2025 annual report

Department of Regulation and Prequalification

World Health Organization

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Foreword

Dr Rogério Gaspar, Director, Department of Regulation and Prequalification. © WHO

The year 2025 presented a pivotal moment for global health, marked by ongoing challenges and emerging threats. As nations continue to recover from the impacts of recent pandemics, focus is shifting towards strengthening healthcare systems, improving access to medical services and enhancing international cooperation. Climate change remains a significant concern exacerbating health risks such as the spread of infectious diseases, and the rise in non-communicable diseases needs particularly focused decision-making.

Additionally, disparities in healthcare between developed and developing countries persist, highlighting the urgent need for equitable distribution of resources and innovative solutions. Addressing these challenges require collaborative action, investment in research and a commitment to resilient and inclusive health policies.

Unfortunately, the start of 2025 was shaken by major disruptive decisions that could have jeopardized years of advancement in global health. Areas such as resource mobilization, long-term planning and commitment from key partners were challenged by the impact of WHO transformation which took place during the period from June to December 2025. The Department of Regulation and Prequalification faced every single of these challenges with resilience and the energy to implement adequate solutions, with clear focus on the need for continued high-level impact at country level.

Emerging from intensive COVID-19 response, we started preparation of a new and challenging cycle, accelerating the electronic prequalification portal, advancing the WHO Listed Authorities framework, the WHO regulatory Benchmarking Tool and other critical initiatives. We also developed and published the new Strategic Action Plan 2025-2028 which aligns with the WHO 14th General Programme of Work and the WHO Roadmap for Access. During 2025, in the ‘midst of a storm’ we never stopped the necessary responses and continued the medium and long-term strategic and operational planning for implementation of the mandate of the Department of Regulation and Prequalification.

The last years have certainly been challenging times for the UN specialized agency for health and for multilateral cooperation, and have marked a turn of history for the world. The Department of Regulation and Prequalification has been impacted both financially and in human capital. The departure of 35 experienced colleagues equals a considerable loss of knowledge and capacity to deliver the department’s mandate.

Their contribution to our work will not be forgotten.

Meanwhile, 2025 was also a time refocus our mission on what really matters: impact at country level. Through challenges we delivered solutions, starting by communicating closely with stakeholders, prioritizing, re-engineering procedures and changing mindsets.

Among different axis of action, we continue implementation of the reform of prequalification procedures by increasing transparency, improving efficiency, with better use of ePQS (live from May 19th 2025) and leveraging results already emerging from continuous improvement in consistency in methods of work and constant review of gaps in several prequalification product streams (now being extended to all product streams). We are also exploring the decentralization of certain regulatory functions to move services closer to Member States, with technical coordination from WHO Headquarters and focus on strengthening the capacity of WHO Regional and Country Offices.

Doing better with less seems impossible. It is certainly a challenge. Changing attitudes and streamlining procedures and quality-assurance processes are critical to bring back a stronger and more purpose-oriented Organization. The scope, KPIs and impact of our activities, expressed in the current report push impactful delivery to new frontiers. The intense transformational process that took place in WHO has only been possible with the strong professional ethics of colleagues. To them, my first and last words of recognition, encouragement and motivation to continue, as always, in the frontline of support to Member States.

We know how health systems are fragile in a significant number of Member States. We experience every day the need to solve critical gaps in equitable, timely and affordable access to safe, effective and quality-assured health products and technologies. We contribute every day to support Member States in building robust, resilient and reliable regulatory systems for health products and technologies. The new milestones reached in 2025 can only be surpassed in 2026. To achieve this, our commitment is to do better, and when needed, more, to achieve the objectives of universal health coverage for all and everywhere.

January 2026

Rogério Gaspar
Director
Department of Regulation and Prequalification

Acknowledgements

WHO would like to thank and acknowledge the collaborative nature and continued support of all our partners contributing to the important co-funding landscape which enables WHO to ensure the regulation of medical products across their life cycle:

Gavi, the Vaccine Alliance, the European Commission Directorate-General for International Partnerships, the Fleming Fund, the Gates Foundation, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Government of Belgium, the Government of Japan, the Government of the Republic of Korea, the Swiss Agency for Development and Cooperation, the Uppsala Monitoring Centre in Sweden, the United Nations Children's Fund and Unitaid.

All external engagements are collaborative in nature.

The Department of Regulation and Prequalification will continue to leverage the critical contributions of scientific and technical expertise and resources from extensive networks, advisor groups and task forces and build on the successful platform of the WHO Coalition of Interested Parties, now counting 33 partners.

We would also like to thank and acknowledge the important contributions of its WHO collaborating centres.

- Since 1977, the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre, Uppsala, Sweden
- Since 1985, the WHO Collaborating Centre for Diagnostics and Laboratory Support for HIV/AIDS and Other Blood-borne Infections; National Serology Reference Laboratory, St Vincent's Institute of Medical Research, Victoria, Australia
- Since 1986, the WHO Collaborating Centre for HIV/AIDS Diagnostics and Laboratory Support, Clinical Reference Laboratory, Institute of Tropical Medicine, Antwerp, Belgium

[The current report follows the structure of the previous Strategic Action Plan of the Department of Regulation and Prequalification since the new Strategic Action Plan was only introduced in July 2025.]

Abbreviations

AEFI	adverse event following immunization
API	active pharmaceutical ingredient
CCE	cold chain equipment
CRO	contract research organization
CRP	collaborative registration procedure
ePQS	electronic prequalification system
ERPD	Expert Review Panel for Diagnostics
EUL	emergency use listing
FDA	Food and Drug Administration
FPP	finished pharmaceutical product
GBT	WHO global benchmarking tool
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
IDP	institutional development plan
ImD	immunization device
IVD	in vitro diagnostic
ITN	insecticide-treated net
LMICs	low- and middle-income countries
ML	WHO maturity level
NAP	national action plan
NCL	national control laboratory
NRA	national regulatory authority
PHEIC	public health emergency of international concern
PQT	WHO Prequalification Team
PV	pharmacovigilance
QMS	quality management system
RDT	rapid diagnostic test
RSS	regulatory systems strengthening
SAV	snake antivenom
SBE	snakebite envenoming
SF	substandard and falsified
SRA	stringent regulatory authority
TB	tuberculosis
TSS	technical specifications series
UNICEF	United Nations Children's Fund
VAX	Vaccines
VCP	vector control product
WHO	World Health Organization
WHO-GNP	WHO Global Network of National Quality Control Laboratories for Pharmaceuticals
WHO-NNB	WHO National Control Laboratory Network for Biologicals
WLA	WHO Listed Authority

WHO Department of Regulation and Prequalification

"To support Member States in strengthening robust, resilient and reliable regulatory systems through diverse, tailored approaches that ensure the quality, safety, effectiveness and accessibility of medicines, vaccines and other essential health products supplied to low-income and other countries, reaching all populations in need."

Mandate of the WHO Department of Regulation and Prequalification

WHO has a unique role in improving access to safe, effective and quality assured health products and technologies, ensuring that more people attain the highest possible standard of health. Access to health products is considered essential for reaching universal health coverage and the principles of primary health care, and critical to ensure resilient health systems for emergency and pandemic preparedness and response.

The Department of Regulation and Prequalification provides two critical functions towards these goals: capacity-building to strengthen regulatory systems to ensure the quality and safety of health products throughout the life cycle, and the prequalification of health products needed by countries that have not yet established a robust, resilient and reliable regulatory authority.

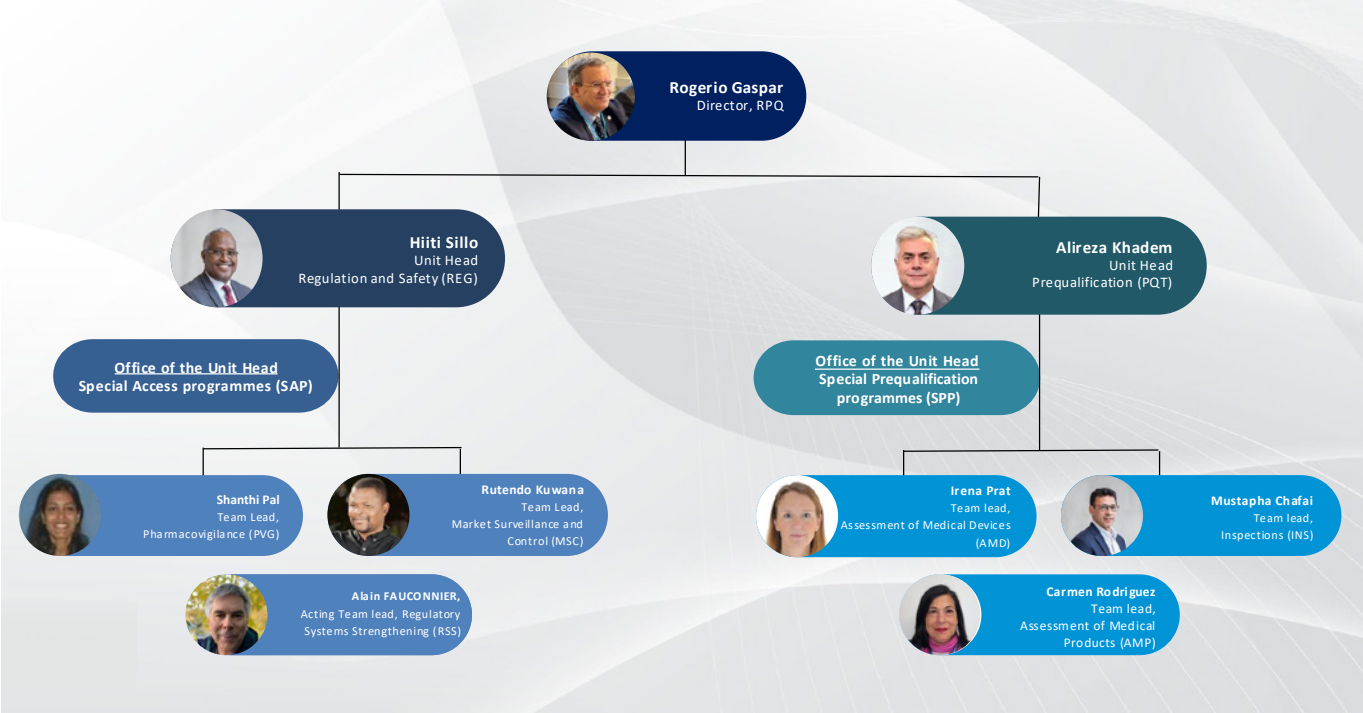
Dramatic cuts and changes in prioritization of Official Development Assistance led WHO to launch an organizational reprioritization in June 2025, to ensure focus on core functions and use its comparative advantage for biggest possible impact. Resulting from this reorganization, the Department of Regulation and Prequalification is now embedded as one of seven departments in the new WHO Health Systems, Access and Data Division.

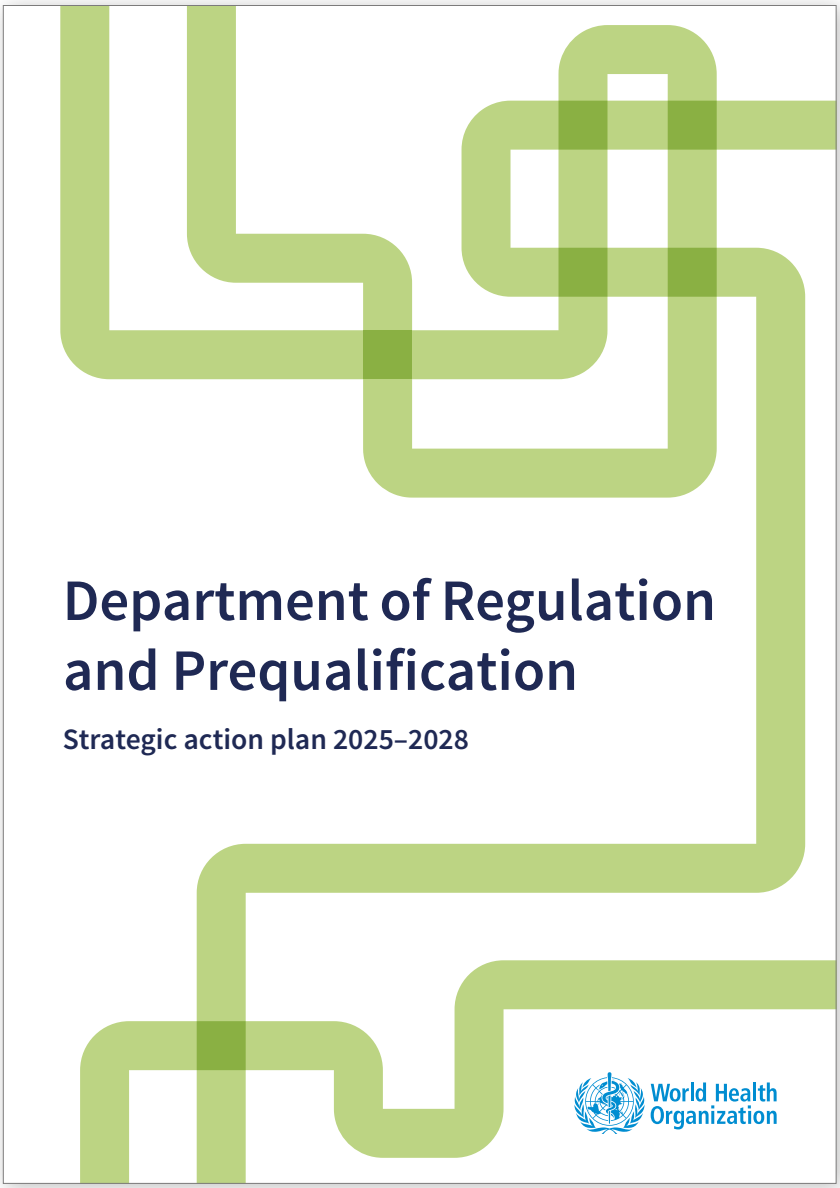
WHO's work in the area of access and regulation is guided by the WHO 14th General Programme of Work 2025–2028; the WHO Triple Billion Targets, the Health Emergency Preparedness and Response architecture, the Pandemic Agreement (adopted by WHO Member States in April 2025), relevant resolutions adopted by Member States in the World Health Assembly and by Roadmap for action 2025–2030: Access to safe, effective and quality-assured health products and technologies, presenting WHO's strategy for increasing access to safe, effective and quality-assured health products and technologies in order to reach Sustainable Development Goal targets for achieving universal health coverage.

Fig. 1. Health Systems, Access and Data Division Organigram as of December 2025

Note: Director positions for ACD and TMC remain vacant at this stage with the current transitional arrangements.

Fig. 2. Department of Regulation and Prequalification Organigram as of December 2025





Launch of new Strategic Action Plan 2025–2028

The Strategic Action Plan 2025–2028 for the Department of Regulation and Prequalification was launched in July 2025 providing a clear, forward-looking framework for strengthening regulatory systems and expanding access to quality-assured health products globally. Through five strategic priorities, the plan presents practical actions that cut across health system strengthening and disease-specific programmes, reinforcing regulation as a foundational enabler of public health impact. The plan supports coherent implementation across WHO while aligning closely with the strategies and operational needs of its main partners, or major global health actors. The mandate of the Department of Regulation and Prequalification and the Strategic Action Plan 2025–2028 support a long-term-transition from prequalification towards functional national and regional regulatory capacities, through a process of regulatory system strengthening, harmonization, reliance, convergence and networking.

Fig. 2. Snapshot of strategic priorities

SP 1: Strengthen country and regional regulatory systems in line with the drive towards UHC
SP 1.1: Implement regulation in an increasing number of countries through reliance and national regulatory authority networks
SP 1.2: Increase regulatory convergence through wider implementation of WHO quality standards
SP 1.3: Strengthen national regulatory capacity to ensure quality of medical products
SP 1.4: Strengthen pharmaceutical sector capacity, especially in countries that manufacture products for LMICs and/or local supply
SP 1.5: Strengthen safety surveillance to support and safeguard uptake of new innovative products by LMICs
SP 1.6: Improve prevention, detection and response to substandard and falsified medical products
SP 1.7: Regulatory convergence is facilitated through the convening power of WHO
SP 2: Increase regulatory preparedness for public health emergencies
SP 2.1: Strengthen national and regional regulatory procedure for risk-based evaluation during public health emergencies (PHE)
SP 2.2: Increase WHO's capacity to support regulatory preparedness for PHEs
SP 2.3: Increase the number of countries that have adapted their regulatory preparedness for PHEs and are using regional networks for expedited evaluation
SP 2.4: Streamline PQ processes to support public health emergencies, shortages and other public health needs
SP 3: Strengthen and expand WHO prequalification and product risk assessment processes
SP 3.1: Improve efficiency, capacity and awareness
SP 3.2: Strengthen and expand WHO's prequalification lists
SP 3.3: Expand prequalification and risk assessment pathways via collaborations and reliance mechanisms
SP 3.4: Expand the range eligible for prequalification
SP 4: Increase the scope and impact of WHO's regulatory support activities
SP 4.1: Ensure that WHO's regulatory support capacity and resources are sufficient to implement RPQ's strategic priorities
SP 4.2: Improve targeting and alignment of WHO regulatory support activities
SP 4.3: Enhance monitoring of WHO's impact on regulation of and access to medi
SP 4.4: Establish and initiate implementation of a QMS
SP 5: Optimize operational and accountability processes for greater country
SP 5.1: Develop and publish action plans and annual reports
SP 5.2: Develop a communication strategy to include tools such as a newsletter ta stakeholder group, providing regular updates of activities, events and accomplish
SP 5.3: Develop and implement a knowledge management framework to streamli
SP 5.4: Demonstrate continuous improvement though ongoing implementation of a
SP 5.5: Collaborate with WHO Communications team to proactively share insights and alignment with WHO's goals and objectives
SP 5.6: Develop an electronic system to track and monitor activities associated wi the ePQS for submission monitoring and tracking
SP 5.7: Analyze existing PQ fee structure and recommendations to update this mo including PQT/VCP which to date has not charged for service

Fig. 8. Way forward

2025 at a glance

Prequalification of medicines

- 29 finished pharmaceutical products
- 3 biotherapeutic products
- 12 active pharmaceutical ingredients
- First-in-class and first-time listings including:
  - Lenacapavir tablet and injectable for HIV/AIDS treatment
  - DMPA SubQ, the first generic self-injectable contraception
  - Tuberculosis skin test
  - Caffeine citrate injection for treatment of apnea in preterm infants
  - 2 new sources of rifampicin active pharmaceutical ingredient for the manufacture of anti-tuberculosis medicines

Prequalification of in vitro diagnostics

- 13 in vitro diagnostics prequalified with 3 first time listings
- 8 in vitro diagnostics for mpox listed under the Emergency Use Listing
- The first-time transition of 2 in vitro diagnostics from Emergency Use Listing to full prequalification
- The launch of the parallel process for prequalification and guideline development of in vitro diagnostics
- A revised prequalification procedure for in vitro diagnostics ready for launch in 2026
- A revised change procedure for in vitro diagnostics implemented

Prequalification of immunization devices

- WHO Immunization Devices strategy 2025–2030 published in July 2025
- 3 new temperature monitoring device laboratories accredited to manage high volume of applications

WHO National Control Laboratory Network for Biologicals

- 3 new members in 2025, expanding to 60 member laboratories, including 23 full members and 37 associate members since its establishment in 2017
- Updated Laboratory Information Management System (version 2.0)

Collaborative Registration Procedure

- 198 new CRP registrations in 2025 (1712 in total for all cumulative registrations)
- Reactivation of the prequalification CRP for vaccines with first approval obtained in 23 working days; 11 procedures ongoing
- Launch of prequalification CRP for vector control products on 5 June 2025
- Increased interest in CRP in PAHO/AMRO and EMRO regions;
- 9 new countries joined CRP (Burkina Faso, Cameroon, El Salvador, the Gambia, Honduras, Mali, Montenegro, Serbia, Sri Lanka)

WHO Global Network of Quality Control Laboratories for Pharmaceuticals

- Launched in 2024, welcomed 21 new members in 2025, across 20 countries
- Second annual meeting held and development of network SharePoint

Regulatory capacity and learning

- 64 learning solutions delivered, reaching 1978 learners worldwide (excluding e-learning)
- Strong participation from low- and middle-income countries, with 56% female trainees
- Expanded use of on-the-job training, WHO Rotational Fellowship and virtual delivery models

Vector control product prequalification and CRP

- 9 vector control products prequalified with a ~50% reduction in time to prequalification with 28 insecticide-treated nets under reassessment
- First time prequalification of spatial emanators demonstrated to repel, disorient and kill mosquitoes which may transmit malaria

Regulatory strengthening

- Ethiopia formally recognized for achievement of Maturity Level 3, which defines a stable and well-functioning regulatory system
- 24 self- and formal benchmarking of national regulatory authorities
- 488 regulators trained based on needs in Institutional Development Plans

Emergency preparedness and diagnostics

- Overall 12 mpox virus nucleic acid assays granted Emergency Use Listing following 43 pre-submission consultations with manufacturers

Prequalification of vaccines

- 9 prequalified vaccines
- 2 COVID-19 vaccines transitioned from Emergency Use Listing to full WHO prequalification and one under prequalification assessment
- 138 post-prequalification variations were assessed, and 182 prequalification annual reports assessed and approved

Digital transformation of prequalification

- Electronic Prequalification System portal launched for applicants in May 2025, enabling secure online submission, tracking, and communication, including first-ever receipt of eCTD-formatted dossiers
- Steady flow of registrants for the portal with file applications becoming compulsory in 2026

Technical support to the operationalization of the African Medicines Agency

- Continued technical assistance, support to development of guidelines and capacity-building and WHO Rotational Fellowship Programme
- 10 assessors from the AMRH/AMA continental pool serving as prequalification assessors and 3 regional assessors/inspector engaged as prequalification rotational fellows

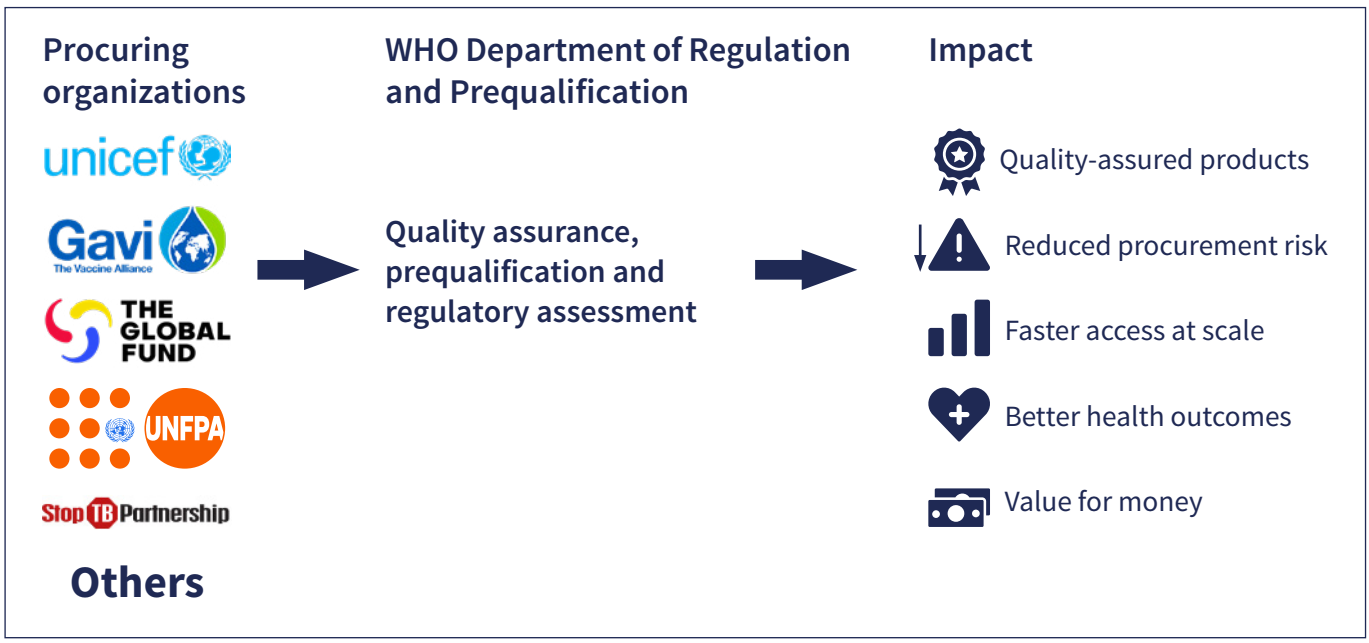
Pharmacovigilance

- Global smart pharmacovigilance strategy published
- Vaccines, thimerosal and autism spectrum disorder: report published confirming vaccines do not cause autism

Impact

Safeguarding global health investments

The Department of Regulation and Prequalification plays a critical role in safeguarding the return on investment of global health procurement by ensuring that products purchased with donor and public funds meet internationally recognized standards of quality, safety and performance. Major global procurers – including the Global Fund to Fight AIDS, Tuberculosis and Malaria, Gavi, the Vaccine Alliance, the United Nations Children's Fund, the Global Drug Facility, the United Nations Population Fund and others collectively invest billions of US dollars each year in essential medical products. WHO's independent prequalification and risk-based assessment functions help to reduce procurement risk, strengthen confidence in supply chains and support informed purchasing decisions and overall maximize the health impact and value for money of global health financing.



Delivering in times of disruption

The 2025 Joint WHO-UNICEF-UNFPA annual meeting with manufacturers took place virtually in September/ October 2025 with the attendance of over 990 participants including manufacturers and suppliers of in vitro diagnostic products, vaccines and immunization devices, finished pharmaceutical products, active pharmaceutical ingredients, contraceptive devices and vector control products. Under the theme 'Delivering in Times of Disruption: Building resilient, quality supply systems for sustainable impact', participants shared updates on regulation and safety, norms and standards and issues related to access, supply financing and procurement. These Joint WHO-UNICEF-UNFPA meetings have served as an important platform for collaboration and updates and discussion on crucial topics since 2012. In future, WHO plans to return to hybrid format and in locations closer to the highest concentration of manufacturers supporting low-and middle-income countries.

