Pakistan	China, Viet Nam
SOF/VEL **(5)**			Bangladesh, India, Thailand		Egypt, Pakistan	
SOF/VEL/VOX **(2)**			Bangladesh			Lao People's Democratic Republic

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

In Viet Nam, where comparable data on public procurement prices was available, locally produced generic SOF was less expensive than imported SOF (Fig. 3.30). However local production status had no price impact on other DAAs being produced in the country. In other countries with local production, such as Brazil, China and Morocco, locally produced generic medicines remain more expensive than global benchmark prices.

Fig. 3.30. Variation in treatment prices of generic and originator medicines for hepatitis C based on local production status in Viet Nam, 2023



Source: WHO survey among focus countries for the viral hepatitis response, 2023.

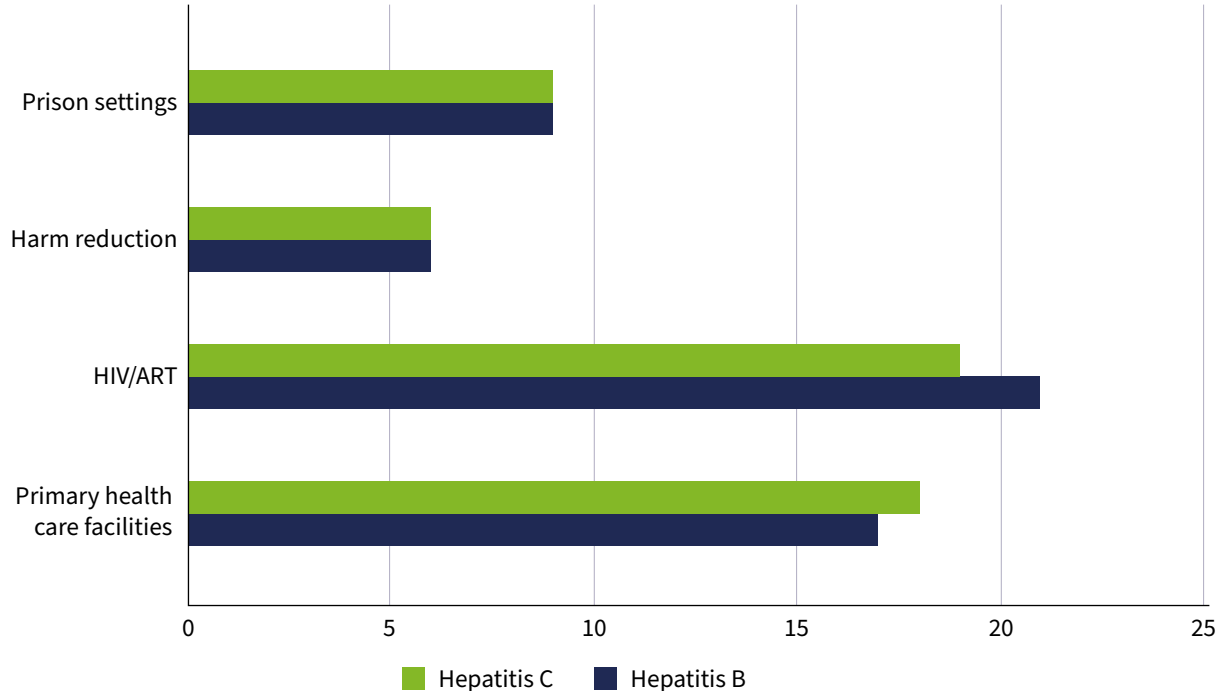
3.3.3 Cross-cutting considerations for viral hepatitis medicines

3.3.3.1 Decentralizing and integrating service delivery

Offering person-centred services at local health facilities is key to successfully ending hepatitis. Historically, viral hepatitis services in many countries have been delivered based on specialist-led care models (usually by a hepatologist or gastroenterologist) in hospital-based settings to administer complex treatment. Decentralizing hepatitis services at peripheral health or community-based facilities and integrating them with primary care and other existing health service delivery points are essential to make services more accessible and convenient for all patients.

Data on service integration were collected through the Global Hepatitis Reporting System. Of the 27 WHO focus countries that reported information on service integration, 78% reported that hepatitis B testing and treatment services are integrated with existing services in HIV and antiretroviral therapy clinics and/or PrEP sites, and about 63% reported that these are integrated into primary health care. For hepatitis C, 70% reported that services are integrated with existing services in HIV and antiretroviral therapy clinics and/or PrEP sites, and 67% reported that these are integrated into primary health care. Fewer countries reported that hepatitis services are integrated with existing services for harm reduction and in prison settings (Fig. 3.31).

Fig. 3.31. Integration of viral hepatitis testing and treatment services with other health services, WHO focus countries for the viral hepatitis response, 2023



Source: Global Hepatitis Reporting System, 2023.

A systematic review and meta-analysis of 142 studies from 33 countries examined the effectiveness of simplified service delivery interventions in terms of outcomes across the hepatitis C cascade of care. The review found that people who inject drugs had higher uptake of HCV RNA testing with full decentralization and integration (98%, 95% CI: 95–100%) at harm-reduction sites than with partial decentralization (81%, 95% CI: 69–91%) or no decentralization (82%, 95% CI: 13–100%). DAA treatment uptake levels were also higher with full decentralization and integration versus partial and no decentralization. Similar findings were noted for people in prison settings. The proportion of people achieving cure (sustained viral response after 12 weeks) was high (>95%) across all levels of decentralization and integration and for all populations *(67)*.

In 2022, WHO published new guidance recommending the expansion of HCV testing and treatment services, ideally at the same site, by decentralizing care to lower-level facilities. The guidance also recommends integrating hepatitis C services with existing services, such as in primary care, harm-reduction programmes, prisons and HIV services and promoting task sharing with appropriately trained non-specialist doctors and nurses *(37)*. The 2024 updated WHO recommendations on prevention, diagnosis, care and treatment for people with chronic hepatitis B infection also emphasize the importance of simplified service delivery for a public health approach to testing, care and treatment for people with chronic hepatitis B *(18)*.

3.3.3.2 Procurement and supply

Several international procurement mechanisms such as those operated by the United Nations Children's Fund (UNICEF), the Global Fund and the Pan American Health Organization Strategic Fund are supporting low- and middle-income countries to access cost-effective, quality-assured products in a timely manner. These pooled procurement mechanisms consolidate demand and negotiate favourable pricing for participating countries. Other forms of collective negotiation, such as the Organisation of Eastern Caribbean States Pooled Procurement Service *(68)*, can also be useful in reducing prices and accessing quality-assured products.

High prices and restrictive prescribing affect access to viral hepatitis treatment in countries of all income levels. The availability of generic medicines has improved access for some products, but not all treatments are widely available yet in generic form. Diagnostic capacity can vary greatly, which affects the reliability of the quantification of demand for the medicines. Access problems can be exacerbated in countries that have weak procurement and supply chain management systems, including limited human resources, ineffective logistics and inventory management capacity and lack of financing. Risks of supply chain disruptions caused by climate disasters, conflict or pandemics affect countries worldwide.

Australia, Canada, India, Saudi Arabia, United Kingdom, the United States of America and others have had intermittent shortages of tenofovir and ETV in 2022 and 2023 *(69–71)* according to the public databases of medicines shortages maintained by a select group of countries. For hepatitis C treatments, stock-outs were reported in India *(72)*. These shortages were reported by manufacturers, which suggests that the shortage would affect other countries as well. In the WHO 2023 survey among focus countries, Ethiopia, the Republic of Moldova and Thailand reported national shortages of hepatitis B medicines. Colombia, Ethiopia, Nigeria and Republic of Moldova also reported national stock-outs of hepatitis C medicines. The most common reasons mentioned for national stock-outs were inefficiency in procurement and supply chain management. Other challenges related to procurement included limited suppliers or problems with suppliers, challenges because of small markets and no or limited government financing.

Countries can increase access to quality-assured medicines by registering and procuring WHO-prequalified products either nationally or through international procurement mechanisms, especially when they are available in generic form. The WHO collaborative procedure can accelerate the national registration of prequalified finished pharmaceutical products by sharing WHO prequalification assessment reports with national regulatory authorities. This eliminates duplicative regulatory work. A similar procedure for accelerated registration of finished pharmaceutical products that have been approved by stringent regulatory authorities is also in operation. Countries can also optimize their quantification and procurement by linking diagnostics to treatments. If a country has pricing policies, reducing mark-ups may improve affordability.

3.3.3.3 Advancing research in drug optimization

The development of long-acting therapies for hepatitis B and C offer the potential to further simplify care pathways, increase adherence and retention and improve outcomes. Improved and accessible treatment formulations for children are also needed, as is research into affordable and acceptable treatment solutions for hepatitis D.

3.4 Access to vaccination

This section presents information on the global status of access to hepatitis B vaccination, including the hepatitis B birth dose.

Key findings

1 The coverage of the hepatitis B birth dose remains low, especially in the African Region, which has the highest prevalence of hepatitis B. The coverage of the hepatitis B birth dose varies between 18% in the African Region and 80% in the Western Pacific Region. Globally, 115 countries have introduced a universal hepatitis B birth dose. Of the 38 WHO focus countries for the viral hepatitis response, 25 countries (65%) have introduced birth-dose programmes as of 2022.

2 Globally, low-income countries pay a median price of US$ 0.40 per dose of the monovalent hepatitis B vaccine and US$ 0.85 for the pentavalent vaccine. Nearly all focus countries report that hepatitis B infant vaccination is available free of charge in the public sector, and more than 70% report that hepatitis B birth-dose vaccination is available free of charge in the public sector. Nevertheless, in practice, access to the birth-dose vaccination is often hampered by a lack of a policy within the national immunization programme or a lack of access to newborn infants within the first 24 hours of life for in-facility or out-of-facility births. Out-of-pocket expenditure for hepatitis B vaccines can also be a barrier to access, and this should be minimized to expand coverage of the vaccination.

3 Efforts to develop an effective vaccine against HCV continue to be an important component of the viral hepatitis research agenda.

3.4.1 Hepatitis B birth-dose vaccination in routine immunization

WHO recommends that all children receive a monovalent dose of hepatitis B vaccine within the first 24 hours after birth followed by an additional 2–3 doses in infancy. This vaccination schedule enables reduction in maternal-to-newborn transmission of HBV (vertical transmission) and in horizontal transmission that could occur at other times.

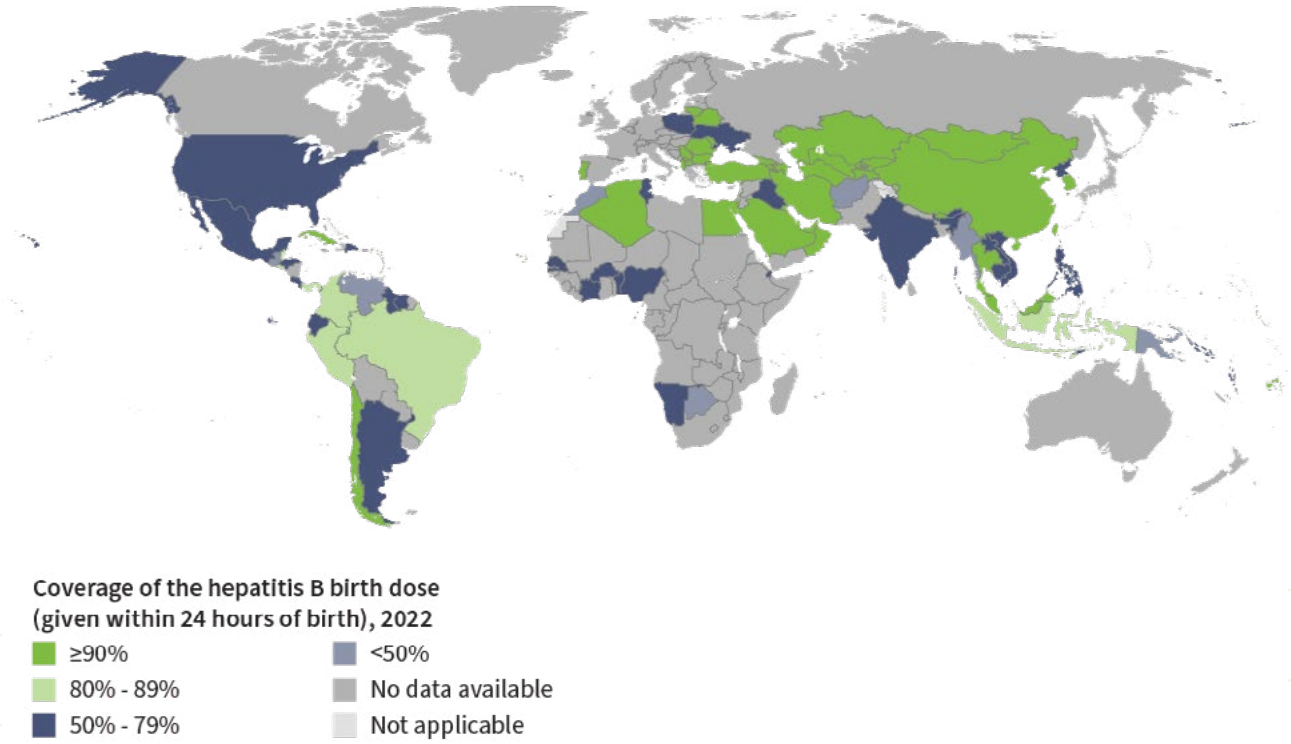
Globally, 115 countries have introduced universal hepatitis B birth-dose vaccination, and 45% of infants received the hepatitis B birth dose within the first 24 hours of birth in 2022. Twenty-three countries have selective programmes with targeted provision of the hepatitis B birth dose (the vaccine is provided to the infants of mothers who are HBsAg positive). Infant immunization schedules in 190 countries include the hepatitis B vaccine. Of the 38 WHO focus countries for the viral hepatitis response, 25 have introduced birth-dose programmes and all provide the hepatitis B vaccine (usually as part of pentavalent vaccines) in their infant vaccination programme. In theory, if these vaccines are included in the national programme, all children should have access; however, in practice, coverage varies widely across regions and countries (Table 3.23 and Fig. 3.32). Chapter 4 presents detailed information for the 38 WHO focus countries for viral hepatitis.

Table 3.23. Coverage of the hepatitis B birth-dose and hepatitis B infant vaccination, by WHO region, 2022

WHO region	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
African Region	18	72
Region of the Americas	65	83
South-East Asia Region	58	91
European Region	42	91
Eastern Mediterranean Region	32	84
Western Pacific Region	80	93

Source: WHO/UNICEF Joint Reporting Form on Immunization

Fig. 3.32. Coverage of the hepatitis B birth dose (given within 24 hours of birth), 2022



Source: WHO/UNICEF Joint Reporting Form on Immunization.

Access to the birth-dose vaccination is often hampered by a lack of a policy within the national immunization programme or a lack of access to newborn infants within the first 24 hours of life by the Expanded Programme on Immunization (either in-facility or out-of-facility births) for the hepatitis B birth dose. In 2018, Gavi, as part of the Vaccine Investment Strategy, planned to support the introduction of the hepatitis B birth dose in eligible countries. The programme was put on hold because of the COVID-19 pandemic. Gavi intends to open this funding window in early 2024. This funding has the potential to improve access in countries that have not yet introduced the birth dose.

3.4.2 Product quality, safety and performance

The WHO prequalification of vaccines was developed in 1987 to provide advice to United Nations agencies for international procurement of vaccines. The purpose is to provide assurance that candidate vaccines: *(i)* meet the WHO recommendations on quality, safety and efficacy, including complying with WHO recommended Good Manufacturing Practice and Good Clinical Practice standards; and *(ii)* meet the operational specifications for packaging and presentation of the relevant United Nations agency. This is to ensure that vaccines provided through the United Nations for use in national immunization services in various countries are safe and effective and are suitable for the target populations at the recommended immunization schedules and with appropriate concomitant products.

The hepatitis B vaccine was considered a low priority for prequalification assessment from 2018 to 2023 and is being updated for 2024–2026 as a medium-priority vaccine. As of December 2023, four hepatitis B stand-alone vaccines and eight vaccines containing the hepatitis B component (seven pentavalent vaccines and one hexavalent vaccine) have been prequalified *(73)*.

3.4.3 Product pricing and affordability

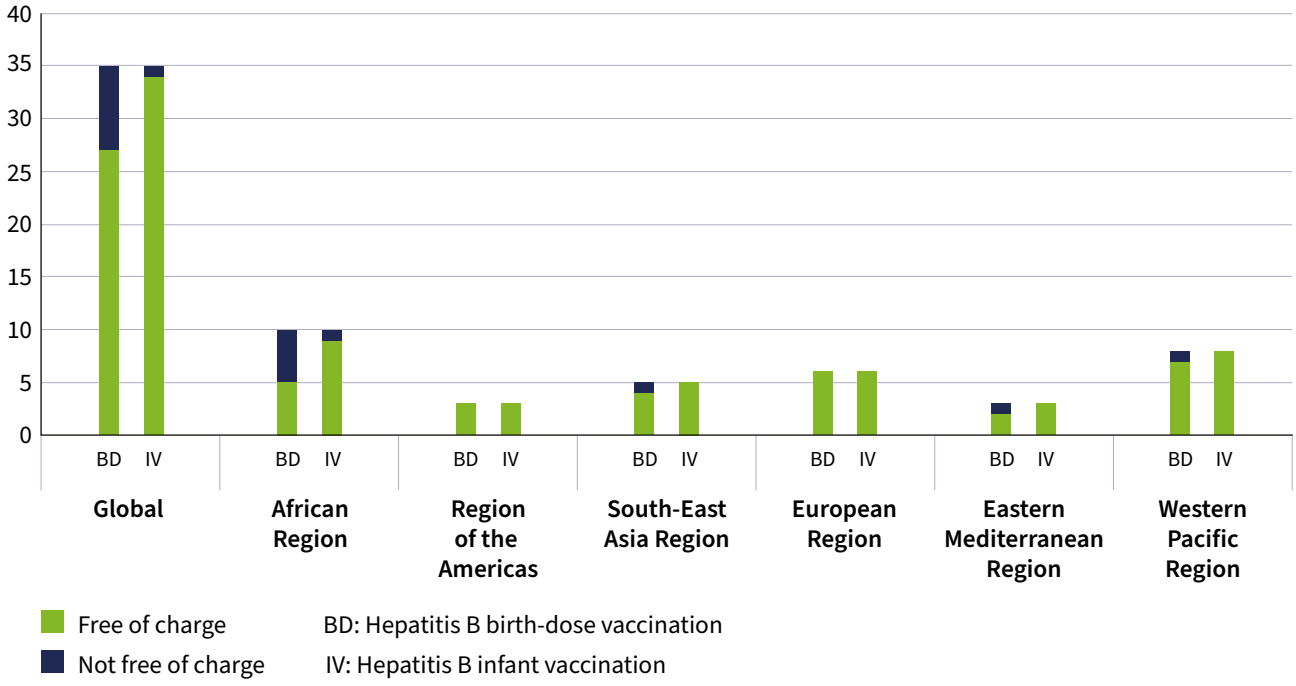
The cost for procuring the hepatitis B vaccine varies with the specific product used and by country. Based on data available through the Market Information for Access to Vaccines project reports, low-income countries pay a median price of US$ 0.40 per dose of the monovalent hepatitis B vaccine and US$ 0.85 for the pentavalent vaccine. Middle-income countries pay a median price of US$ 0.60 per dose of monovalent hepatitis B birth dose and about US$ 1 per dose for the pentavalent vaccine (Table 3.24).

Table 3.24. Median cost of hepatitis B vaccines by country income level, US$, 2023

Income grouping	Hepatitis B (monovalent)	DTwP-HepB-Hib-(IPV) (pentavalent and hexavalent)	DTaP-HepB-Hib-(IPV) (pentavalent and hexavalent)
Low-income countries	US$ 0.40	US$ 0.85	
Middle-income countries	US$ 0.50 (lower-middle-income) US$ 0.75 (upper-middle-income)	US$ 0.95 (lower-middle-income) US$ 1.05 (upper-middle-income)	US$ 25.40 (upper middle-income)
High-income countries	US$ 7.70	US$ 1.10	US$ 28.70

Source: Market Information for Access to Vaccines, 2023.

Fig. 3.33. Availability of hepatitis B vaccination free of charge in the public sector, WHO focus countries for the viral hepatitis response, 2023



Source: : WHO survey among focus countries for the viral hepatitis response, 2023 and WHO/UNICEF Joint Reporting Form for Immunization, 2022.

Within immunization programmes in general, there can be out-of-pocket expenditure ranging from providers fees for administration of the vaccine, to payment required for the vaccine. Of a total of 35 WHO focus countries for the viral hepatitis response for which this information was available either through the WHO survey or the WHO/UNICEF Joint Reporting Form, 34 provided infant vaccination and 25 countries provided the hepatitis B birth-dose vaccination free of charge in the public sector. Two additional countries are expected to introduce the birth-dose vaccination, bringing the total to 27 countries (Fig. 3.33). The countries that do not yet provide hepatitis B birth-dose vaccination free of charge have not yet included this dose in the national immunization schedule. Out-of-pocket expenditure for hepatitis B vaccines can be a barrier to access, and this should be minimized to expand coverage of vaccination.

Outside the infant immunization schedule, hepatitis B vaccine is also relevant for health-care workers. Based on a survey conducted in 2020, 55 of 103 countries reported having a national policy to vaccinate health-care workers against hepatitis B *(74)*. The 2023 WHO survey among focus countries did not provide information on out-of-pocket expenditure for the vaccine among health-care workers. Other higher-risk groups that should receive the hepatitis B vaccine include people who frequently require blood or blood products, people undergoing dialysis, people with diabetes, recipients of solid organ transplantation, people with chronic liver disease, including those with hepatitis C, household and sexual contacts of people with chronic hepatitis B, people living with HIV, people who use drugs, people in prisons and other closed settings, men who have sex with men, and people with multiple sexual partners.

Overall, access to the hepatitis B birth-dose vaccination remains limited in many settings. Additional doses through infancy are also needed to optimally protect children and are available through multi-antigen vaccines such as pentavalent vaccines. Immunization programmes need to continue to work towards optimizing access and coverage through catch-up activities. In addition, health-care workers are an important adult group who should also receive the hepatitis B vaccine.

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4.
Regional landscape of access to health products

4. Regional landscape of access to health products

This chapter presents information on access to viral hepatitis medicines, IVDs and vaccines in each WHO region. It provides country-specific data from the 38 WHO focus countries for the viral hepatitis response and on the operational aspects of access to health products, the regional achievements and priorities and WHO support. When additional countries provided data, these are also included in the tables.

4.1 African Region

Key findings

Epidemiology and service coverage: In 2022, nearly 65 million people were living with hepatitis B and nearly 8 million people were living with hepatitis C in the African Region. The African Region accounts for 63% of new hepatitis B infections globally. Less than 5% of people with hepatitis B in the Region have been diagnosed, and only 5% of these have received treatment. An estimated 13% of people with hepatitis C have been diagnosed, and only 3% have received treatment.

Access to health products: WHO focus countries in the Region have updated national treatment guidelines in accordance with WHO recommendations; however, product availability in primary health care is limited. Many countries are paying higher prices than the global benchmark. The lowest reported price of the last public sector procurement of TDF varies between US$ 2.20 in South Africa and US$ 26.70 in the Democratic Republic of the Congo for a generic 30-tablet supply of TDF. The lowest reported price of the last public sector procurement of SOF and DAC varies between USD$ 60.0 in Nigeria and US$ 491.40 in Cameroon for a generic 12-week supply. The African Region has the lowest coverage of the hepatitis B birth-dose vaccination, at 18%. The availability of IVDs in the African Region is relatively limited.

Regional priorities: Regional priorities for 2030 include leveraging HIV, primary health care and maternal and child health care services, expanding access to IVDs as an entry point to expand access to treatment and care, addressing the variability in prices paid for health products in the Region and continuing to advocate for increased domestic funding.

4.1.1 Regional epidemic profile and progress towards impact

Tables 4.1.1 and 4.1.2 present epidemiological and service coverage information for viral hepatitis B and C, respectively, in the African Region.

Table 4.1.1. Hepatitis B in the African Region, 2022

Indicator	
Number of people living with hepatitis B infection	64.7 million
Number of new hepatitis B infections per year	771 000
Number of deaths caused by hepatitis B per year	272 000
Percentage of people living with hepatitis B who are diagnosed	4.2%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	5.5%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	0.2%

Table 4.1.2. Hepatitis C in the African Region, 2022

Indicator	
Number of people living with hepatitis C infection	7.8 million
Number of new hepatitis C infections per year	172 000
Number of deaths caused by hepatitis C per year	35 100
Percentage of people living with hepatitis C who are diagnosed	13.0%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	3.0%

4.1.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the African Region.

4.1.2.1 Access to viral hepatitis testing in the African Region

Three of the 10 WHO focus countries for the viral hepatitis response in the African Region provided responses to the WHO 2023 survey on viral hepatitis IVDs: Ethiopia, Ghana and Uganda.

Hepatitis B IVDs

Product availability

The number of products available for procurement in the African Region is relatively limited. However, decentralization is a clear priority across countries. Of the countries for which information was available, all report that hepatitis B RDTs are available in primary health care and in some cases also in community settings. Further, Ethiopia also aims to support decentralized access to NAT by using dried blood spot specimens.

4.1.2.2 Access to viral hepatitis medicines in the African Region

Nine of the 10 WHO focus countries for the viral hepatitis response in the African Region provided responses to the WHO 2023 survey on viral hepatitis medicines – Cameroon, Democratic Republic of the Congo, Ethiopia, Ghana, Nigeria, Rwanda, South Africa, Uganda and United Republic of Tanzania. Two additional countries (Benin and Burkina Faso) also provided some information in response to the medicines questionnaire in 2023. When available, this information is also reflected in the analysis below.

Hepatitis B medicines

Countries have included hepatitis B medicines in their national guidelines in accordance with WHO recommendations; however, product inclusion in essential medicines lists and availability in primary health care are lagging behind. Viral hepatitis treatment services may not be available in primary health care in many countries but may be available at tertiary levels and in specialized care.

All of the 11 countries in the African Region for which information was available have included TDF in their national treatment guidelines. Six countries have included it in their national essential medicines lists and four countries have TDF available in primary health care. Similarly, for ETV, nine of these countries have included the medicine in national guidelines for adults and 10 countries for children; however, only one country had ETV available in primary health care for adults and two for children. Seven countries include TAF, which is newly introduced in the updated 2024 WHO guidelines on chronic hepatitis B, in national viral hepatitis guidelines.

Product registration varies. Ten of the 11 countries for which this information was available had registered at least one TDF product, of which six include a WHO-prequalified generic product. Five countries had registered at least one ETV product for adults and only one country for children.

The prices paid for hepatitis B medicines vary, and many countries in the Region are paying prices higher than the global benchmark of US$ 2.40 per 30 tablets of TDF (300 mg) from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. The lowest reported price of the last public sector procurement of a generic 30-tablet supply of TDF varies between US$ 2.20 in South Africa and US$ 26.70 in the Democratic Republic of the Congo. The price paid by the Democratic Republic of the Congo is 21 times the price paid by China, which has a higher gross national income per capita. Similarly, Benin pays more for TAF (25 mg) than more than half of all reporting countries, despite having the lowest gross national income per capita among the reporting countries.

Only one country, South Africa, has local production of hepatitis B medicines (TDF). Five countries provide hepatitis B diagnosis and treatment free of charge in the public sector, either fully or partly for specific subpopulations.

Table 4.1.3. Hepatitis B IVD products in the African Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (in parentheses: number of those listed by WHO prequalification)				
	RDT HBsAg	**Lab-based HBsAg**	**Lab-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Ethiopia	1			1	
Ghana	10 **(2)**			1	
Uganda	1 **(1)**		1	1	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis B RDT prices paid by selected countries within the African Region range between US$ 0.63 and US$ 2.40 *(38)*.

- Cameroon: US$ 0.90
- Nigeria: US$ 0.63–2.40
- Rwanda: US$ 0.75
- South Africa: US$ 1.22
- Uganda US$ 0.90

Only Nigeria and Rwanda from the African Region provided indicative hepatitis B NAT prices *(38)*.

- Nigeria: US$ 20.00–41.00
- Rwanda: US$ 9.36–9.40

Hepatitis C IVDs

Product availability

The number of products available for procurement in the Region is relatively limited. However, decentralization is a clear priority across countries. Of the countries for which information was available, all reported that hepatitis C RDTs are available in primary health care and in some cases also in community settings. Further, Ethiopia also aims to support decentralized access to NAT by using dried blood spot specimens.

Table 4.1.4. Hepatitis C IVD products in the African Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (in parentheses: number of those listed by WHO prequalification)							
	HCV Self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Ethiopia		1				1 **(1)**		
Ghana		4	2					

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.1.6. Access to TDF in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			**Product registration**		**Price** 300 mg, 30 tablets, US$		**Local production in the country**
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses:** number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Benin[a]	X	X			1		12.86	
Burkina Faso[a]	X	X			1 **(1)**		**2.25**	
Cameroon	X	X		O	2		3.10	
Democratic Republic of the Congo		X	X		1	75	26.70	
Ethiopia	X	X						
Ghana		X			2 **(1)**			
Nigeria	X	X		O	2 **(1)**	14.0	**6.00**	
Rwanda		X	X		1 **(1)**		**3.00**	
South Africa	X	X	X		12 **(4)**		2.23	X
Uganda		X	X		G		7.50	
United Republic of Tanzania		X			1 **(1)**		2.40	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

[a]In addition to the WHO focus countries for the viral hepatitis response.
O: originator product is registered.
G: generic TDF is registered; but the number or name of products is not specified.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

HCV RDT prices paid by select countries within the African Region range between US$ 0.75 and US$ 1.56 *(45)*.

- Nigeria: US$ 1.44–1.56
- Rwanda: US$ 0.75
- Sierra Leone: US$ 1.36

HCV RNA prices paid by select countries within the African Region range between US$ 9.36 and US$ 23.43 *(45)*.

- Nigeria: US$ 16.77–23.43
- Rwanda: US$ 9.36

Cross-cutting aspects of viral hepatitis testing

Service delivery settings

Facility-based screening and testing is the primary way for finding people with hepatitis. All three countries reporting facility-based testing included inpatient and outpatient settings and routine testing in antenatal care. Uganda includes a number of additional facility-based settings for hepatitis case-finding and screening.

Table 4.1.5. Service delivery settings for viral hepatitis testing in the African Region, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings for viral hepatitis testing in the country		
Ethiopia	**Ghana**	**Uganda**
Inpatient and outpatient settings Routine testing in antenatal care	Inpatient and outpatient settings Routine testing in antenatal care	Primary clinics Inpatient and outpatient settings Routine testing in antenatal care HIV service delivery points Chronic care clinic Harm-reduction services for people who use drugs Occupational health services

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

Although there is a variety of financial sources across the three countries, reliance is primarily on government funding and out-of-pocket payments, limiting the ability of each country to implement and expand access to viral hepatitis testing.

Product registration and availability

Both Ethiopia and Uganda apply the reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval, primarily WHO prequalification. Ethiopia considers a number of other conformity assessment bodies, regulatory authorities or other entities. Ghana does not apply any reliance principles for viral hepatitis IVDs.

Table 4.1.7. Access to ETV in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	ETV										
	National programme						Product registration			Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children			
	Model List of Essential Medicines	Guidelines	primary health care	Model List of Essential Medicines	Guidelines	primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (bold: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Benin[a]					X								
Burkina Faso[a]	X	X		X	X								
Cameroon	X	X			X			3					
Democratic Republic of the Congo					X	X							
Ethiopia	X	X		X	X			1					
Ghana		X			X								
Nigeria	X	X		X	X								
Rwanda		X	X		X	X		1				8.00	
South Africa		X											
Uganda		X			X			G		G			
United Republic of Tanzania		X			X			G				8.50	

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

[a]In addition to the WHO focus countries for the viral hepatitis response.
G: generic ETV is registered; but the number or name of products is not specified.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.1.8. Access to TAF in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							
	National programme			Product registration		Price 25 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Benin[a]		X			1		30.00	
Burkina Faso[a]	X	X						
Cameroon					2			
Democratic Republic of the Congo		X	X		1			
Ethiopia		X		O	1			
Ghana								
Nigeria		X				16.00	7.30	
Rwanda		X			1			
South Africa		X			1[b]			
Uganda								
United Republic of Tanzania					1			

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
[a]In addition to the WHO focus countries for the viral hepatitis response.
[b]Plus one additional product for which registration is filed as of October 2023 but not approved.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.1.9. Inclusion in licensing agreements for hepatitis B medicines in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Benin[a]	Yes
Burkina Faso[a]	Yes
Cameroon	Yes
Côte d'Ivoire	Yes
Democratic Republic of the Congo	Yes
Ethiopia	Yes
Ghana	Yes
Nigeria	Yes
Rwanda	Yes
South Africa	Yes
Uganda	Yes
United Republic of Tanzania	Yes

[a]In addition to the WHO focus countries for the viral hepatitis response. TDF and ETV are off patent.

Source: MPP.

Table 4.1.10. Availability of HBV testing and treatment services free of charge in the public sector in the African Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic hepatitis B	Treatment	Liver staging – elastography	Liver staging – other
Benin[a]	✓ (partial)	✓ (partial)		
Burkina Faso[a]	✓ (partial)	✓ (partial)		
Cameroon				
Democratic Republic of the Congo				
Ethiopia				
Ghana				
Nigeria				
Rwanda	✓	✓	✓ (partial)	✓ (partial)
South Africa	✓	✓	✓	✓
Uganda	✓	✓		✓
United Republic of Tanzania				

[a]In addition to the WHO focus countries for the viral hepatitis response **Shaded:** service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.
Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

Similar to hepatitis B medicines, countries have also included hepatitis C medicines in national treatment guidelines in accordance with WHO recommendations. Fewer countries have included these medicines in national essential medicines lists so far. Product availability in primary health care is lagging behind. Viral hepatitis treatment services may not be available in primary health care in all countries but may be available at tertiary levels and in specialized care.

All of the 11 countries in the African Region for which information was available have included SOF and DAC (both or co-blistered or fixed-dose combination) in national guidelines for adults. Five countries have included both in national essential medicines lists for adults, and Benin has included SOF only. Six countries have registered at least one generic product of both medicines; and of these, Nigeria and Uganda reported having registered the SOF/DAC fixed-dose combination. Only Rwanda reported that SOF and DAC are available in primary health care, and the Democratic Republic of the Congo and Rwanda report that SOF/VEL is available in primary health care.

The availability of these medicines for children is more limited. Six countries have included SOF and DAC (both or co-blistered or fixed-dose combination) in treatment guidelines for children, and three countries have included these in essential medicines lists for children. SOF and DAC and SOF/VEL were registered for children in only two countries.

The prices paid for hepatitis C medicines vary, and countries in the Region continue to pay higher prices than the global benchmark of US$ 60 for a 12-week treatment course (or US$ 20 per 28-day supply) from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. The lowest reported prices of the last public sector procurement of SOF (400 mg) and DAC (60 mg) vary from US$ 69 in Rwanda (SOF and DAC purchased separately), US$ 60 in Nigeria (fixed-dose combination) and US$ 491 in Cameroon (fixed-dose combination) for a generic 12-week supply. Low-income countries in the Region are paying higher prices that some other upper-middle-income countries. For example, Burkina Faso, a low-income country, pays more than the United Republic of Tanzania and Nigeria, both lower-middle-income countries. For a 12-week supply of SOF/VEL (400 + 100 mg), the lowest reported prices for generic products range between US$ 174.0 in the United Republic of Tanzania and US$ 1050.0 in the Democratic Republic of the Congo.

No country is producing hepatitis C medicines locally. Ghana has received a donation of SOF and DAC from Egypt, as part of the Egyptian Presidential Initiative to Treat One Million Africans with hepatitis C, to treat 50 000 people; however, the cost of testing remains high for people to benefit fully from this initiative.

Only Rwanda and South Africa provide hepatitis C diagnosis and treatment free of charge in the public sector, either fully or partly for specific subpopulations.

Table 4.1.11. Access to SOF and DAC in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC										
	National programme						Product registration			Price SOF 400 mg ; DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children			
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Benin[a]	X[s]	X						SOF: 2 **(1)**					
Burkina Faso[a]	X	X		X	X			SOF +DAC: 1 **(1)**				SOF+DAC: **74.55**	
Cameroon	X	X						SOF: 5 **(2)** DAC: 5 **(2)**				SOF/DAC: 491.40	
Democratic Republic of the Congo	X	X	X				O				SOF and DAC combined: 350.0		
Ethiopia	X	X		X	X			SOF: 5 **(2)** DAC: 5 **(2)**		SOF: 4 **(1)** DAC: 4 **(2)**		SOF/DAC: 69.00[b]	
Ghana		X											
Nigeria	X	X		X	X			SOF/DAC: 1 **(1)**				SOF/DAC: **60.00**	
Rwanda		X	X		X	X		SOF: 1 **(1)** DAC: 1 **(1)**				SOF: **48.00** DAC: **21.00**	
South Africa		X											
Uganda		X			X			G				SOF/DAC: 450.00	
United Republic of Tanzania		X			X							SOF/DAC: 66.00	

Model List of Essential Medicines: included in national essential medicines list.Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.Originator: originator product is registered in the country.
Generic: generic products are registered in the country.[a]In addition to the WHO focus countries for the viral hepatitis response.
[b]Other published data *(45)* (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).
X[s]: SOF only.O: originator product is registered.
G: generic SOF and DAC are registered; but the number or name of products is not specified. Source: WHO survey among focus countries for the viral hepatitis response, 2023

Table 4.1.12. Access to SOF/VEL in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL											
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (**in parentheses**: number of WHO prequalification products)	Originator	Generic (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Benin[a]	X	X			X			**1**				588.00	
Burkina Faso[a]	X	X		X	X								
Cameroon	X	X					O	2 **(1)**				**491.40**	
Democratic Republic of the Congo		X	X		X	X						1050.00	
Ethiopia	X	X		X	X			3 **(1)**		2		195.00[b]	
Ghana		X											
Nigeria		X			X		O	1 **(1)**				399.00	
Rwanda		X	X		X	X		1 **(1)**		1 **(1)**		**210.00**	
South Africa		X			X							1167.00[b]	
Uganda								G				1200.00	
United Republic of Tanzania		X			X							174.00	

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country. [a]In addition to the WHO focus countries for the viral hepatitis response.
[b]Other published data (*45*) (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).
O: originator product is registered. G: generic SOF/VEL is registered, but the number or name of products is not specified. Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.1.13. Inclusion in licensing agreements for hepatitis C medicines in the African Region, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or 2020 patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Benin[a]	Yes	Yes	Yes
Burkina Faso[a]	Yes	Yes	Yes
Cameroon	Yes	Yes	Yes
Côte d'Ivoire	Yes	Yes	Yes
Democratic Republic of the Congo	Yes	Yes	Yes
Ethiopia	Yes	Yes	Yes
Ghana	Yes	Yes	Yes
Nigeria	Yes	Yes	Yes
Rwanda	Yes	Yes	Yes
South Africa	Yes	Yes	Yes
Uganda	Yes	Yes	Yes
United Republic of Tanzania	Yes	Yes	Yes

[a]In addition to the WHO focus countries for the viral hepatitis response.

Source: MPP.

Table 4.1.14. Availability of HCV testing and treatment services free of charge in the public sector in the African Region, WHO focus countries for the viral hepatitis response, 2023

	Self-testing	Diagnosis of chronic hepatitis C	Treatment	Liver staging – elastography	Liver staging – other	Confirmation of cure
Benin[a]			✓ (partial)			✓
Burkina Faso[a]						
Cameroon						
Democratic Republic of the Congo						
Ethiopia						
Ghana			✓			
Nigeria						
Rwanda	✓	✓	✓	✓ (partial)	✓ (partial)	✓
South Africa	✓	✓	✓	✓	✓	✓
Uganda					✓	
United Republic of Tanzania						

[a]In addition to the WHO focus countries for the viral hepatitis response.
Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.1.2.3 Access to hepatitis B vaccination in the African Region

Five of 12 focus countries have included the hepatitis B birth dose in the universal national immunization programme, and two additional countries are expected to introduce it. All countries report the provision of infant vaccination free of charge in the public sector.