Risk-based assessment to speed up access to medical products for neglected tropical diseases

WHO's risk-based assessment approach helps close critical access gaps for neglected tropical diseases, by enabling time-limited, evidence-based recommendations for products not covered under standard prequalification pathways. Applying this approach to lymphatic filariasis, visceral leishmaniasis and dengue fever recently resulted in the listing of eight diagnostics and two medicines, informing procurement decisions and expanding access to quality-assured products in priority settings. For lymphatic filariasis, following WHO review and recommendation, 2 million rapid diagnostic tests were procured and supplied to 48 countries in 2025, contributing to meet the global targets set out in the Global Roadmap for Neglected Tropical Diseases 2021–2030. WHO's ground-breaking risk-benefit assessment for snake antivenoms used in the treatment of snakebite envenoming provides evidence of efficacy and safety for products used in high-risk communities across the African Region, Eastern Mediterranean Region and South-East Asia Region.

2025: A record year for WHO in vitro diagnostics quality assurance

In 2025, WHO prequalified a record 13 in vitro diagnostics, including several important firsts such as first HIV test using urine samples, the first antenatal care panel, the first triple diagnostic test for HIV, hepatitis B and syphilis and the first two SARS-CoV-2 diagnostics to transition from Emergency Use Listing to full prequalification, marking a critical step from emergency response to long-term quality assurance. In addition, eight in vitro diagnostics were listed under the Emergency Use Listing Procedure, bringing the total number of products listed across prequalification and Emergency Use Listing to 21, the highest number achieved in a single year. This record-setting performance includes multiple mpox assays, with the total number of Emergency Use Listing listed MPXV assays now reaching 12. Through WHO prequalification and Emergency Use Listing, these products undergo rigorous quality assessment, which is critical for safeguarding public health, expanding access to essential diagnostics and supporting health systems in low- and middle-income countries. These efforts help protect the most vulnerable populations and advance progress toward universal health coverage.

Major milestones in accelerating access to quality-assured medicines

WHO prequalification remains a globally trusted signal of safety, quality and efficacy or performance across the medical product supply chain. As of 2025, nearly 1750 medical products are either prequalified or recommended through Emergency Use Listing. According to the Global Fund to Fight AIDS, Tuberculosis and Malaria, in 2024, 26 million people accessed ARVs, 11 million received tuberculosis treatment, and 170 million malaria cases were treated, with 18 million women receiving preventive malaria therapy. According to UNITAID, scale-up of optimal HIV treatments and malaria prevention averted 86 million infections and 930 000 deaths, generating US$10 billion in savings. This demonstrates a substantial return on investment for global procurement of medical products, the efforts of global health initiatives and ultimately the considerable public health impact.

Cornerstone of global health product quality assurance

WHO prequalification inspection services remain a critical pillar of global health product quality assurance, performing prequalification and post-prequalification inspections of manufacturers across most product streams – pharmaceuticals, active pharmaceutical ingredients, vaccines, vector control products, medical devices, in vitro diagnostics as well as contract research organizations and national quality control laboratories. In 2025, WHO conducted 186 inspections using onsite (135), desk-based (50) and remote real-time (1) approaches and published 111 WHO Public Inspection Reports now available on the WHO Prequalification website. A hybrid assessment model (combining online inspection and desk-based assessment) was piloted to maintain continuity of oversight when on-site inspections were not feasible. In addition, post-market surveillance activities – including the review of recalls, complaints, and reported quality defects – were used to identify potential systemic weaknesses, emerging trends, and areas requiring corrective and preventive action to strengthen ongoing compliance with good manufacturing practice of relevant manufacturers.

WHO prequalifies first maternal respiratory syncytial virus vaccine to protect infants

WHO prequalified 9 vaccines in 2025, including the first respiratory syncytial virus vaccine, two additional polio vaccines (OPV and sIPV), and new vaccines for cholera, hepatitis B and pneumococcal disease, expanding the range of quality-assured vaccines available for use in low- and middle-income countries. More than 2.8 billion doses of WHO-prequalified vaccines were delivered to 99 countries, primarily through routine immunization programmes targeting young children. Since 2000, immunization programmes using WHO-prequalified vaccines have contributed to an estimated 20.6 million deaths averted. Maternal respiratory syncytial virus vaccination is already reducing severe disease and hospitalizations among newborns and young infants, while deployment of more than 1.5 billion prequalified polio vaccine doses has supported continued reductions in global polio cases. In addition, over 100 million children were immunized against measles using WHO-prequalified vaccines, preventing illness and saving lives.

Ethiopia reaches WHO Maturity Level 3 in medicines regulation

Ethiopia has achieved WHO Maturity Level 3 for medicines regulation, marking a major milestone in strengthening national regulatory capacity. The designation recognizes the Ethiopian Food and Drug Authority's ability to ensure the quality, safety and efficacy of medicines and imported vaccines through a stable and well-functioning regulatory system, following a comprehensive WHO assessment using the Global Benchmarking Tool. Ethiopia now joins Egypt, Ghana, Nigeria, Rwanda, Senegal, South Africa, the United Republic of Tanzania and Zimbabwe among African countries that have reached Maturity Level 3, supporting greater regulatory convergence and improved access to quality-assured health products across the region.

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Lenacapavir approved in the initial 6 African countries in record time through WHO Collaborative Registration Procedures and WHO Listed Authorities

On 4 November 2025, the Zambia Medicines Regulatory Authority approved lenacapavir tablets and injectable formulations for HIV prevention after just 12 working days of review, drawing on the WHO Collaborative Registration Procedures which allow rapid decision-making by leveraging the assessment of trusted regulatory authorities, i.e. WHO Listed Authorities. Shortly thereafter, the Medicines Control Authority of Zimbabwe completed its review in 18 working days. Lenacapavir was also approved in an accelerated manner in Botswana, Malawi, Rwanda and Tanzania in 2025. These rapid approvals demonstrate the value of regulatory reliance in accelerating access to innovative health products and highlight a practical pathway to expanding next-generation HIV prevention options across Africa.

Australia, Canada, Indonesia, Japan and the United Kingdom achieve status as WHO Listed Authorities

In 2025, Australia, Canada, Indonesia, Japan and the United Kingdom have been recognized by WHO as listed authorities for medical products regulation, marking a significant milestone in global regulatory excellence. Their inclusion brings the WHO Listed Authorities network to 41 authorities across 38 countries, reflecting growing confidence in diverse regulatory systems. The WHO Listed Authorities framework supports regulatory reliance, reduces duplication and accelerates access to safe, quality-assured medicines and vaccines, strengthening collaboration and supply chain resilience worldwide.

> **By expanding and diversifying the network of listed authorities, WHO and its Member States are moving closer to a more inclusive, efficient and globally connected regulatory ecosystem – one that supports equitable and timely access to safe, effective and quality-assured health products for all, everywhere.**
>
> **Dr Yukiko Nakatani,** *WHO Assistant Director-General for Health Systems, Access and Data*

Building a skilled regulatory workforce at global scale

WHO strengthened regulatory systems by investing in people. Through 64 targeted learning solutions spanning assessment, inspection, laboratory oversight and safety surveillance, WHO supported 1978 regulators worldwide, excluding those trained through e-learning. Training focused on practical, applied skills aligned with real regulatory gaps, with more than 40% of the training investment supporting on-the-job learning, including coached audits, joint inspections and rotational fellowships. The African Region received the largest share of activities, reflecting priority capacity needs, and 56% of participants worldwide were women, supporting a more inclusive and sustainable regulatory workforce. New training offers addressed urgent risks such as crisis communication for substandard and falsified medical products and detection of toxic substances like diethylene glycol and ethylene glycol in high-risk excipients. Delivered in collaboration with the WHO Academy and partner authorities such as Swissmedic, these efforts directly supported Institutional Development Plans, benchmarking and reliance, reinforcing WHO's impact where it matters most: stronger national regulators making better decisions, faster, for public health.

Contribution to building climate-resilient and environmentally sustainable health systems

Climate change is widely recognized as the single greatest health threat facing humanity. This is reflected in major multilateral agreements and policy frameworks, including the United Nations Framework Convention on Climate Change, the Paris Agreement on Climate Change, ongoing Plastic Treaty negotiations and World Health Assembly resolutions WHA 76.17 and WHA 77.14, as well as in numerous global strategies and action plans.

Avoidable environmental risks are estimated to account for approximately one quarter of the global burden of disease and premature mortality. There is now broad consensus on the priority actions required to address climate-related health risks, as articulated in the WHO Global Strategy on Health, Environment and Climate Change, the Joint WHO-World Meteorological Organization Collaboration Framework on Climate, Environment and Health and, most recently, the Belém Health Action Plan launched at COP30 in November 2025. The importance of sustained investment in climate stability and environmental sustainability was further reaffirmed by the United Nations Environment Assembly in Nairobi on 9 December 2025.

Health systems represent the frontline of protection against emerging climate and environmental threats. WHO supports countries in strengthening human and institutional capacities to build climate-resilient and environmentally sustainable health systems, and the Department of Regulation and Prequalification contributes to this agenda in multiple ways.

In December 2024, WHO launched the Greener Pharmaceuticals Regulatory Highway initiative, calling on national regulatory authorities and the wider regulatory community to consider the establishment of standards and guidance that support innovative approaches to the manufacturing, distribution and use of medical products to reduce environmental and carbon footprints, promote digital transformation of regulatory services and adopt more streamlined and efficient regulatory procedures.

In collaboration with Unitaid, WHO is developing a White Paper examining the challenges and opportunities for regulation of medical products for regulators to play a more active role in accelerating decarbonization. In parallel, WHO is updating key normative guidance, including Good Manufacturing Practices for pharmaceuticals, guidelines on packaging and disposal of medicines and medical device policies and procurement guidance, with the aim of addressing environmental impacts across manufacturing, supply and procurement chains. The WHO Prequalification Team is also advancing decarbonization objectives through its assessment processes for pharmaceuticals and vector control products.

Collaboration across the United Nations System

The United Nations is a network of entities and specialized agencies, each with its unique mandate and focus area, working together towards peace, security, development and human rights globally. WHO including the Department of Regulation and Prequalification contribute to the work across the United Nations System.

Contribution to the realization of health as a human right

The United Nations Office of the High Commissioner for Human Rights and international treaty bodies

The right to health is recognized in the Universal Declaration of Human Rights (1948), the International Covenant on Economic, Social and Cultural Rights (1966), the United Nations Declaration on the Right to Development (1986) and other human rights treaties. More specifically, equitable access to good-quality, safe and efficacious medicines as fundamental to the right to health was reinforced by Human Rights Council resolutions in 2009, 2011, 2022 and most recently discussed in the Human Rights Council meeting in July 2025.

The right to the highest attainable standard of health as expressed in WHO's Constitution underpins all WHO's work. Through its important functions to improve access to safe and quality health products, the Department of Regulation and Prequalification contributes to advance universal health coverage and the principles of primary health care, as key contributions to the realization of the right to health.

Contribution to high-level agenda of the United Nations General Assembly

The UN General Assembly holds its annual meeting in September with focus on specific themes and related high-level events. The Department of Regulation and Prequalification contributes to these, most notably to:

- the high-level meetings of the United Nations General Assembly on the Prevention and Control of Noncommunicable Disease in 2015, 2018, 2019 and 2025, following the adoption of the Global action plan for the prevention and control of noncommunicable diseases 2013–2030
- the high-level meetings of the United Nations General Assembly on universal health coverage 2019 and 2023, with the subsequent adoption of the Political declaration on universal health coverage.

Contribution to the work of the wider United Nations

In the context of the wider United Nations system, the Department of Regulation and Prequalification provides scientific advice and collaborates across the United Nations specialized agencies including with:

- The United Nations Children's Fund in the area of immunization and children's health;
- The United Nations Populations Fund in the area of reproductive medicines;
- The Joint United Nations Programme on HIV/AIDS in the area of HIV prevention and treatment;
- The United Nations Development Programme in influencing policy, legal and regulatory environments in support of access to medicines and health products;
- The United Nations Food and Agricultural Organization in the area of pest and vector control;
- The United Nations Office for Drugs and Crimes in the area of combatting substandard and falsified medical products-related crimes.

Strategic priority 1

Strengthen country and regional regulatory systems in line with the drive towards universal health coverage

In 2014 the World Health Assembly adopted resolution WHA 67.20 on Regulatory System Strengthening, recognizing and reinforcing the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related Sustainable Development Goals and Universal Health Coverage. Since the introduction of the five-step capacity-building programme to strengthen national regulatory authorities in 1996, WHO has operated a dual and inter-linked systems of quality-assurance through prequalification and regulatory capacity-building.

Effective regulation underpins access to safe, effective, and quality-assured medicines and health products, supports resilient health systems, and enables countries to respond to both routine health needs and public health emergencies. As reflected in recent regulatory status assessments and regional regulatory strengthening discussions, progress has been made through reliance, work-sharing and convergence approaches. However, many countries still lack sufficient capacity to invest in the development and maintenance of robust, resilient and reliable regulatory systems needed to oversee today's increasingly diverse and complex medicines and health products. Collectively, these approaches strengthen regulatory reliance, support informed national decision-making, and contribute to timely access to quality-assured medical products.

Strategic priority 1.1. Implement regulation in an increasing number of countries through reliance and national regulatory authority networks

Regulatory reliance has been a cornerstone of WHO's regulatory strengthening approach for more than two decades, dating back to year 2000 when it was requested that the national regulatory authority of a vaccine-producing country be assessed as "functional," revolutionizing the impact of WHO efforts to strengthen vaccine regulation capacity, especially in low-and middle-income countries. Subsequent revisions to WHO prequalification procedures increased collaboration with national authorities and reliance on regulatory assessments, inspection reports and test results generated by those authorities.

198
new registrations through collaborative regulatory procedures

23
working days for vaccine prequalification approval

39
regulatory authorities evaluated under the WHO Listed Authorities framework

12
products recommended through regional joint assessments

17
reliance-based post-authorization change pilots implemented

These principles were further strengthened in 2012, as WHO adapted regulatory approaches to address the growing volume, cost and complexity of new vaccines, and again with the launch of the Collaborative Registration Procedures in 2013, and the subsequent introduction of the framework of a WHO Listed Authority in 2022, as a pathway for national regulatory authorities operating at an advanced level of performance to be globally recognized, replacing the principles of stringent regulatory authorities.

WHO continues its efforts to strengthen and expand the Collaborative Registration Procedure mechanism, including joint regulatory assessments; promote the concept of WHO Listed Authorities, initiate and manage global and regional platforms for discussions on regulatory convergence and harmonization of regulatory requirements and strengthen the capacity of national quality control laboratories to monitor the quality of medicines, vaccines and in vitro diagnostic devices.

Collaborative Registration Procedures

Introduced in 2013, the Collaborative Registration Procedures is grounded in the principle of regulatory reliance and promotes cooperation and information-sharing among participating national regulatory authorities, enabling more efficient, evidence-based decisions while reducing duplication of effort and supporting regulatory capacity-building.

Interest in the Collaborative Registration Procedures continued to grow during 2025, with expansion across regions, particularly in the Region of the Americas and the Eastern Mediterranean Region. Globally, nine new countries joined the CRP mechanism across medicines, vaccines, in vitro diagnostic devices, vector control products and pathways linked to the WHO Listed Authorities framework.

In the **Region of the Americas,** following a regional workshop for 10 countries, two new countries joined the CRP in 2025; a total of three countries and one regional economic community, CARICOM now participating. In the **Eastern Mediterranean Region,** increased technical dialogue reflected growing interest in reliance-based approaches to improve regulatory efficiency.

As of December 2025, 69 national regulatory authorities and the regional economic community of CARICOM participated in the WHO Prequalification CRP for medicines and vaccines, 68 regulatory authorities and CARICOM participated in the Stringent Regulatory Authority CRP for medicines and vaccines; 41 regulatory authorities participated in the WHO Prequalification CRP for in vitro diagnostics and seven regulatory authorities participated in the WHO Prequalification CRP for vector control products. In total, 198 new registrations were made through CRP in 2025, including 115 registrations for WHO Prequalification medicines and vaccines, 38 for WHO Prequalification in vitro diagnostics, 41 for SRA CRP medicines and vaccines, and 4 for vector control products.

9 countries

Burkina Faso, Cameroon, El Salvador, the Gambia, Honduras, Mali, Montenegro, Serbia, Sri Lanka

2 countries

Honduras and El Salvador joined PQ CRP medicines and vaccines, in vitro diagnostics and WLA CRP

1 country

Serbia joined PQ CRP medicines and vaccines and WLA CRP

1 country

Montenegro joined WLA CRP

2 countries

Montenegro and Sierra Leone joined WLA CRP

4 countries

Burkina Faso, Cameroon, Mali and Sri Lanka joined PQ CRP for in vitro diagnostics

1 country

The Gambia joined PQ CRP vector control products

Important programmatic advances

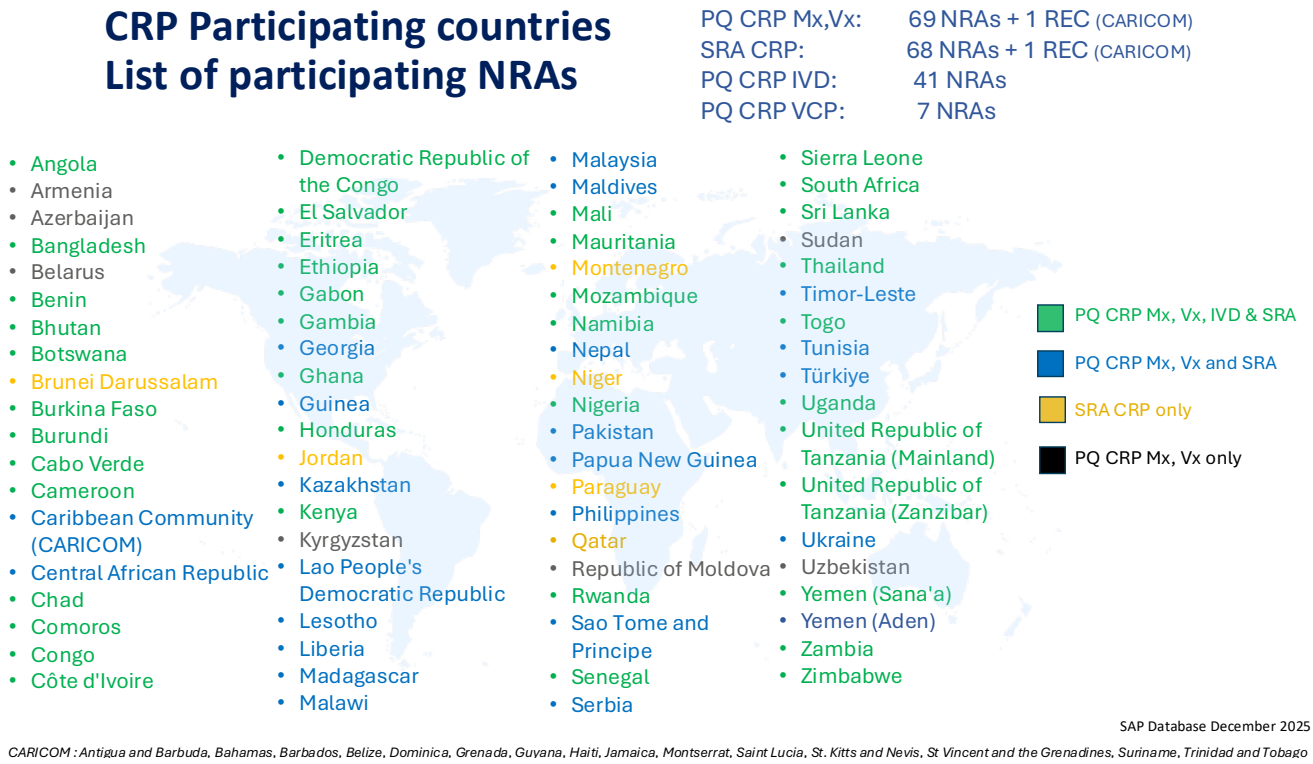
WHO reactivated the WHO Collaborative Registration Procedure for prequalified vaccines, with the first approval completed in 23 working days and 11 procedures ongoing at year-end. In June 2025, a new WHO collaborative registration pathway for vector control products was launched, extending reliance-based approaches to products critical for disease prevention and control.

Guidance and tools

WHO also strengthened reliance through development and refinement of regulatory guidance and procedures, addressing an expanding and increasingly diverse range of medical products. Following public consultation, new regulatory considerations for medical oxygen were adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2025, reflecting regulation of a widening range of medical products.

Fig. 3. Publication on accelerating access to vector control products

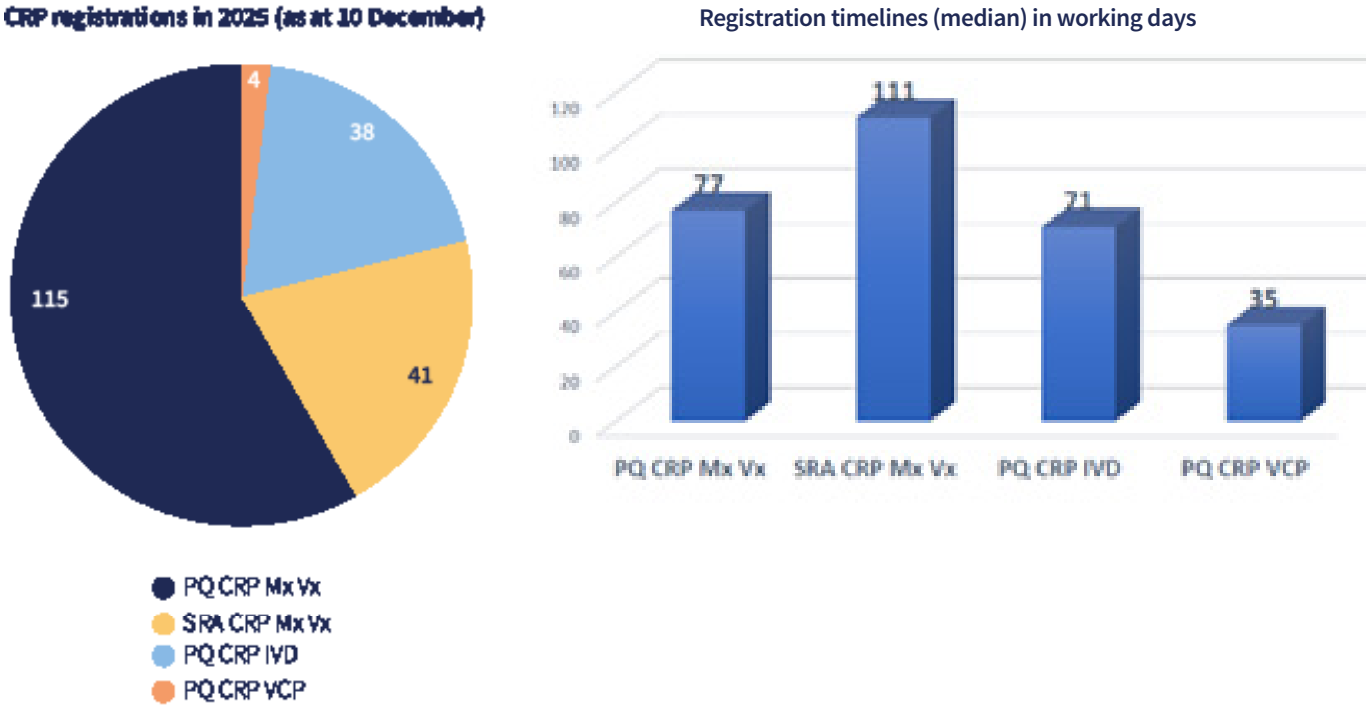
Fig. 4. CRP participating countries as of December 2025



SAP Database December 2025

CARICOM : Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname, Trinidad and Tobago

Fig. 5. CRP registrations in 2025 a median registration time



Reliance in post-authorization change management

WHO also supported increased use of reliance in post-authorization change management, demonstrating efficiency gains compared with standard regulatory processes. Reliance-based approaches enabled most approvals to be completed within six months, compared with timelines of several years under traditional pathways. During 2025, WHO was consulted on seven additional industry-led post-authorization change pilot projects, bringing the total to 28 pilots involving nine companies and participation of more than 77 regulatory authorities. This work was undertaken in close collaboration with the European Medicines Agency, and applied a combination of reliance models, including collaborative assessments through the International Coalition of Medicines Regulatory Authorities and unilateral reliance approaches. These pilots demonstrated the feasibility of harmonized, reliance-based management of post-authorization changes across multiple regulatory jurisdictions.

The benefits of partners: regulatory reliance and work-sharing

Throughout 2025, WHO continued to support reliance-based regulatory collaboration through regional **joint assessment initiatives:**

In the context of the African Medicines Regulatory Harmonization Programme:

- Joint assessments with the Southern African Development Community's collaborative medicines registration initiative (Zazibona) resulted in the recommendation of 12 new products for national registration, reaching a total of 211 products recommended since 2013;
- Joint assessments with the East African Community resulted in the recommendation of 24 new products for national registration, reaching a total of 158 products recommended since 2015;
- Twelve medical products were recommended following the pilot for the African continental assessment under the Technical Committee for evaluation of medical products in preparation for the African Medicines Agency.

In the context of the Association of Southeast Asian Nations (ASEAN):

- Joint assessments with ASEAN resulted in the recommendation of 3 new products, 1 line extension and 1 post-approval changes for national registration (5 joint assessments in 2025) reaching a total of 10 joint assessments since 2017.

In the context of the Global Health Product Procedure:

- Support to Global Health Product Procedure involving WHO experts and target national regulatory authorities; two Swissmedic Marketing Authorization for Global Health Products procedures (one scientific advice and one assessment) and eight EU-Medicines for All procedures, comprising three eligibility reviews, two scientific advice procedures, two assessments and one post-authorization change.