Table 4.1.15. Access to hepatitis B birth dose and infant vaccination in the African Region, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Benin[a]	Yes	75	76
Burkina Faso[a]	Yes	53	91
Cameroon			68
Côte d'Ivoire	Yes	67	76
Democratic Republic of the Congo			65
Ethiopia			65
Ghana			99
Nigeria	Yes	52	62
Rwanda	Yes[a]		98
South Africa	Yes[a]		85
Uganda	Yes	24	89
United Republic of Tanzania			88

Source: WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

[a]Based on available information, hepatitis B birth dose is to be introduced.

Table 4.1.16. Availability of hepatitis B vaccination free of charge in the public sector in the African Region, WHO focus countries for the viral hepatitis response, 2023

	Vaccination- birth dose	Vaccination-infancy
Benin[a]	✓	✓
Burkina Faso[a]	✓	✓
Cameroon		✓
Côte d'Ivoire	✓	✓
Democratic Republic of the Congo		✓
Ethiopia		✓
Ghana		✓
Nigeria	✓	✓
Rwanda	✓	✓
South Africa	✓	✓
Uganda	✓	✓
United Republic of Tanzania		✓

[a]Information received in addition to the focus countries.
[b]Information from WHO/UNICEF Joint Reporting Form on Immunization, data from 2022 (https://immunizationdata.who.int).
[c]Based on available information, hepatitis B birth dose is to be introduced.

Shaded: service is free of charge in the public sector.

4.1.3 Regional achievements

Regional achievements since 2020 include the following.

- The African Region has developed a regional integrated framework for action for HIV, TB, hepatitis and sexually transmitted infections 2021–2030, with a people-centred and life-cycle approach.
- A regional hepatitis scorecard comparing data from 2019 and 2021 was developed and launched at the World Hepatitis Day in 2022. Countries are using this tool for advocacy and strategic planning.
- The Region has developed 15 training modules for viral hepatitis: four cross-cutting modules, six modules related to hepatitis B and five modules related to hepatitis C; with translations into French, Portuguese and Spanish. These materials were launched during World Hepatitis Day 2022, and countries are using them to update their own material for national and decentralized training.
- Thirteen countries in the Region (Algeria, Chad, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Mali, Niger, Nigeria, Sierra Leone, South Africa, South Sudan and Uganda) have developed or updated their national strategic plans for viral hepatitis, and four countries (Mali, Niger, Sao Tome and Principle and Sierra Leone) have conducted viral hepatitis programme reviews.
- Rwanda was among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country.
- Countries such as Benin, Burkina Faso, Uganda and South Africa are committing domestic resources to the viral hepatitis response.
- Leadership and advocacy efforts in the Region are increasing to raise awareness on viral hepatitis, as witnessed by the Cairo Declaration on Viral Hepatitis in Africa adopted by the African Union in 2020 *(75)*, the involvement of the First Ladies of Burundi, the Central African Republic and Niger and a partnership with the World Hepatitis Alliance for organizing the African Summit on Viral Hepatitis in 2023.

4.1.4 Regional priorities for elimination

Regional priorities to eliminate viral hepatitis by 2030 include:

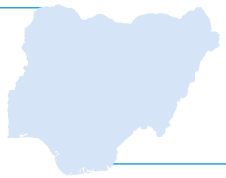
- scaling up access to viral hepatitis testing as an entry point to expand access to treatment and care;
- leveraging HIV and primary health care services, and strengthening linkage with maternal and child health services to promote triple elimination of mother-to-child transmission of HIV, HBV and syphilis in the Region;
- continuing to advocate for greater domestic funding for the viral hepatitis response in the context of universal health coverage and leveraging external funding opportunities such as from the Global Fund in the context of eliminating mother-to-child transmission and HIV and hepatitis coinfection and from Gavi for hepatitis B vaccination as important entry points to expand the viral hepatitis response;
- accelerating the registration of viral hepatitis medicines in the Region;
- addressing the variation in the prices paid for viral hepatitis medicines and IVDs across countries in the Region and promoting strategies to facilitate affordable access for all;
- strengthening strategic information on viral hepatitis; and
- building strategic multistakeholder partnerships to support the viral hepatitis response in the Region.

4.1.5 WHO support for countries

WHO support has enhanced advocacy and visibility of viral hepatitis in the Region, promoted policy and programme development, and strengthened surveillance and capacity building. Since 2020, the key areas of WHO support have included:

- developing national strategic plans and conducting programme reviews;
- disseminating WHO normative guidelines at the country level and providing support for translation, adoption and operationalization;
- supporting capacity building for the viral hepatitis response, including through webinars on priority topics such as eliminating vertical transmission and developing training modules in four languages, including English, French, Portuguese and Spanish;
- supporting the integration of viral hepatitis interventions, including for preventing the mother-to-child transmission of HBV, HCV and HIV coinfection and HCV management among key populations, in funding applications to the Global Fund;
- developing a hepatitis scorecard for all countries in the Region; and
- supporting advocacy efforts, including organizing World Hepatitis Day with the involvement of First Ladies of multiple countries.

Box 4.1.1



Nigeria

The cost of HCV treatment was historically high in Nigeria as a result of a lack of domestic or external financing, limited suppliers, low service uptake and treatment access limited to out-of-pocket payments in the private sector in the absence of a national programme. In 2022–2023, Nigeria reviewed and updated national policy guidelines to ensure that these documents included the recommended treatment regimens. The Government also collaborated with key stakeholders to facilitate the introduction of the SOF/DAC fixed-dose combination in the programme, engage additional suppliers to drive competition and reduce prices and conduct comprehensive forecasts, to adequately estimate commodity needs and ensure efficient uptake. With support from the World Hepatitis Alliance and the Clinton Health Access Initiative, Nigeria successfully undertook price negotiations with Viatris to lower the price of a 12-week HCV treatment course from US$ 135 in 2020 to US$ 60 by 2023, which has reduced the estimated cost to reach elimination by 24% (*76*). Similar gains were achieved in pricing engagements for HCV viral load testing, resulting in a price reduction from more than US$ 100 per test to US$ 24 per test.

Looking ahead, Nigeria has identified preventing the vertical transmission of HBV as a key priority, with a need to strengthen integration of antenatal services and services to prevent vertical transmission across disease areas to ensure comprehensive quality of care for pregnant women and also ensure efficient use of available resources. Nigeria will also be exploring innovative models to achieve the triple elimination of vertical transmission of HIV, HBV and syphilis. Further, the Nigerian expanded programme on immunization includes the hepatitis B birth-dose and pentavalent vaccination, funded through the Nigerian government and Gavi to increase vaccination coverage. The country has also identified the need to strengthen key population programming, including harm reduction, to ensure that effective prevention strategies and interventions are instituted to reduce disease transmission. In 2023, Nigeria approved the use and distribution of HCV self-testing kits in the context of an implementation study to test the acceptability, feasibility and cost–effectiveness of their use among people living with HIV and key populations in Nasarawa State.

4.2 Region of the Americas

Key findings

Epidemiology and service coverage: In 2022, an estimated 5 million people were living with hepatitis B or C in the Region of the Americas. Of people living with hepatitis B, 21% have been diagnosed, and 21% of those diagnosed have received treatment. Of people living with hepatitis C, 44% have been diagnosed, and 26% of those diagnosed have received treatment. The prevalence of chronic hepatitis B among children younger than five years in the Americas is estimated to be <0.5%, the lowest among all WHO regions.

Access to health products: WHO focus countries in the Region have updated national treatment guidelines in accordance with WHO recommendations, and product availability in primary health care varies. Although countries in the Region have access to hepatitis medicines through pooled procurement mechanisms such as the Pan American Health Organization Strategic Fund, many countries in the Region are either not eligible or pay higher prices for viral hepatitis medicines even if eligible.

For example, the price of generic TDF ranges between US$ 5.22 in Brazil to US$ 9.60 in Colombia for a generic monthly supply. Brazil reported a combined total price of US$ 1022.20 for a 12-week supply of SOF and DAC. Facility-based screening and testing is the primary way for finding people with hepatitis in focus countries, and all focus countries have established lists of priority populations for screening. Most focus countries are providing hepatitis services free of charge in the public sector.

Regional priorities: Regional priorities for 2030 include providing equitable access for key populations in the Region, addressing intellectual property-related barriers to affordable access and expanding the availability of testing.

4.2.1 Regional epidemic profile and progress towards impact

Tables 4.2.1 and 4.2.2 present the epidemiological and service coverage information for viral hepatitis B and C, respectively, in the Region of the Americas.

Table 4.2.1. Hepatitis B in the Region of the Americas, 2022

Indicator	
Number of people living with hepatitis B infection	5 million
Number of new hepatitis B infections per year	8000
Number of deaths caused by hepatitis B infection per year	20 000
Percentage of people living with hepatitis B who are diagnosed	21.2%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	20.9%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	4.4%

Table 4.2.2. Hepatitis C in the Region of the Americas, 2022

Indicator	
Number of people living with hepatitis C infection	5.3 million
Number of new hepatitis C infections per year	176 000
Number of deaths caused by hepatitis C infection per year	38 000
Percentage of people living with hepatitis C who are diagnosed	44.0%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	26.0%

4.2.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the Region of the Americas.

4.2.2.1 Access to viral hepatitis testing in the Region of the Americas

All of the four WHO focus countries for the viral hepatitis response in the Region of the Americas provided responses to the WHO 2023 survey on viral hepatitis IVDs: Brazil, Colombia, Mexico and Peru.

Hepatitis B IVDs

Product availability

Although Brazil has a limited number of products available, the viral hepatitis national testing algorithm is clear, with specific brands noted for the serology and follow-up NAT. Colombia and Mexico have several laboratory-based HBsAg assays available for procurement and product selection, and Colombia also has five HBV DNA NATs available. The viral hepatitis national testing algorithm does not provide specific brands and/or depends on the procurement bidding process.

Table 4.2.3. Hepatitis B IVD products in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (**in parentheses**: number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Lab-based HBsAg**	**Lab-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Brazil	1			2	1
Colombia	5	25	7	5	
Mexico	2	19	1	2	2

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C IVDs

Product availability

Brazil and Mexico have a relatively limited number of products available, but the viral hepatitis national testing algorithm is clear with specific brands noted for the serology and follow-up NAT. Colombia, in particular, has a number of anti-HCV RDTs, laboratory-based anti-HCV and HCV RNA NAT assays available for procurement and product selection. Neither Colombia nor Mexico provides specific brands within the viral hepatitis national testing algorithm and/or these depend on the procurement bidding process.

Table 4.2.4. Hepatitis C IVDs in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses**: number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Brazil		2 **(1)**				2 **(2)**	1 **(1)**	
Colombia		12 **(3)**	25 **(2)**	2	1	16 **(4)**		
Mexico		2	5		5 **(1)**	2 **(2)**		

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Only Peru from the Region of the Americas provided indicative hepatitis C RDT prices paid of US$ 1.18 (*45*).

Cross-cutting aspects of viral hepatitis testing

Service delivery settings

Facility-based screening and testing is the primary way for finding people with hepatitis. Facility-based screening and testing occurred within primary clinics and HIV service delivery points in all three reporting countries.

Table 4.2.5. Service delivery settings for viral hepatitis testing in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings for viral hepatitis testing in the country		
Brazil	Colombia	Mexico
Primary clinics	Primary clinics	Primary clinics
Routine testing in antenatal care	Inpatient and outpatient settings	Inpatient and outpatient settings
HIV service delivery points	Routine testing in antenatal care	HIV service delivery points
	HIV service delivery points	Harm-reduction services for people who use drugs
	Harm-reduction services for people who use drugs	Occupational health services
		Sexually transmitted infection and HIV clinics
		PrEP services
		Community centres

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

Brazil, Colombia and Mexico reported government funding as the primary source of viral hepatitis diagnostic funding. Colombia supplements with some support from testing projects led by community-based organizations and others.

Product registration and availability

All four countries conduct or require post-market surveillance for all or some products related to viral hepatitis. All conduct incident reporting, and Brazil also conducts field safety correction action reporting. Mexico conducts both field safety correction action reporting and annual reporting.

Colombia and Mexico apply reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval, primarily the United States Food and Drug Administration. Brazil and Peru do not apply reliance principles to support their national regulatory approval processes.

4.2.2.2 Access to HBV medicines in the Region of the Americas

All of the four WHO focus countries for the viral hepatitis response in the Region of the Americas provided responses to the WHO 2023 survey on viral hepatitis medicines: Brazil, Colombia, Mexico and Peru.

Hepatitis B medicines

The focus countries in the Region of the Americas have updated hepatitis B guidelines in accordance with WHO recommendations and taken steps towards expanding their implementation.

All four WHO focus countries in the Region have included TDF in national hepatitis treatment guidelines and essential medicines lists in accordance with WHO guidance. All four countries have also included ETV in national guidelines and essential medicines lists for adults, but only two have included ETV in guidelines for children. TAF is included in national guidelines in two countries.

All four countries have registered TDF and TAF, and three have registered at least one WHO-prequalified product for TDF. ETV is registered in all countries for adults but only in two countries for children.

Product availability in primary health care varies. Three countries report that TDF is available, and one country reports that TAF is available in primary health care. ETV is not available in primary health care.

Countries in the Region are paying higher prices for viral hepatitis medicines than the global benchmark of US$ 2.40 per 30 tablets from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Prices for generic TDF (300 mg) in the Region of the Americas range from US$ 5.20 in Brazil to US$ 9.60 in Colombia for a monthly supply. Brazil, Colombia and Peru have local production of TDF and can access generic medicines at lower prices. For TAF (25 mg), none of the four countries is included in the Gilead-MPP licensing agreement, and countries report purchase prices between US$ 94.5 and US$ 99.0 for a monthly supply. Countries from the Region of the Americas pay up to 70 times more for TAF than countries in the Western Pacific Region.

All three focus countries for which this information was available (Brazil, Colombia and Mexico) provide hepatitis B diagnosis and treatment services free of charge in the public sector.

Table 4.2.6. Access to TDF in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			Product registration		Price 300 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Brazil	X	X	X		4	5.22	X	
Colombia	X	X			2 **(1)** 94.0	**9.60**	X	
Mexico	X	X	X		4 **(2)**			
Peru	X	X	X		4 **(1)**		X	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.2.7. Access to ETV in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	ETV											
	National programme						Product registration				Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Brazil	X	X		X	X			1				55.80	X
Colombia	X	X		X	X			7			143.70	50.10	X
Mexico	X	X						2		3			
Peru	X	X		X				6		6			

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.2.8. Access to TAF in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							
	National programme			Product registration		Price 25 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Brazil	X	X		O		94.50		
Colombia	X			O	3			
Mexico	X	X	X		1		99.00[a]	
Peru					1			

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.2.9. Inclusion in licensing agreements for hepatitis B medicines in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Brazil	No
Colombia	No
Mexico	No
Peru	No

TDF and ETV are off patent.

Source: MPP.

Table 4.2.10. Availability of HBV testing and treatment services free of charge in the public sector in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other
Brazil	✓	✓	✓	✓
Colombia	✓	✓	✓	✓
Mexico	✓	✓	✓	✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

Three of the four WHO focus countries in the Region have included SOF and DAC in national treatment guidelines in accordance with WHO guidance, and all have included SOF/VEL. One country, Brazil, has included SOF and DAC in the national essential medicines list and has them available in primary health care. Brazil and Peru report having registered these products for adults. Mexico reports that SOF/VEL is available for adults in primary health care. Viral hepatitis treatment services may not be available in primary health care in all countries but may be available at tertiary levels and in specialized care.

The availability of medicines for children is more limited. Only Brazil has included SOF and DAC in national guidelines and essential medicines lists for children and made them available in primary health care. No country has registered SOF and DAC products for children. Only Peru has registered SOF/VEL for children.

Most lower-middle-income and upper-middle-income countries in the Region, including the four WHO focus countries, are not included in the Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX nor in the AbbVie and MPP licensing agreement for G/P.

The countries without patent barriers can access a 12-week treatment course of SOF + DAC at US$ 102 through the Pan American Health Organization Strategic Fund (*45*). Most countries are unable to utilize this price. Despite being an eligible member of the Strategic Fund, Brazil is paying nine times more for SOF (400 mg) than the Strategic Fund pooled procurement price. Brazil reported a total of US$ 1022.20 for the 12-week treatment course of SOF and DAC combined, which is also much higher than the global benchmark of US$ 60 for a 12-week treatment course from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Until 2022, Brazil imported DAAs for hepatitis C. Since December 2022, a national manufacturer has been developing SOF and DAC through a public–private partnership agreement, which is expected to make these medicines available at more affordable prices to priority populations. Further, Mexico is obtaining hepatitis C medicines through a national procurement strategy and reported a public sector procurement price of originator SOF/VEL (400 + 100 mg) at US$ 8653 per 12-week treatment course and originator G/P (50 + 20 mg) at US$ 15 780.30 per eight-week treatment course. Prices for eight-week G/P treatment regimens significantly differed, with Mexico (US$ 15 780.3) paying 2.8 times as much as Brazil (US$ 5680.40).

Table 4.2.11. Access to SOF and DAC in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC											
	National programme						Product registration				Price SOF 400 mg, DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Brazil	X	X	X	X	X	X	O[S]	SOF:4 DAC:1				SOF: 551.88 DAC: 470.40	
Colombia		X											
Mexico													
Peru		X						SOF: 2 **(1)**		SOF: 2 **(1)**			

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O[S]: SOF only.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.2.12. Access to SOF/VEL in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL										
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (in parentheses: number of WHO prequalification products)	Originator	Generic (in parentheses: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Brazil	X	X		X	X		O				1419.94		
Colombia		X					O				3825.00		
Mexico	X	X	X	X	X	X		1			8652.48		
Peru	X	X		X						1	4050.00[a]		

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
[a]Other published data *(45)* (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.2.13. Inclusion in licensing agreements for hepatitis C medicines in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or 2020 patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Brazil	**No**	Yes[a]	**No**
Colombia	**No**	Yes	**No**
Mexico	**No**	Yes	**No**
Peru	**No**	Yes	**No**

[a]Additional to the countries in the licence territory.

Source: MPP

Table 4.2.14. Availability of hepatitis C testing and treatment services free of charge in the public sector in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

Country	Self-testing	Diagnosis of chronic hepatitis C	Treatment	Liver staging – elastography	Liver staging – other	Confirmation of cure
Brazil		✓	✓	✓	✓	✓
Colombia		✓	✓	✓	✓	✓
Mexico	✓	✓	✓		✓	✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.2.2.3 Access to hepatitis B vaccination in the Region of the Americas

All four focus countries in the Region have included the hepatitis B birth dose in the universal immunization programme. All three countries for which this information was available provide hepatitis B vaccination free of charge in the public sector.

Table 4.2.15. Access to hepatitis B birth-dose and infant vaccination in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Brazil	Yes	82	77
Colombia	Yes	85	87
Mexico	Yes	50	83
Peru	Yes	79	82

Source: : WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

Table 4.2.16. Availability of hepatitis B vaccination free of charge in the public sector in the Region of the Americas, WHO focus countries for the viral hepatitis response, 2023

	Vaccination – birth dose	Vaccination – infancy
Brazil	✓	✓
Colombia	✓	✓
Mexico	✓	✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.2.3 Regional achievements

Regional achievements since 2020 include the following.

- All countries and territories in the Region have introduced the hepatitis B vaccine (or hepatitis B–containing vaccine) in their routine immunization schedules. The prevalence of chronic hepatitis B infection among children younger than five years in the Americas is estimated to be <0.5%, the lowest among all WHO regions, making it feasible to eliminate vertical transmission and early childhood transmission of HBV (77).
- Brazil was among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country.
- The Region has access to regional pooled procurement mechanisms (the Revolving Fund for access to vaccines and the Strategic Fund for access to essential medicines and other health supplies) to facilitate access to quality-assured and affordable medicines and IVDs. The products for viral hepatitis include WHO-prequalified DAAs for hepatitis C, tenofovir for hepatitis B, RDTs for hepatitis B and C and GeneXpert for hepatitis C viral load. A number of countries in the Central Americas and the Caribbean that do not have patent protection for SOF can access SOF/DAC at pooled procurement prices. Other countries pay higher prices.