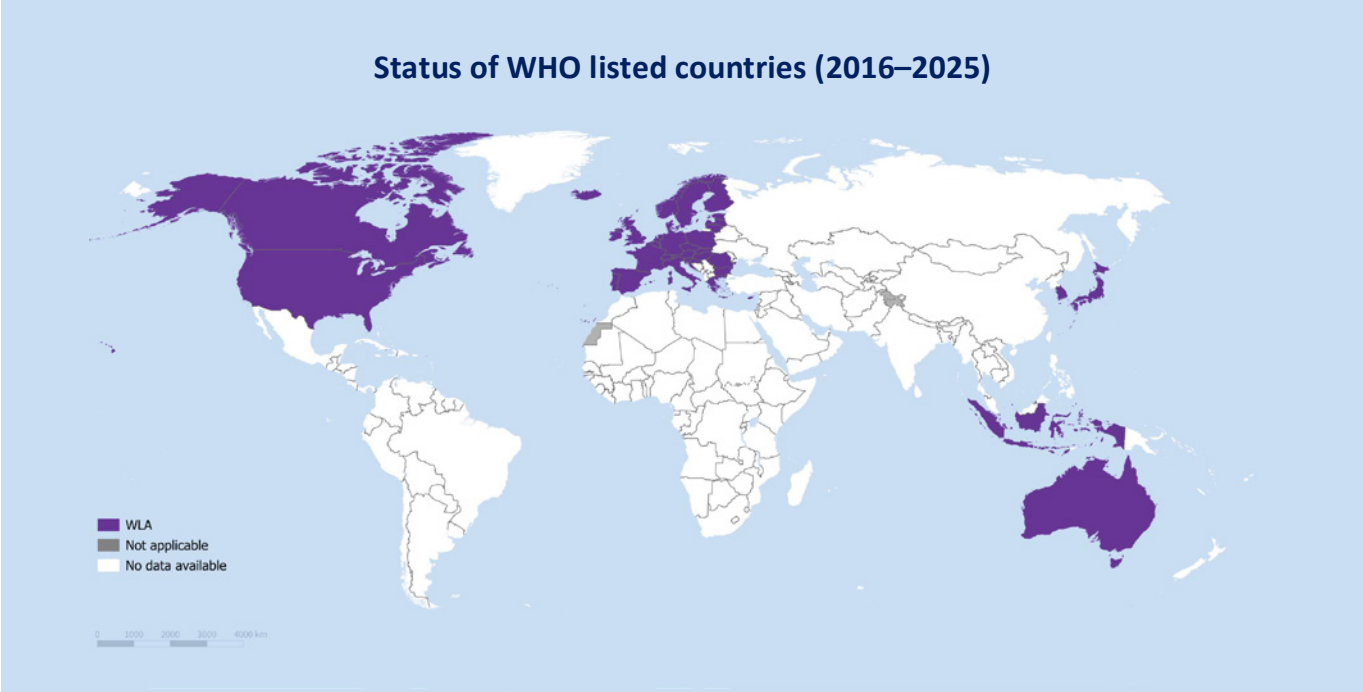
WHO Listed Authorities

WHO continues to strengthen regulatory systems globally through implementation and expansion of the WHO Listed Authority framework, a cornerstone of WHO's approach to promoting regulatory reliance, replacing the concept of stringent regulatory authorities. While not a capacity-building initiative, the framework offers a detailed, performance-based picture of regulatory maturity and supports informed reliance by other regulators, procurement agencies and global health partners. By 2025, a total of 38 Member States and 41 regulatory authorities had been evaluated and listed as a WHO Listed Authority across 2023–2025. Technical advisory group meetings were convened in June 2025 to guide implementation. Performance evaluations were concluded for several authorities through abridged, standard and streamlined pathways, including authorities in Canada, Japan, the Republic of Korea, Singapore, the United States and the European regulatory network. Operational guidance related to reliance mechanisms and the WHO Listed Authorities framework was further refined and translated to support consistent application across regions. Initial discussions were also initiated on extending the WHO Listed Authorities approach to medical devices.

WHO-contracted, prequalified and network-affiliated testing laboratories

WHO hosts two global networks for national laboratories supporting prequalification and national regulatory authorities to ensure the quality of medicines and vaccines pre- and post-market. Through sharing, these important networks optimize the use of expertise and laboratory resources, facilitate reliance and/or recognition of testing data across laboratories, enable the development of harmonized common standards and serve as a channel for regulatory capacity-building.

Fig. 6. Countries that have been assessed as WHO Listed Authorities as of December 2025



Medicines testing and laboratory services

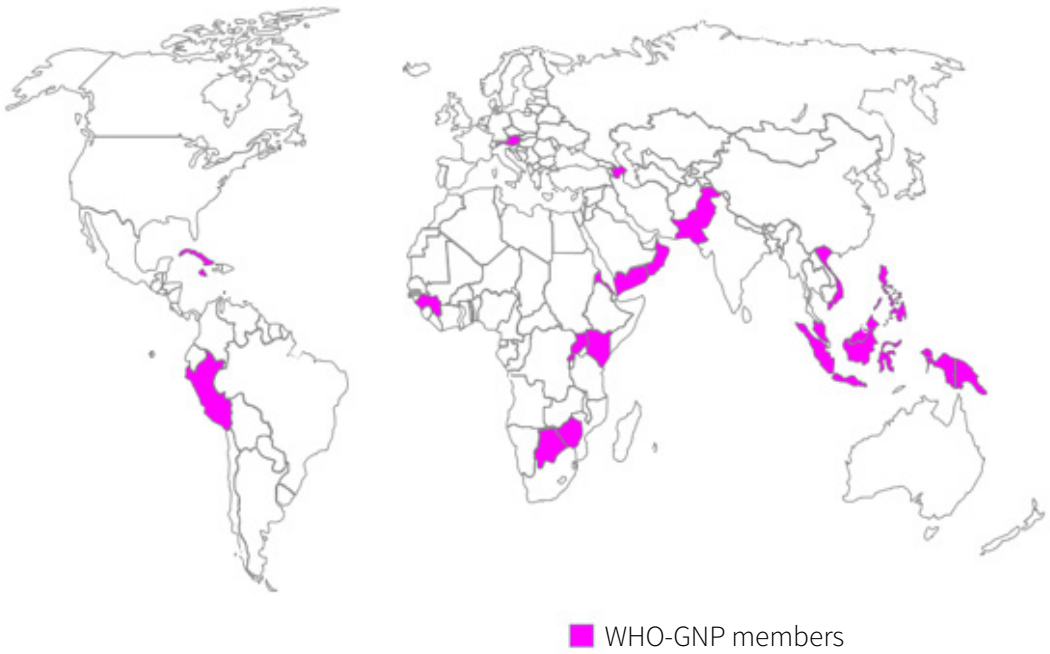
In 2025, the WHO Global Network of National Quality Control Laboratories for Pharmaceuticals welcomed 21 member laboratories across 20 countries, in its first year of effective activity after its inaugural meeting in Brazil in late 2024 and the second annual network meeting held in Lyon, France in November 2025. Throughout 2025, WHO provided technical assistance to laboratories in Ethiopia, Mexico, Mozambique, Peru and Zambia and undertook WHO peer audits for candidate laboratories in Mozambique, Namibia, Pakistan and Peru.

Vaccine testing and laboratory services

WHO also continues to deliver independent testing services to support vaccine prequalification and post-market oversight. Testing was conducted for six vaccine applications undergoing initial prequalification, including nOPV2, measles, bOPV, PCV, BCG and HPV vaccines, while compliance monitoring covered 48 different vaccines. Out-of-specification investigations were conducted as needed, and work progressed on tools to support risk-based testing strategies.

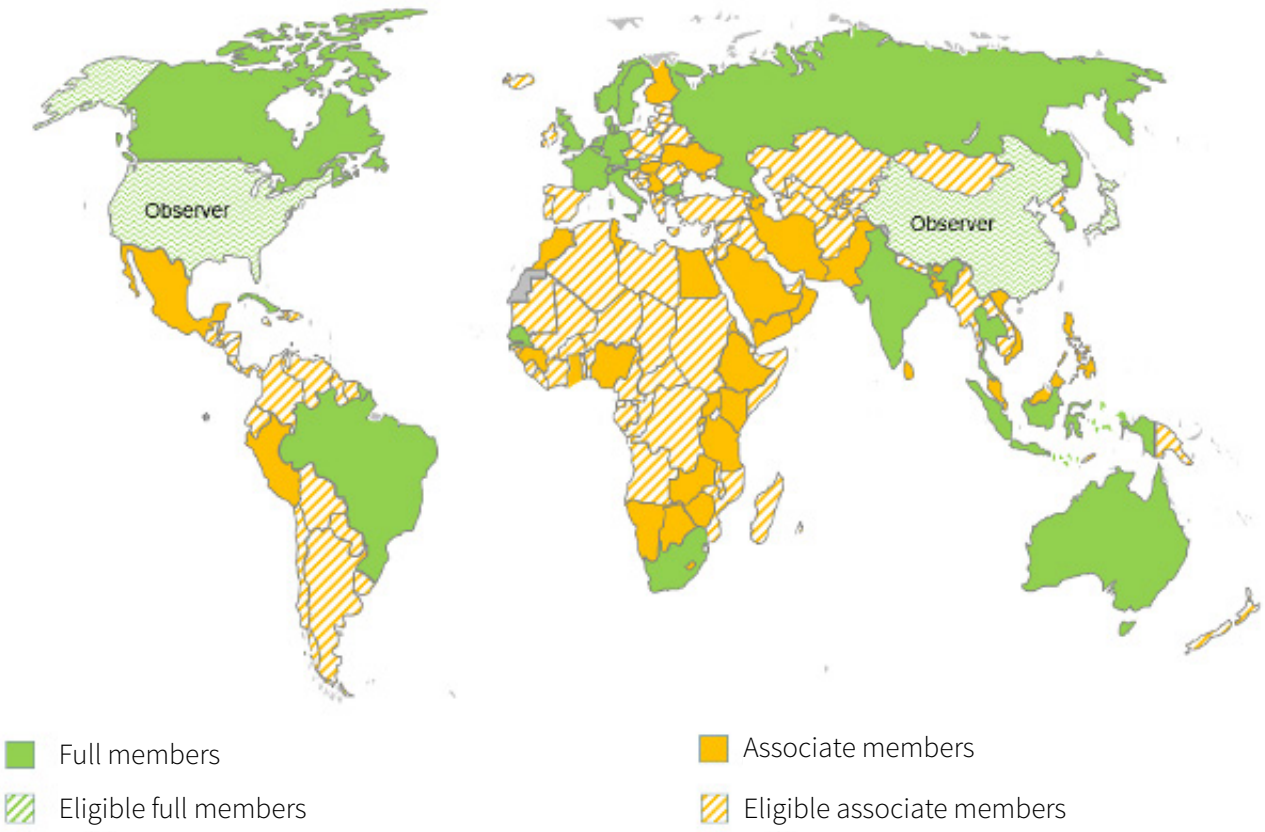
In 2025, the **WHO National Quality Control Laboratories Network for Biologicals** welcomed another three member laboratories from Eritrea, Kenya, and Viet Nam, bringing the network to 60 members in total, issuing 16 contracts over the 2024–2025 biennium. The network is made up of full and associate members; full members are national control laboratories from countries producing WHO prequalified vaccines and/or WHO-contracted laboratories, and associate members are laboratories or national regulatory authorities in countries that are recipients of UN-procured vaccines. The 7th annual meeting of the network took place in the WHO Academy in Lyon, France in November 2025. The network is supported by the Laboratory Information Management System, which has been updated and now available in its version 2.0.

Fig. 7. WHO Global Network of National Quality Control Laboratories for Pharmaceuticals members



Capacity-building across laboratory networks was supported through audit observer programmes, regional technical working groups, hands-on training, twinning activities and targeted webinars. Audits of established and candidate laboratories were conducted in the People's Republic of China, India and South Africa, alongside increased reliance on mutual joint audit outcomes from trusted authorities including Paul Ehrlich Institute, Sciensano in Belgium, the Bulgarian Drug Agency, the National Institute for Biological Standards and Control in the United Kingdom and the Instituto Superiore di Sanita, Italy.

Fig. 8. WHO National Quality Control Laboratories Network for Biologicals members



Strategic priority 1.2. Increase regulatory convergence through wider implementation of WHO quality standards

WHO continues to advance global regulatory convergence by promoting wider and more consistent implementation of WHO quality standards across product streams, through guidance, regulatory training and support to global and regional converge and harmonization. These efforts support more efficient regulatory decision-making and accelerate access to safe, effective and quality-assured health products, particularly in low- and middle-income countries.

10

Technical Committees of the African Medicines Regulatory Harmonization Initiative supported in preparation for the African Medicines Agency

Digital

digitalization of the WHO Global Competency Framework with subsequent piloting

1

new global training course on the regulatory life cycle of in vitro diagnostics

New

version of WHO Global Benchmarking Tool, now including benchmarking for medical devices

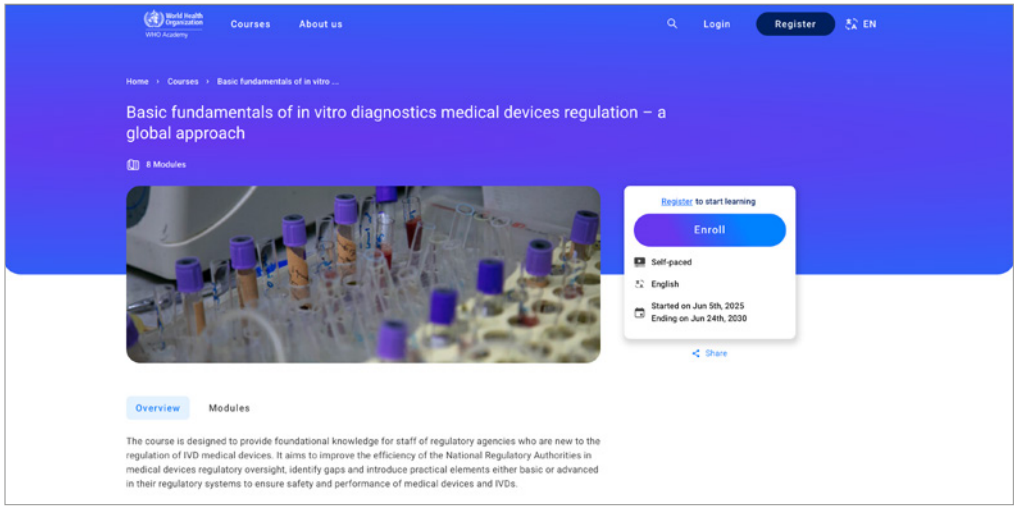
Guidance and tools

A major focus in 2025 was capacity-building for in vitro diagnostics regulation. WHO launched a new global training course providing a foundational overview of in vitro diagnostic regulation for regulators and other stakeholders across the product life cycle. WHO validated training materials on assessment of technical files, and the first in vitro diagnostic assessment training for regulators was delivered at the WHO Academy, Lyon, France, with participation from ten African national regulatory authorities. This was complemented by development of a dedicated in vitro diagnostic assessor training curriculum, comprising 17 modules covering key regulatory elements and scientific principles for assessing in vitro diagnostic safety and performance, complemented by training materials to support consistent application of assessment principles.

WHO also continued to **strengthen regulatory convergence through global health product procedures** and training including:

- digitalization of the WHO Global Competency Framework, with subsequent piloting initiated in Rwanda, November 2025;
- face-to-face and launch of e-learning for regulatory assessors;
- publication of a revised WHO Global Benchmarking Tool, now including benchmarking for the regulation of medical devices;

Fig. 9. New WHO training course



- migration of the Multi-regional Clinical Trials e-learning course launched in 2024, to the WHO Academy in 2025, reaching over 6,500 enrolled participants;
- update of WHO Points to Consider in Paediatric Formulations, approved by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2025;
- in collaboration with the WHO Antimicrobial Resistance Department and the WHO Immunization Programmes, WHO published policy and regulatory interventions to address antibiotic shortages in low- and middle-income countries;

Fig. 10. Publication on policy and regulatory interventions

- continuous update of the **WHO Certification of Pharmaceutical Products Scheme** (CPP Scheme), which has facilitated global exchange on the quality of pharmaceutical products circulating in international commerce since 1969;
- in July 2025, WHO issued a publication presenting an overview of the CPP Scheme and welcomed the national regulatory authority of Colombia as a new member;
- in April 2025, WHO organized a stakeholder consultative workshop to discuss implementation and revisiting of the **WHO Pharmaceutical Starting Materials Certification Scheme (SMACS),** introduced in 2003 to address concerns related to the quality pharmaceutical starting materials and the increasing complexity of supply chains. A questionnaire was distributed to countries, and a White Paper is under development to inform the future of SMACS.

Support to global and regional convergence and harmonization

WHO continues to offer its convening power bringing regulators together through international and regional meetings, technical committees and global forums focused on convergence and harmonization, providing important opportunities for regulators to exchange experience, align technical approaches and coordinate responses to emerging regulatory challenges. In 2025, this included:

- **Harmonization and convergence through the African Medicines Regulatory Harmonization Initiative**
  WHO contributed its technical expertise through participation in ten Technical Committees of the African Medicines Regulatory Harmonization Initiative and supporting preparations for transition to the African Medicines Agency. WHO also co-organized a Scientific Conference on Medical Regulation in Africa in Mombasa, Kenya, November 2025, attended by over 600 participants from over 100 entities across 55 countries – providing an important platform for regulatory dialogue across regions.

- **Support to African Regional Economic Communities**
  WHO also provided support to the establishment and operationalization of the North Africa Medicines Regulatory Harmonization initiative, composed of Algeria, Egypt, Libya, Mauritania, Morocco and Tunisia, and supporting training of Good Manufacturing Practices inspectors from regional economic communities (AMRH/AMA, IGAD and OCEAC); advanced training on bioequivalence studies assessment for junior assessors from IGAD Member States; workshops on guidelines development and joint assessment workshop to support ZAZIBONA procedures for assessors from SADC and enabling a twinning initiative for three francophone countries, Benin, Cote d'Ivoire and Guinea) hosted by the Senegalese national regulatory authority. This series of WHO engagement serves to strengthen coordination among regulatory authorities, promote convergence of regulatory requirements, and support harmonized regulatory decision-making across regions.
- **Contribution to international fora and global networks and conferences**
  Framed by its constitutional authority to act as the directing and coordinating authority on international health, WHO continues as lead co-organizer and contributor of technical expertise to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Conference of Drug Regulatory Authorities, as observer to the International Coalition of Medicines Regulatory Authorities, ongoing engagement with the Regulatory Authorities Global Network of Regulators on Antimicrobial Resistance and contribution to preparations of the Second Global Regulatory Authorities Summit on Antimicrobial Resistance held in January 2026. With leading global health actors, WHO also continues to facilitate the WHO Pediatric Regulatory Network for exchange of information on pediatric medical products to support the regulatory pathway of essential pediatric medicines and formulations.
- **WHO's key role in international collaboration in the evaluation of medicines to be used globally**
  WHO continues to work through global health products procedures such as the EU-Medicines for all (EU-M4all) or Swissmedic Marketing Authorization for Global Health Products, whereby WHO experts and national regulators combine EU/Swiss regulatory and scientific expertise with national disease knowledge and epidemiology to expedite timely national regulatory approvals. These reliance mechanisms support regulatory harmonization and strengthen global regulatory capacity and reducing time to market for essential medicines and health products.

Technical support to the operationalization of the African Medicines Agency

The African regulatory landscape operates across three interconnected levels: national, regional, and continental. At the regional level, these activities are coordinated through Regional Economic Communities fostering regulatory convergence, harmonization, work-sharing, and collaboration among Member States. WHO has long-standing engagement with national regulatory authorities in Africa through the African Medicines Regulatory Harmonization Initiative, established in 2009 to among others, expedite marketing authorization of medical products and to facilitate the alignment of national regulatory requirements, processes and procedures for timely approval of quality-assured medical products. In the wider context of Africa's long-term plan for development, integration, peace and prosperity (Agenda 2063), WHO collaborates closely with the African Union Development Agency (AUDA-NEPAD) to lay the strong foundations for, and support operationalization of the African Medicines Agency.

The African Medicines Agency was established in 2019 by the African Union as a specialized agency and independent regulatory institution to oversee approval and access to lifesaving products for the African population. As one of its mandates, the African Medicines Agency will coordinate the regional regulatory harmonization programmes. Since its establishment, WHO has provided continuous technical expertise, technical assistance and capacity-building support. In 2025, WHO support has included technical expertise through participation in ten Technical Committees of the African Medicines Regulatory Harmonization Initiative in preparation for transition to the African Medicines Agency, regulatory assessment training for 100 participants across 21 national regulatory authorities and regional harmonization initiatives and participation of regulators from Cameroon and Egypt to the WHO Prequalification Programme.

Dr Tedros Ghebreyesus, Director-General of the World Health Organization, with Dr Delese Mimi Darko, Director General of the African Medicines Agency, during her inaugural visit to WHO on 15 December 2025.

Strategic priority 1.3. Strengthen national regulatory capacity to ensure the quality of medical products

As part of its core mandate, WHO supports the long-term transition from prequalification towards functional national and regional regulatory capacities, through a process of regulatory system strengthening, harmonization, reliance, convergence and networking. Since 1996, WHO supports countries through a five-step regulatory capacity-building programme, with introduction of the WHO Global Benchmarking Tool (including computerized cGBT) as a game changer, providing a very first globally accepted tool for assessing and strengthening national regulatory authorities – reflecting the benefits of a common language and the power of measurement. The related Institutional Development Plan and the concept of 'maturity level' guide implementation of actionable steps to advance systems functionality and maturity.

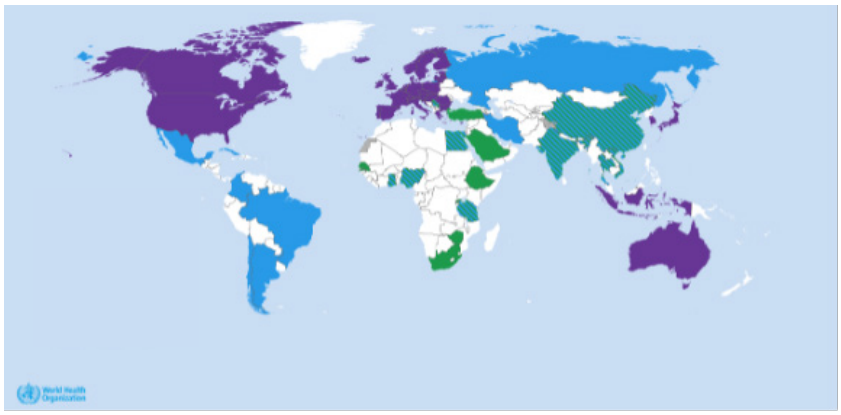
82
countries supported in 2025 through benchmarking and institutional development plan implementation

59
self-benchmarking and 39 formal benchmarking exercises completed using the WHO global benchmarking tool

62
Member States reached advanced maturity ML 3 or WLA

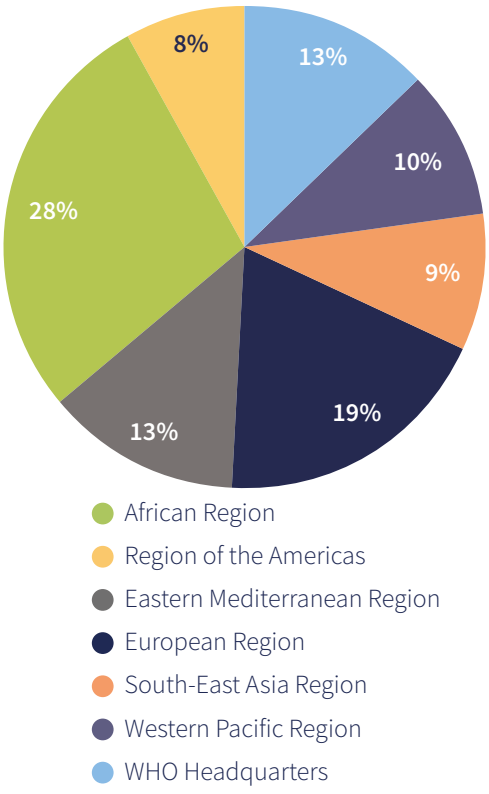
1571
regulators trained over five years

Fig. 11. Global status of national regulatory systems (2016 to December 2025)



Benchmarked ML3/4
tWLA, Benchmarked ML3
WLA
Not applicable
tWLA
No data available

Fig. 12. Expanding pool of regulatory experts to support regulatory strengthening



Technical assistance to strengthen national regulatory authorities through benchmarking and Institutional Development Plans

Many countries continue to face challenges in establishing and sustaining regulatory functions capable of overseeing increasingly complex medical products across their full life cycle. Strengthening national regulatory capacity therefore remains essential to ensure access to safe, effective and quality-assured medical products and to support resilient health systems. In 2025, WHO supported regulatory pre-benchmarking in 2 countries; formal benchmarking/re-benchmarking in 8 countries; self-benchmarking in 18 countries and benchmarking finalization in 4 countries. Since 2016, WHO has supported benchmarking and performance evaluations in 59 Member States through self-benchmarking; 36 Member States through formal benchmarking and 38 Member States through reliance of WHO Listed Authorities. Through sustained technical assistance missions, capacity-building activities and workshops since 2016, WHO has supported regulatory system assessments across 98 Member States, representing approximately 77% of the world's population. To date, 62 Members States authorities have been benchmarked at Maturity Level 3 or assessed as WHO Listed Authorities or transitional WHO Listed Authorities.

After a period of sustained investment, Ethiopia officially reached regulatory Maturity Level 3, marking a significant milestone in the country's health sector, and placing it among 9 African countries with this status, reflecting a stable, well-functioning and integrated regulatory system for medical products. As of December 2025, 19 countries operate at Maturity Level 3 and Maturity Level 4 as benchmarked against the WHO Global Benchmarking Tool (for medicines and/or vaccines) – crucial for ensuring the quality, safety and efficacy or medical products and essential for public health and safety.

WHO also expanded the pool of experts from national regulatory authorities available to support the global benchmarking tool and WLA assessments. Now counting 278 trained assessors, the pool serves as a shared resource for countries to support self-benchmarking, Institutional Development Plan implementation, and continuous regulatory improvements.