4.2.4 Regional priorities for elimination

Regional priorities to eliminate viral hepatitis by 2030 include:

- high-level advocacy and engagement with national programmes, civil society, academia and partners to increase political commitment and awareness, and disseminate WHO guidelines;
- promoting the expansion and integration of viral hepatitis prevention, testing and care services by leveraging existing capacity, with a focus on primary health care;
- providing equitable access for vulnerable and key populations, leveraging interventions such as combination prevention and elimination of mother-to-child transmission as entry points;
- promoting continued integration of viral hepatitis with other diseases under the PAHO's Regional Framework for Multi-disease elimination, focusing identifying opportunities for synergy and optimization of efforts and resources; and
- continuing the expansion of viral hepatitis products in the Region's Revolving Funds, prioritizing generic essential products and addressing intellectual property–related barriers to affordable access.

4.2.5 WHO support for countries

WHO support has strengthened strategic planning and investment cases for the viral hepatitis response in the Region, improved strategic information systems, and promoted access to health products through pooled procurement mechanisms. Since 2020, the key areas of WHO support have included:

- supporting strategic planning for viral hepatitis and the review and implementation of national viral hepatitis guidelines;
- supporting the update of national essential medicines and IVD lists;
- providing support for pooled procurement of medicines and IVDs for viral hepatitis;
- developing investment cases for the national viral hepatitis response in countries including Brazil, Chile, Colombia, Ecuador Mexico, and Peru, in collaboration with the CDA Foundation;
- developing National Hepatitis Elimination Profiles in countries including Argentina, Brazil, Canada, Colombia, Mexico, Peru, and the United States of America, in a partnership led by the Coalition for Global Hepatitis Elimination – The Task Force for Global Health; and
- supporting the strengthening of surveillance systems for viral hepatitis.

Box 4.2.1

Mexico

Recognizing the barriers to access for hepatitis C testing and treatment in the country, Mexico initiated a national hepatitis C elimination programme in 2020 to provide universal, free access to hepatitis C services. The programme was based on an innovative national procurement strategy to enable reduction in the price of DAAs, with efforts to improve efficiency in the use of resources. Mexico adopted a primary health care approach to viral hepatitis to provide services free of charge, accompanied by raising awareness about hepatitis C through a communication strategy and telementoring network and creating a person-centred online patient registry to monitor health outcomes and foster research. Mexico also identified the most severely affected population groups and tailored interventions to cover their needs. Community leaders participated actively in programme implementation, with a national observatory meeting every two weeks and a case register to evaluate outcomes. Progress is analysed and publicly presented in quarterly bulletins.

During the first year of implementation, the number of public health-care units certified to treat hepatitis C tripled from 106 to 390 nationwide, and nearly 100 000 people living with HIV, the initial target population, were screened for HCV. By 2023, more than 650 public health-care units were implementing the programme. A cost–effectiveness analysis concluded that eliminating hepatitis C in Mexico will require an up-front investment in hepatitis C diagnosis and treatment and that as the programme is implemented, the reduction in disease burden will reduce total expenditure by reducing both direct costs (health-care costs from advanced disease) and indirect costs (loss of productivity due to life lost and disability). The study demonstrated that hepatitis C elimination can be accomplished at net-zero cost to the government, either by extending the procurement agreement through 2035 or by further reducing the cost of hepatitis C treatment (78). The programme has also enabled progress in addressing other types of viral hepatitis through coordinated detection of and treatment for hepatitis B and hepatitis C in priority population groups. Clinical guidelines for HIV and viral hepatitis have also been updated to address common risk factors and coinfections.

4.3 South-East Asia Region

Key findings

Epidemiology and service coverage: In 2022, an estimated 61 million people were living with hepatitis B and 9 million people with hepatitis C in the South-East Asia Region. The South-East Asia Region accounts for the second largest number of new hepatitis B infections after the African Region. Less than 5% of people living with hepatitis B have been diagnosed and received treatment. Of people living with hepatitis C, 26% have been diagnosed and 14% have received treatment.

Access to health products: The Region includes a number of countries with local production of generic viral hepatitis medicines, and yet product availability in primary health care is limited and the prices countries pay vary. The lowest reported price for generic TDF in the Region is US$ 1.20 for a 30-day supply in India, which is lower than the global benchmark. The reported lowest price paid for a 12-week supply of generic SOF and DAC (both or co-blistered or fixed-dose combination) varies between US$ 40.40 in India and US$ 126.00 in Indonesia. Reporting focus countries have many IVD products available, including in primary health care, and report the implementation of diagnostic integration. Four of the five focus countries in the Region have included the hepatitis B birth dose in the universal national immunization programme and provide it free of charge in the public sector.

Regional priorities: Regional priorities for 2030 include defining screening strategies or approaches for viral hepatitis, expanding access to testing beyond larger hospitals and referral centres, addressing price variability and cost barriers to accessing services and expanding advocacy for greater political commitment and resource allocation at the national level.

4.3.1 Regional epidemic profile and progress towards impact

Tables 4.3.1 and 4.3.2 present epidemiological and service coverage information for viral hepatitis B and C, respectively, in the South-East Asia Region.

Table 4.3.1 Hepatitis B in the South-East Asia Region, 2022

Indicator	
Number of people living with hepatitis B infection	61.4 million
Number of new hepatitis B infections per year	266 000
Number of deaths caused by hepatitis B infection per year	218 000
Percentage of people living with hepatitis B who are diagnosed	2.8%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	3.5%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	0.1%

Table 4.3.2 Hepatitis C in the South-East Asia Region, 2022

Indicator	
Number of people living with hepatitis C infection	9.1 million
Number of new hepatitis C infections per year	225 000
Number of deaths caused by HCV infection per year	42 000
Percentage of people living with hepatitis C who are diagnosed	26.0%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	15%

4.3.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the South-East Asia Region.

4.3.2.1 Access to viral hepatitis testing in the South-East Asia Region

Four of the five WHO focus countries for the viral hepatitis response in the South-East Asia Region (India, Indonesia, Myanmar and Thailand) provided responses to the WHO 2023 survey on viral hepatitis IVDs.

Hepatitis B IVDs

Product availability

Indonesia and Thailand have many products available for hepatitis B testing. Myanmar reports having one RDT available for hepatitis B testing. Decentralization is a clear priority across countries, and most RDTs are available in primary health care. All reporting countries implement serology testing followed by NAT within their national viral hepatitis B testing algorithm.

Table 4.3.3. Hepatitis B IVD products in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (**in parentheses**: number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Laboratory-based HBsAg**	**Laboratory-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Indonesia	41 **(2)**	12	3	3	1
Myanmar	1 **(1)**				
Thailand	16 **(2)**	4	4	4	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis B RDT prices paid by select countries within the South-East Asia Region range between US$ 0.09 and US$ 1.05 *(38)*.

- India: US$ 0.09
- Indonesia: US$ 0.49–1.05
- Myanmar: US$ 0.30–0.50

Only India and Myanmar from the South-East Asia Region provided indicative hepatitis B NAT prices *(38)*.

- India: US$ 15.07
- Myanmar: US$ 24.00

Hepatitis C IVDs

Product availability

Indonesia and Thailand have many products available for hepatitis C testing. Myanmar reports having one anti-HCV RDT, laboratory-based anti-HCV and HCV RNA NAT available for hepatitis C testing. Decentralization is a clear priority across countries, with most RDTs being available in primary health care. All reporting countries implement serology testing followed by NAT within their national viral hepatitis C testing algorithm.

Table 4.3.4. Hepatitis C IVD products in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses**: number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Indonesia		25 **(3)**	8 **(1)**			4 **(2)**	3 **(2)**	
Myanmar		1 **(1)**	1			1 **(1)**		
Thailand		14 **(4)**	4	1	1	3 **(2)**	1 **(1)**	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis C RDT prices paid by select countries within the South-East Asia Region range between US$ 0.21 and US$ 1.54 *(45)*.

- India: US$ 0.21
- Indonesia: US$ 0.50–0.90
- Myanmar: US$ 0.50–0.70
- Thailand: US$ 1.54

Hepatitis C NAT prices paid by select countries within the South-East Asia Region range between US$ 6.12 and US$ 35.70 *(45)*.

- India: US$ 6.12–13.67
- Indonesia: US$ 27.64
- Myanmar: US$ 26.50–35.70
- Thailand: US$ 10.00

Cross-cutting aspects of viral hepatitis testing

Facility-based testing is the primary way for finding people with hepatitis. All four countries give priority to facility-based screening and testing in inpatient and outpatient settings, routine testing in antenatal care and HIV service delivery points.

Table 4.3.5. Service delivery settings for viral hepatitis testing in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings for viral hepatitis testing in the country			
India	Indonesia	Myanmar	Thailand
Inpatient and outpatient settings Routine testing in antenatal care HIV service delivery points Harm-reduction services for people who use drugs	Primary clinics Inpatient and outpatient settings Routine testing in antenatal care HIV service delivery points Harm-reduction services for people who use drugs	Inpatient and outpatient settings Routine testing in antenatal care HIV service delivery points Harm-reduction services for people who use drugs Occupational health services Pre-departure screening of migrants	Primary clinics Inpatient and outpatient settings Routine testing in antenatal care HIV service delivery points

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

All four countries reported government funding as a key source of funding for viral hepatitis testing. Indonesia and Myanmar also reported out-of-pocket payments, which could limit access for those with less resources and ability to pay. Myanmar, however, also has Global Fund support for some hepatitis IVDs.

Multi-disease platforms and integrating viral hepatitis IVDs across critical services

All four countries report implementing diagnostic integration to create efficiency. All four countries use and share multi-disease platforms. All reporting countries also share services with their respective HIV programmes, while two countries (Indonesia and Thailand) also share with their respective TB, human papillomavirus and COVID-19 programmes. Although the countries report some challenges with integration due to concerns over disease priorities or limited policies, all reporting countries report that they share human resources with other disease programmes, especially their respective HIV programmes. Indonesia also shares some diagnostic services with their TB programme, and Thailand shares with several additional disease programmes, including cervical cancer, influenza and COVID-19. Three countries (India, Myanmar and Thailand) also share other diagnostic services with the disease programmes mentioned above, including specimen transport, supply chain, quality assurance, data connectivity, waste management and training.

4.3.2.2 Access to viral hepatitis medicines in the South-East Asia Region

All five WHO focus countries for the viral hepatitis response in the South-East Asia Region (Bangladesh, Indonesia, India, Myanmar and Thailand) provided responses to the WHO 2023 survey on viral hepatitis medicines.

Hepatitis B medicines

Focus countries in the South-East Asia Region have updated national hepatitis B guidelines in accordance with WHO recommendations; however, product availability in primary health care is limited. All five countries have included TDF in national essential medicines lists, and four countries have included it in national guidelines; but only Indonesia, reports that TDF is available in primary health care. Four countries have also included ETV in national guidelines for adults and children; and three countries have included TAF; however, none of the countries report that ETV or TAF is available in primary health care. Viral hepatitis treatment services may not be available in primary health care in many countries but may be available at tertiary levels and in specialized care.

All hepatitis B medicines are produced locally in the Region. Four countries reported having registered at least one generic product for these medicines. The lowest reported price for generic TDF (300 mg) in the Region is US$ 1.20 for a 30-day supply in India, which is lower than the global benchmark of US$ 2.40 per 30 tablets from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. The price of ETV (0.5 mg) ranges between US$ 1.00 and US$ 29.90 for a 30-day supply. All focus countries are included in the Gilead-MPP licensing agreement for TAF, and the lowest reported price of TAF (25 mg) is US$ 5.10 for a 30-day supply. Only Thailand, provides all hepatitis B diagnosis and treatment services free of charge in the public sector. In Bangladesh, people can receive a government subsidy for testing services.

Table 4.3.6. Access to TDF in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			Product registration		Price 300 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (in parentheses: number of WHO prequalification	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Bangladesh	X							X
India	X	X			G		1.22	X
Indonesia	X	X	X		3		4.80	X
Myanmar	X	X			5 **(1)**			X
Thailand	X	X			3 **(1)**		9.31[a]	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

G: generic TDF is registered; but the number or name of products is not specified.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.3.7. Access to ETV in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	ETV										
	National programme						Product registration			Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children			
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator	Generic (number) (in parentheses: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Bangladesh													X
India	X	X		X	X			G		G		1.00	X
Indonesia	X	X		X	X			4				18.00	X
Myanmar		X			X			4					
Thailand	X	X		X	X			9		10			**X**

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

G: generic ETV is registered; but the number or name of products is not specified.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.3.8. Access to TAF in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							
	National programme			Product registration		Price 25 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Bangladesh								X
India								
Indonesia	X	X			2	40.20	5.10	
Myanmar		X		O	4			
Thailand	X	X			5		14.14[a]	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.3.9. Inclusion in licensing agreements for hepatitis B medicines in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Bangladesh	Yes
India	Yes
Indonesia	Yes
Myanmar	Yes
Thailand	Yes

TDF and ETV are off patent.

Source: MPP.

Table 4.3.10. Availability of HBV testing and treatment services free of charge in the public sector in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other
Bangladesh	✓		✓	✓
India	✓	✓		✓
Indonesia	✓	✓		✓
Myanmar	✓ (partial)			
Thailand	✓	✓	✓	✓

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

Three of the five focus countries in the South-East Asia Region (India, Indonesia and Myanmar) have included SOF and DAC (both or co-blistered or fixed-dose combination), in national treatment guidelines for adults. India and Indonesia have also included these in the national essential medicines list. None of the countries have included these medicines in national guidelines or essential medicines lists for children, and none report these medicines being available in primary health care. Four countries (India, Indonesia, Myanmar and Thailand) have included SOF/VEL in national guidelines for adults. In Thailand, SOF/VEL is provided as a component of the universal health coverage package. One country, Indonesia, has included SOF/LED in national guidelines for both adults and children, but it is not reported to be available in primary health care. Viral hepatitis treatment services may not be available in primary health care in all countries but may be available at tertiary levels and in specialized care.

Four countries report have registered generic products of SOF and DAC (both or co-blistered or fixed-dose combination) for adults. Of these countries, only Myanmar reported having registered the SOF/DAC fixed-dose combination. One country, Thailand, also reports registration of these medicines for children.

The reported lowest price paid for generic SOF and DAC (both or co-blistered or fixed-dose combination) varies between US$ 40.30 for SOF (400 mg) and DAC (60 mg) combined in India (which is lower than the global benchmark of US$ 60 for a 12-week treatment course from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative) and US$ 126.00 in Indonesia, much higher. Similarly, the lowest reported price for a 12-week supply of SOF/VEL, globally, is reported in India at US$ 75.70.

Two countries, Bangladesh and India, report local production of SOF, DAC, SOF/DAC and SOF/VEL. Although these medicines are produced locally, Bangladesh is paying high prices compared with the benchmark. The lowest reported price for a 12-week supply of SOF/VEL (400 + 100 mg) is US$ 823.20 in Bangladesh, 4.7 times more than the Global Fund benchmark of US$ 174 per 12-week treatment.

Four countries report hepatitis C testing and hepatitis C treatment services being available free of charge in the public sector, either fully or partly for specific subpopulations and/or with co-payment. Self-testing is not available in any of the focus countries.

Table 4.3.11. Access to SOF and DAC in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC											
	National programme						Product registration				Price SOF 400 mg, DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Bangladesh													X
India	X	X						SOF: G DAC: G				SOF: 33.85 DAC: 6.54	X
Indonesia	X	X						SOF: 2 **(2)** DAC: 1 **(1)**				SOF: **68.88** DAC: **152.88**	X
Myanmar		X					O	SOF: 21 **(3)** DAC: 11 **(4)** SOF/DAC: 4 **(1)**					
Thailand								SOF: 2 **(1)** DAC: 3 **(2)**		SOF: 2 **(1)** DAC: 3 **(2)**		SOF: 305.76[a]	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
G: generic SOF and DAC are registered, but the number or name of products is not specified.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.3.12. Access to SOF/VEL in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL											
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Bangladesh												823.20[a]	X
India		X						G				75.68	X
Indonesia		X			X		O	1 **(1)**				1122.00[b]	
Myanmar		X					O	8 **(1)**				189.00[a]	
Thailand	X	X		X	X			3 **(1)**		3 **(1)**		654.33[a]	**X**

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
G: generic SOF/VEL is registered, but the number or name of products is not specified.
[a]Not specified whether this is originator or generic.
[b]Other published data (*45*) (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.3.13. Inclusion in licensing agreements for hepatitis C medicines in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or 2020 patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Bangladesh	Yes	Yes	Yes
India	Yes	Yes	**No**
Indonesia	Yes	Yes	Yes
Myanmar	Yes	Yes	Yes
Thailand	Yes	Yes	**No**

Source: MPP.

Table 4.3.14. Availability of hepatitis C testing and treatment services free of charge in the public sector in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

Country	Self-testing	Diagnosis of chronic hepatitis C	Treatment	Liver staging – elastography	Liver staging – other	Confirmation of cure
Bangladesh						
India		✓	✓		✓	✓
Indonesia		✓	✓	✓	✓	✓
Myanmar		✓ (partial)	✓	✓ (partial)	✓	✓
Thailand		✓	✓	✓	✓	✓

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.3.2.4 Access to hepatitis B vaccination in the South-East Asia Region

Four of the five focus countries in the Region have included the hepatitis B birth dose in the universal national immunization programme and provide it free of charge in the public sector. All countries provide infant vaccination free of charge in the public sector.

Table 4.3.15. Access to hepatitis B birth-dose and infant vaccination in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Bangladesh			98
India	Yes	63	93
Indonesia	Yes	85	86
Myanmar	Yes	8	71
Thailand	Yes	99	97

Source: WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

Table 4.3.16. Availability of hepatitis B vaccination free of charge in the public sector in the South-East Asia Region, WHO focus countries for the viral hepatitis response, 2023

	Vaccination-birth dose	Vaccination-infancy
Bangladesh		✓
India	✓	✓
Indonesia	✓	✓
Myanmar	✓	✓
Thailand	✓	✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.3.3 Regional achievements

Regional achievements since 2020 include the following.

- Nine of 11 countries in the Region have updated their viral hepatitis national strategic plans. Three countries (Bhutan, Maldives and Timor-Leste) have developed integrated national strategic plans for viral hepatitis, HIV and sexually transmitted infections.
- Most countries in the Region have included HBsAg and anti-HCV testing into the national programme or in universal health coverage packages and provide HBV and HCV treatment free of charge. In India and Thailand, the national viral hepatitis programme is fully integrated into the general health system.
- Thailand was among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country.
- In Timor-Leste, community-based outreach helped to expand HBV and HCV testing among key populations and people living with HIV, and HBV vaccination was provided to those eligible.
- The Region is expanding efforts to eliminate the vertical transmission of HBV. Indonesia and Thailand have introduced hepatitis B prophylaxis with TDF for pregnant women.
- Countries are working to develop an integrated strategic information system for HIV and hepatitis (through DHIS-2 or other systems).

4.3.4 Regional priorities for elimination

Regional priorities for eliminating viral hepatitis by 2030 include:

- defining screening strategies for hepatitis B and C, expanding access to HBV DNA and HCV RNA NAT facilities beyond larger hospitals and referral centres and facilitating the uptake of innovations such as HCV self-testing;
- addressing price variability across countries in the Region.
- addressing cost barriers for accessing services: although the tests may be provided free of charge, people still need to pay the associated costs out of pocket in many countries, making diagnosis inaccessible to most, and in some countries, free treatment is available only at referral centres, which also limits access for people who need to travel long distances;
- facilitating product registration in countries, including through the WHO collaborative procedure for accelerated registration;
- improving market transparency on procurement mechanisms, approved products and associated prices across countries in the Region and strengthening the stock monitoring and management systems for viral load testing, to prevent stock-outs and ensure regular supplies;
- relocating financial, technical and human resources that were diverted to the COVID-19 response to the viral hepatitis programme and reinvigorating viral hepatitis services in a post-COVID-19 context;
- expanding advocacy for greater political commitment, multistakeholder engagement and resource allocation at the national level and costing the national strategic plans;
- expanding engagement with civil society and networks of priority population groups to understand barriers and increase diagnosis and treatment uptake; and
- advancing integration across HIV, viral hepatitis, sexually transmitted infections, TB, harm reduction and other related programme areas to promote efficiency in the use of resources and facilitate person-centred care, such as leveraging triple elimination of the vertical transmission of HIV, syphilis and viral hepatitis.