Institutional Development Plans Implementation in 2025

Regulatory Institutional Development Plans provide a blueprint for government investment and technical assistance by WHO and development partners. In 2025, WHO supported implementation of such plans through technical assistance to 19 countries, including through a series of targeted capacity-building workshops for regulatory systems and regulatory preparedness:

- **Good Manufacturing Practices inspection workshops,** including through coached audits in the United Republic of Tanzania (May), Kazakhstan (May), Ghana (October) and India (December)
- **Good Clinical Practices inspection workshops,** including through coached audit in Kenya (September)
- **Regulatory performance indicators workshops** in Viet Nam (May) and regional for Africa (October)
- **Regulatory Practices workshops** in Indonesia and regional for Africa (September)
- **Regulatory preparedness for the oversight of pandemic vaccines through bi-regional workshop** for the Eastern Mediterranean Region and South-East Asia Region (in English, June) and a regional workshop (in Spanish, October)
- **WHO-Swissmedic hands-on regulatory training** through training sessions in June and October annually

Coalition of Interested Parties (CIP) advancing global regulatory capacity through a unified, strategic and coordinated approach

Through coordinated support and investment across six WHO regions, the Coalition of Interested Parties empowers countries to strengthen their regulatory systems through advanced regulatory effectiveness. In 2025, the CIP Network focused on strengthening governance, coordination, and strategic alignment. The network held its Global Steering Group meeting in WHO Headquarters in December 2025; complemented by Regional Steering Group meetings in the South-East Asia Region in January, July and December 2025 and in country coordination processes in Rwanda, March 2025 and Senegal, April 2025 – all with the purpose to enhance regulatory operations through aligning priorities and resources. The network also held capacity-building webinars and continued implementation of the CIP Network Strategic Plan, finalization of the CIP Network Coordination Mechanism, development of partner profiling tools (all scheduled for publication in Q1 2026) and preparation of the CIP Network Operational Plan for 2026–2027. A 2025 CIP member satisfaction survey conducted in November 2025 reflected overall satisfaction with the operations of the CIP Network, also highlighting areas for improvement related to SharePoint accessibility and need for stronger tools to aid coordination of regulatory interventions in countries.

33 members (28 + 5 observers)

6 regions

38 countries

288 activities

Over **US$ 125** million investment

Regulatory capacity-building and training

In 2025, the foundations for a coherent, standards-based learning ecosystem were strengthened through:

- Launch of the RPQ training M&E framework: efforts have focused on monitoring and analyzing the learning offerings, the events organized, the participants' profiles and satisfaction. As next steps, focus will be on the integration of data analytics from WHO Academy on RPQ e-learnings for more comprehensive reporting, as well as the systematic implementation of mechanisms to evaluate and report on training effectiveness.
- Improvements to training processes, use of shared templates, tools, and standard operating procedures enabling greater efficiency amid tightening constraints on time, staffing and funding.
- Launch of the Health Products Regulation and Prequalification learning catalogue, a comprehensive learning resource. Through a centralized platform, the Catalogue makes all WHO regulatory learning opportunities easily accessible and searchable for target audiences, covering various regulatory functions and health products. Going forward, the WHO Academy in Lyon, France through its learning platform will enable the development of even more advanced learning solutions, in collaboration with a broad network of partner institutions.

Strategic priority 1.5. Strengthen safety surveillance to support and safeguard uptake of new or innovative products by low- and middle-income countries

Pharmacovigilance is a core component of effective regulatory systems and an integral part of regulatory system strengthening, as recognized by Member States through World Health Assembly resolutions on the safety of medical products. Strong safety surveillance systems enable countries to detect, assess and manage risks associated with medical products, support evidence-based regulatory decision-making and sustain public confidence in the introduction and scale-up of new and innovative health technologies.

Global coordination and safety advisory functions

Global safety advisory functions remain central to WHO's work to strengthen global and national safety surveillance systems to support the safe introduction, scale-up and sustained uptake of new and innovative health products. In May 2025, the WHO Global Advisory Committee on Vaccine Safety through its 43rd meeting, and the Advisory Committee on Safety of Medicinal Products through its 21st meeting, conducted safety reviews covering priority products and conditions. These included vaccines for COVID-19, mpox, respiratory syncytial virus and dengue fever, as well as medicines such as sodium valproate, topiramate, lenacapavir, moxidectin, arPraziquantel and glucagon-like peptide-1 receptor agonists. WHO also provided safety review inputs to multiple WHO programmes and goal-driven initiatives, including immunization, malaria, maternal health and brain health.

1200+
professionals trained in safety surveillance and regulatory decision-making

1
global smart pharmacovigilance strategy published

900
learners enrolled in multilingual pharmacovigilance e-learning courses

1
comprehensive review and publication confirming vaccines do not cause autism

182
countries strengthened safety surveillance through the global drug monitoring programme

2
global safety committees conducted formal reviews of vaccines and priority medicines

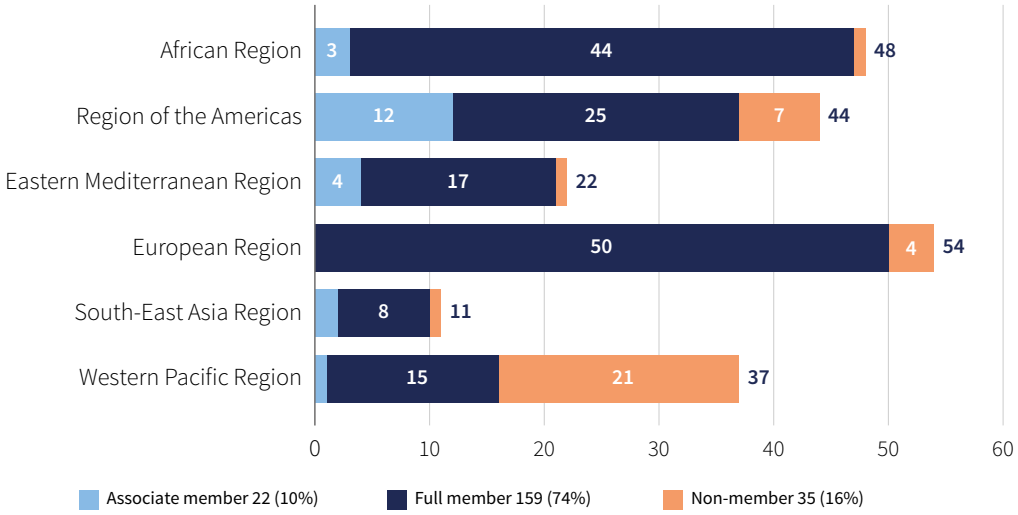
3
protocols published, designed to estimate the background rates of adverse events of special interest in low- and middle-income countries

5
new Vaccine Safety Network members

Global collaboration through the WHO Programme for International Drug Monitoring

Global collaboration in safety monitoring continues through the WHO Programme for International Drug Monitoring, established in 1968 and implemented in collaboration with the Uppsala Monitoring Centre, a WHO Collaborating Centre since 1977. By December 2025, the programme had expanded to 182 member countries. The 43rd meeting of the Programme for International Drug Monitoring took place in Egypt in October 2025, convening 128 in-person participants representing pharmacovigilance focal points and national immunization programmes from 62 countries, strengthening collaboration across regulatory and scientific communities and reinforcing shared approaches to safety surveillance.

Fig. 13. WHO Programme for International Drug Monitoring, membership status as of December 2025



Total members = 182

New full members: Lesotho, South Sudan and Zanzibar (United Republic of Tanzania)

New associate members: Cook Islands, Seychelles and Somalia

Tools and guidance

New global smart pharmacovigilance strategy

A key highlight in 2025 was the launch of the WHO global smart pharmacovigilance strategy, building on historical achievements and collaborative lessons to provide a modern, adaptive framework for ensuring the safety of medicines and vaccines. WHO will now work with countries to operationalize the strategy, in close collaboration with global and regional networks, drawing on the principles of work-sharing and reliance.

Vaccines, thimerosal and autism spectrum disorder

The Global Advisory Committee on Vaccine Safety reviewed all evidence from 2010 – 2025 regarding a potential link between vaccines and autism, and concluded that vaccines do not cause autism, reinforcing the conclusion from multiple reviews between 2002 and 2012. As the WHO Director-General noted in his end-of-the year press briefing: 'vaccines do not cause autism, vaccines cause adults.'

Fig. 14. New strategy on global smart pharmacovigilance

Safety risk communication and monitoring

Safety risk communication and public trust remained integral to safety surveillance. The Vaccine Safety Net continues to grow with five new members between November 2024 and October 2025, including four from low- and middle-income countries. As at the end of 2025, the Vaccine Safety Net comprises 118 trusted websites from 50 countries with information in 41 languages, and with updated membership criteria endorsed and increased participation from institutions in low- and middle-income countries. In 2025, the Vaccine Safety Net undertook pilot studies on social-media-based vaccine safety messaging to reinforce safety awareness and reporting, and going forward, will benefit from advice on strategies and policies, from the Working Group on Vaccine Safety Communication, established in May 2025 as an initiative of the Global Advisory Committee on Vaccine Safety.

Resulting from important safety monitoring work, WHO issued a safety alert in June 2025, informing health-care professionals and regulatory authorities to the health associated with the use of semaglutide medicines used to treat type 2 diabetes and obesity.

"Your pharmacovigilance system is only as strong as your data."

WHO/UMC

In collaboration with the Uppsala Monitoring Centre in Sweden, WHO continues to maintain and develop VigiBase, established in 1978 as the world's largest source of post-marketing safety data, containing adverse event reports for medicines and vaccines from more than 180 member countries of the WHO Programme for International Drug Monitoring. VigiBase is complemented by sub-components including VigiFlow (web-based national database for adverse event reporting), VigiLyze (analytical tool improving signal detection and report generation using global data) and VigiMobile (offline app connected to VigiFlow allowing healthcare workers to collect adverse event data using smartphones, tablets, or laptops, with or without an internet connection). In 2025, WHO continued its efforts to strengthen the capacity of national and provincial pharmacovigilance focal points in capturing safety events following medicines and vaccine use. In 2025, more than 3.2 million reports on adverse events were made to the portal, bringing the cumulative number of adverse events reported to 44.7 million.

Fig. 15. Map of Vaccine Safety Net as of October 2025

Fig. 16. Reporting into VigiBase by high-income countries and low- and middle-income countries

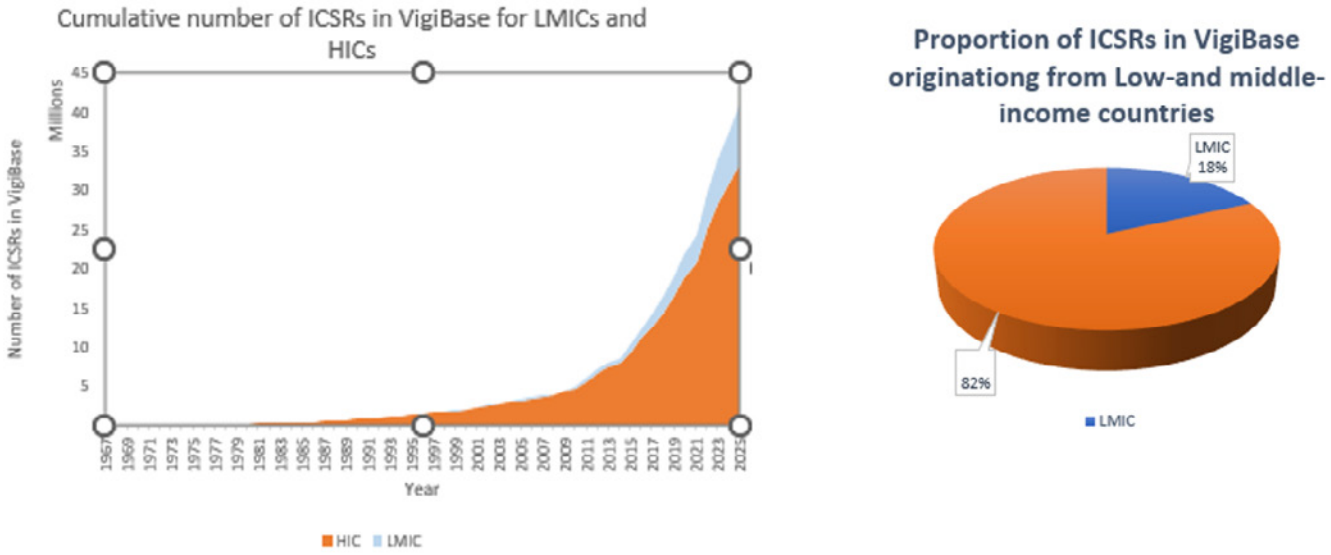
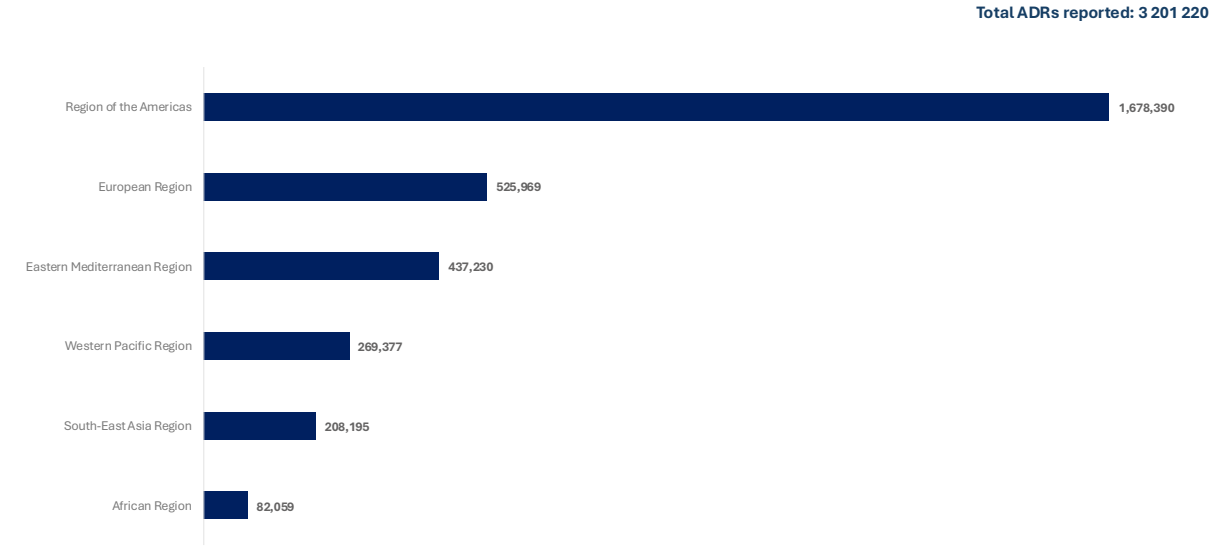


Fig. 17. Cumulative adverse drug reaction reporting to Vigibase from January to December 2025



Source : VigiLyze Data as on 29 January 2026,

WHO guidance and assessment protocols

WHO continues to develop evidence-based tools and guidance to strengthen safety surveillance. In 2025, this included the publication of three protocols supporting the safety monitoring adverse events of special interest in low-and middle-income countries; development of WHO Minimum Maternal and Newborn Health Data, initially promoted for intrapartum care in five countries.; and standard protocols for active surveillance of mpox vaccines with implementation supported in the Democratic Republic of the Congo.

WHO also advanced the digitalization of its safety monitoring tools, important in improving real-time reporting of adverse events following immunization and adverse drug events. In 2025, this included the launch of an AI-assisted platform to track national reporting performance, alongside continued deployment of digital tools, including VigiMobile, for frontline reporting and the development of new software for causality assessment of adverse events following maternal immunization to improve assessment of vaccine safety in maternal populations.

Technical assistance and capacity-building

Pharmacovigilance is a core component of effective regulatory systems, and the WHO Global Benchmarking Tool helps to benchmark and assess the maturity level of a national regulatory authority, categorized into nine regulatory functions, including pharmacovigilance. Through sustained technical assistance and capacity-building, 20 Member States have now reached Maturity Level 3 or 4 in pharmacovigilance; informing the implementation of Institutional Development Plans. From November 2024 to November 2025, pharmacovigilance was a core component of benchmarking missions to Botswana (assisted self-benchmarking, August 2025), Kazakhstan (formal WHO benchmarking, September 2025) , Namibia (assisted self-benchmarking, October 2025) and Uganda (assisted self-benchmarking, August 2025).

Through the WHO Adverse Events Following Maternal Immunization Causality Assessment Project, WHO works to strengthen vaccine safety monitoring in pregnant women and their newborns, specifically addressing safety monitoring for pregnancy-specific outcomes such as antenatal bleeding, preterm birth, low birth weight, preeclampsia and hypertension. The project contributes to implementation of global goals set out both in the Global Strategy for Women's, Children's and Adolescents' Health (2016–2030) and in the Immunization Agenda 2030.

Capacity-building and training for safety monitoring

In 2025, more than 1200 participants were trained through workshops and courses now available in the WHO Academy, Lyon, France. Through the year, this included a pharmacovigilance webinar in August 2025 with 389 participants across 89 countries, organized jointly by WHO, the Uppsala Monitoring Centre and the Health Sciences Authority in Singapore; the attendance of over 900 participants across 8 WHO pharmacovigilance e-learning courses available in Chinese, English, French, Russian and Spanish; VigiMobile training in Uganda in May 2025 and Eritrea in October 2025 and a series of Risk Management Planning and Assessment workshops held face-to-face in June 2025 organized jointly by WHO and the Paul-Ehrlich Institute, Germany virtually in September 2025; for regulatory assessors and pharmacovigilance officers in Uganda, face-to-face in November 2025 for hands-on pharmacovigilance training for the Uganda National Drug Authority and for assessors from national regulatory authorities in South-East Asia in December 2025.

Strategic priority 1.6. Improve prevention, detection and response to substandard and falsified medical products

Substandard and falsified medical products remain a significant global public health threat, with disproportionate impact in low- and middle-income countries, where an estimated one in ten medicines may be affected. These products are often distributed through informal supply chains and online markets, undermining treatment outcomes, contributing to antimicrobial resistance, and eroding trust in health systems. In response to a clear mandate from its Member States, WHO supports coordinated national and international action to prevent, detect and respond to substandard and falsified medical products.

3255
suspect products recorded

7
WHO Medical Product Alerts issued

1460
regulators trained through targeted capacity-building activities and e-learning

1031
incidents of substandard and falsified medical products reported globally

5
countries advanced national action plans on substandard and falsified medical products, launch of national action plan in South Africa

8
countries expanded risk-based post-market surveillance targeting antibiotics and tuberculosis medicines

GSMS
(Global Surveillance and Monitoring System) upgraded to a multilingual platform with enhanced reporting and analytics

Global coordination and advisory functions

The WHO Member States Mechanism on Substandard and Falsified Medical Products

The WHO Member States Mechanism on Substandard and Falsified Medical Products was established in 2012 as an intergovernmental platform of WHO Member States supporting countries to prevent, detect and respond to substandard and falsified medical products through collaboration, information-sharing, and the development of global tools and strategies. The mechanism is an important global coordination and advisory function in WHOs efforts to address substandard and falsified medical products. The mechanism held its 14th meeting in a hybrid format in November 2025, chaired by Rwanda, with representatives from 64 Member States. In an environment of resource constraints, the mechanism will prioritize its activities in 2026-2027, with a focus on detection and prevention tools, internet and informal markets, and strengthening vulnerable supply chains. These priorities will inform the development of national action plans to combat substandard and falsified medical products in countries.

Collaboration across borders

The trans-national nature of the combat against substandard and falsified medical products requires international coordination and collaboration with a wide range of stakeholders beyond the health sector. WHO works closely with national and regional regulatory bodies, public health, trade and law enforcement agencies, technical bodies and fora and a range of regional and international organizations including the Asia-Pacific Economic Cooperation Forum, the International Criminal Police Organization (Interpol), the United Nations Office on Drugs and Crime, the World Organization for Animal Health, the World Customs Organization, the Working Group of Enforcement Officers, the International Pharmaceutical Excipients Council and the International Medical Device Regulatory Forum to promote regulatory convergence and harmonized quality assurance standards. Combatting substandard and falsified medicines also requires close collaboration with the WHO Emergency Programme and the Department for Antimicrobial Resistance.

Tools and guidance

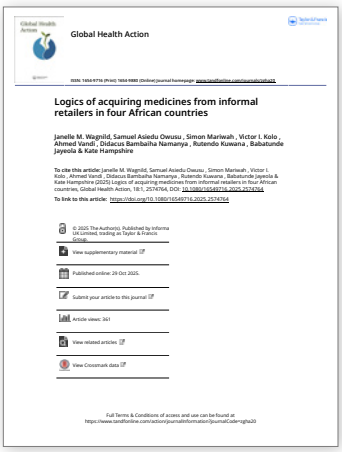
WHO continues to develop and disseminate technical and scientific guidance and tools as well as risk communication materials supporting demand-side interventions, with key achievements including:

- risk-based post-market Surveillance through the Epione e-tool, now piloted through 8-country surveys on antibiotics ongoing in Burkina Faso, the Republic of the Congo, Malawi and Niger, and a survey on nitrosamine impurities in tuberculosis medicines completed in Burundi, Ghana, Kenya, Namibia (testing ongoing), with roll-out of the e-tool expected soon;
- risk communication and community engagement toolkit for substandard and falsified medicines, now in editorial phase with subsequent publication;
- peer review publication 'Can public education campaigns equitable counter the use of SF medical products in 4 African countries', in Ghana, Nigeria, Sierra Leone and Uganda;
- peer review publication 'Logics of acquiring medicines from informal retailers in four African countries', describing the informal medicine sector in four Anglophone African countries;
- report on existing technologies used to screen and detect substandard and falsified medical products;
- guidance to support integration of substandard and falsified medical product topics into pharmacy curricula under development;
- country experiences on implementation of traceability for medical products.

Fig. 18. Recent WHO tools and guidance to support the combat against substandard and falsified medical products

Country experiences on implementation of traceability for medical products

Report of existing technologies used to screen and detect substandard and falsified medical products



Logics of acquiring medicines from informal retailers in four African countries

Can public education campaigns equitably counter the use of substandard and falsified medical products in African countries?

WHO Global Surveillance and Monitoring System

Launched in 2013, the WHO Global Surveillance and Monitoring System is a cornerstone of WHO's global response to substandard and falsified medical products, enabling countries to share verified information, identify emerging risks and support coordinated regulatory action across borders, underpinning WHO Medical Product Alerts and global communications. In 2025, system upgrades resulted in a multilingual platform, now available in English, French and Spanish, which went live in December 2025 with expanded functionality to support reporting on in vitro diagnostic devices. A digital transformation handbook for reporting substandard and falsified medical products is nearing publication and enhancements to the platform also enable more direct reporting and own-data review by national regulatory authorities and more efficient information sharing.

In 2025, nearly 1030 incidents of substandard and falsified medical products were reported to WHO, 83% were reported by national regulatory authorities with 24% of reports made directly via the portal. These represented 3255 products recorded as suspected substandard and falsified. Throughout the year, WHO issued 7 Medical Product Alerts related to antibiotics, oncology medicines and contamination involving nitazenes and diethylene glycol and ethylene glycol – important alerts supporting timely regulatory action and removal of high-risk products from circulation in the global markets.

Fig. 19. WHO alerts on substandard and falsified medical products issued in 2025

WHO Medical Product Alerts

- **7 global medical product alerts issued:** antineoplastic agents, analgesics and immunosuppressants are the top three sub therapeutic categories for global alerts in 2025
- **1 information notice for users of medical devices issued:** WHO warns malaria rapid diagnostic tests may show faint lines causing false negatives
- **4 targeted market surveillance request watchlists issued:** Antineoplastic agents, analgesics and psycholeptics are the top 3 sub therapeutic categories for watchlists in 2025

Fig. 20. New countries/year using the Global Surveillance and Monitoring System

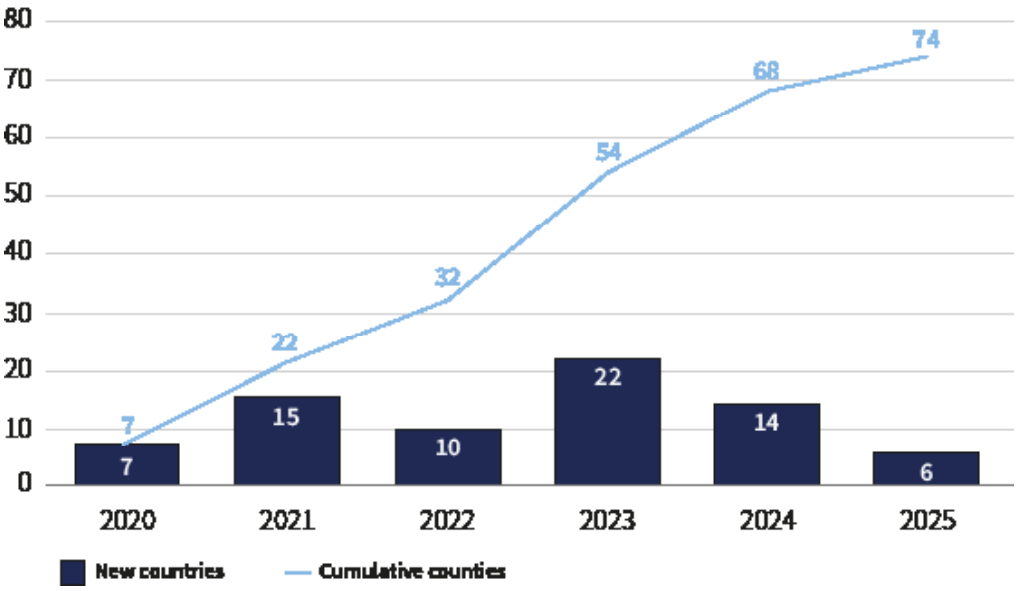
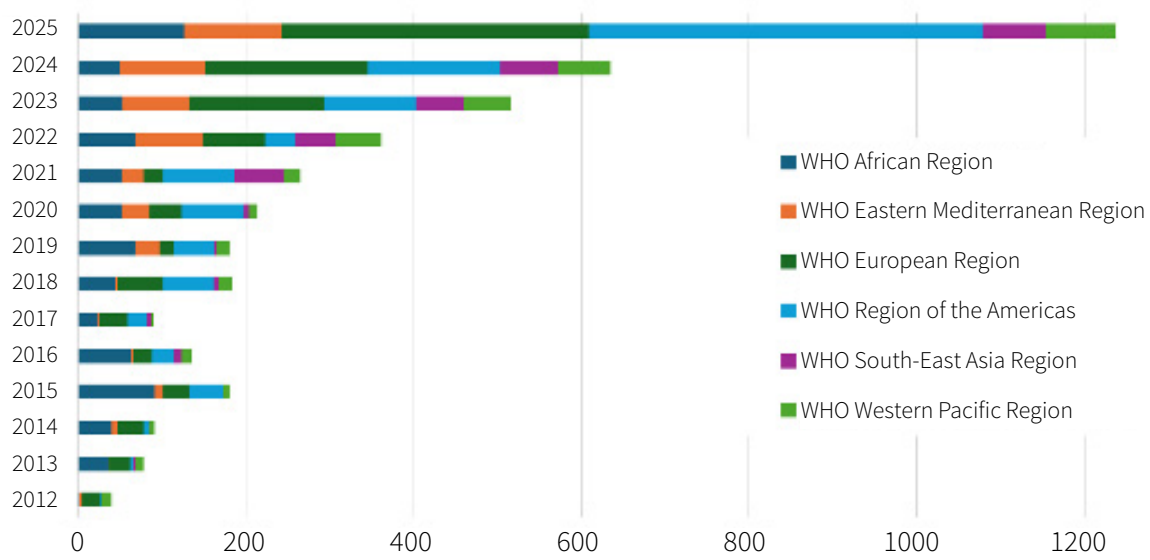


Fig. 21. WHO Global Surveillance and Monitoring System incident records per year and by WHO region



The WHO Global Surveillance and Monitoring System for SF medical products includes a case-report database. The data cannot and should not be extrapolated to represent any form of prevalence. Notifications to this database reflect the efficacy of surveillance systems. Reporting levels are indicative of the capacity to detect and report incidents .

Technical assistance and capacity-building for development of national action plans

WHO continues to provide targeted technical assistance to strengthen national capacity to prevent, detect and respond to substandard and falsified medical products, through support to the development of national action plans. Through sustained technical assistance and support, the South African National Action Plan on Combatting Substandard and Falsified Medical Products was launched by the country's Minister of Health in September 2025, positioning South Africa as a continent leader in the fight against falsified and poor-quality medicines.

WHO also supported regulatory system strengthening through benchmarking and self-assessment activities linked to market surveillance and control functions. Formal benchmarking using the WHO Global Benchmarking Tool was conducted in Viet Nam, while self-benchmarking support was provided to Botswana, Namibia and Senegal. In parallel, 8 countries in the African Region – Ethiopia, Ghana, Kenya, Mozambique, Rwanda, South Africa, the United Republic of Tanzania and Zambia – were supported to undertake medical device regulatory self-assessments. To address governance vulnerabilities, WHO, with support from the United Nations Office on Drugs and Crime, conducted an assistive self-assessment of corruption risks in Sri Lanka, identifying key regulatory vulnerabilities and the subsequent adoption of a focused national action plan to mitigate prioritized corruption risks.

Capacity-building and training to combat substandard and falsified medical products

As of December 2025, more than 1400 learners have benefitted from the substandard and falsified medical products e-learning courses offered by WHO, supporting broader access to knowledge and more consistent application of good practices across regions. Throughout 2025, WHO offered training for national focal points, assisted self-benchmarking and corruption risk assessments, deployment of digital reporting tools, and expanded access to learning resources.

A Training Toolkit on Substandard and Falsified Medical Products was launched in September 2025, with open access for national regulatory authorities, academia and law enforcement institutions, including a competency framework, curriculum guide, trainers' guide and technical resources; with more than 400 participants attending the launching webinar.

Strategic priority 2

Increase regulatory preparedness for public health emergencies

The WHO Health Emergencies Programme works with all countries and partners to ensure the world is better prepared for all-hazards health emergencies that threaten global health security, with the overarching goal of strengthening health emergency preparedness and response. This encompasses emergency preparedness (building national public health and health system capacities); health emergency prevention (pandemics, natural disasters and (re-) emergence of high threat pathogenic diseases); and detection and response (rapid detection, verification, assessment and communication on potential health threats to reduce the negative impact of health emergencies).

After three years of negotiations sparked by the COVID-19 pandemic, the historic Pandemic Agreement was adopted by the World Health Assembly in May 2025, as a first ever international agreement to better prevent, prepare for, and respond to future pandemics, marking a major step towards ensuring stronger global collaboration to protect lives and avoid the devastating consequences of future outbreaks. The Department of Regulation and Prequalification contributes to WHO health emergency preparedness and response, and to the operationalization of the new Pandemic Agreement through increasing regulatory preparedness, speedy approval of medical products and post-approval safety.

2025

Pandemic Agreement adopted by the World Health Assembly, strengthening the global framework for regulatory preparedness

8

in vitro diagnostic products from 10 manufacturers listed through Emergency Use Listing for mpox diagnostics

WHO

Academy leveraged as a global platform for regulatory preparedness training

Pathways

emergency regulatory pathways applied across vaccines and diagnostics

To expedite access to medical countermeasures during a public health emergency, the Emergency Use Listing Procedure was introduced to assess and list unlicensed products, i.e., in vitro diagnostics for Ebola (2014); in vitro diagnostics for Zika (2016); novel oral polio vaccine (2020); vaccines and in vitro diagnostics for COVID-19 (2020); and vaccines and in vitro diagnostics for mpox (2024). contributing to averting more than 5 million deaths through COVID-19 vaccination. In 2025, eight mpox assays were listed under WHO's Emergency Use Listing, bringing the total to 12, in addition to the WHO listed mpox vaccines, reinforcing outbreak preparedness and response to mpox. Two COVID-19 in vitro diagnostics also transitioned to prequalification, marking a critical step from emergency response to long-term quality assurance.

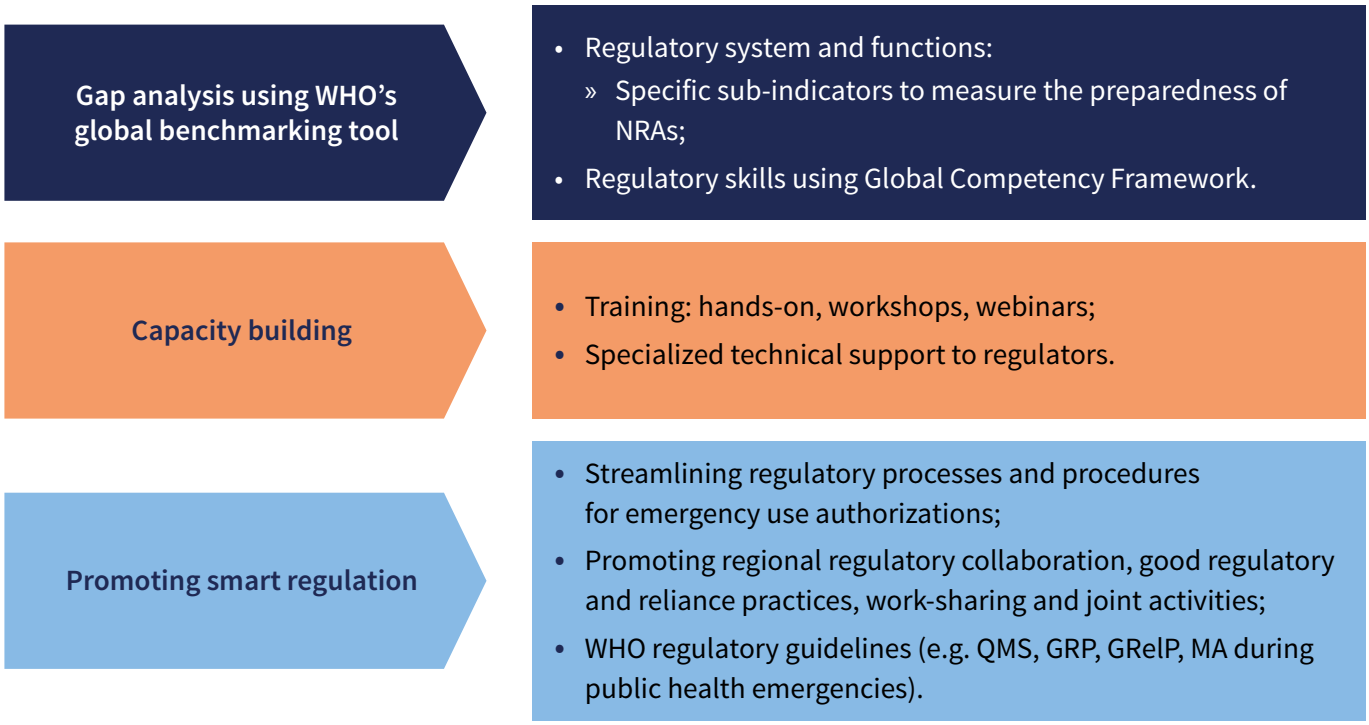
Guidance, tools and technical assistance for regulatory preparedness and oversight

WHO continues to support implementation of the WHO Guidelines on regulatory preparedness for oversight of pandemic or other emergency use of vaccines in importing countries,' published in April 2024. In 2025, this included two workshops for English-speaking countries in the Eastern Mediterranean Region and the South-East Asia Region held in Thailand, June 2025 and for Spanish-speaking countries in the Americas held in El Salvador, October 2025. WHO continues to support Collaborative Registration Procedure and works with regulatory authorities to facilitate marketing authorization/emergency-use-authorization of WHO prequalified and Emergency Use Listed medical countermeasures.

WHO Expert Review Panels improving access to innovations

Upon request from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies and with the support of Unitaid, WHO undertakes Expert Review Panels to assess potential risks and benefits associated with the use of finished pharmaceutical products, in vitro diagnostic or medical devices which may have substantial public health impact, but that are not in the scope of prequalification, or have not yet been prequalified or undergone stringent regulatory assessment. WHO oversees selection of the experts and hosts the panel and in 2025 WHO Expert Review Panels undertook 20 reviews of pharmaceutical dossiers and 24 reviews of in vitro diagnostics dossiers (including additional data and extension reviews). Additionally, WHO undertook seven reviews to address the shortage of rifampicin active pharmaceutical ingredients and provided feedback to UNICEF on the quality of 13 products, such as insulin, insulin analogues, and chemotherapy medication. Since 2023, the WHO Neglected Tropical Diseases Programme has launched several pilot rounds of Expert Review Panels for neglected tropical diseases, and Gavi, the Vaccine Alliance has launched an Expert Review Panel for Diagnostics for vaccine-preventable diseases, facilitating faster access to innovative products.

Fig. 22. WHO support to improve regulatory preparedness



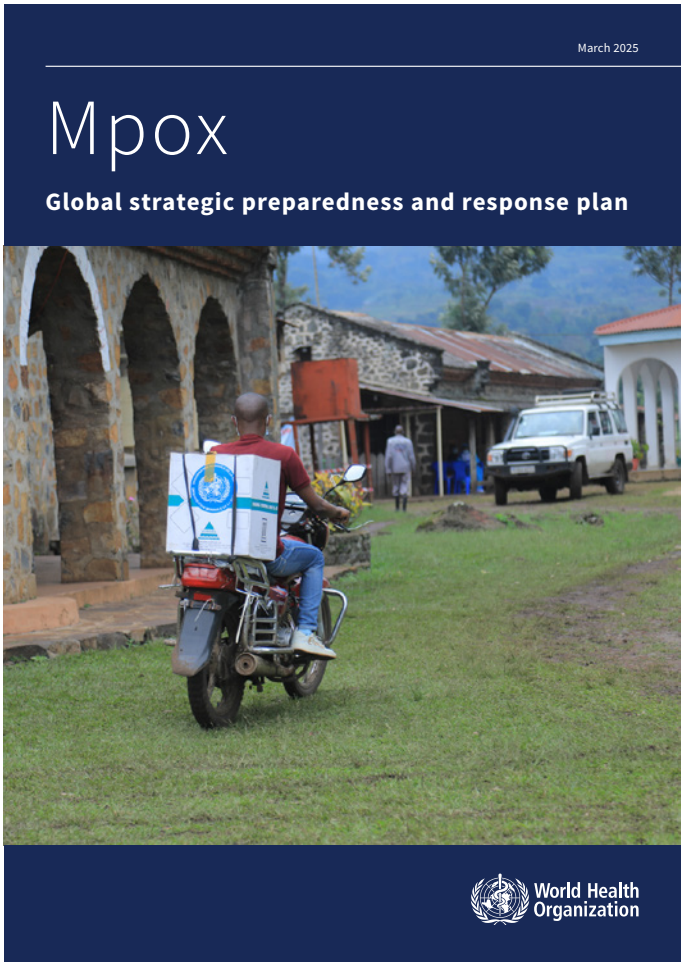
The WHO Technical Advisory Group on COVID-19 Vaccine Composition continued to play a central role in global regulatory preparedness by closely monitoring the genetic and antigenic evolution of circulating SARS-CoV-2 variants. Through regular review of emerging evidence on immune responses following infection and vaccination, as well as real-world vaccine performance, the group provided timely scientific advice to inform whether updates to COVID-19 vaccine antigen composition may be warranted.

Continued regulatory response to mpox

The detection and rapid spread of a new clade of Monkeypox virus in the Democratic Republic of Congo prompted the renewal of its classification as a Public Health Emergency of International Concern in August 2024. Building on the initial WHO Mpox Strategic Preparedness and Response Plan covering the period September 2024 – February 2025, an updated Plan was issued in March 2025 presenting a set of actions through to August 2025.

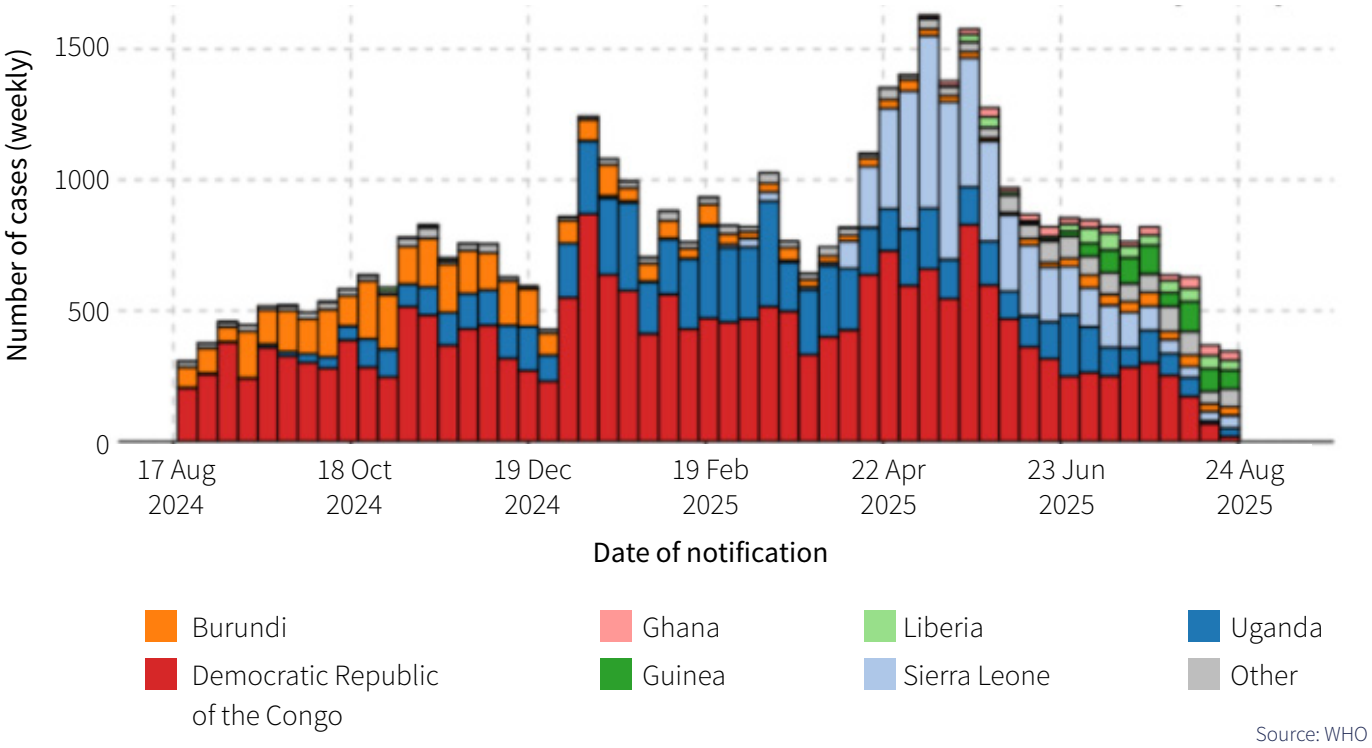
On 28 August 2024 WHO published an invitation to manufacturers to submit in vitro diagnostics for mpox detection for review by WHO through the Emergency Use Listing. As of November 2025, over 70 manufacturers had expressed interest, WHO had conducted 43 pre-submission meetings with manufacturers, received 16 Emergency Use Listing dossiers and listed 12 products, from 10 manufacturers for use. In parallel, WHO continues to provide technical assistance to the manufacturer of the mpox vaccines recommended under Emergency Use Listing in 2024, focusing on regulatory compliance, quality assurance, mock Good Manufacturing Practice inspection, and capacity-building aligned with WHO and international standards. WHO also support the active safety surveillance of mpox vaccines and routine safety reporting in the Democratic Republic of the Congo, Nigeria and Uganda and during 2025 convened two meetings of the Global Advisory Committee on Vaccine Safety to review accumulating mpox vaccine safety data.

Fig. 23. Mpox global strategic preparedness and response plan



On 5 September 2025, the WHO Director-General declared that mpox no longer constitutes a Public Health Emergency of International Concern, however WHO continues to assist national regulatory authorities in accelerating regulatory approvals for diagnostics and vaccines and support to safety monitoring of mpox vaccines in countries.

Fig. 24. Epidemic curve of confirmed mpox cases in Africa, by country from August 2024 to August 2025



Source: WHO

Collaborations and networks

The critical role of WHO in strengthening regulatory preparedness for pandemic and public health emergency response was reinforced with the recent adoption of the Pandemic Agreement in April 2025. WHO's role in expediting regulatory review and/or emergency regulatory authorization, intensified use of regulatory reliance mechanisms and oversight of pandemic-related health products, will continue to require the collaboration with a wide network of entities, ranging from independent experts in WHO Expert Review Panels, the Advisory Committee on Safety of Medicinal Products, the WHO Strategic Advisory Group of Experts on Immunization, the African Vaccine Regulatory Forum, the International Coalition of Medicines Regulatory Authorities, the International Medical Device Regulators Forum, the EU-Medicines for all (EU-M4all) procedures and many more. The International Medical Countermeasures Network established in 2023 is of particular value as it applies a 'Network of Networks' approach to enable scalable coordination across the medical countermeasures value chain.

Fig. 25. Interim Medical Countermeasures Network

i-MCM-Net partners forum

Capacity-building and training for regulatory preparedness

Building on the WHO Guidelines on regulatory preparedness for oversight of pandemic or other emergency use of vaccines in importing countries, published in April 2024, a 4-modules e-learning course was launched in the WHO Academy, Lyon, France, supporting national competence in decision-making to authorize the use and deployment of pandemic vaccines to address a public health emergency in a timely and coordinated manner.

WHO health product regulation and prequalification course

Regulatory Preparedness to Authorize the Use of Pandemic Vaccines in Importing Countries

Strategic priority 3

Strengthen and expand WHO prequalification and product risk assessment processes

Evolution and expansion of WHO prequalification

The mandate for WHO to develop, establish and promote international standards is rooted in the WHO Constitution, which entered into force in 1948 following its adoption at the International Health Conference in New York in 1946. This mandate gave rise to the establishment of WHO Expert Committees and laid the foundation for WHO's normative role in quality, safety and efficacy of medical products. With the introduction of the Expanded Programme on Immunization in 1974, vaccines were increasingly supplied by multinational manufacturers and national producers and procured through United Nations agencies. In 1987, the United Nations Children's Fund and WHO formalized an agreement under which WHO would assess the acceptability of vaccines for procurement. This marked the establishment of the WHO prequalification procedures.

Since its inception, WHO prequalification has remained adaptive and responsive to emerging public health needs and Member States' requests. Initially focused on vaccines (1987), the programme progressively expanded.

Fig. 26. Expansion in the scope of WHO prequalification services over the years

WHO Prequalification

Aims to ensure access to key health products that meet global standards of quality, safety and efficacy/ performance, to optimize use of health resources and improve health outcomes in low- and middle-income countries.

1987 Vaccines
2000 Immunization devices and cold chain equipment – switched from a paper-based listing to an electronic listing
2001 Inspection services
2001 Medicines
2010 In vitro diagnostics (IVDs)
2017 Vector control products (VCPs)
2022 Snake antivenoms

The list of WHO prequalified products is available on the WHO website and informs the Supply Catalogue managed by the United Nations Children's Fund Supply Division, which includes specifications for more than 2000 commodities procured globally. In parallel, WHO catalogues of products with positive assessments supports pooled procurement by countries, contributing to more efficient purchasing and sustained access to quality-assured medical products.

Risk-based assessment through Emergency Use Listing and Expert Review Panels

Emergency Use Listing procedures were introduced to assess and list unlicensed products in order to meet urgent assessment demands where no stringently approved or prequalified version yet exists and to expedite access to medical products during public health emergencies. These procedures were applied to in vitro diagnostics for Ebola (2014), in vitro diagnostics for Zika (2016), the novel oral polio vaccine (2020), vaccines and in vitro diagnostics for COVID-19 (2020), and most recently in vitro diagnostics and a vaccine for mpox (2024).

Upon request from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies and with the support of Unitaid, the WHO Prequalification Programme also undertakes Expert Review Panels to assess potential risks and benefits associated with the use of finished pharmaceutical products, in vitro diagnostic or medical devices which may have substantial public health impact, but that are not in the scope of prequalification, or have not yet been prequalified or undergone stringent regulatory assessment. Since 2023, the WHO Neglected Tropical Diseases Programme has launched several pilot rounds of Expert Review Panels for in vitro diagnostics for neglected tropical diseases, and most recently Gavi, the Vaccine Alliance has launched an Expert Review Panel for in vitro diagnostics for vaccine-preventable diseases, facilitating faster access to innovative products.

Impact and transition towards mature national regulatory capacities

Through its adaptive approach, WHO prequalification has to date quality-assured more than 1750 medical products across product streams, ensuring the quality and safety of medical throughout the lifecourse, across diseases and health conditions, in health emergencies and through pandemics. Its inherent ecosystem of human and institutional regulatory capacity-building has been endorsed and supported by Member States in numerous World Health Assembly resolutions. However, since its inception, WHO prequalification is considered a time-limited mechanism, decreasing in importance with the improving status of national regulatory systems. The mandate of the Department of Regulation and Prequalification supports this transition from prequalification towards functional national and regional regulatory capacities, through a process of regulatory system strengthening, harmonization, reliance, convergence and networking. Until this vision is fully realized, WHO prequalification remains a cornerstone for supporting harmonized international procurement decisions and ensuring equitable access to quality-assured, priority public health medical products.

A trusted global symbol and sound investment

WHO prequalification remains a globally trusted signal of safety, quality and efficacy or performance across the medical product supply chain. As of 2025, nearly 1750 products are either prequalified or recommended through Emergency Use Listing. Independent impact assessments conducted in 2019 and 2023 estimate that WHO prequalification generates savings of approximately US$ 30–40 for every US$ 1 invested. These assessments also estimate that WHO prequalification has enabled approximately US$ 3.5 billion in donor funding to be spent on safe and effective medicines, vaccines and diagnostics, reaching an estimated 400 million additional patients annually. This demonstrates a substantial return on investment for global procurement of medical products and the efforts of global health initiatives.

Strategic priority 3.1. Improve efficiency, capacity and awareness of the prequalification programme

Expansion in prequalification scope and capacity, through new pathways, alignment and streamlining

Scope

In 2025, WHO prequalification expanded its scope to several new first time listings including lenacapavir tablet and injectables for HIV/AIDS treatment, generic self-injectable contraception, a second generic medicine to treat drug resistant tuberculosis, two new sources of active pharmaceutical ingredient for the manufacture of tuberculosis; HIV test using urine samples, antenatal care diagnostic tests, a triple diagnostic test for HIV, hepatitis B and syphilis, two SARS-CoV-2 diagnostics and spatial emanators (repellents) for vector control. Among other firsts in 2025, WHO also supported a first transition to full prequalification of an in vitro diagnostics previously under Emergency Use Listing, organized a first virtual assessment session for vector control products; launched prequalification of vector control products through the Collaborative Registration Procedures (following medicines and in vitro diagnostics) and permitted the submission of dossiers through the ePQS portal.

Capacity

Through the application of quality management standards, the WHO prequalification process is showing reduced screening and assessment timelines, better quality dossiers, and strong engagement from stakeholders across product streams. In 2025, WHO prequalification ensured better alignment with other WHO technical departments, prequalification of vector control products experienced an average 50% decrease in time to prequalification, the pool of expert assessors expanded across product streams including an increasing share of female assessors and assessors from low- and middle-income and a new call for expression of interest from new experts was launched, with over 600 applications received and selected candidates to be added to the existing roster, complementing existing assessment capacity.

500+

participants reached through regulator and manufacturer training workshops

50%

faster average time to prequalification for vector control products

67%

assessors from low- and middle-income countries across recent assessment sessions

36

days to prequalification for first lenacapavir products using reliance-based pathways

100%

dossiers for vector control products met key performance indicators for screening, first action and final decision

New regulatory pathways for medicines

WHO prequalification is now introducing a series of new regulatory pathways including new reliance pathways, through reliance on WHO Listed Authorities (as a reference) and reliance on national regulatory authorities at Maturity Level 3 and 4 i.e. considering the assessment of products approved by these regulatory authorities in certain situations. The expanded abridged pathways which includes new prequalification pathway for products already approved by a stringent or WHO Listed Authorities for use only outside the region of these authorities and an abridged prequalification procedure for products already marketed by stringent or WHO Listed Authorities, whereby these authorities share unredacted assessment and inspection reports with WHO Prequalification and as needed for further sharing with the national regulatory authority participating in WHO Collaborative Registration Procedures.

Alignment and streamlining

Building on an interim approach introduced during the COVID-19 pandemic, WHO is currently engaged in the development of a synchronized and parallel assessment process, for a broader range of products beyond emergency contexts. The new procedures are being developed under the coordination of a WHO working group across 16 WHO departments. The Department of HIV, Hepatitis, Sexually Transmitted Diseases and Tuberculosis and the Department of Regulation and Prequalification is currently piloting the new parallel assessment process, assessing simultaneously the evidence on new tuberculosis diagnostics to inform future tuberculosis policy guidance and the product, for possible prequalification, speeding up the overall assessment process with subsequent positive impact on access to needed tuberculosis diagnostic services.