4.3.5 WHO support for countries

WHO support has enhanced strategic planning for viral hepatitis in the Region, promoted the integration of viral hepatitis services within universal health coverage packages, and strengthened surveillance. Since 2020, the key areas of WHO support have included:

- developing the Integrated Regional Action Plan for Viral Hepatitis, HIV and Sexually Transmitted Infections in South-East Asia 2022–2026 and supporting country-level implementation by establishing a Strategic and Technical Advisory Group, and a regional committee on validating the elimination of vertical transmission;
- supporting countries in strategic planning, costing and implementation of national viral hepatitis responses and developing or updating national guidelines;
- supporting HIV and viral hepatitis programme reviews;
- promoting advocacy efforts to advance political commitment and resource allocation by organizing high-level events, supporting resource mobilization, including by integrating viral hepatitis in funding proposals to the Global Fund and providing some catalytic funds for procuring medicines;
- developing guidance on strategic information for viral hepatitis in collaboration with the Peter Doherty Institute for Infection and Immunity in Melbourne, Australia (WHO Collaborating Centre for Viral Hepatitis) and strengthening strategic information systems for viral hepatitis at the country level; and
- building capacity for programme managers, clinicians and other health personnel in programmatic, clinical, laboratory and strategic information areas.

Box 4.3.1

Thailand

Thailand has taken several steps in recent years to expand access to hepatitis C testing and treatment. In 2021, Thailand included SOF/VEL for hepatitis C treatment in the national list of essential medicines and as a component of the universal health coverage package. An analysis of the patient care pathway found that access to treatment and referrals was restricted by requirements such as the qualification of the treating physician, diagnostic protocols and treatment criteria. Through collaboration with the Thai Association for the Study of the Liver and the Department of Medical Services, the Thai Department of Disease Control adjusted the indications of SOF/VEL in the national essential medicines list to enable general physicians who have undergone training to prescribe hepatitis treatment and established a consultation system for general practitioners or gastroenterologists. Through the same collaboration, Thailand also developed guidelines to diagnose and treat people with hepatitis C using a test-and-treat approach that aims to provide prompt confirmation of diagnosis and timely treatment to everyone through decentralized community hospitals. Thailand is also assessing the feasibility of local production of hepatitis C treatment, which would enable the medicines to be available at a lower cost than through import.

With high coverage of the hepatitis B vaccine, including the birth dose, Thailand achieved the target of <1% prevalence of HBsAg among five-year-old children by 2020. The national health benefit package includes laboratory testing for HBV (HBeAg) and provision of tenofovir to prevent vertical transmission from mother to child. In an integrated approach, the Department of Disease Control has proposed extending the benefit package to screening for hepatitis B and C. Everyone born before 1992 can be tested once for both HBsAg and anti-HCV, whereas priority population groups (including people living with HIV, people who inject drugs, gay men and other men who have sex with men, health-care personnel and prisoners) can receive the anti-HCV test annually.

4.4 European Region

Key findings

Epidemiology and service coverage: In 2022, an estimated 10.6 million people were living with hepatitis B and 8.6 million with hepatitis C in the European Region. Of those living with hepatitis B, about 16% have been diagnosed and 12% of those diagnosed have received treatment. Of people living with hepatitis C, 29% have been diagnosed and 9% of those diagnosed have received treatment. People who inject drugs are especially vulnerable to hepatitis, and coinfection with hepatitis and HIV is common.

Access to health products: The prices paid for viral hepatitis medicines in the European Region vary greatly, and middle-income countries in the Region have limited access to generic products. The lowest reported price paid for a 30-day supply of generic TDF ranges between US$ 2.00 in Ukraine and US$ 34.0 in the Russian Federation. For hepatitis C medicines, Ukraine reported a price of US$ 46.20 for generic SOF and US$ 14.20 for generic DAC for a 12-week supply. In contrast, the Russian Federation reported a price of US$ 1543.00 for the originator 12-week supply of SOF and US$ 1508.60 for a 28-day supply of DAC.

All six focus countries in the Region have introduced the hepatitis B birth dose in the universal immunization programme. Numerous products are available for implementing hepatitis B testing in the European Region, and focus countries report decentralization of testing services in primary health care and within communities.

Regional priorities: Regional priorities for 2030 include increasing political and financial commitment in countries in the Region for the viral hepatitis response, enhancing hepatitis surveillance and early detection, addressing intellectual property-related barriers and price variation and ending stigma and discrimination against key and marginalized populations.

4.4.1 Regional epidemic profile and progress towards impact

Tables 4.4.1 and 4.4.2 present epidemiological and service coverage information for viral hepatitis B and C, respectively, in the European Region.

Table 4.4.1. Hepatitis B in the European Region, 2022

Indicator	
Number of people living with hepatitis B infection	10.6 million
Number of new hepatitis B infections per year	18 000
Number of deaths caused by hepatitis B infection per year	32 000
Percentage of people living with hepatitis B who are diagnosed	15.7%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	12.2%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	1.9%

Table 4.4.2. Hepatitis C in the European Region, 2022

Indicator	
Number of people living with hepatitis C infection	8.6 million
Number of new hepatitis C infections per year	126 000
Number of deaths caused by hepatitis C infection per year	21 000
Percentage of people living with hepatitis C who are diagnosed	29%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	9%

4.4.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the European Region.

4.4.2.1 Access to viral hepatitis testing in the European Region

Five of the six WHO focus countries for the viral hepatitis response in the European Region (Georgia, Kyrgyzstan, Republic of Moldova, Russian Federation, Ukraine and Uzbekistan) provided responses to the WHO 2023 survey on viral hepatitis diagnostics: Georgia, Republic of Moldova, Russian Federation, Ukraine and Uzbekistan.

Hepatitis B IVDs

Product availability

Numerous products are available for implementing hepatitis B testing in the European Region. Georgia, the Russian Federation and Uzbekistan incorporate additional assays into their national viral hepatitis B testing algorithm than the WHO-recommended algorithm, such as multiple serology assays. The Republic of Moldova focuses the procurement and implementation of hepatitis B testing on one assay per product category, which may support the simplification of algorithm implementation and uptake. Further, decentralization is a clear priority across all countries. The hepatitis B RDTs are available in primary health care and in several cases also in community settings.

Table 4.4.3. Hepatitis B IVD products in the European Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Laboratory-based HBsAg**	**Laboratory-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Georgia	4	9	1	4	
Republic of Moldova	1	1	1		1
Russian Federation	3	3	3	3	
Ukraine	3 **(1)**			1	
Uzbekistan	**1**	4	1	1	1

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Only Ukraine in the European Region provided an indicative hepatitis B RDT price paid of US$ 0.58 *(38)*.

Hepatitis C IVDs

Product availability

Numerous products are available for implementing hepatitis C testing in the European Region. The Republic of Moldova focuses procurement and implementation of hepatitis C testing on one assay (or three assays for laboratory-based HCV testing) per product category, which may support the simplification of algorithm implementation and uptake. The Russian Federation and Uzbekistan incorporate additional assays into their national viral hepatitis C testing algorithm than the WHO-recommended algorithm, such as multiple serology assays. Further, decentralization is a clear priority across all countries. Hepatitis C RDTs are available in primary health care and in several cases also in community settings.

Table 4.4.4. Hepatitis C IVD products in the European Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Georgia		4	7 **(1)**	1		3 **(1)**	1 **(1)**	
Republic of Moldova		1	3				1 **(1)**	
Russian Federation	1	1	2	1	1	3		1
Ukraine		2				2 **(2)**		
Uzbekistan		1	2			**2**	2	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Only Kyrgyzstan in the European Region provided an indicative hepatitis C RDT price paid of US$ 2.42 *(45)*.

Hepatitis C RNA NAT prices paid by select countries within the European Region range between US$ 8.17 and US$ 23.90 *(45)*.

- Georgia: US$ 23.90
- Kyrgyzstan: US$ 8.17

Cross-cutting aspects of viral hepatitis testing

Service delivery settings

Facility-based screening and testing is the primary way for finding people with hepatitis. Four of the five countries (except for Russian Federation) screen and test for hepatitis at harm-reduction services for people living with HIV. Except for Georgia, the other reporting countries screen and test at primary clinics, inpatient and outpatient settings and HIV service delivery points.

Table 4.4.5. Service delivery settings for viral hepatitis testing in the European Region, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings for viral hepatitis testing in the country				
Georgia	**Republic of Moldova**	**Russian Federation**	**Ukraine**	**Uzbekistan**
Harm-reduction services for people who use drugs	Primary clinics	Primary clinics	Primary clinics	Primary clinics
	Inpatient and outpatient settings	Inpatient and outpatient settings	Inpatient and outpatient settings	Inpatient and outpatient settings
	Routine testing in antenatal care	HIV service delivery points	Routine testing in antenatal care	Routine testing in antenatal care
	HIV service delivery points	Sexually transmitted infection clinics	HIV service delivery points	HIV service delivery points
	TB and sexually transmitted infection clinics		Harm-reduction services for people who use drugs	Harm-reduction services for people who use drugs
	Harm-reduction services for people who use drugs		Occupational health services	
			Prisons	
			Military service exam	
			Healthy lifestyle events	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

All five reporting countries note government funding as a key source of funding for viral hepatitis testing. The Russian Federation and Ukraine also reported out-of-pocket funding. None of the five reporting countries reported any procurement challenges for viral hepatitis IVDs.

Product registration and availability

Three reporting countries (Georgia, Kyrgyzstan and Republic of Moldova) apply reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval, primarily WHO prequalification.

4.4.2.2 Access to viral hepatitis medicines in the European Region

All six WHO focus countries for the viral hepatitis response in the European Region provided responses to the WHO 2023 survey on viral hepatitis medicines.

Hepatitis B medicines

All six focus countries in the European Region have included TDF in national treatment guidelines. Five countries have also included TDF in essential medicines lists, and four countries report it being available in primary health cares. All six focus countries have also included ETV in national guidelines for adults, and three have included ETV in national guidelines for children. ETV is available in primary health care in four countries for adults and in one country for children. Three countries (Georgia, Kyrgyzstan and Uzbekistan) have also included TAF in the national guidelines.

Generic TDF is registered in all countries, and generic TAF is registered in five countries. Two countries (Kyrgyzstan and Ukraine) report the registration of generic ETV for both adults and children.

Many countries in the European Region pay higher prices for TDF than the global benchmark of US$ 2.40 per 30 tablets (300 mg) from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Of the focus countries, only Ukraine reported a public sector procurement price of US$ 2.00 for a generic 30-day supply of TDF. In the other countries, the lowest reported price paid for a 28-day supply of generic TDF ranges between US$ 7.00 in Kyrgyzstan and US$ 34.00 in the Russian Federation. The price for a 30-day supply of generic ETV (0.5 mg) ranges between US$ 4.80 in Ukraine and US$ 39.60 in the Russian Federation. The lowest reported price for a 30-day supply of generic TAF (25 mg) is US$ 7.00 in Kyrgyzstan. One focus country in the Region, the Russian Federation, is not included in the Gilead-MPP licensing agreement for TAF.

Five countries provide hepatitis B diagnosis and treatment services free of charge in the public sector, either fully or partly for specific subpopulations and/or with co-payment.

Table 4.4.6. Access to TDF in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			Product registration		Price 300 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (bold: WHO prequalification product)	
Georgia		X		O	4			
Kyrgyzstan	X	X	X		4 **(1)**		7.00	
Republic of Moldova	X	X	X		3 **(1)**			
Russian Federation	X	X	X	O	9		34.20	X
Ukraine	X	X		O	4 **(3)**		**2.09**	
Uzbekistan	X	X	X		12 **(2)**		10.71	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.4.7. Access to ETV in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	ETV											
	National programme						Product registration				Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Georgia		X					O		O				
Kyrgyzstan	X	X	X	X	X	X		4		7		8.00	
Republic of Moldova	X	X	X	X	X								
Russian Federation	X	X	X				O	5				39.6	X
Ukraine	X	X		X	X			1		1		4.80	
Uzbekistan	X	X	X					4				26.79	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.4.8. Access to TAF in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							
	National programme			Product registration		Price 25 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Georgia		X			1			X
Kyrgyzstan		X	X		5		7.00	X
Republic of Moldova								
Russian Federation	X		X	O		96.00		X
Ukraine					2			
Uzbekistan	X	X	X		10		16.07	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.4.9. Inclusion in licensing agreements for hepatitis B medicines in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Georgia	Yes
Kyrgyzstan	Yes
Republic of Moldova	Yes
Russian Federation	**No**
Ukraine	Yes
Uzbekistan	Yes

TDF and ETV are off patent.
Source: MPP.

Table 4.4.10. Availability of HBV testing and treatment services free of charge in the public sector in the European Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other
Georgia				
Kyrgyzstan	✓	✓		✓
Republic of Moldova	✓ (partial)	✓	✓ (partial)	✓ (partial)
Russian Federation	✓	✓	✓	✓
Ukraine	✓ (partial)	✓		✓
Uzbekistan	✓	✓ (partial)	✓ (partial)	

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

Five of the six WHO focus countries in the Region have included SOF and DAC (both or co-blistered or fixed-dose combination) in national guidelines for adults, and one country, Georgia, has included SOF only. Kyrgyzstan and the Republic of Moldova have also included both of these medicines in national guidelines for children. Four countries have included both SOF and DAC in essential medicines lists for adults, and three countries have included both in essential medicines lists for children. Five countries report these medicines being available in primary health care for adults. Five countries have included SOF/VEL in national guidelines for adults and report it being available in primary health care. In addition, four countries have included SOF/LED in national guidelines for adults and report it being available in primary health care. Fewer countries report these medicines being available in primary health care for children.

Five countries have registered at least one generic product of SOF and DAC (both or co-blistered or fixed-dose combination) for adults, and one country has registered both for children. Georgia and Russian Federation have registered only SOF for both adults and children.

Three of the six focus countries in the Region (Georgia, Republic of Moldova and Russian Federation) are not included in the Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX. Countries in the Region are paying higher prices for hepatitis medicines than the global benchmark of US$ 60 for a 12-week treatment course from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Of the focus countries, only Ukraine reported a public sector procurement price for 12 weeks of US$ 46.20 for generic SOF (400 mg) and US$ 14.20 for generic DAC (60 mg). The Russian Federation reported the highest prices in the Region for a 12-week supply of SOF (originator, US$ 1543.00), DAC (originator, US$ 1508.60), SOF/LED (originator US$ 4492.3) and SOF/VEL (originator, US$ 3929.50).

All countries provide hepatitis C testing and treatment services free of charge in the public sector, either fully or partly for specific subpopulations. One country – Uzbekistan – provides hepatitis C self-testing free of charge in the public sector.

Table 4.4.11. Access to SOF and DAC in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC											
	National programme						Product registration				Price SOF 400 mg, DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Georgia		X[s]						SOF: 1		SOF: 1			
Kyrgyzstan	X	X	X	X	X	X		SOF: 3 DAC: 2		SOF: 3 DAC: 2		SOF/DAC: 874[a]	
Republic of Moldova	X	X	X	X	X			SOF: 1 DAC: 2				SOF: 78.74 DAC: 18.80	
Russian Federation	X	X	X	X		X	O	SOF: 2 DAC: 1	O	SOF: 2	SOF: 1543.08 DAC: 1508.64		X (DAC)
Ukraine	X[s]	X	X	X[s]	X[s]			SOF: 4 **(3)** DAC: 2 **(2)** SOF + DAC: 1 **(1)**		DAC: 1 **(1)**		SOF: 46.20 DAC: 14.28	
Uzbekistan	X	X	X					SOF: 6 **(1)** DAC: 6 **(1)**				SOF: 180.00 DAC: 120.00	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

X[s]: SOF only.
O: originator product is registered.
[a]Other published data *(45)* (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.4.12. Access to SOF/VEL in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL												Local production in the country
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		
	Adults			Children			Adults		Children				
	Model List of Essential	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Georgia		X	X		X		O	1	O	1			
Kyrgyzstan	X			X	X	X		3		3		135.00	
Republic of Moldova	X	X	X	X				1		1		143.57	
Russian Federation		X	X			X	O		O		3929.50		
Ukraine		X	X		X		O	3 **(1)**				130.20	
Uzbekistan	X	X	X					6				255.00	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.
O: originator product is registered.

Table 4.4.13. Inclusion in licensing agreements for hepatitis C medicines in the European Region, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or 2020 patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Georgia	**No**	Yes	Yes
Kyrgyzstan	Yes	Yes	**No**
Republic of Moldova	**No**	Yes	**No**
Russian Federation	**No**	**No**	**No**
Ukraine	Yes	Yes	**No**
Uzbekistan	Yes	Yes	**No**

Source: MPP.

Table 4.4.14. Availability of HCV testing and treatment services free of charge in the public sector in the European Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other	Liver staging – other	Confirmation of cure
Georgia		✓	✓	✓	✓	✓
Kyrgyzstan		✓	✓		✓	✓
Republic of Moldova		✓ (partial)	✓	✓ (partial)	✓ (partial)	✓
Russian Federation		✓	✓	✓	✓	✓
Ukraine		✓ (partial)	✓		✓	✓
Uzbekistan	✓	✓ (partial)		(partial)		

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.4.2.3. Access to hepatitis B vaccination in the European Region

All six focus countries in the Region have introduced the hepatitis B birth dose in the universal immunization programme and provide hepatitis B vaccination free of charge in the public sector.

Table 4.4.15. Access to hepatitis B birth dose and infant vaccination in the European Region, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Georgia	Yes	95	85
Kyrgyzstan	Yes	96	90
Republic of Moldova	Yes	93	90
Russian Federation	Yes	Not available	97
Ukraine	Yes	53	62
Uzbekistan	Yes	99	99

Source: WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

Table 4.4.16. Availability of HBV vaccination in the public sector in the European Region, WHO focus countries for the viral hepatitis response, 2023

	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose
Georgia	✓	✓
Kyrgyzstan	✓	✓
Republic of Moldova	✓	✓
Russian Federation	✓	✓
Ukraine	✓	✓
Uzbekistan	✓	✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023

4.4.3 Regional achievements

Regional achievements since 2020 include the following.

- Nine countries in the Region (Belarus, Georgia, Italy, Kyrgyzstan, Netherlands (Kingdom of the), Republic of Moldova, Turkmenistan, United Kingdom and Uzbekistan) have reached regional hepatitis B control targets by 2023 through high coverage of hepatitis B vaccination and prevention of vertical transmission of hepatitis B – bringing Region closer to eliminating viral hepatitis *(79)*.
- Georgia and United Kingdom were among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country.
- The National Center for Disease Control and Public Health in Georgia was designated as the WHO Collaborating Centre on Viral Hepatitis Elimination in 2023, acknowledging Georgia's pioneering efforts to address viral hepatitis with high coverage of testing and treatment services, a good surveillance system and a favourable policy landscape. The Collaborating Centre will act as a demonstration platform for viral hepatitis elimination in the Region and facilitate the sharing of experiences across countries *(80)*.

4.4.4 Regional priorities for elimination

Regional priorities for eliminating viral hepatitis by 2030 include:

- increasing political commitment in countries in the Region to prevent and control chronic viral hepatitis;
- strengthening hepatitis prevention by integrating it into existing health systems and services, including blood transfusion services, immunization programmes, national cancer programmes, sexually transmitted infection services, HIV services and specific programmes for people who inject drugs;
- enhancing hepatitis surveillance and early detection and strengthening strategic information systems;
- improving case management and access to diagnosis and treatment;
- addressing intellectual property-related barriers to affordable access, including the lack of access to generic options in middle-income countries and their exclusion from voluntary licensing agreements;
- addressing price variation across countries in the Region and among commodities – for example, many countries in the Region pay a higher price for tenofovir as part of the viral hepatitis programme versus the HIV programme procuring it; and
- ending stigma and discrimination and providing equitable access for key and marginalized populations, including people who inject drugs, people in prisons and closed settings and migrant populations.