Raising awareness of prequalification procedures, achievements and challenges

WHO continues to raise awareness of the WHO prequalification process, new procedures, achievements and challenges across product streams, through:

- pre-submission meetings, technical training workshops and regular briefings for manufacturers and national regulatory authorities to ensure understanding of the prequalification process and a more efficient prequalification assessments through and quality dossiers submitted by the manufacturers;
- regular meetings with procurement agencies and global partners, including the annual Joint WHO-UNICEF-UNFPA meetings for technical updates and discussions;
- through the WHO Rotational Fellowship Programme, offering a unique opportunity for assessors and inspectors, primarily from national medicine regulatory authorities in low- or middle-income countries to enhance their capacities and subsequently contribute to update of good regulatory and manufacturing practices in their countries;
- WHO Prequalification website, newsletters, the annual report of the Department of Regulation and Prequalification and regular meetings and communications with its contributors.

Strategic priority 3.2. Strengthen and expand WHO's prequalification lists across product streams

Snapshot of WHO prequalification activities

In vitro diagnostics

- Cholera
- G6PD
- Glucose meter and test strips
- HbA1c point of care test*
- Hepatitis B
- Hepatitis C
- HIV/AIDS
- HPV
- Malaria
- SARS-CoV-2
- Syphilis
- Tuberculosis

13 prequalified in 2025, 162 to date

* Inlcuding Emergency Use Listing

Vaccines

- 24 priority diseases, covering all vaccines required for routine immunization
- Cholera
- COVID-19
- Dengue
- Ebola virus diseases
- Malaria
- Mpox
- SAVs for snakebite envenoming

9 prequalified in 2025, 175 to date

Medicines

FPP, active pharmaceutical ingredient, biotherapeutic products and similar biotherapeutic product

- BTP/SBP (cancer, COVID-19, insulin and tuberculosis skin test)
- Child health
- COVID-19
- Diarrhea
- Ebola virus diseases
- Hepatitis B
- Hepatitis C
- HIV/AIDS
- Influenza
- Malaria
- MDR bacterial infections
- Neglected tropical diseases
- New-born and young infant
- Nicotine replacement therapy
- Sleep apnea
- Reproductive health
- Tuberculosis

32 prequalified medicines, including 3 biotherapeutics and 12 active pharmaceutical ingredients in 2025, 759 to date

Vector control products*

- Insecticide-treated nets, including products which include use pattern for self-treatment of bednets
- Indoor residual spraying products
- Larviciding products
- Space spray products, including indoor and outdoor use patterns

9 prequalified in 2025, 96 to date

Medical devices

Immunization devices and cold chain equipment

- Cold/freezer room
- Cold box and vaccine carrier
- Cold chain accessory
- Coolant pack
- Injection device for vaccine
- Injection device for therapeutic
- Refrigerated vehicle
- Refrigerator and freezer
- Temperature monitoring device
- Waste management equipment

21 prequalified in 2025, 602 to date

Inspection

- Active Pharmaceutical Ingredients
- Biotherapeutics and Biosimilars
- Finished Pharmaceutical Products
- Immunization Devices
- In Vitro Diagnostics
- Vector Control Products
- Vaccines
- Bioequivalence Studies
- Quality Control Laboratories

186 inspections in 2025, 1222 to date

WHO prequalification of vaccines

WHO continues to play a central role in ensuring timely, equitable access to safe, effective and quality-assured vaccines worldwide. Through independent, science-based regulatory assessment and lifecycle oversight, WHO vaccine prequalification supports prevention across 24 priority diseases covering essential childhood vaccines required for routine immunization in more than 90 countries as well as vaccines for public health priorities such as polio, influenza, malaria, mpox and COVID-19. The global reach and public health impact of WHO prequalification contributes to strengthen regulatory confidence and underpins procurement decisions that protect millions of lives every year and reinforcing

Prioritization of vaccine prequalification is established by WHO in consultation with UN procurement agencies, based on the priority category established for each vaccine including demand in UN-supplied markets and planned new vaccine introductions; suitability for WHO programmatic needs, recommendations of WHO's Strategic Advisory Group of Experts on Immunization and supply security, indicated by the number, diversity and production capacity of suppliers.

In 2025, WHO prequalified nine new vaccines bringing the cumulative total of WHO-prequalified vaccines to 175. WHO also supported the transition of two COVID-19 vaccines from Emergency Use Listing to full prequalification, with one additional COVID-19 vaccine remaining under assessment. WHO continues the post-Emergency Use Listing and post-prequalification monitoring activities to ensure vaccine quality, safety and effectiveness. In 2025 WHO received 138 post-prequalification variations, reviewed and closed 120 prequalification variations, with 62 remaining under review at year end, including post-prequalification commitments and periodic safety update reports, supporting continued assurance of vaccine quality, safety and performance. Post-Emergency Use Listing oversight included assessment of three post- Emergency Use Listing variations and review of two periodic safety update reports. Assessment of vaccine prequalification dossiers were complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

Increasing efficiencies and reducing the median time to prequalification of vaccines

Prequalification of vaccines has been using streamlined assessment procedure for over 10 years thus shortening the assessment times of vaccines assessed by WHO Listed Authorities (formerly known as Stringent Regulatory Authorities). During the COVID-19 pandemic the streamlined procedure was also used to ensure rapid Emergency Use Listing recommendations which were followed by timely approvals by national regulatory authorities of vaccine receiving countries.

PQ **assessment,** 9 prequalified vaccines
Total to date: 175 vaccines

Post-EUL **activities,** 3 post-EUL variations, 2 PSUR reviewed

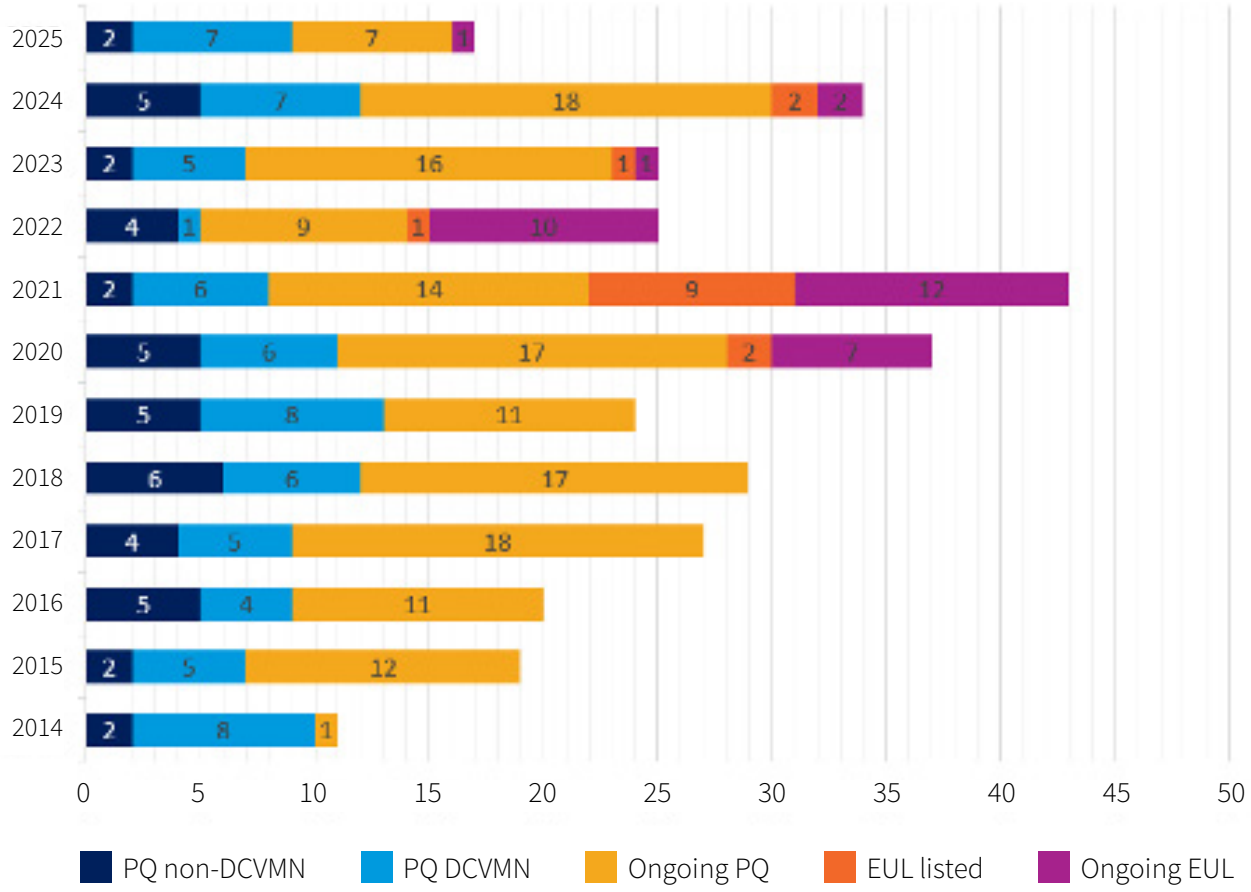
Polio contribution to release of 810 million doses into the global polio stockpile under the Global Polio Eradication Initiative

EUL **vaccines,** 2 COVID-19 vaccines transitioned from Emergency Use Listing to prequalified, 1 still pending

UNICEF **tenders** (vaccines and specific immunoglobulins), Typhoid conjugated, Yellow fever, Pneumococcal conjugated, Bivalent Oral Polio Type 1&3 (bOPV 1&3), Meningococcal, Influenza seasonal, Hepatitis A, COVID-19

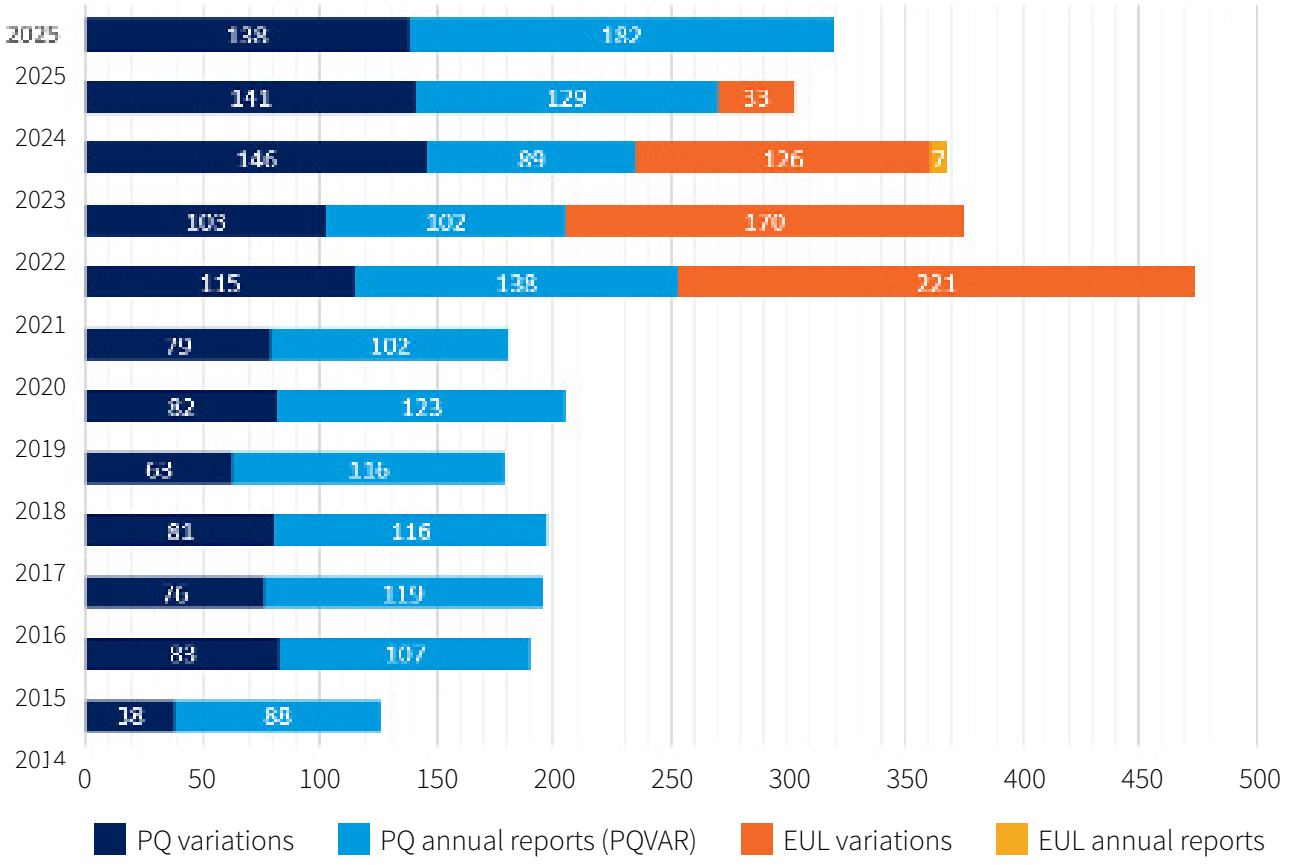
EUL: Emergency Use Listing | **PQ:** prequalification | **PSUR:** periodic safety update report | **UNICEF:** United Nations Children's Fund

Fig. 27. Vaccines prequalified and approved for Emergency Use Listing from 2014 to 2025



DCVMN: Developing Countries Vaccine Manufacturers Network | **EUL:** Emergency Use Listing | **PQ:** Prequalification

Fig. 28. Post-prequalification and post-Emergency Use Listing vaccine activities from 2024 to 2025



EUL: Emergency Use Listing | **PQ:** Prequalification | **PQVAR:** Prequalified vaccine annual report

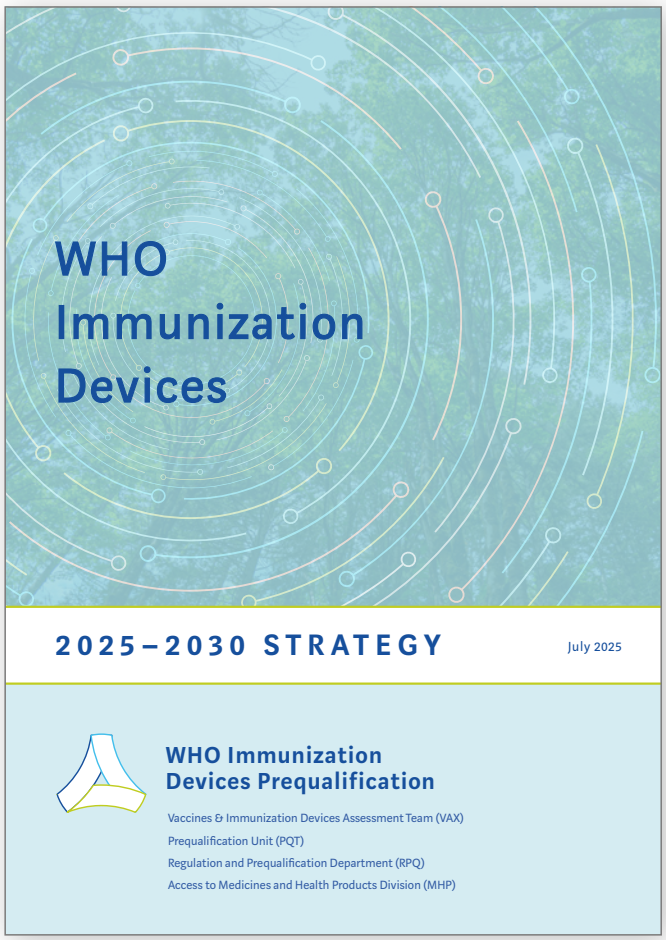
Contribution to polio eradication

The global incidence of polio has decreased by 99.9% since the Global Polio Eradication Initiative was established in 1988. WHO prequalification of polio vaccines is an important component of these efforts. After a decade of research and testing, the novel oral polio vaccine type 2 was rolled out for field use in March 2021 under the then newly introduced Emergency Use Listing procedures. As of today, about 1.3 billion doses have been administered in 41 countries. In December 2023, novel oral polio vaccine type 2 achieved prequalification status, becoming the first vaccine to successfully transition from the Emergency Use Listing pathway to full prequalification, setting a precedent for future drug innovations. In 2025, WHO contributed to the release of 810 million doses into the global polio stockpile under the Global Polio Eradication Initiative and an additional oral polio vaccine type 2 was prequalified.

WHO Prequalification of immunization devices

The WHO prequalification services has contributed to ensure the quality and safety of immunization equipment since 1974, when it was first involved in the development of standards for equipment intended for the vaccine supply chain. WHO prequalification of immunization devices plays a critical role in ensuring that national immunization programmes have access to reliable, high-quality products for the storage, transport and administration of prequalified vaccines. These devices are essential to maintaining required temperature conditions, safeguarding vaccine potency in challenging environments and supporting equitable access to immunization services, particularly in underserved and hard-to-reach settings.

Fig. 29. New WHO Immunization Devices Strategy



WHO Immunization Devices, 2025–2030 Strategy

New WHO Immunization Devices Strategy 2025–2030

In July 2025, WHO published the Immunization Devices Strategy 2025–2030, introducing new emergency preparedness and environmental sustainability targets and reinforcing long-term support for national immunization programmes. Through prequalification of immunization devices, WHO helps protect substantial global investments in vaccine development, procurement and delivery, and is a key enabler to the implementation of the WHO Expanded Programme on Immunization and to the Immunization Agenda 2030.

In 2025, WHO prequalified 21 immunization devices and 421 prequalified immunization devices were reassessed in the annual review process in April 2025. WHO also continued the post-prequalification monitoring activities to ensure the continued quality, safety and effectiveness of prequalified immunization devices, reviewing 30 product variations throughout the year, ensuring continued compliance with WHO performance and quality requirements across the cold chain and delivery ecosystem. Quality assurance also included 1 audit of a new vaccine vial monitor manufacturer. Assessment of immunization devices prequalification dossiers was complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

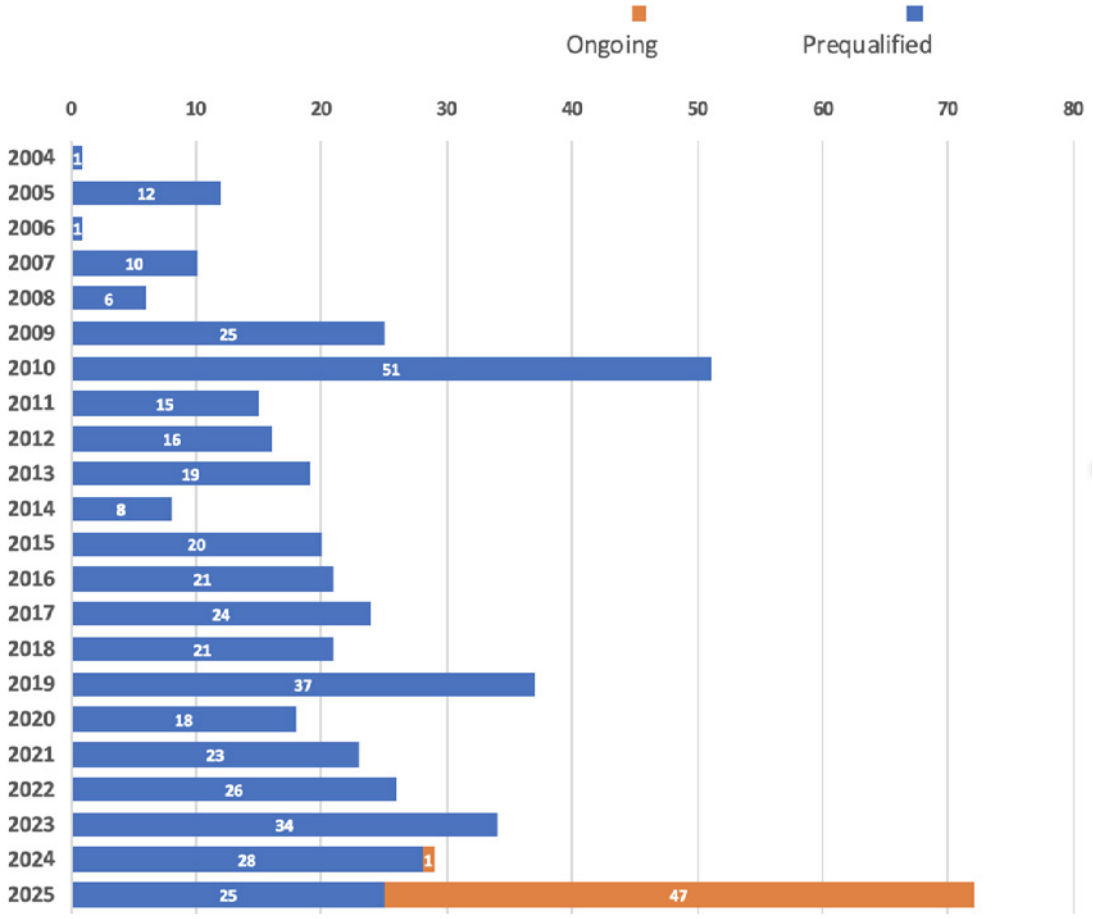
Fig. 30. Prequalification of immunization devices, performance, quality and safety categories

- **E001: Cold rooms, freezer rooms and related equipment**
- **E002: Refrigerated vehicles**
- **E003: Refrigerators and freezers**
- **E004: Cold boxes and vaccine carriers**
- **E005: Coolant-packs**
- **E006: Temperature monitoring devices**
- **E007: Cold chain accessories**
- **E008: Single-use injection devices**
- **E010: Waste management equipment**
- **E013: Therapeutic injection devices**

Increasing efficiencies and reducing the median time to prequalification of immunization devices

Over the past years prequalification of immunization devices has identified and developed a network of partner organizations and individual technical experts to support dossier assessments. The 'team' of experts combined with establishing an effective project management system has reduced time to prequalification.

Fig. 31. Immunization devices prequalified from 2004 to 2025



Guidance and tools

WHO continues to strengthen the normative foundation for immunization device regulation with publication of the 7th edition of the WHO Guidelines for the international packaging and shipping of vaccines as guidance to support safe, effective and compliant global vaccine distribution. Throughout 2025, WHO continued the revision of 8 immunization device specifications including for refrigerated transport medical devices, refrigerated vehicles and freeze-preventive vaccine carriers, with several specifications reaching advanced stages. A solar-direct-drive cold room field study was conducted in Senegal to generate real-world performance evidence. As part of the prequalification process, WHO works with accredited evaluation laboratories to test whether the products under prequalification satisfy the requirements of the relevant WHO performance specifications. In 2025, three new laboratories were accredited for assessment of temperature monitoring devices, specifically to manage the increasing volume of equipment monitoring system dossiers.

421 products underwent reassessment

Field study on solar-direct-drive cold room conducted in Senegal

8 immunization device specifications under review or revision

1 audit of a new vaccine vial monitor manufacturer

Coordination and international collaboration

WHO continues close collaboration with the WHO Expanded Programme on Immunization, global procurement agencies and partners to support access to safe and quality immunization devices. In 2025 this included close collaboration with the United Nations Children's Fund Supply Division and the United Nations Children's Fund Programme Group, Gavi, the Vaccine Alliance; PATH and the Clinton Health Access Initiative to support innovation, quality assurance and market readiness for immunization devices. The WHO Prequalification Programme also ensured alignment with the WHO Health Emergencies Programme and support for emergency-use carriers capable of maintaining low-temperature conditions, reinforcing preparedness for outbreak response and emergency deployment.

WHO Prequalification of medicines

Major milestones in accelerating access to quality-assured medicines

Access to safe, effective and quality-assured medicines is a cornerstone of public health and essential to achieving equitable health outcomes. WHO prequalification of medicines was first established in 2001, in response to the HIV/AIDS pandemic and has since expanded its scope to covered additional therapeutic areas. Simultaneously, there is growing request from manufacturers for quality assurance services for biotherapeutic medicines for treating cancer and of insulin for treating diabetes, with foreseen expansion to additional non-communicable diseases. This mirrors the changing global disease burden and underscores WHO's role in supporting both regulatory maturity and access to next-generation health technologies.

The prequalification of medicines process includes assessment of product dossiers for finished pharmaceutical products (medicines) and active pharmaceutical ingredients, and inspections of the corresponding manufacturing and clinical sites. WHO also prequalifies medicines quality control laboratories by evaluating the quality of their chemical and microbiological testing services.

The standards used to evaluate the finished pharmaceutical products and the active pharmaceutical ingredients, and their manufacturing sites, are based on the principles and practices agreed by the world's leading regulatory agencies and adopted by the WHO Expert Committee on Specification for Pharmaceutical Preparations. WHO prequalification of medicines is closely aligned with the various WHO clinical guidelines and the WHO Model List of Essential Medicines, ensuring that products prioritized for assessment and listing address evidence-based public health needs and support coherent decision-making across policy, procurement and national regulatory systems.

In 2025, WHO prequalified a total of 32 medicines (including three biotherapeutic products) and 12 active pharmaceutical ingredients, with the prequalification of the first lenacapavir products (tablet and injection) in just 36 days under a new abridged procedure, the first tuberculosis skin test, multiple pediatric formulations, a second generic antibiotic medication for treatment of multi-drug-resistant tuberculosis, increasing competition and lowering prices; a first generic self-injectable contraceptive potentially bringing significant cost reductions and improved access for women in low-and middle-income countries. WHO also ensured the first prequalified caffeine products for treatment of apnea in preterm infants and two new active pharmaceutical ingredients for the manufacture of antibiotic treatment against tuberculosis, addressing important global shortages. Assessment of medicines and active pharmaceutical ingredients was complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

WHO also continued the post-prequalification monitoring activities to ensure the continued quality, safety and effectiveness of prequalified medicines, reviewing more than 500 product variations for medicines and API amendments, all within the published first action target times. At the same time, 75 products were requalified and the WHOPARs for all prequalified products were maintained. These activities contributed to ensuring continued supply of prequalified products.