4.4.5 WHO support for countries

WHO support has enhanced the visibility of viral hepatitis in the Region, promoted strategic planning to strengthen national responses, and improved strategic information systems. Since 2020, the key areas of WHO support have included:

- providing technical support to countries in planning and strengthening national responses to viral hepatitis, including awareness raising, situation analysis, surveillance, prevention, strengthening laboratory capacity and providing guidance on testing and treatment; and
- supporting regional partnerships for the viral hepatitis response.

Box 4.4.1

Uzbekistan

In 2019, Uzbekistan began a pilot project to test adults for chronic hepatitis B and C infection in the capital city Tashkent and to link them to care. The pilot project was supported by catalytic funding from the CDA Foundation, which covered upfront costs for purchasing the first round of diagnostic tests and medicines. The pilot project enabled general practitioners to carry out testing and treatment in primary health care and enabled patients to obtain access to free testing and affordable treatment. In the first year, the project recruited 13 polyclinics in the city through a task-shifting model that trained primary care physicians to treat people with hepatitis C and B infection who did not have advanced liver disease. It was planned to test an estimated 250 000 adults (aged >18 years) in one year. During the first three months, more than 24 000 people were tested for HBV or HCV and 438 initiated treatment *(81)*. COVID-19-related closures interrupted the activities in early 2020, but after the clinics reopened in September 2020, nearly 62 000 people had been tested as part of the pilot phase.

The project demonstrated that large-scale screening for viral hepatitis is feasible using RDTs and simplified guidelines. It also acted as a catalyst in increasing the literacy of the population about viral hepatitis and encouraging them to seek testing and treatment. However, rates of attrition remained high, emphasizing the importance of complementing the screening campaign by an awareness campaign for the general population and for general practitioners and the importance of addressing stigma and sociocultural barriers *(82)*. In 2021, the project was expanded and free screening was offered to a further 500 000 people in seven regions of the country. The success of the pilot project facilitated the signing of a presidential decree in 2022 that provides the budget and resources for screening 2 million adults across Uzbekistan for hepatitis B and C between 2022 and 2025 and providing hepatitis C treatment either free of charge or at a subsidized price as part of the national viral hepatitis elimination programme *(83)*. It is also planned to integrate private clinics into the national response through a national electronic register.

4.5 Eastern Mediterranean Region

Key findings

Epidemiology and service coverage: In 2022, an estimated 15 million people were living with hepatitis B and 11.7 million people with hepatitis C in the Eastern Mediterranean Region. The Region has the highest prevalence of hepatitis C in the world. Of the people living with hepatitis B, 14.7% have been diagnosed and, of these, 13.6% have received treatment. Of people living with hepatitis C, 49% have been diagnosed and 35% of these have received treatment, largely supported by the large public health programme to diagnose and treat hepatitis C in Egypt.

Access to health products: Countries in the Region manufacture generic viral hepatitis medicines locally. Egypt, which produces TDF, ETV and TAF locally, reported a price for a 30-day supply of generic TDF of US$ 5.70. Egypt reported a combined price for a 12-week supply of generic SOF and DAC of US$ 36.80 and Pakistan US$ 33.60, both of which are lower than the global benchmark. The WHO focus countries in the Region have updated treatment guidelines in accordance with WHO recommendations and products are registered in the country, however the availability of medicines in primary health care is limited. The reported number of IVD products at decentralized level is limited. Three of the five focus countries in the Region have introduced hepatitis B birth-dose vaccination into the universal immunization programme.

Regional priorities: Regional priorities for 2030 include moving to full elimination in Egypt and building on the successful model from Egypt to accelerate access to viral hepatitis testing and treatment for all countries in the Region. Decentralizing the delivery of hepatitis services, defining screening strategies by geographical subregion and subpopulation group in accordance with the local country context, addressing practical barriers in access to affordable testing and treatment and strengthening the role of civil society in the viral hepatitis response will also be critical to achieve elimination goals in the Region.

4.5.1 Regional epidemic profile and progress towards impact

Tables 4.5.1 and 4.5.2 present epidemiological and service coverage information for viral hepatitis B and C, respectively. in the Eastern Mediterranean Region.

Table 4.5.1 Hepatitis B in the Eastern Mediterranean Region, 2022

Indicator	
Number of people living with hepatitis B infection	15.1 million
Number of new hepatitis B infections per year	86 000
Number of deaths caused by hepatitis B infection per year	41 000
Percentage of people living with hepatitis B who are diagnosed	14.7%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	13.6%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	2.0%

Table 4.5.2 Hepatitis C in the Eastern Mediterranean Region, 2022

Indicator	
Number of people living with hepatitis C infection	11.7 million
Number of new hepatitis C infections per year	183 000
Number of deaths caused by HCV infection per year	65 000
Percentage of people living with hepatitis C who are diagnosed	49%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	35%

4.5.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the Eastern Mediterranean Region.

4.5.2.1 Access to viral hepatitis testing in the Eastern Mediterranean Region

Four of the five WHO focus countries for the viral hepatitis response in the Eastern Mediterranean Region provided responses to the WHO 2023 survey on viral hepatitis diagnostics: Egypt, Morocco, Pakistan and Yemen.

Hepatitis B IVDs

Product availability

The number of products available for procurement and the decentralization of testing to primary health care are relatively limited in the Region.

Table 4.5.3. Hepatitis B IVD products in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Laboratory-based HBsAg**	**Laboratory-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Egypt		3		2	
Pakistan	1			1	
Yemen	6	4		3	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C IVDs

Product availability

Three of the four reporting countries (Egypt, Pakistan and Yemen) report having more than one assay available for each product category. Hepatitis C RDTs are available in primary health care in Egypt, Morocco and Pakistan and in some cases also in community settings.

Table 4.5.4. Hepatitis C IVD products in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Egypt		2	3			2 **(1)**		
Morocco		1				1		
Pakistan		2		1		1		
Yemen		6	4			3 **(1)**		

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis C RDT prices paid by select countries within the Eastern Mediterranean Region range between US$ 0.30 and US$ 1.99 *(45)*.

- Morocco: US$ 1.99
- Pakistan: US$ 0.30

Only Pakistan from the Eastern Mediterranean Region provided an indicative hepatitis C RNA NAT price paid of US$ 6.72 *(45)*.

Cross-cutting aspects of viral hepatitis testing

Service delivery settings

Facility-based testing is the primary way for finding people with hepatitis. All four reporting countries conduct screening and testing in multiple settings, including and especially inpatient and outpatient settings. HIV service delivery points are a priority setting for three of the four reporting countries (Egypt, Morocco and Pakistan). Egypt includes several additional settings, including addiction clinics, hepatitis clinics, blood banks, high schools and private laboratories.

Table 4.5.5. Service delivery settings for viral hepatitis testing in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings for viral hepatitis testing in the country			
Egypt	**Morocco**	**Pakistan**	**Yemen**
Primary clinics	Primary clinics	Inpatient and outpatient settings	Inpatient and outpatient settings
Inpatient and outpatient settings	Inpatient and outpatient settings	Routine testing in antenatal care	National laboratory
Routine testing in antenatal care	HIV service delivery points	HIV service delivery points	Blood transfusion
HIV service delivery points	Harm-reduction services for people who use drugs	Occupational health services	Private reference laboratories
Harm-reduction services for people who use drugs			
Addiction clinics			
Hepatitis clinics			
Blood banks			
Central public health laboratory			
High schools			
Private laboratories			

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

The four reporting countries in the Region use a variety of financial sources to support viral hepatitis testing, including and primarily government funding and out-of-pocket payments.

Product registration and availability

Three of the reporting countries (Egypt, Morocco and Yemen) apply reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval, primarily WHO prequalification. Egypt and Yemen both use WHO prequalification to support their national regulatory approvals, and Yemen includes a broader set of other conformity bodies, including the United States Food and Drug Administration and CE marking of IVD.

Multi-disease platforms and integration of viral hepatitis testing across critical services

Within diagnostic integration, only Egypt reports the sharing of multi-disease platforms with the HIV, COVID-19 (SARS-CoV-2), and cervical cancer (HPV) testing programmes. Further, Egypt, Morocco, and Yemen report that they share diagnostic services with other disease programmes, in particular human resources. Egypt and Morocco also share a number of other diagnostic

services with their respective HIV disease programmes, including specimen transportation, waste management, and training. Egypt also shares testing services with the COVID-19 and influenza disease programmes, while Morocco also shares with their TB disease programme.

4.5.2.2 Access to viral hepatitis medicines in the Eastern Mediterranean Region

Three of the five WHO focus countries for the viral hepatitis response in the Eastern Mediterranean Region – Egypt, Morocco and Pakistan – provided responses to the WHO 2023 survey on viral hepatitis medicines.

Hepatitis B medicines

Of the three focus countries in the Eastern Mediterranean Region for which this information was available, Egypt has included TDF, ETV and TAF in national guidelines and essential medicines lists. Morocco has included only TDF in national guidelines and the essential medicines list, and Pakistan has included ETV and TAF in national guidelines and essential medicines lists. Only Egypt has included ETV for children in national guidelines or essential medicines lists.

The products are registered in the reporting countries, but no country reports these products being available in primary health care. Viral hepatitis treatment services may not be available in primary health care in these countries but may be available at tertiary levels and in specialized care.

Egypt, which produces TDF, ETV and TAF locally, reported a price for a 30-day supply of generic TDF (300 mg) of US$ 5.70, which is higher than the global benchmark price of US$ 2.40 per 30 tablets from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Pakistan, which produces ETV and TAF locally in the country, reported a price for a 30-day supply of generic ETV (1 mg) of US$ 0.60 and US$ 3.00 for a 30-day supply of generic TAF (25 mg).

Egypt and Morocco are not included in the Gilead-MPP licensing agreement for TAF.

Table 4.5.6. Access to TDF in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			Product registration		Price 300 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Egypt	X	X			3		5.70	X
Morocco	X	X						
Pakistan								

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

Source: WHO survey among focus countries for the viral hepatitis response, 2023

Table 4.5.7. Access to ETV in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	ETV											
	National programme						Product registration				Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Egypt	X	X		X	X			3		3		3.00	X
Morocco													
Pakistan	X	X					O	G					X

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country. Source: WHO survey among focus countries for the viral hepatitis response, 2023.
O: originator product is registered. G: generic ETV is registered; but the name and number are not provided.

Table 4.5.8. Access to TAF in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							Local production in the country
	National programme			Product registration		Price 25 mg, 30 tablets, US$		
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Egypt	X	X			1		9.60	X
Morocco								
Pakistan	X	X		O	G		3.00	X

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country. Source: WHO survey among focus countries for the viral hepatitis response, 2023

Table 4.5.9. Inclusion in licensing agreements for hepatitis B medicines in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Egypt	**No**
Morocco	**No**
Pakistan	Yes
Sudan	Yes
Yemen	Yes

TDF and ETV are off patent

Source: MPP.

Table 4.5.10. Availability of HBV testing and treatment services free of charge in the public sector in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other
Egypt	✓	✓	✓	✓
Morocco		✓	✓	✓
Pakistan	✓ (partial)	✓ (partial)	✓ (partial)	✓ (partial)

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Pakistan – selected provinces

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

All three countries in the Eastern Mediterranean Region for which this information was available have included SOF and DAC (both or co-blistered or fixed-dose combination) in national guidelines and essential medicines lists for adults. Two countries, Egypt and Pakistan, have also included these for children. These countries have also included SOF/VEL in national guidelines for adults. None of the countries report these hepatitis C medicines being available in primary health care across the country; however, between 2018 and 2022, Egypt conducted a nationwide campaign to eliminate hepatitis C, offering free testing and treatment for hepatitis C with locally manufactured medicines, and became the first country to achieve gold tier status on the path to eliminating hepatitis C in accordance with WHO criteria *(84)*. In Pakistan, hepatitis C medicines are available at the district or rural health centre level in selected provinces. In other countries, viral hepatitis treatment services may be available at tertiary levels and in specialized care.

Generic SOF and DAC (both or co-blistered or fixed-dose combination) are registered in Egypt and Pakistan, and both countries have local production of these medicines. Egypt reported a combined price for generic SOF (400 mg) and DAC (60 mg) at US$ 36.80, and Pakistan reported a combined price for a 12-week treatment course of generic SOF and DAC of US$ 33.60, both of which are lower than the global benchmark of US$ 60 for a 12-week treatment course from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. Both countries are also producing SOF/VEL and SOF/LED locally in the country.

All three countries provide hepatitis C testing and treatment services free of charge in the public sector, either fully or partly for specific subpopulations. Self-testing is not available as part of public sector programmes but may be available as part of research pilots.

Table 4.5.11. Access to SOF and DAC in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC											
	National programme						Product registration				Price SOF 400 mg ;, DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Egypt	X	X		X	X			SOF: 2 DAC: 2		SOF: 2 DAC: 2		SOF: 29.49 DAC: 7.32	X
Morocco	X	X											
Pakistan	X	X		X	X		O	G	O	G		SOF: 30.24 DAC: 3.36	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
G: generic SOF and DAC are registered, but the number or name of products is not specified.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.5.12. Access to SOF/VEL in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL											
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Egypt	X	X		X	X			1		1		103.92	X
Morocco	X	X										187.11	
Pakistan	X	X					O	G				100.80	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
G: generic SOF/VEL is registered; but the number or name of products is not specified.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.5.13. Inclusion in licensing agreements for hepatitis C medicines in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Egypt	Yes	Yes	Yes
Morocco	Yes	Yes	Yes
Pakistan	Yes	Yes	Yes
Sudan	Yes	Yes	Yes
Yemen	**No**	Yes	Yes

Table 4.5.14. Availability of HCV testing and treatment services free of charge in the public sector in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

Country	Self-testing	Diagnosis of chronic hepatitis C	Treatment	Liver staging – elastography	Liver staging – other	Confirmation of cure
Egypt		✓	✓	✓	✓	✓
Morocco		✓	✓	✓	✓	✓
Pakistan		✓ (partial)	✓ (partial)	✓ (partial)	✓ (partial)	✓ (partial)

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.5.2.3 Access to hepatitis B vaccination in the Eastern Mediterranean Region

Three of the five focus countries in the Region have introduced hepatitis B birth-dose vaccination into the universal immunization programme. Two countries reporting providing birth-dose vaccination free of charge in the public sector.

Table 4.5.15. Access to hepatitis B birth-dose and infant vaccination in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Egypt	Yes	93	97
Morocco	Yes	41	99
Pakistan	Yes[a]	Not available	85
Sudan	Not available	Not available	84
Yemen	Not available	Not available	74

[a]Not implemented nationwide.

Source: WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

Table 4.5.16. Availability of hepatitis B vaccination free of charge in the public sector in the Eastern Mediterranean Region, WHO focus countries for the viral hepatitis response, 2023

	Vaccination – birth dose	Vaccination –infancy
Egypt	✓	✓
Morocco	✓	✓
Pakistan		✓

Shaded: service is free of charge in the public sector.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.5.3 Regional achievements

Regional achievements since 2020 include the following.

- The Eastern Mediterranean Region has been at the forefront of global public health efforts to eliminate viral hepatitis. In 2023, Egypt became the first country to achieve gold tier status on the path to eliminating HCV in accordance with WHO criteria. Egypt's successful response was supported by a large-scale public health testing and treatment programme, backed by strong political commitment and domestic financing, and local production of generic DAAs. Egypt's success accounts for most of the regional progress in addressing viral hepatitis. Egypt was also among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country.
- In Pakistan, the programme is mobilizing national resources to implement the Prime Minister's initiative for the viral hepatitis testing and treatment programme.
- Morocco conducted an economic modelling exercise to guide testing and treatment for hepatitis B and C and is pursuing targeted elimination efforts.
- Many countries in the Region have established governance mechanisms, policies and strategic plans towards eliminating hepatitis. Fourteen countries have national strategies to address viral hepatitis, and 15 countries have established national hepatitis programmes.
- Some countries in the Region, including Egypt and Pakistan, manufacture viral hepatitis medicines locally and have the capacity to support scale-up efforts in the Region.

4.5.4 Regional priorities for elimination

Regional priorities for eliminating viral hepatitis by 2030 include:

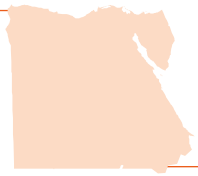
- building on the successful model from Egypt to accelerate access to viral hepatitis testing and treatment for all countries in the Region by integrating hepatitis services with primary health care as part of universal health coverage;
- decentralizing the delivery of hepatitis services when appropriate as a means to expand access to comprehensive people-centred services;
- defining screening strategies at the country level (such as by geographical subregion and by population group) that would be most effective in the local epidemiological and country context;
- addressing the high cost of IVDs in the Region, and optimizing existing infrastructure for NAT, such as multi-disease platforms that are already being used for other disease programme areas (e.g. NAT platforms for TB), and capacity developed in response to COVID-19;
- addressing practical barriers in expanding access to hepatitis medicines, for example those related to product registration, pricing, and patent laws that prevent access to generic medicines;
- advocating at the highest levels for national and local stewardship so that countries can secure commitment, allocate resources and leverage partnerships to implement high-impact cost-effective viral hepatitis interventions *(85)*; and
- strengthening the involvement of civil society in the viral hepatitis response.

4.5.5 WHO support for countries

WHO support has enhanced the visibility of viral hepatitis in the Region, promoted policy and strategic plan development, strengthened surveillance and provided the technical guidance and tools for Egypt's achievements on the path to elimination of hepatitis C. Since 2020, the key areas of WHO support have included:

- developing the regional action plan for the implementation of the global health sector strategies on HIV, hepatitis and sexually transmitted infections 2022–2030;
- supporting Egypt's national viral hepatitis elimination efforts and validating the gold tier status on the path to eliminating hepatitis C in accordance with WHO criteria;
- supporting countries, including Egypt, Morocco, Pakistan, Sudan and Yemen, to develop and cost national strategic plans, develop monitoring and evaluation frameworks and update national guidelines;
- supporting the design and implementation of micro-elimination efforts in Morocco and Pakistan; and
- supporting advocacy efforts at the highest policy-making levels for investing in viral hepatitis responses related to Region.

Box 4.5.1



Egypt

In 2023, Egypt became the first country to achieve gold tier status on the path to eliminating hepatitis C in accordance with WHO criteria. This means that Egypt has fulfilled WHO's programmatic coverage targets that will set the country up to achieve the reduced incidence and mortality targets of full elimination before 2030. Egypt has implemented one of the world's largest nationwide public health screening and treatment programmes for hepatitis C, supported by strong national political commitment and domestic allocation of resources. Between 2014 and 2020, Egypt screened more than 50 million people for hepatitis C, and 92% of those who required treatment received DAAs. A case study of the success factors and lessons learned from the programme concluded that five key elements contributed to Egypt's successful programme, including the availability of sufficient and reliable epidemiological data; a robust public health care infrastructure; inclusive care that reached all sectors of society; political commitment with increased health-care spending and a comprehensive long-term strategy for viral hepatitis; and use of innovation and information technology *(86)*.

A modelling exercise conducted in 2022 estimated that the total number of HCV viraemic cases would be expected to decrease by 86% by 2030 under the national screening and treatment programme versus 41% under the historical base, which assumed that no programme had been implemented. The analysis found Egypt's national screening and treatment programme to be highly cost-effective by 2021 and cost-saving by 2029. It estimated that in 2018–2030, the programme would save about US$ 35 million in direct health-care costs, with 883 333 cumulative disability-adjusted life-years (DALYs) averted, equivalent to an economic gain of US$ 4.705 billion in indirect costs compared with the base case *(87)*.

4.6 Western Pacific Region

Key findings

Epidemiology and service coverage: In 2022, an estimated 97 million people were living with hepatitis B and 7.1 million with hepatitis C in the Western Pacific Region. The Western Pacific Region has the second highest prevalence of hepatitis B in the general population (the African Region is higher). Of people living with hepatitis B, 26% have been diagnosed and of these, 23% have received treatment. Of people living with hepatitis C, 45% have been diagnosed; and of these, 16% have received treatment.