Fig. 32. Number of Finished Pharmaceutical Products, including Biotherapeutics and active pharmaceutical ingredients prequalified from 2019 to 2025

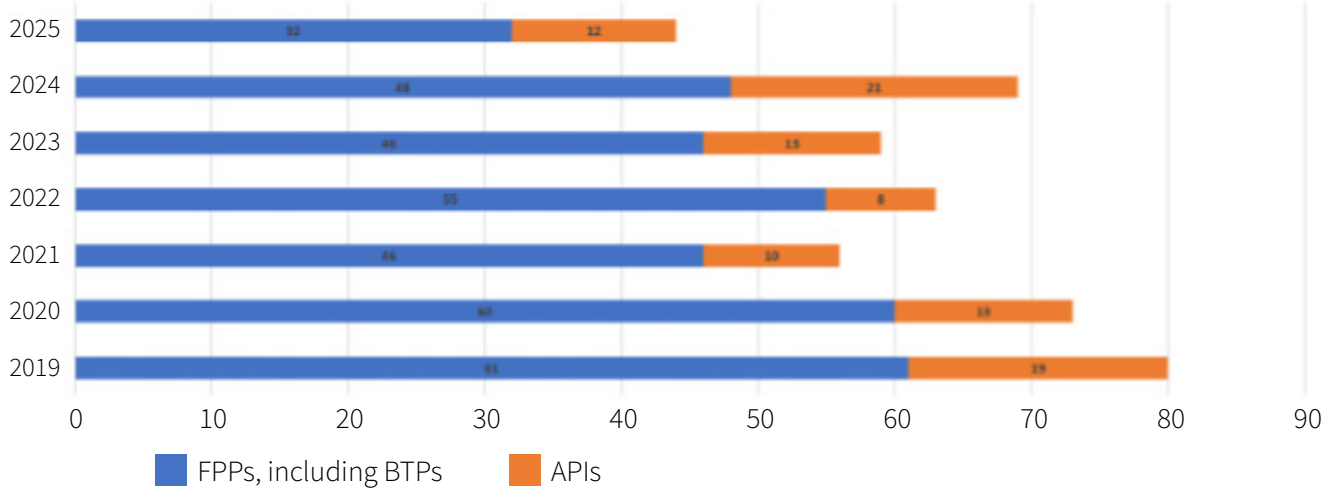
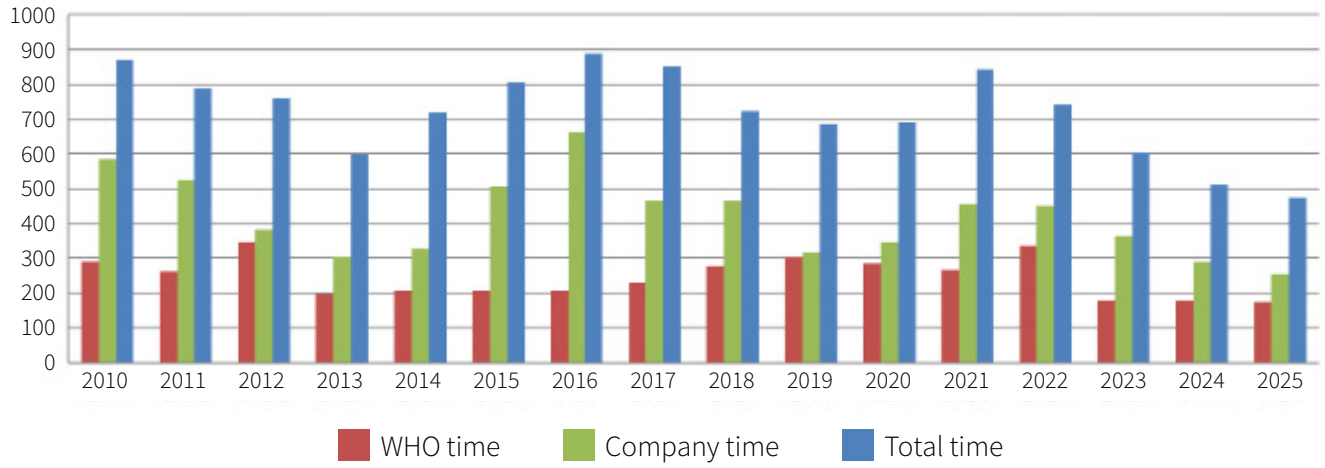


Fig. 33. Median time to medicine prequalification 2010 to 2025



Increasing efficiencies and reducing the median time to prequalification of medicines

In 2025, the median WHO assessment time was 175 days, and the median time to prequalification was 473 days. Similar good achievements were observed for abridged assessments and for prequalification of active pharmaceutical ingredients. The continuing reduction in screening and assessment timelines stems from several factors, including application of quality management standards and introduction of operational measures to address back-logs, enhanced regulatory support to manufacturers and better understanding of WHO requirements and a growing number of prequalified active pharmaceutical ingredients, which can support submission of multiple dossiers for medicine prequalification.

Risk-based assessment through WHO Expert Review Panels for Medicines

Upon request from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies and with the support of Unitaid, WHO undertakes Expert Review Panels for medicines to assess potential risks and benefits associated with the use of finished pharmaceuticals, in vitro diagnostics or medical devices which may have substantial public health impact, but that are not in the scope of prequalification, or have not yet been prequalified or undergone stringent regulatory assessment. WHO oversees selection of the experts and in 2025 the WHO Expert Review Panel for Medicines undertook 20 reviews of pharmaceutical dossiers (including additional data and extension reviews) for pediatric antimalarials, a reproductive health product, and a neglected tropical disease treatment. Additionally, WHO undertook 7 reviews to address the shortage of rifampicin active pharmaceutical ingredients and provided feedback to UNICEF on the quality of 13 products, such as insulin, insulin analogues, and a chemotherapy medication.

Guidance and tools

Throughout 2025, WHO produced 71 new or updated notes on design of bioequivalence studies to support development of generic products, with additional guidance on an innovative pathway for biotherapeutics under revision.

Expanding the use of regulatory reliance and abridged pathways

WHO prequalification is now introducing a series of new regulatory pathways including **new reliance pathways,** through reliance on WHO Listed Authorities (as a reference) and reliance on national regulatory authorities at Maturity Level 3 and 4, i.e. considering the assessment of products approved by these regulatory authorities in certain situations. The **expanded abridged pathways** which includes a new prequalification pathway for products already approved by a stringent or WHO Listed Authorities for use only outside the region of these authorities and an abridged prequalification procedure for products already marketed by stringent or WHO Listed Authorities, whereby these authorities share unredacted assessment and inspection reports with WHO Prequalification and as needed for further sharing with the national regulatory authority participating in WHO Collaborative Registration Procedures.

Coordination and international collaboration

The WHO Prequalification Programme continues close collaboration with the WHO Science Division in delivering scientific advice to product developers under the Coordinated Scientific Advice procedure as well as with other WHO technical/clinical departments, UN and global health procurement agencies to shape invitations for Expressions of Interest for WHO prequalification.

Capacity-building and training for quality assurance of medicines

An important part of the prequalification of medicines process is to build the capacity of staff from national regulatory authorities, quality control laboratories and manufacturers to ensure that medicines quality is attained and maintained. In 2025, more than 40 assessors from low-and middle-income countries were trained through participation in the bimonthly prequalification of medicines assessment sessions, offering a unique platform for hands-on mentoring and exchange of experience with highly experienced assessors and experts.

WHO also organized four virtual training workshops for regulators and manufacturers with close to 900 participants; held 12 pre-submission meetings and additional advisory meetings to with manufacturers to ensure quality submissions. In support of the African Medicines Agency, WHO organized a dedicated assessment training for 100 affiliated assessors, from 21 national regulatory authorities and regional harmonization initiatives, and facilitated the participation of regulators from Cameroon and Egypt to the WHO Rotational Fellowship Programme.

Prequalification of in vitro diagnostics

Major milestones in accelerating access to quality-assured in vitro diagnostics

Reliable and quality-assured in vitro diagnostics are essential for effective diagnosis, monitoring of therapeutic efficiency and the prevention of the development of drug resistance. Rapid advances in development of medical devices combined with a growing number of in vitro diagnostics entering the market, led WHO to establish the Prequalification Programme for In Vitro Diagnostics and Medical Devices in 2010, focusing on priority diseases and adapted to the rapidly evolving diagnostics landscape. Since 2010, WHO's prequalification assessments have expanded in scope and diversity. The prequalification of in vitro diagnostic process includes assessment of product dossiers, labelling reviews and inspection of manufacturing sites. As of 2026, a revised prequalification assessment will be in place, whereby the performance evaluation is no longer part of the prequalification assessment and is a separate procedure.

In 2025, WHO received 26 new applications for prequalification assessment of in vitro diagnostics, spanning 13 different product types currently eligible for prequalification assessment. WHO prequalified 13 in vitro diagnostics, marking an exceptional year for expanding global access to quality-assured testing. These included several notable firsts: the first HIV test using urine samples, the first comprehensive antenatal care panel, the first triple diagnostic test for HIV, hepatitis B, and syphilis, and the first two SARS-CoV-2 assays to successfully transition from Emergency Use Listing to prequalification – an important milestone signaling a shift from emergency response mechanisms toward sustained, long-term quality assurance. Further 8 in vitro diagnostics were listed under the Emergency Use Listing procedure, bringing the total number of 2025 listings to 21, the highest annual figure to date. This record performance also included several mpox assays, raising the total number of mpox diagnostics listed under the Emergency Use Listing to 12. This was complemented by the inclusion of point-of-care haemoglobin analyzers, a critical asset within the noncommunicable diseases' portfolio. Collectively, these milestones significantly broadened the global landscape of quality-assured diagnostics and expanded the range of reliable tools available to public health programmes worldwide. Assessment of in vitro diagnostic prequalification dossiers was complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

13 additional in vitro diagnostics prequalified, including the first HIV rapid test using urine samples and the first comprehensive antenatal care diagnostic panel

21 total product listings across prequalification and Emergency Use Listing, the highest annual total achieved to date

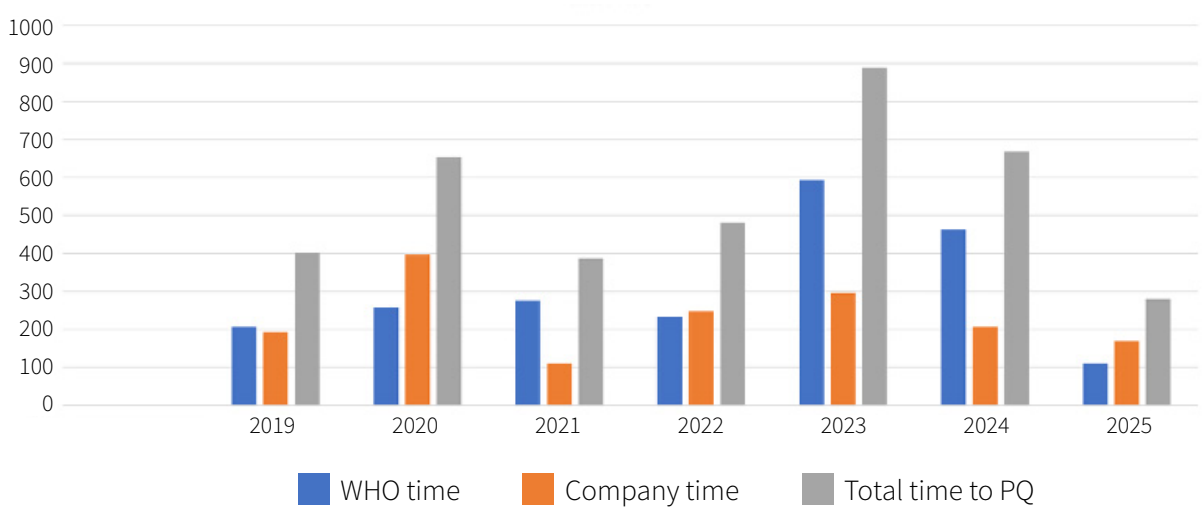
1st successful transition from Emergency Use Listing to full prequalification, marking a milestone in continuity from emergency use to long-term quality assurance

3 global manufacturer workshops delivered, engaging more than 300 participants

8 mpox diagnostic assays listed under Emergency Use Listing

1st pilot parallel assessment process for tuberculosis tests using swabs

Fig. 34. Median time to prequalification of in vitro diagnostics



Increasing efficiencies and reducing the median time to prequalification of in vitro diagnostics

In 2025, WHO reduced the median prequalification time for in vitro diagnostics to 95 days, with manufacturers' median time at 228 days and a total median time of 468 days. This efficiency gain resulted from coordinated measures, including strengthened manufacturer education through targeted workshops and webinars, and the introduction of a streamlined assessment pathway with fewer review cycles and strict timelines. Further improvements were achieved through expansion of the expert network and enhanced cooperation with regulatory authorities. WHO also implemented a revised procedure for changes to prequalification and Emergency Use Listed diagnostics, increasing reliance on recognized approvals and applying a reinforced risk-based framework, resulting in more efficient reviews and shorter decision timelines.

Risk-based assessment through WHO Expert Review Panels for Diagnostics

Upon request from the Global Fund to Fight AIDS, Tuberculosis and Malaria and other agencies and with the support of Unitaid, WHO coordinates the Expert Review Panel for Diagnostics to assess potential risks and benefits associated with the use of in vitro diagnostics which may have substantial public health impact, but that are not in the scope of prequalification, or have not yet been prequalified or undergone stringent regulatory assessment by a founding member of the Global Harmonization Task Force (now replaced by the International Medical Device Regulators Forum). Through the Expert Review Panel, WHO coordinates technical reviews with selected experts and in 2025 undertook the review of 22 submissions. Since 2023, the WHO Neglected Tropical Diseases Programme has launched several pilot rounds of Expert Review Panels for Diagnostics for neglected tropical diseases.

Contributing to implementation of the global roadmap for neglected tropical diseases 2021–2030

In contribution to improving access to quality health products for neglected tropical diseases, WHO prequalification continues to support the expanded implementation of risk-based assessments for selected neglected tropical diseases. Throughout 2025, the Expert Review Panel for Neglected Tropical Diseases undertook review of 10 in vitro diagnostics. As an outcome of the review the WHO Neglected Tropical Diseases Programme recommended 8 in vitro diagnostics for limited procurement and use, including 1 rapid diagnostic test for lymphatic filariasis and 7 in vitro diagnostics for dengue, comprising 3 rapid diagnostic tests, 2 PCR tests and 2 immunoassays. The risk-based assessment also provided support to respond to the 2024-2025 global dengue outbreak by guiding the selection and use of appropriate diagnostic tools. For lymphatic filariasis, following the WHO Neglected Tropical Diseases Programme recommendation, 2 million rapid diagnostic tests were procured and supplied to 48 countries, contributing to meet the targets set out in the Global Roadmap for Neglected Tropical Diseases 2021–2030.

Fig. 35. Publication on neglected tropical diseases

Guidance and tools

Throughout 2025, WHO published several new technical specifications to support clear requirements and efficient assessment processes. To further streamline assessment and align regulatory and normative processes, WHO is currently engaged in the development of a synchronized and parallel assessment process with new procedures being developed under the coordination of a WHO working group across 16 WHO departments. The Department of HIV, Hepatitis, Sexually Transmitted Diseases and Tuberculosis and the Department of Regulation and Prequalification are currently piloting the new parallel assessment process, assessing simultaneously the evidence on new tuberculosis diagnostics to inform future tuberculosis policy guidance and the product, for possible prequalification, speeding up the overall assessment process with subsequent positive impact on access to needed tuberculosis diagnostic services. In addition, an amended and streamlined prequalification procedure for in vitro diagnostics was developed, expected to enable further efficiencies.

Coordination and international collaboration

The WHO Prequalification Programme continues to engage with manufacturers and regulators to support quality improvement and regulatory preparedness across the in vitro diagnostics pipeline alongside engagement with global procurement agencies and partners to support access, market stability and long-term supply security of in vitro diagnostics. WHO in vitro diagnostics works closely with WHO technical/clinical departments, UN, and global health procurement agencies to shape the invitations for Expression of Interest for WHO prequalification.

Capacity-building and training for quality assurance of in vitro diagnostics

An important part of the prequalification of in vitro diagnostics process is to build the capacity of staff from national regulatory authorities and manufacturers to ensure that the medical device quality is attained and maintained. WHO continued direct engagement with manufacturers to support quality improvement and regulatory preparedness across the in vitro diagnostics pipeline, including three workshops for Asian in vitro diagnostic manufacturers throughout the year, in Jakarta, Indonesia, Seoul, Republic of Korea and in Guangzhou, the People's Republic of China, engaging over 300 participants to strengthen understanding of prequalification requirements, submission of higher-quality dossiers, industry capacity and regulatory alignment. WHO also convened a dedicated in vitro diagnostics workshop focusing on neglected tropical diseases.

Prequalification of vector control products

Major milestones in the expansion of the vector control toolbox

Vector-borne diseases account for more than 17% of all infectious diseases globally, underscoring the need for timely access to safe, effective and quality-assured vector control products. WHO prequalification of vector control products fills a critical global gap by providing rigorous, transparent regulatory assessments that support national decision-making, procurement and deployment. Vector control interventions are considered health products and have contributed substantially to preventing vector-borne diseases, primarily malaria deaths worldwide, but have also been critical in preventing the transmission of other major vector-borne diseases such as dengue fever, chikungunya, Zika virus disease, Chagas disease, lymphatic filariasis, visceral leishmaniasis, and human African trypanosomiasis.

WHO has worked to support the development, evaluation and adoption of new safe, effective and high-quality vector control products for over 50 years and to modernize WHO evaluation of vector control products, the Prequalification Unit for Vector Control Product Assessment Team was created in 2016, to assess public health pesticide active ingredients to determine that they can be used safely and effectively, and that these manufactured to a high-quality standard. This is done by assessing product dossiers and inspecting manufacturing sites, including contract research organizations as necessary. These efforts are continually evolving, to better support entry of new and innovative products into the market.

In 2025, WHO prequalified nine new vector control products, bringing the total to 96, with another seven products under assessment and four under screening, representing a 75% increase in the number of product prequalified compared to 2024. A major milestone was the first-ever prequalification of two spatial emanators, Mosquito Shield and Guardian, which were prequalified on the same day that WHO issued its policy recommendation supporting this new intervention class for malaria control. Spatial emanator products have demonstrated the ability to repel, disorient and even kill mosquitoes which may transmit malaria. Prequalification also included five insecticide-treated nets including two dual active-ingredient nets and one manufactured using 100% recycled polyester, and new products for indoor residual spraying and space spraying, strengthening malaria and aedes-borne disease interventions and managing vector resistance. Throughout 2025, WHO also initiated re-assessment of 28 insecticide-treated nets and reviewed 36 minor, and 11 major changes to the product portfolios.

To advocate for and expand the prequalification opportunities, WHO held 110 pre-submission meetings with manufacturers, facilitated engagement through the Joint WHO-UNICEF-UNFPA annual meeting with manufacturers and continued bi-weekly stakeholder discussions through Wednesday webinars. WHO also hosted an open meeting with contract research organizations in February 2025, facilitated the global launch of Collaborative Registration Procedures for vector control products, and contributed to the insecticide-treated net workshop for the Ministry of Health of Indonesia in July 2025. Assessment of vector control products prequalification dossiers was complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

Fig. 36. Key achievements

100% of vector control product dossier submitted in 2025 were screened within 60 days, meeting WHO targets for time to first action and final decision

47 changes closed in 2025

28 regulatory pathway determinations completed with an average completion time of 59 days, meeting the 90-day WHO target

75% growth in the number of prequalified vector control products compared with 2024

50% reduction in average time to prequalification following process and capacity strengthening

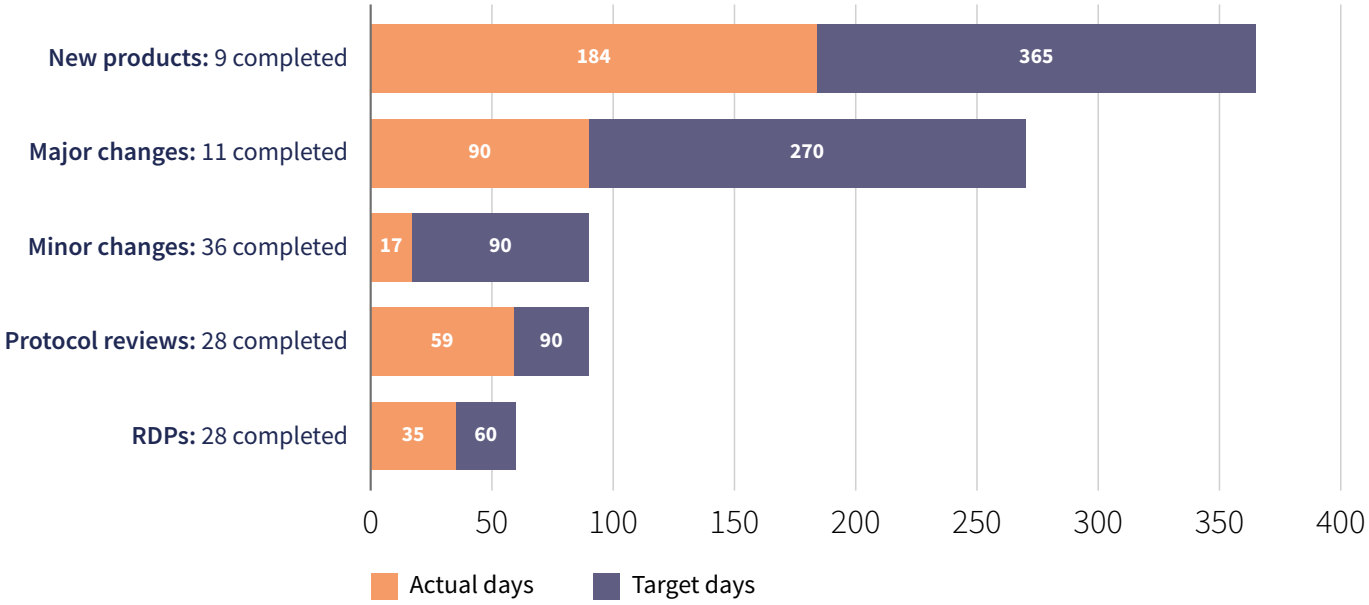
110 pre-submission meetings held with manufacturers, supported by bi-weekly webinars and targeted outreach

New interim regulatory guidance for spatial emanators and implementation of full virtual assessment sessions

Increasing efficiencies and reducing the mean time to prequalification of vector control products

In 2025, prequalification of vector control achieved 100% of applications screened and 100% of first actions within the target time. The continuing reduction in screening and assessment timelines stems from several factors, including efficiencies gained through staffing of the programme, application of quality management standards, consistency in the assessment process and communication, expansion of the assessor's pool and strong case management, ensuring that submitted dossiers and responses were made available expeditiously and that prioritization of actions aligned with the KPIs.

Fig. 37. Prequalification of vector control products: 2025 average WHO review days from acceptance for assessment to closure



Guidance and tools

In support of the prequalification process, WHO published the "Interim Guidance for the prequalification of spatial emanator products," meeting the needs of national regulatory authorities, manufacturers and stakeholders providing the necessary information required for the prequalification process. The guidance is supported by 29 implementation guidance documents clarifying dossier structure, data requirements and testing expectations. it was published concurrently with the first two prepublication decisions for such products to enable expansion of the intervention class and enable the submission of complete product dossiers.

WHO also published two major guidance documents for insecticide treated nets, long-term community studies and "Considerations for post-market surveillance of WHO prequalified insecticide treated nets." In complementarity, procedures for confirmation of compliance of vector control active ingredient sources was published to enable the listing of source materials found to meet WHO specifications based on scientific assessments conducted through the Joint Meeting on Pesticide Specifications. From its work through the Joint Meeting, 11 updated WHO and specifications were issued jointly in 2025 by WHO and the UN Food and Agricultural Organization.

Fig. 38. New publication on vector control active ingredient products

Expanding the pool of vector control assessors

WHO continued to strengthen regulatory capacity for vector control product prequalification through expanded assessor engagement and targeted training initiatives. The assessor pool grew to include representation from all WHO regions, with 75% of assessors from the Global South and 47% women, supporting more inclusive and regionally grounded assessments.

Coordination and international collaboration

WHO Prequalification works closely with the WHO Department of Malaria and Neglected Tropical Diseases, global procurement agencies and partners to support access, market stability and long-term supply security of vector control products.

Capacity-building and training for quality assurance of vector control products

Capacity-building efforts included a pilot national regulatory training held at the WHO Academy in Lyon from 9–12 December 2025, which brought together 11 representatives from Ghana, Kenya, Rwanda and the United Republic of Tanzania. The training focused on vector control product prequalification dossiers, with emphasis on how quality data inform safety and efficacy assessments. In parallel, WHO launched its first rotational fellowship for vector control products with the Food and Drugs Authority of Ghana, further strengthening practical regulatory expertise and knowledge exchange. WHO prequalification also contributes to building the assessment capacity of vector control products in national regulatory authorities through training assessors from Member States through the actual WHO assessments, harmonizing quality and regulatory systems and supporting collaborative registrations.

WHO risk-benefit assessment for snake antivenoms

Each year, an estimated 5.4 million people worldwide are bitten by snakes, resulting in 1.8 to 2.7 million cases of snakebite envenoming and between 81 000 and 138 000 deaths annually with approximately three times as many suffering amputations or other permanent disabilities. Snake antivenom immunoglobulins (snake antivenoms) are the only specific treatment for snakebite envenoming and have been used for 125 years. Antivenom are manufactured by fractionating plasma collected from animals that have been immunized against relevant venoms and that as a result develop neutralizing antibodies. The plasma is processed to extract the active immunoglobulin fraction, which becomes the antivenom. These preparations are included in the WHO List of Essential Medicines and following a consultative process and are endorsed by the WHO Expert Committee on Biological Standardization. WHO Guidelines for the Production, Control and Regulation of Snake Antivenom were first published in 2010 and updated in 2016 and cover all steps in the production and control of both venoms and antivenoms.

Although snake antivenoms are the cornerstone of effective treatment, access to quality-assured products remains limited, due to lack of manufacturing and regulatory capacities to assess the quality and specificity of the antivenom manufactured or imported. In response, the World Health Assembly adopted a resolution in 2018 'Addressing the burden of snakebite envenoming', calling on WHO to ensure the quality and safety of antivenoms. In response WHO has developed a risk-benefit assessment procedure for snake antivenoms, to assist interested WHO Member States, United Nations' procurement agencies, international organizations and other stakeholders in determining the acceptability of using specific snake antivenom products, based on an evaluation of an essential set of available quality, safety, efficacy, and performance data.