Access to health products: Countries in the Region have local manufacturing of generic viral hepatitis medicines; however, the prices paid for viral hepatitis medicines vary and many countries are paying prices higher than global benchmark prices. The lowest reported price of the last public sector procurement of for a 30-day supply of generic TDF ranges between US$ 1.20 in China and US$ 10.00 in the Lao People's Democratic Republic. The lowest reported price of the last public sector procurement of a 12-week treatment course of generic SOF and DAC varies between US$ 84.00 in Cambodia and more than US$ 10 000 in China. The number of IVD products available for procurement in the Region is relatively varied across focus countries, and decentralization of testing to primary health care is relatively limited. All eight WHO focus countries in the Region have included the hepatitis B birth dose in the universal immunization programme.

Regional priorities: Regional priorities for 2030 include tailoring screening and testing strategies to the diverse epidemic profiles in the Region, integrating viral hepatitis services with related programme areas, sustaining prevention interventions for viral hepatitis such as the hepatitis B birth dose and infant vaccination and reducing the prices of viral hepatitis diagnosis and treatment.

4.6.1 Regional epidemic profile and progress towards impact

Tables 4.6.1 and 4.6.2 present epidemiological and service coverage information for viral hepatitis B and C, respectively, in the Western Pacific Region.

Table 4.6.1. Hepatitis B in the Western Pacific Region, 2022

Indicator	
Number of people living with hepatitis B infection	96.8 million
Number of new hepatitis B infections per year	83 000
Number of deaths caused by hepatitis B infection per year	518 000
Percentage of people living with hepatitis B who are diagnosed	25.5%
Percentage of people living with hepatitis B who receive treatment (among those diagnosed)	23.2%
Percentage of people living with hepatitis B who receive treatment (among all people with hepatitis B)	5.9%

Table 4.6.2. Hepatitis C in the Western Pacific Region, 2022

Indicator	
Number of people living with hepatitis C infection	7.1 million
Number of new hepatitis C infections per year	98 000
Number of deaths caused by hepatitis C infection per year	43 000
Percentage of people living with hepatitis C who are diagnosed	45.0%
Percentage of people living with hepatitis C who receive treatment (among all people with hepatitis C)	16.0%

4.6.2 Regional access to health products

This section provides information on access to viral hepatitis health products in the WHO focus countries for the viral hepatitis response in the Western Pacific Region.

4.6.2.1 Access to viral hepatitis testing in the Western Pacific Region

Five of the eight WHO focus countries for the viral hepatitis response in the Western Pacific Region provided responses to the 2023 WHO survey on viral hepatitis testing: Cambodia, China, Lao People's Democratic Republic, Mongolia and Vanuatu.

Hepatitis B IVDs

Product availability

The number of products available for procurement in the Western Pacific Region varies across countries. Cambodia and Mongolia report using RDTs and near point-of-care technologies for HBV DNA NAT at the decentralized level. No country reported community testing. Further, Vanuatu has limited access to NAT as part of their national hepatitis B testing algorithm and only considers HBV NAT if needed.

Table 4.6.3. Hepatitis B IVD products in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis B IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)				
	RDT HBsAg	**Laboratory-based HBsAg**	**Laboratory-based HBeAg**	**HBV DNA NAT**	**HBV DNA NAT for point-of-care**
Cambodia	1 **(1)**			1	1
China	4	4	3	5	
Lao People's Democratic Republic	5			1	
Mongolia	14	6	2	1	1
Vanuatu	1 **(1)**			1	

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis B RDT prices paid by select countries within the Western Pacific Region range between US$ 0.60 and US$ 1.10 *(38)*.

- Cambodia: US$ 0.60
- Mongolia: US$ 0.94–1.10

Hepatitis B NAT prices paid by select countries within the Western Pacific Region range between US$ 28.00 and US$ 62.00 *(38)*.

- Indonesia: US$ 28.00–62.00
- Viet Nam: US$ 55.00

Hepatitis C IVDs

Product availability

The number of products available for procurement in the Western Pacific Region varies across countries. Decentralization to primary health care is relatively limited across the Region except in Cambodia and Mongolia, which report using RDTs and near point-of-care technologies for HCV RNA NAT. No country reported community testing. Further, Vanuatu has no access to NAT as part of their national hepatitis C testing algorithm.

Table 4.6.4. Hepatitis C IVD products in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

	Number of hepatitis C IVD products available in the country (**in parentheses:** number of those that are listed by WHO prequalification)							
	HCV self-testing	**Anti-HCV RDT**	**Laboratory-based anti-HCV**	**Laboratory-based HCVcAg**	**Laboratory-based HCV Ag/Ab**	**HCV RNA NAT**	**HCV RNA NAT for point-of-care**	**Multiplex RDT**
Cambodia		1 **(1)**				1 **(1)**	1 **(1)**	
China		2	5	4	3	2		2
Lao People's Democratic Republic		6 **(1)**				1 **(1)**		
Mongolia		14	4			1	1 **(1)**	
Vanuatu		1 **(1)**						

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Product prices

Hepatitis C RDT prices paid by select countries within the Western Pacific Region range between US$ 0.50 and US$ 1.00 *(45)*.

- Cambodia: US$ 0.83
- Mongolia: US$ 0.50–1.00

Only Viet Nam in the Western Pacific Region provided an indicative hepatitis C NAT price paid of US$ 35.00-56.40 *(45)*.

Cross-cutting aspects of viral hepatitis testing

Service delivery settings

Facility-based testing is the primary way for finding of people with hepatitis. All four reporting countries give priority to testing for hepatitis C in inpatient and outpatient settings. Cambodia, Mongolia and Vanuatu also give priority to routine testing in antenatal care.

Table 4.6.5. Service delivery settings for viral hepatitis testing in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Service delivery settings			
Cambodia	**Lao People's Democratic Republic**	**Mongolia**	**Vanuatu**
Primary clinics	Inpatient and outpatient settings	Primary clinics	Inpatient and outpatient settings
Inpatient and outpatient settings	Routine testing in antenatal care	Inpatient and outpatient settings	Routine testing in antenatal care
Routine testing in antenatal care	HIV service delivery points		
HIV service delivery points	TB clinics		
Harm-reduction services for people who inject drugs	Hepatology and gastroenterology clinics		
Occupational health services			
Hotspots			

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

National diagnostic planning and financing

All four reporting countries use government funding as a primary source of funding for viral hepatitis testing programmes. Cambodia, the Lao People's Democratic Republic and Mongolia also use out-of-pocket funding, and Cambodia and Vanuatu have additional bilateral support to finance their viral hepatitis testing programmes.

Product registration and availability

Of the five reporting countries, only Cambodia applies reliance principles of other conformity assessment bodies, regulatory authorities or other entities to expedite national regulatory approval and that is WHO prequalification.

4.6.2.2 Access to viral hepatitis medicines in the Western Pacific Region

Six of the eight WHO focus countries for the viral hepatitis response in the Western Pacific Region – Cambodia, China, Lao People's Democratic Republic, Mongolia, Vanuatu and Viet Nam – provided responses to the WHO 2023 survey on viral hepatitis medicines.

Hepatitis B medicines

All six focus countries in the Western Pacific Region for which this information was available have included TDF in national viral hepatitis guidelines and essential medicines lists. Three countries report TDF being available in primary health care.

Five countries have included ETV in viral hepatitis guidelines for both adults and children, and four countries have included ETV in essential medicines lists. TAF is included in guidelines in four countries. Fewer countries report ETV and TAF being available in primary health care versus the availability of TDF.

Generic TDF is registered in all six countries, and of these, two have registered a WHO-prequalified product. Four countries have registered generic ETV and TAF.

The prices paid for hepatitis B medicines in the Region vary, and some countries are paying more than the global benchmark of US$ 2.40 per 30 tablets from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. The lowest reported price of the last public sector procurement of a 30-day supply of generic TDF (300 mg) ranges between US$ 1.20 in China and US$ 10.00 in the Lao People's Democratic Republic. The price of a 30-day supply of ETV (0.5 mg) ranges between US$ 0.77 and US$ 18.00; and between US$ 1.30 and US$ 33.00 for TAF (25 mg). Hepatitis B medicines are locally produced in the Region in China and Viet Nam. Of the six focus countries, China and Niue are not included in the Gilead-MPP licensing agreement for TAF.

Four of the five countries for which this information was available provide hepatitis B testing and treatment free of charge in the public sector, either fully or partly for specific subpopulations.

Table 4.6.6. Access to TDF in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	TDF							
	National programme			Product registration		Price 300 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Cambodia	X	X	X		G			
China	X	X			27	46.12	1.22	X
Lao People's Democratic Republic	X	X			4		10.00	
Mongolia	X	X	X		1 **(1)**		3.90	
Vanuatu	X	X			1		3.30	
Viet Nam	X	X	X		76 **(4)**		2.10	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

G: generic TDF is registered, but the number or name of products is not specified.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.6.7. Access to ETV in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	ETV												
	National programme						Product registration				Price 0.5 mg, 30 tablets, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Cambodia	X	X		X	X			G		G		9.00[a]	
China	X	X	X	X	X		O	42	O	30	84.92	0.77	X
Lao People's Democratic Republic	X	X		X	X			1		1			
Mongolia	X	X	X		X	X		3		3		10.20	
Vanuatu													
Viet Nam		X		X	X		O	33			84.92	0.77	X

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
G: generic ETV is registered; but the number or name of products is not specified.
[a]Not specified whether this is originator or generic.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.6.8. Access to TAF in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	TAF							
	National programme			Product registration		Price 25 mg, 30 tablets, US$		Local production in the country
	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement	
Cambodia								
China		X			31	52.86	1.34	X
Lao People's Democratic Republic		X			2		17.00	X
Mongolia	X	X	X		2		10.20	
Vanuatu								
Viet Nam		X		O	7	54.00	33.00	X

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country. Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.6.9. Inclusion in licensing agreements for hepatitis B medicines in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	Inclusion in Gilead-MPP licensing agreement for TAF
Cambodia	Yes
China	**No**
Lao People's Democratic Republic	Yes
Mongolia	Yes
Niue	**No**
Philippines	Yes
Vanuatu	Yes
Viet Nam	Yes

TDF and ETV are off patent

Source: MPP.

Table 4.6.10. Availability of HBV testing and treatment services free of charge in the public sector in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

	Diagnosis of chronic HBV	Treatment	Liver staging – elastography	Liver staging – other
Cambodia	✓	✓		✓
Lao People's Democratic Republic				
Mongolia	✓	✓ (partial)		✓
Vanuatu	✓ (partial)	✓ (partial)		✓ (partial)
Viet Nam	✓	✓		✓

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Hepatitis C medicines

Four of the six focus countries in the Region for which this information was available included SOF and DAC (both or co-blistered or fixed-dose combination) in national guidelines for adults and one country, China, included only SOF. Three countries included SOF and DAC for children, and China included only SOF for children. Two countries reported these medicines being available in primary health care. China, the Lao People's Democratic Republic, Mongolia and Viet Nam have also included SOF/VEL in national guidelines for adults, but only Mongolia reports SOF/VEL being available in primary health care.

All four countries reported that SOF and DAC (both or co-blistered or fixed-dose combination) were registered in the country for adults. Only Cambodia reported having registered the SOF/DAC fixed-dose combination. Only one country, Mongolia, had registered these medicines for both adults and children. Four countries report having registered SOF/VEL for adults, and only two report product registration for children.

The prices paid for these medicines vary and are higher than the global benchmark of US$ 60 for a 12-week treatment course from the 2023 pricing agreement negotiated by The Hepatitis Fund and the Clinton Health Access Initiative. The lowest reported price of the last public sector procurement of generic SOF (400 mg) and DAC (60 mg) combined varies between US$ 84.00 in Cambodia, US$ 195.00 in the Lao People's Democratic Republic and more than US$ 10 000 in China for a 12-week supply. Among the focus countries in the Region, China and Niue are not included in the Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX, and China and Mongolia are not included in the AbbVie and MPP licensing agreement for G/P. Since 2021, China has been added to the list of additional countries that can access DAC under the Bristol-Myers Squibb and MPP licensing agreements.

Table 4.6.11. Access to SOF and DAC in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF and DAC both or SOF + DAC or SOF/DAC											
	National programme						Product registration				Price SOF 400 mg, DAC 60 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Cambodia	X	X	X	X				SOF: G DAC: G SOF/DAC: 1 **(1)**				SOF/DAC: 84.00	
China		X[S]			X[S]		O[S]	SOF: 5 DAC: 1	O[S]		SOF: 8257.20 DAC: 2203.24	SOF: 8232.00	X
Lao People's Democratic Republic	X	X		X	X							SOF/DAC: **195.00**	
Mongolia	X	X	X		X	X		SOF:2 **(2)** DAC:2 **(2)**[a]				SOF: **99.12** DAC: 49.56	
Vanuatu													
Viet Nam		X			X			SOF: 10 **(1)** DAC: 4 **(1)**				SOF: 781.20 DAC: 569.52	X

Model List of Essential Medicines: included in national essential medicines list. Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care. Originator: originator product is registered in the country.
Generic: generic products are registered in the country.
O[S]: SOF only. G: generic SOF and DAC are registered; but the number or name of products is not specified.
[a]Expired. Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.6.12. Access to SOF/VEL in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	SOF/VEL											
	National programme						Product registration				Price 400 + 100 mg 12-week supply, US$		Local production in the country
	Adults			Children			Adults		Children				
	Model List of Essential Medicines	Guidelines	Primary health care	Model List of Essential Medicines	Guidelines	Primary health care	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator	Generic (number) (**in parentheses**: number of WHO prequalification products)	Originator: lowest reported price of last public sector procurement	Generic: lowest reported price of last public sector procurement (**bold**: WHO prequalification product)	
Cambodia												600.00[a]	
China	X	X		X	X		O					2000.00[a]	
Lao People's Democratic Republic	X	X		X	X			1		1		375.00	
Mongolia	X	X	X					1		1			
Vanuatu													
Viet Nam		X			X		O	2 **(1)**			1948.80	940.80	

Model List of Essential Medicines: included in national essential medicines list.
Guidelines: included in national hepatitis guidelines.
Primary health care: available in primary health care.
Originator: originator product is registered in the country.
Generic: generic products are registered in the country.

O: originator product is registered.
[a]Other published data *(45)* (may not be comparable with data from WHO survey among focus countries for the viral hepatitis response, 2023).

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

Table 4.6.13. Inclusion in licensing agreements for hepatitis C medicines in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

Country	Gilead licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX	Bristol-Myers Squibb and MPP licensing agreement or patent withdrawal or lapse for DAC	AbbVie and MPP licensing agreement for G/P
Cambodia	Yes	Yes	Yes
China	**No**	Yes	**No**
Lao People's Democratic Republic	Yes	Yes	Yes
Mongolia	Yes	Yes	**No**
Niue	**No**	Yes	Yes
Philippines	Yes	Yes	Yes
Vanuatu	Yes	Yes	Yes
Viet Nam	Yes	Yes	Yes

Source: MPP.

Table 4.6.14. Availability of hepatitis C testing and treatment services free of charge in the public sector in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

	Self-testing	Diagnosis of chronic hepatitis C	Treatment	Liver staging – elastography	Liver staging – other	Confirmation of cure
Cambodia		✓	✓		✓	
Lao People's Democratic Republic						
Mongolia		✓	✓ (partial)			✓ (partial)
Vanuatu		✓ (partial)			✓	
Viet Nam		✓ (partial)	✓ (partial)	✓ (partial)	✓ (partial)	✓ (partial)

Shaded: service is free of charge in the public sector.
(partial): for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.6.2.3 Access to hepatitis B vaccination in the Western Pacific Region

All eight WHO focus countries in the Region have included the hepatitis B birth dose in the universal immunization programme. All countries also provide hepatitis B infant vaccination free of charge in the public sector.

Table 4.6.15. Access to hepatitis B birth dose and infant vaccination in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2022

Country	Hepatitis B birth dose introduced into universal immunization programme	Percentage coverage of hepatitis B birth dose	Percentage coverage of hepatitis B third dose
Cambodia	Yes	78	85
China	Yes	95	99
Lao People's Democratic Republic	Yes	65	80
Mongolia	Yes	98	95
Niue	Yes	93	99
Philippines	Yes	53	72
Vanuatu	Yes	69	68
Viet Nam	Yes	77	91

Source: WHO/UNICEF electronic Joint Reporting Form on Immunization, data from 2022.

Table 4.6.16. Availability of hepatitis B vaccination free of charge in the public sector in the Western Pacific Region, WHO focus countries for the viral hepatitis response, 2023

	Vaccination – birth dose	Vaccination –infancy
Cambodia	✓	✓
China[a]	✓	✓
Lao People's Democratic Republic	✓	✓
Mongolia		✓
Niuea	✓	✓
Philippines[a]	✓	✓
Vanuatu	✓ (partial)	✓
Viet Nam	✓	✓

Shaded: service is free of charge in the public sector.
[a]Information from WHO/UNICEF Joint Reporting Form on Immunization, data from 2022.
(partial) – for specific subpopulations or geographical regions and/or with co-payment.

Source: WHO survey among focus countries for the viral hepatitis response, 2023.

4.6.3 Regional achievements

Regional achievements since 2020 include the following.

- The Region has achieved significant progress in controlling hepatitis B through national vaccination programmes. As of 2022, 22 of the 37 countries and territories in the Region (60%) had achieved coverage of >90% for the hepatitis B third dose. The Region has also achieved the 2020 target of <1% HBsAg prevalence among children five years old and is on track to achieve the 2025 target of <0.5%, since 11 countries have already achieved this milestone.
- The number of countries that have developed viral hepatitis national strategic plans for eliminating hepatitis B and C by 2030 increased from four in 2014 to 22 in 2022. During 2021–2022, Cambodia, the Lao People's Democratic Republic, the Philippines, and Viet Nam developed (or updated) their national action plans with the support of WHO.
- Countries in the Western Pacific Region have committed to eliminating the mother-to-child transmission of HIV, syphilis and hepatitis B as a public health priority.
- Mongolia was among the seven WHO pilot studies conducted in 2021–2022 to evaluate the feasibility of accurately measuring the impact and programmatic targets for validating viral hepatitis elimination in a country. WHO is also collaborating with UNICEF and UNAIDS in the Region, in a joint partnership with the Nossal Institute for Global Health (University of Melbourne, Australia) to examine the progress in achieving triple elimination of mother-to-child transmission across nine countries in the Western Pacific Region.
- Several countries are making efforts to improve viral hepatitis data. The Western Pacific Region coordinates with the Centre for Disease Analysis Foundation to strengthen capacity to identify and measure gaps in viral hepatitis service coverage and quality. For example, the Philippines has conducted disease modelling and facilitated communication between the Chinese Center for Disease Control and Prevention and the Centre for Disease Analysis Foundation to develop modelling-based estimations for hepatitis C in China using the most recent data inputs. Mongolia and the Philippines have implemented national viral hepatitis seroprevalence surveys. Mongolia is also implementing sentinel surveillance for the sequelae of viral hepatitis such as liver cirrhosis and liver cancer.

4.6.4 Regional priorities for elimination

Regional priorities for eliminating viral hepatitis by 2030 include:

- tailoring screening and testing strategies to the diverse epidemic profiles in the Region, ranging from countries with a high burden of viral hepatitis such as China and the Philippines to small island countries with low disease burden but high vulnerability to health and natural disasters;
- developing a nationally coordinated and well-established model of care for viral hepatitis that integrates service delivery between the public and private sectors;
- integrating viral hepatitis services with related programme areas such as HIV and with primary health care, especially in the small island countries, and expanding the use of multi-disease diagnostic infrastructure;
- sustaining prevention interventions for hepatitis, including improving harm-reduction interventions, condom use, blood safety, safer injections and better infection control practices;
- sustaining the high coverage of the hepatitis B birth dose and at least two further doses of hepatitis B vaccine, especially in countries in which COVID-19 affected supply and delivery chains;
- raising political awareness on viral hepatitis and securing additional domestic financial commitments as part of universal health coverage packages;
- reducing the prices of viral hepatitis testing and treatment and making essential viral hepatitis services available free of charge;
- strengthening strategic information for viral hepatitis, including to identify geographical disparities and coverage gaps across the diverse countries in the Region and in relation to unreached groups in distant areas such as the remote Pacific islands with small island states;
- leveraging opportunities for external financing, such as for eliminating vertical transmission and harm reduction through the Global Fund and for hepatitis B vaccination through Gavi; and
- addressing stigma and discrimination towards people living with viral hepatitis.

4.6.5 WHO support for countries

WHO support has enhanced strategic planning and programme implementation in the Region, guided the development of integrated approaches to addressing viral hepatitis, and strengthened strategic information, including seroprevalence surveys. Since 2020, the key areas of WHO support have included:

- providing support for developing national strategic plans for viral hepatitis and conducting programme reviews, such as support for developing the Healthy Liver national programme 2022–2025 in Mongolia with revision of national guidelines and a situation assessment and sentinel surveillance for sequalae of viral hepatitis;
- providing support for adapting WHO guidelines for hepatitis testing and treatment at the country level, such as support for updating national guidelines for diagnosis and treatment for hepatitis C and developing a national action plan on micro-elimination of hepatitis C among key populations and people living with HIV in Viet Nam
- providing support for strengthening integrated care and treatment of viral hepatitis and establishing people-centred testing and service delivery models, such as in pilot sites in the Philippines and Viet Nam;
- developing a Regional Framework for Triple Elimination of Mother-to-Child Transmission of HIV, Hepatitis B and Syphilis in Asia and the Pacific, 2018–2030 and establishing a regional validation committee on elimination of mother-to-child transmission of HIV, hepatitis B and syphilis in the Region;
- in the context of the Regional Framework for Reaching the Unreached in the Western Pacific 2022–2030, supporting countries to develop contextually relevant national and local plans to ensure that the Region's health systems leave no one behind; and
- in collaboration with the Centre for Disease Analysis Foundation, strengthening country capacity to identify and measure gaps in service access, coverage and quality across the hepatitis B and C services cascade and to develop model-based estimates of disease burden.

Box 4.6.1

China

China represents one third of the global burden of hepatitis B and one fifth of the global burden of hepatitis C. China has recently developed a new national strategic plan to end viral hepatitis by 2030 and has committed to achieving triple elimination of vertical transmission of HIV, HBV and syphilis.

China introduced hepatitis B vaccines into the Expanded Programme on Immunization in 1992 and has implemented successive strategies to strengthen the prevention of vertical transmission of HBV in the country. According to data from the National Children Immunization Information System, the coverage of three doses of the hepatitis B vaccine has remained greater than 99% since 2008, and coverage of the timely birth dose has exceeded 95% since 2013. Further, China provides free HBsAg testing for all pregnant women under the national integrated programme for prevention of mother-to-child transmission of HIV, syphilis and hepatitis B. Building on a pilot project for eliminating HBV in the Hainan Province, China planned an initial round of validation in the first six provinces by the end of 2023, with the goal of validating two thirds of provinces for elimination by 2024 and all provinces by 2026 *(88)*. Access to treatment for HBV is increasing, supported by central price negotiations, national insurance coverage and pooled procurement of quality-assured off-patent medicines. The costs of locally manufactured TDF and ETV in China are among the lowest in the world.

In parallel, China has expanded efforts to expand prevention, testing and treatment for HCV. Sentinel hospitals across the country have been designated to manage HCV, and community methadone maintenance clinics are being used as a platform for integrated HIV and HCV prevention and treatment for key populations. Starting in 2020, several DAAs have been included in the national health insurance medicines reimbursement list. A national review of China's viral hepatitis response concluded that integrating hepatitis C with other infectious disease programmes and ensuring a stronger role of primary care in an integrated health-care delivery system would be important in scaling up a public health response to hepatitis C. Continued efforts are needed to fully remove the intellectual property barriers to producing and distributing SOF, with the aim of forming more competitive pangenotypic DAA combinations based on the locally developed DAAs. Further, a micro-elimination strategy with focused screening and proactive diagnosis and treatment for priority population groups may be a practical approach for China to advance towards the goal of eliminating hepatitis C *(89)*.

WHO is providing support to China to achieve these targets. The main areas of WHO support include working with the National Healthcare Security Administration to advocate for increased access to affordable drugs; raising awareness among the general public and reducing stigma; providing strategic advice for policy improvement and action planning; defining integrated service delivery models (including HIV, noncommunicable diseases, preventing vertical transmission and blood safety); strengthening strategic information and patient monitoring systems; and helping the government to eliminate mother-to-child transmission of hepatitis B, HIV and syphilis *(90)*.

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5.

Looking ahead: public health action to eliminate viral hepatitis in low- and middle-income countries by 2030

5. Looking ahead: public health action to eliminate viral hepatitis in low- and middle-income countries by 2030

This chapter presents 10 key areas of action in 2024–2026 to advance the implementation of a public health approach to viral hepatitis and get the response back on track by 2030 (Box 5.1).

The actions are organized by the strategic directions of the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections 2022–2030 *(4)* and will contribute to achieving the objectives of the strategies.

The actions are listed below. Table 5.1 describes them in further detail, with time frames and the role of various stakeholders in their implementation.

Box. 5.1. Ten actions to advance a public health approach

Strategic Direction 1:
Deliver high-quality, evidence based, people-centred services

- **Action 1.** Testing: expand access to high-quality, affordable viral hepatitis testing and diagnostics services
- **Action 2.** Treatment: shift from policies to implementation for equitable access to viral hepatitis treatment and care
- **Action 3.** Prevention: strengthen investment in primary prevention of viral hepatitis to bridge the coverage gap in pregnancy, especially in Africa

Strategic Direction 2:
Optimize systems, sectors and partnerships for impact

- **Action 4.** Service delivery: simplify and decentralize the delivery of viral hepatitis services through a public health approach
- **Action 5.** Product regulation, procurement and supply: optimize product registration, procurement and supply, improve market transparency and support local production
- **Action 6.** Investment cases: develop investment cases in priority countries for a rapid shift to a public health approach
- **Action 7.** Financing: increase innovative financing from all sources

Strategic Direction 3:
Generate and use data to drive decisions for action

- **Action 8.** Data for action: use improved country data and strengthen country data systems and accountability for viral hepatitis

Strategic Direction 4:
Engage empowered communities and civil society

- **Action 9.** Community engagement: engage the affected populations and civil society in the viral hepatitis response for advocacy and service delivery

Strategic Direction 5:
Foster innovations for impact

- **Action 10.** Innovation: advance the research agenda for viral hepatitis to improve diagnostics and work towards a hepatitis B cure

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
Strategic direction 1: Deliver high-quality evidence-based people-centred services										
Action 1. Testing: expand access to high-quality affordable viral hepatitis testing and diagnostics services										
1.1 Develop national viral hepatitis plans, policies and strategies where these are lacking	•	•		x	x			x	x	
1.2 Define screening strategies at country level (such as by geographical subregion or by population group) that would be most effective in the local epidemiological and country context	•	•		x	x			x	x	
1.3 Include quality-assured hepatitis B and C IVDs into national programmes and universal health coverage packages and provide viral hepatitis testing free of charge at all levels of the health system	•	•		x	x	x		x	x	
1.4 Consider diagnostic integration, for example, by optimizing existing infrastructure for NAT (such as multi-disease platforms that are already being used for other disease programme areas) and capacity developed in response to COVID-19 to reduce overall viral hepatitis testing programmatic costs and maximize hepatitis-specific funding by improving efficiency	•	•		x	x	x		x	x	
1.5 Apply innovative solutions to support broader access to testing, including community-based screening approaches, dried blood spot specimens for NAT, IVDs that can be used at or near to point-of-care and self-testing	•	•		x	x	x		x	x	
Action 2. Treatment: shift from policies to implementation for equitable access to viral hepatitis treatment and care										
2.1 Adopt national guidelines for viral hepatitis in accordance with updated WHO recommendations for adults, adolescents, children, pregnant women and priority populations	•	•		x	x				x	
2.2 Include viral hepatitis medicines in national essential medicines lists for adults and children		•		x	x				x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
2.3 Increase general health workforce competencies for a simplified public health approach to viral hepatitis at all levels of the health system, including primary health care workers, laboratory personnel and community health workers, with adapted training modules in all official United Nations languages	•	•		x	x		x	x	x	
2.4 Adopt policies to provide hepatitis B and C treatment services free of charge at all levels of the health system to expand treatment uptake	•	•		x	x	x				
2.5 Improve treatment retention and monitor hepatitis B and C treatment outcomes for people living with chronic viral hepatitis		•	•	x	x	x	x			
2.6 Strengthen linkage with services to address the chronic care needs of people living with viral hepatitis in an integrated manner, including services related to advanced liver disease and cancer care		•	•	x	x				x	
Action 3. Prevention: strengthen investment in primary prevention of viral hepatitis to bridge the coverage gap in pregnancy, especially in Africa										
3.1 Introduce the hepatitis B birth-dose vaccination in countries where this is not in place and combine routine treatment of pregnant women with the hepatitis B birth-dose vaccination, especially in regions such as sub-Saharan Africa with high hepatitis B incidence	•	•		x	x	x				
3.2 Adopt policies to provide the hepatitis B birth-dose and infant vaccination free of charge and leverage funding opportunities from partners, such as the opportunity from Gavi for support for the hepatitis B birth-dose vaccination in eligible countries		•	•	x	x	x				
3.3 Integrate viral hepatitis prevention into existing health systems and services, including blood transfusion services, immunization programmes, national cancer programmes, HIV services and harm-reduction services for people who inject drugs	•	•		x	x			x	x	
3.4 Leverage HIV and primary health care services and strengthen linkage with maternal and child health services to achieve triple elimination of mother-to-child transmission of HIV, syphilis and HBV	•	•		x	x				x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
Strategic direction 2: Optimize systems, sectors and partnerships for impact										
Action 4. Service delivery: simplify and decentralize the delivery of viral hepatitis services through a public health approach										
4.1 Simplify national hepatitis guidelines by removing prescription restrictions for viral hepatitis by non-specialists	•	•		x	x				x	
4.2 Adopt a simplified model of care for viral hepatitis integrating service delivery between the public and private sectors	•	•		x	x					
4.3 Decentralize viral hepatitis services and implement differentiated service delivery approaches, including through building capacity among primary-level health workers and providing integrated services and community-led delivery	•	•		x	x	x		x	x	
4.4 Strengthen the linkage of viral hepatitis services with other related services, including HIV, harm reduction, antenatal care and primary care	•	•		x	x				x	
4.5. Support community-based outreach to expand hepatitis B and C testing and treatment among key populations and other priority populations, including people living with HIV	•	•		x	x			x	x	
Action 5. Product regulation, procurement and supply: optimize product registration, procurement and supply, improve market transparency and support local production										
5.1 Leverage available tools to address intellectual property barriers for pangenotypic DAAs for hepatitis C treatment (SOF/DAC), including patent not being granted, inclusion in voluntary licensing agreements, patent oppositions and compulsory licences and utilize the off-patent status for hepatitis B medicines (TDF and ETV) or global price agreements and pooled procurement options, to enable generic competition and procure hepatitis B and C medicines at the lowest available market prices	•	•		x	x	x	x		x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
5.2 Assess and accelerate the registration of high-quality generic products for treating adults and children with hepatitis, including through the WHO collaborative procedure for accelerated registration	•	•		x	x		x		x	
5.3. Address regulatory barriers that prevent the registration of generic products if no originator products are registered, notably the fixed-dose combination of SOF/DAC, which does not have an originator manufacturer	•	•		x	x		x	x	x	
5.4 Address the variation in the prices paid for viral hepatitis medicines and diagnostics across countries in a region and across countries with the same income level by implementing pricing policies and procurement strategies that promote affordability	•	•		x	x	x	x	x	x	
5.5 Strengthen capacity for sustainable quality local production and technology transfer for affordable, safe, effective and quality-assured medicines (TDF, ETV for hepatitis B and DAAs such as SOF/DAC for hepatitis C), IVDs and vaccines through a holistic multistakeholder approach		•	•	x	x	x	x		x	
5.6 Improve the market transparency of prices and procurement of viral hepatitis commodities	•	•		x	x	x	x	x	x	
Action 6. Investment cases: develop investment cases in priority countries for a rapid shift to a public health approach										
6.1 Develop and update prioritized, costed and measurable national strategic plans with a focus on the African Region and on 10 priority countries – China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines and the Russian Federation	•	•		x	x	x			x	
6.2 Use investment cases for adopting national public health policy on hepatitis and mobilizing funding		•	•	x	x	x			x	
6.3 Support all countries, including WHO focus countries, across the six WHO regions to progress on the path to elimination			•	x	x	x			x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
Action 7. Financing: increase innovative financing from all sources										
7.1 Ensure that essential health packages or national health insurance schemes cover viral hepatitis services in the context of universal health coverage		•	•	x	x	x			x	
7.2 Unlock additional funding specifically for viral hepatitis by allocating additional government funding and/or seeking support from national, regional and international funding partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, Gavi, the United States President's Emergency Plan for AIDS Relief, The Hepatitis Fund, and other innovative financing strategies or public–private partnerships	•	•		x	x	x			x	
7.3. Support advocacy efforts at the highest policy-making levels for investing in viral hepatitis responses in the six WHO regions	•	•		x	x	x		x	x	
Strategic direction 3: Generate and use data to drive decisions for action										
Action 8. Data for action: use improved country data and strengthen country data systems and accountability for viral hepatitis										
8.1. Strengthen surveillance systems for viral hepatitis and improve linkage to related systems such as vital statistics, cancer registries, immunization and sexual and reproductive health	•	•		x	x				x	
8.2 Strengthen person-centred monitoring for prevention, testing and treatment of viral hepatitis services along the care cascade	•	•		x	x				x	
8.3 Promote disaggregated data collection and analysis by age, sex and priority population group affected by viral hepatitis		•	•	x	x			x	x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
8.4 Integrate and strengthen data collection and reporting on differentiated service delivery in hepatitis patient monitoring systems to improve treatment outcomes and programme efficiency		•	•	x	x				x	
8.5 Use patient-level data to inform commodity inventory, management, dispensing and procurement at the national and facility levels, thus reducing waste and stock-outs	•	•		x	x				x	
8.6 Build on existing accountability frameworks, including the global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections, to monitor and report on progress	•	•							x	
Strategic direction 4: Engage empowered communities and civil society										
Action 9. COMMUNITY ENGAGEMENT. Engage affected populations and civil society in the viral hepatitis response for advocacy and service delivery										
9.1 Adapt service delivery models to meet the needs of affected populations	•	•		x	x			x	x	x
9.2 Address the legal and policy barriers affected populations face in accessing viral hepatitis services	•	•		x	x			x	x	
9.3 Engage and support people living with viral hepatitis, communities and civil society in playing a central role in advocacy, policy-making, service delivery, monitoring and evaluation and research		•	•	x	x			x	x	x
9.4 Address stigma and discrimination towards people living with viral hepatitis		•	•	x	x			x	x	
9.5 Support community-led literacy, peer education and advocacy on hepatitis prevention, testing and treatment programmes	•	•		x	x			x	x	

Table 5.1. Actions to advance a public health approach to eliminate viral hepatitis in low- and middle-income countries by 2030 (continued)

Actions	Time frame			Stakeholders						
	Short	Medium	Long	National health authorities	Technical partners	Funding partners	Industry	Civil society	WHO	Research institutions
Strategic direction 5: Foster innovations for impact										
Action 10. Innovation: advance the research agenda for viral hepatitis to improve diagnostics and work towards a hepatitis B cure										
10.1 Advance research in improving IVDs suited for use in low- and middle-income settings, including integrated testing services, and in strategic testing approaches for viral hepatitis to increase access		•	•	x	x		x	x	x	x
10.2 Support research on optimal doses and formulations of viral hepatitis medicines, such as long-acting therapies for hepatitis B and C virus		•	•	x	x		x	x	x	x
10.3 Support hepatitis C vaccine research		•	•	x	x		x	x	x	x
10.4 Support hepatitis B cure research		•	•	x	x		x	x	x	x
10.5 Convene and facilitate a standing expert group to provide guidance on research priorities and enable timely adoption of research findings		•	•	x	x			x	x	x

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Annex

Annex. Low- and middle-income countries and territories not included in at least one voluntary licensing agreement for viral hepatitis medicines, 2023

The following tables provide information on the countries that are not included in at least one voluntary licensing agreement of the originator manufacturers of viral hepatitis medicines.

Hepatitis B

- Gilead and MPP voluntary licensing agreement for TAF

Hepatitis C

- Gilead voluntary licensing agreement for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX
- Bristol-Myers Squibb and MPP voluntary licensing agreement for DAC or patent withdrawal or lapse following the announcement in 2020 that the marketing authorizations for its originator product will be withdrawn or will be allowed to lapse in countries where the product is no longer routinely prescribed or where there are other therapeutic options available
- AbbVie and MPP voluntary licensing agreement for G/P

The countries in bold are among the 38 WHO focus countries for the viral hepatitis response.

African Region

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
Algeria	Upper middle		Yes	Yes	No

Region of the Americas

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
Argentina	Upper middle	No	No	No	No
Belize	Upper middle	Yes	Yes	No	Yes
Brazil	Upper middle	No	Yes	No	No
Colombia	Upper middle	No	Yes	No	No
Costa Rica	Upper middle	No	Yes	No	No
Dominican Republic	Upper middle	Yes	Yes	No	No
Ecuador	Upper middle	Yes	Yes	No	No
El Salvador	Lower middle	Yes	Yes	Yes	No
Grenada	Upper middle	Yes	Yes	No	Yes
Guatemala	Upper middle	Yes	Yes	Yes	No
Honduras	Lower middle	Yes	Yes	Yes	No
Jamaica	Upper middle	Yes	Yes	No	No
Mexico	Upper middle	No	Yes	No	No
Panama	Upper middle	No	Yes	No	No
Paraguay	Upper middle	No	Yes	Yes	No
Peru	Upper middle	No	Yes	No	No
Saint Lucia	Upper middle	Yes	Yes	No	Yes
Saint Vincent and the Grenadines	Upper middle	Yes	Yes	Yes	No
Venezuela (Bolivarian Republic of)	Upper middle	No	Yes	No	No

South-East Asia Region

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
India	Lower middle	Yes	Yes	Yes	No
Thailand	Upper middle	Yes	Yes	Yes	No

European Region

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
Azerbaijan	Upper middle	Yes	Yes	No	No
Belarus	Upper middle	Yes	Yes	Yes	No
Albania	Upper middle	No	Yes	No	No
Armenia	Lower middle	Yes	Yes	No	No
Bosnia and Herzegovina	Upper middle	No	Yes	No	No
Bulgaria	Upper middle	No	Yes	No	No
Croatia	Upper middle	No	No	No	No
Georgia	Lower middle	Yes	Yes	No	Yes
Kazakhstan	Upper middle	Yes	Yes	No	No
Kosovo[a]	Lower middle	No	Yes	No	No
Kyrgyzstan	Lower middle	Yes	Yes	Yes	No
Montenegro	Upper middle	No	Yes	No	No
Republic of Moldova	Lower middle	Yes	Yes	No	No
Romania	Upper middle	No	Yes	No	No
Russian Federation	Upper middle	No	No[b]	No	No
Serbia	Upper middle	No	Yes	No	No
Tajikistan	Lower middle	Yes	Yes	Yes	No
North Macedonia	Upper middle	No	Yes	No	No
Türkiye	Upper middle	No	Yes	No	No
Ukraine	Lower middle	Yes	Yes	Yes	No

[a]In accordance with United Nations Security Council resolution 1244 (1999).
[b]The Russian Federation has an exclusive licence from Bristol-Myers Squibb under which generic production is possible.

Eastern Mediterranean Region

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
Iran (Islamic Republic of)	Upper middle	No	No	No	No
Iraq	Upper middle	No	Yes	No	No
Jordan	Lower middle	No	Yes	No	Yes
Lebanon	Upper middle	No	Yes	No	No
Syrian Arab Republic	Lower middle	Yes	Yes	No	No
Yemen	Lower middle	Yes	Yes	No	Yes

Western Pacific Region

	Income category	Gilead voluntary licence for TAF	Bristol-Myers Squibb voluntary licence or patent withdrawal or lapse (DAC)	Gilead voluntary licence for SOF, SOF/VEL, SOF/LED and SOF/VEL/VOX)	AbbVie voluntary licence for G/P
China	Upper middle	No	Yes	No	No
Malaysia	Upper middle	Yes	Yes	Yes	No
Mongolia	Lower middle	Yes	Yes	Yes	No

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