The Antivenom Risk-Benefit Assessment Procedure consists of dossier review conducted by a Technical Advisory Group for Snake Antivenom Immunoglobulin Listing which may include international regulatory, veterinary, biologicals manufacturing, quality control, herpetological and medical experts; followed by laboratory assessment and Good Manufacturing Practices inspections of the manufacturing sites.

Fig. 39. Antivenom Risk-Benefit Assessment Procedure

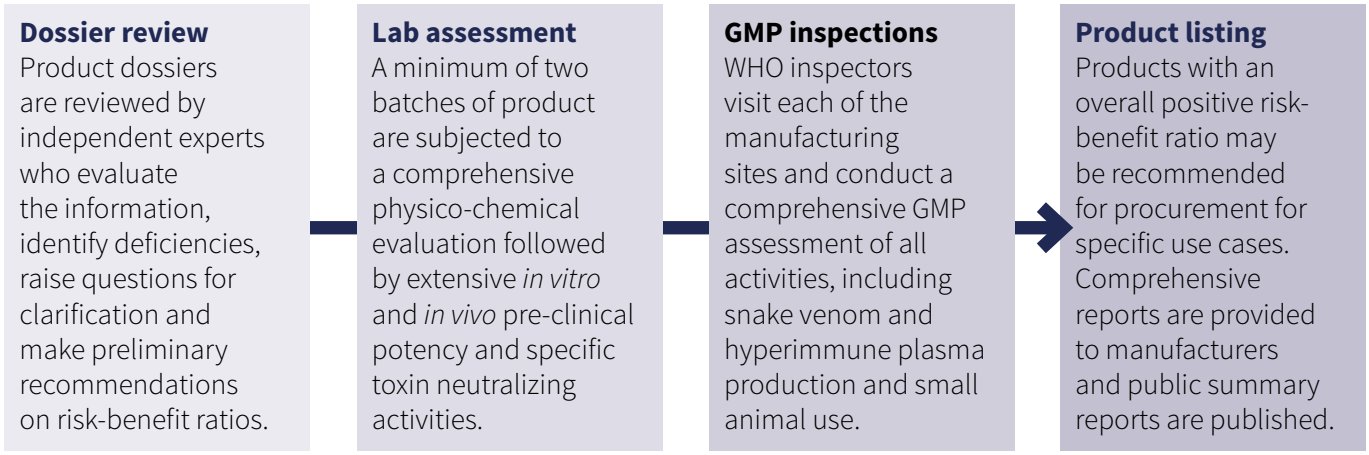


Fig. 40. WHO risk-benefit assessment workflow for review of snake-antivenom products

In 2025, WHO continued the risk-based assessment of antivenoms across three regions, with nine applications received from the Middle East and North Africa region for assessment of polyvalent and monovalent antivenoms of which all are under assessment; 16 applications received from the Sub-Saharan African region, of which 10 assessments are in progress and 3 products have been recommended; and eight applications received from the South-East Asian region, of which all are under assessment, including seven polyvalent products targeting the 'Big Four' snake species. Expansion of the Technical Advisory Group for Snake Antivenom Immunoglobulin Listing from eight to 15 members is currently in progress, and the new Technical Advisory Group will meet virtually twice a year to evaluate applications submitted by manufacturers under the risk-benefit assessment procedure for snake venom immunoglobins.

Through implementation of the risk-benefit assessment approach, WHO strengthened national capacity to navigate complex regulatory decisions where access needs are acute and product quality varies. These efforts enhanced regulators' ability to weigh benefit-risk considerations systematically, supported safer procurement decisions and contributed to improved availability of more effective antivenoms. Collectively, this work supports global efforts to reduce preventable deaths and long-term disability from snakebite envenoming. Risk-assessment of snake antivenom dossiers was complemented by prequalification inspections of manufacturing sites, through on-site inspections and desk assessments.

Coordination and international collaboration

WHO worked with manufacturers, regulators and technical experts to support submission of applications and to clarify evidence expectations under the risk-benefit assessment approach. Engagement with endemic countries supported alignment of assessments with regional snake species, epidemiology and treatment needs, helping ensure relevance of regulatory recommendations to local contexts. Technical advice to procurement agencies helped to guide rational, evidence-based decision-making. The risk-based assessment of is critical to implementation of the WHO Roadmap for Neglected Tropical Diseases 2021–2030 which sets global targets and milestones to prevent, control, eliminate or eradicate 20 diseases and disease groups, including snakebite envenoming.

Guidance and tools

Fig. 41. WHO tools and resources to improve access to snake antivenom resources

Snake antivenoms resources

- WHO snakebite envenoming health topic
- Snakebite information and data platform
- WHO guidelines for production, control and regulation of snake antivenom immunoglobulins
- Target product profiles for animal plasma-derived antivenoms: Africa, South Asia
- Regional action plan for prevention and control of snakebite envenoming in South-East Asia 2022–2030
- WHO strategy for prevention and control of snakebite envenoming

WHO prequalification inspection services

As a cross-cutting service, WHO inspection underpins confidence in WHO prequalification outcomes and support regulatory reliance, convergence and access to quality-assured products across all product streams: in vitro diagnostics, medicines, vaccines, active pharmaceutical ingredients, vector control products, immunization equipment and devices and male circumcision devices. WHO performs inspections or desk assessment to evaluate compliance of manufacturers, contract research organizations and laboratories with good practices, international standards and norms and information submitted by the manufacturers in the prequalification dossier.

In 2025, WHO performed a total of 186 inspections, including 134 onsite inspections contributing to strengthening the pharmaceutical sector capacity, including inspection of 64 finished medicines and active pharmaceutical ingredient sites and six bioequivalence sites, 15 vaccine sites, 13 in vitro diagnostics manufacturing sites, 17 vector control manufacturing sites, one immunization equipment manufacturing site and 18 quality control laboratories. WHO also benefitted from the reliance and recognition of inspections from trusted regulatory partners and performed 50 desk assessments, or reviews of their inspection outcomes across in vitro diagnostics, medicines and active pharmaceutical ingredients, vector control and contract research organizations. Inspections were conducted across all WHO regions, however with a strong focus on the People's Republic of China and India being the major suppliers of medical products.

WHO issued over 50 clearance statements confirming compliance with good practices as part of WHO prequalification assessments across product streams. Over 150 full unredacted inspection reports were shared for the purpose of Collaborative Registration Procedure in 2024 and 2025. As part of the post-listing oversight WHO assessed 25 variations for medicines an active pharmaceutical ingredient, 31 change request and reviewed 124 annual reports submitted by in vitro diagnostic manufacturers, supporting continued compliance with WHO standards. These activities span the full WHO prequalification life cycle. Clearance statements and inspections are conducted during the assessment phase to support prequalification decisions and reliance by other regulators. Finalized inspection reports are subsequently shared with national authorities through FPI to facilitate collaborative registration procedure. Following product listing, prequalification continues oversight through the review of variations, change requests and annual reports to ensure ongoing compliance with WHO standards.

Throughout its activities and across product streams, the prequalification inspection services engage with manufacturers, national and regional regulatory authorities, United Nations and global procurement agencies and fora, supporting convergence of inspection standards, mutual reliance on inspection outcomes and more efficient global regulatory oversight.

50+ clearance statements confirming compliance with good practices as part of WHO prequalification assessments across product streams

25 variations for medicines and active pharmaceutical ingredients assessed

186 prequalification inspections conducted

124 annual reports submitted by in vitro manufacturers reviewed

31 change requests

Fig. 42. Number of manufacturing on-site prequalification inspections across product streams in 2025

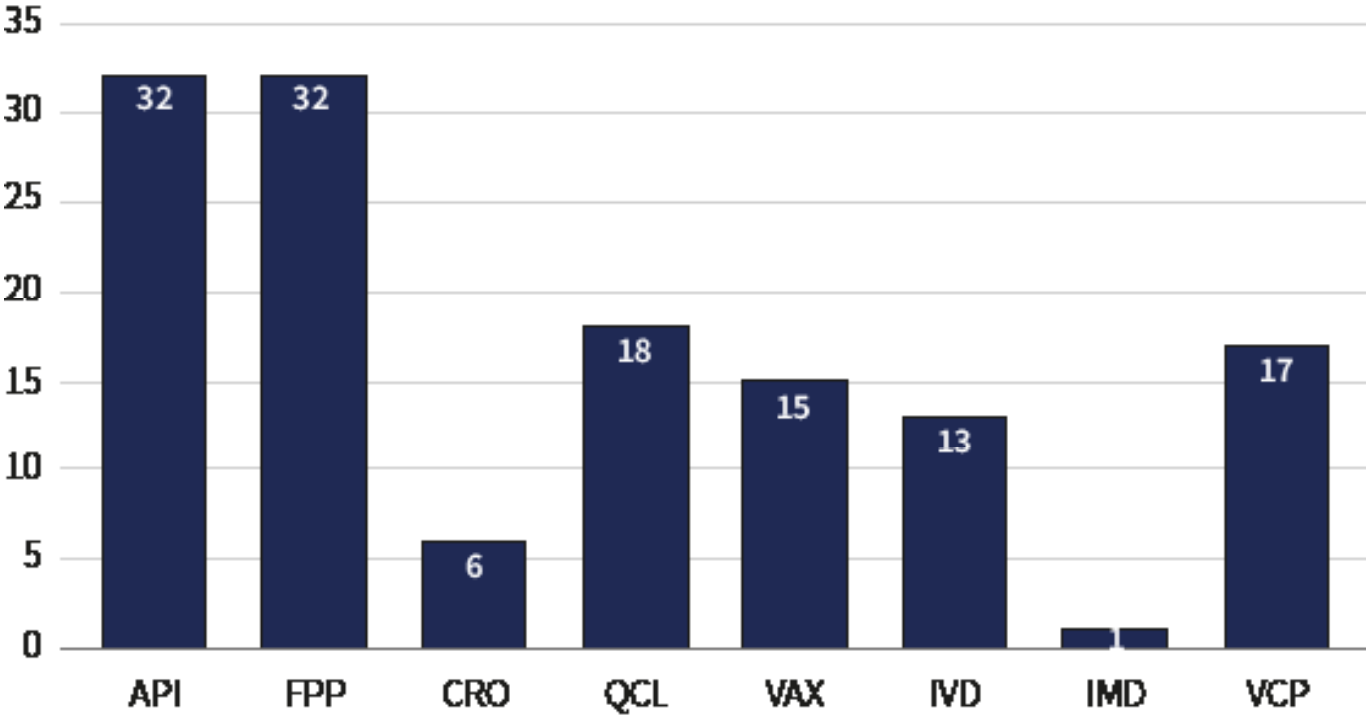


Fig. 43. Number of prequalification inspections per region in 2025

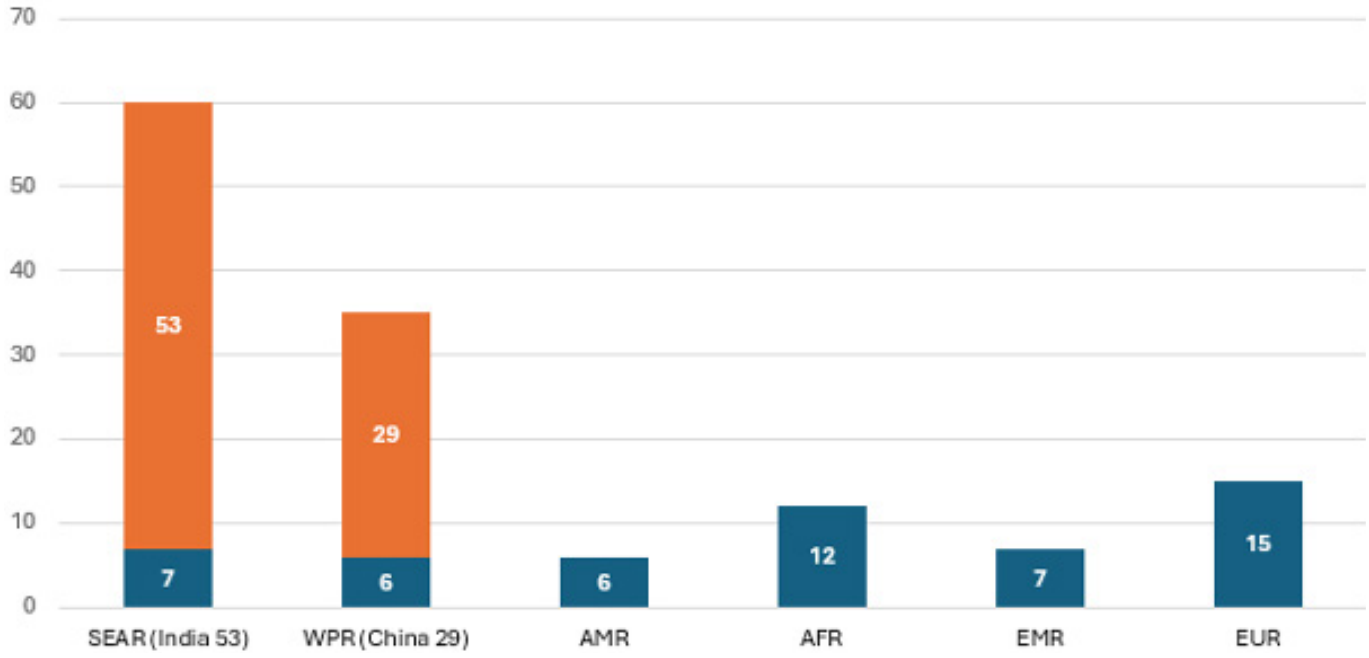


Fig. 44. Onsite prequalification inspections per product stream per country in 2025

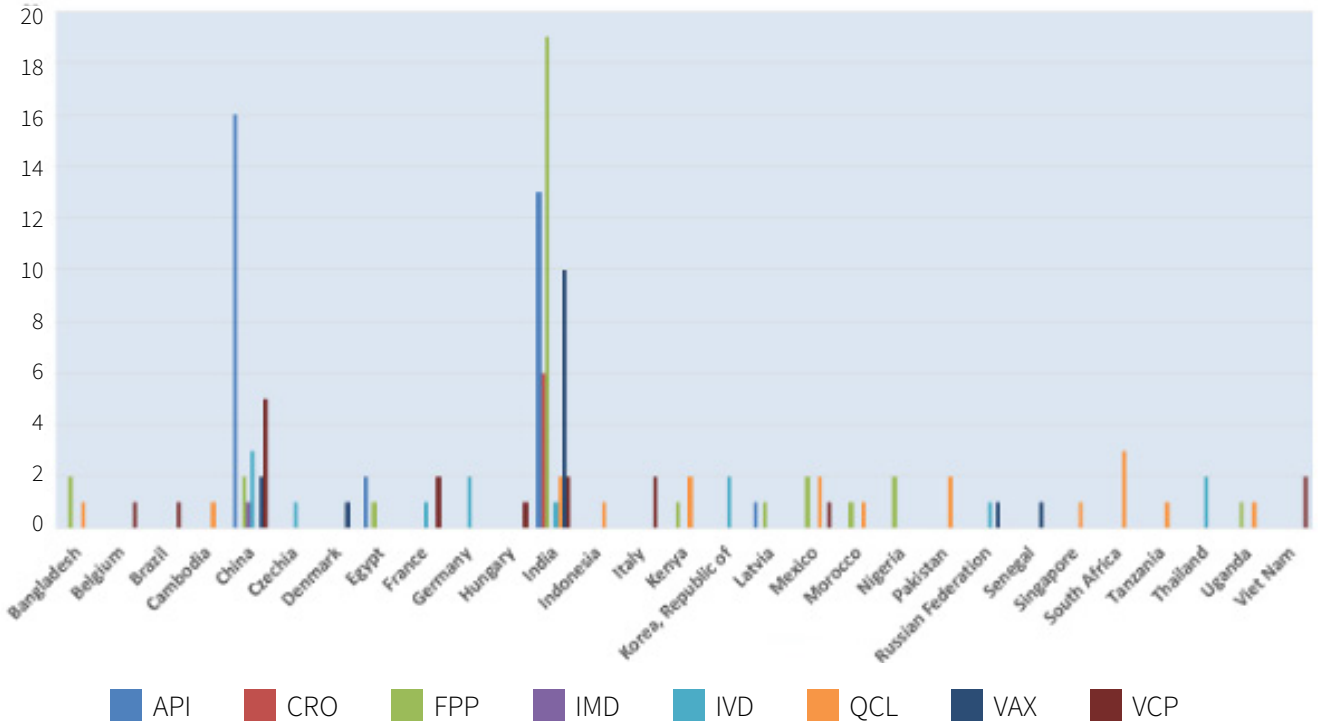
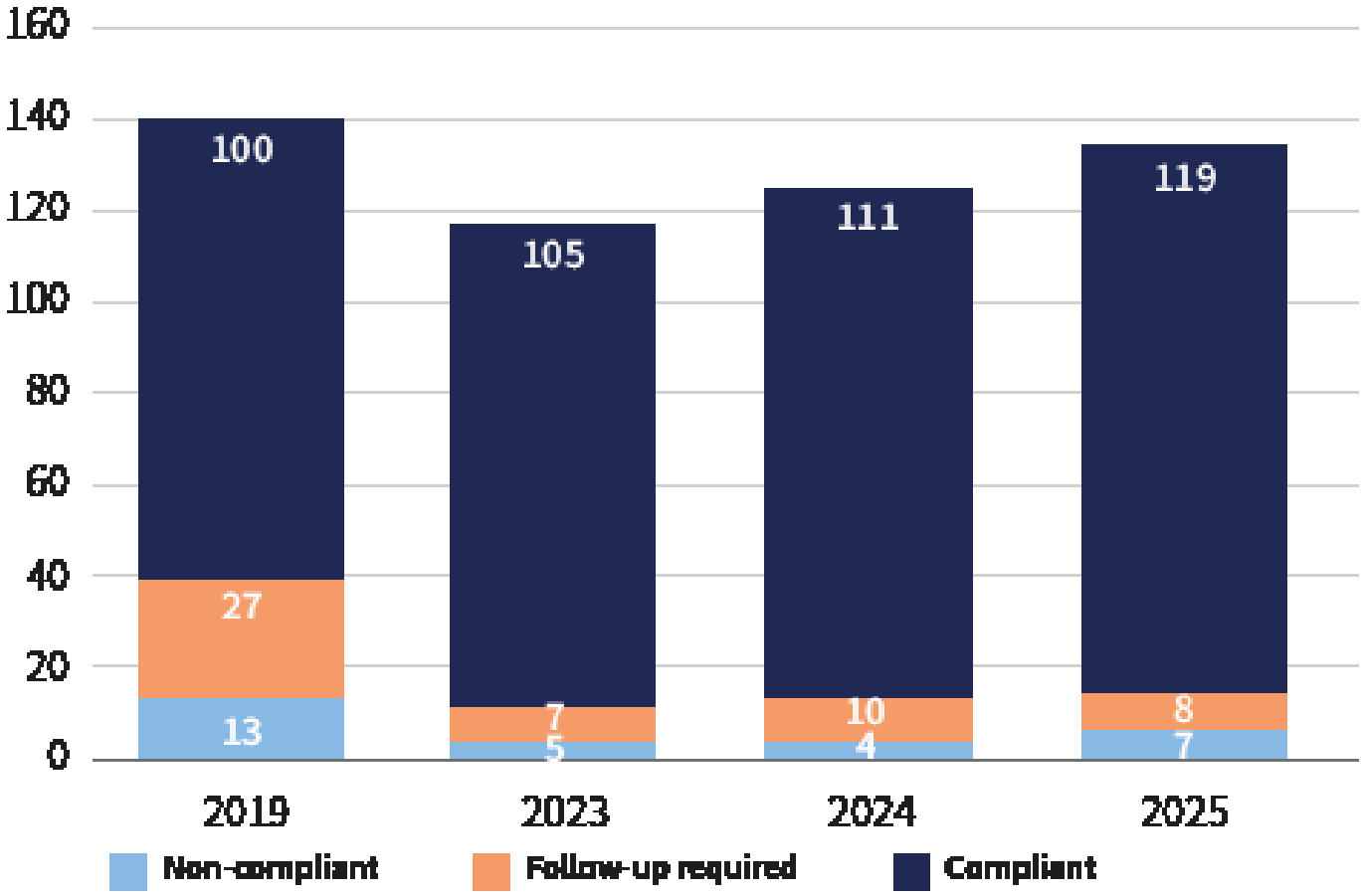


Fig. 45. Outcome of prequalification inspections from 2019 to 2025



Increasing efficiencies and reducing the median time of prequalification inspections

The efficiency of the prequalification inspection services continues to strengthen, supported by several actions including the application of quality management standards, more streamlined and consistent inspection planning and execution; regular review of procedures, improved transparency and accessibility of information; capacity-building to expand the pool of qualified co-inspectors, including reinstating the WHO Rotational Fellowship Programme and engagement of external co-inspectors through professional networks; and enhanced collaboration with regulatory authorities and relevant WHO units to strengthen inspection readiness.

Capacity-building and training through WHO prequalification inspection services

Throughout the year, the WHO Prequalification Inspection services contributed to a series of capacity-building events, including a workshop of Asian manufacturers of in vitro diagnostics in January 2025, a Good Clinical Practices audit in February 2025, training for the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs in September 2025 and a continental Good Manufacturing workshop for the African Medicines Agency in December 2025.

WHO also welcomed two inspectors from the Rwanda Food and Drugs Authority and the Indonesian Food and Drug Authority for six-month rotational positions in the WHO Headquarters in February and July 2025. In addition, 56 staff from national regulatory authorities across five WHO regions participated as observers in WHO inspections, strengthening mutual understanding of inspection standards, processes and decision-making and promoting harmonized inspection practices globally.

Strategic priority 4

Increase the scope and impact of WHO's regulatory support activities

Quality and safety at the core of WHO's mission

Quality and safety have been at the core of WHO's mission since its Constitution entered into force in 1948. Medical products are a key health system building block and ensuring their quality and safety is a pre-condition for global, regional and national investment in health outcomes, as well as an assurance of return-on-investments made by global and regional health initiatives and procurement agencies.

WHO's work in the area of access and regulation is guided by WHO's 14th General Programme of Work 2025–2028; the WHO Triple Billion Targets, the Health Emergency Preparedness and Response architecture, the Pandemic Agreement adopted by Member States in April 2025, relevant resolutions as adopted by Member States in the World Health Assembly and by the recently published WHO Roadmap for Access 2025–2030.

Throughout 2025, WHO has proactively engaged with its partners for the development of the new Strategic Action Plan 2025–2028, published in July 2025. Building on the previous Strategic Action Plan 2019–2023 (extended to 2025 to align with WHO's 14th General Programme of Work), the new Strategic Action Plan reflects findings, recommendations and feedback from a department impact assessment published in March 2023 and a series of consultations with manufacturers, industry associations, procurers, civil society and key partners.

There is strong consensus on the centrality of regulatory system strengthening for global health security and equitable access

Adapting to, and operating in, a changing health ecosystem

2025 will be remembered as a period of upheaval in the global economic and political environment, with profound implications for global health. In response to change in the prioritization of Official Development Assistance, WHO has undergone a reprioritization process which resulted in the announcement of a new organizational organigram and subsequent new headquarter leadership. The Department of Regulation and Prequalification is now merged into larger Health Systems, Access and Data Division, giving opportunities for better alignment, integration and synergy with WHO's efforts to strengthen the wider health systems components.

The WHO reprioritization process was informed by a decision made by WHO Member States in the World Health Assembly in May 2025, to reduce the overall budget for each division/department and the organigrams were aligned accordingly. For the Department of Regulation and Prequalification this has meant a reduction in positions and merging of teams to ensure improve operational synergies and better organizational alignment.

To ensure that WHO's regulatory support capacity and resources are sufficient to implement the strategic priorities set out in the Strategic Action Plan 2025–2028, the department is focusing on critical functions, introducing additional cost efficiency measures, streamlining its operational procedures; partially transferring its knowledge management and learning activities to the WHO Academy and ceasing certain functions, including its investment in a cross-cutting quality management system.

On a path towards financial sustainability

WHO is moving forward on a path towards financial sustainability, with recent prioritization and introduction of cost efficiency measures combined with a gradual increase of WHO assessed contributions of up to 50% of the base Programme Budget over the next eight years, and a 20% increase in assessed contributions approved by Member States in the World Health Assembly in May 2025. In the context of this long-term path, the Department of Regulation and Prequalification continues to rely on a combination of assessed contributions, prequalification fees, voluntary contributions from key contributors and human and technical expertise of core partners.

Evolution of the prequalification fee model

With the introduction of the Expanded Programme on Immunization in 1974, vaccines were increasingly supplied by multinational and national manufacturers and procured through United Nations agencies. In 1987, WHO and UNICEF formalized an agreement under which WHO would assess the acceptability of vaccines for procurement, resulting in the establishment of the first WHO prequalification requirements and procedures, i.e., the WHO Prequalification Programme. Since 2017, over 500 manufacturers worldwide have supported the prequalification services through prequalification fees in the amount of US$ 144 million, covering costs related to applications, assessments, inspections and life cycle oversight. Over this period, however, prequalification fees across all product streams have remained unchanged, despite significant expansion in regulatory scope, scientific complexity, life cycle management requirements and operational costs.

In parallel, legacy fee structures and payment mechanisms such as retroactive invoicing of annual maintenance fees, have contributed to delays, partial payments and instances of non-payment, reducing revenue predictability and limiting effective cost recovery. Thus, parallel with the increasing scope and complexity of the WHO Prequalification Programme, a growing mismatch has emerged between service delivery costs and fee income. In response, a comprehensive review of the existing prequalification fee model is now underway with expected decision on a new 'cost-recovery fee model' to be decided in 2026 and implemented as of January 2028.

Streamlining and expanding learning activities across regulation and prequalification

WHO continues to strengthen and expand the scope of its learning activities as a core enabler of regulatory system strengthening across all product streams. Through a diversified portfolio of learning solutions, WHO supports regulators, assessors, inspectors and technical experts to build practical, applied skills aligned with evolving regulatory needs. These efforts reinforced WHO's commitment to building a skilled, diverse, and resilient global regulatory workforce.

Training delivered in 2025 combined e-learning, on-the-job training and, instructor-led learning with a strong shift toward virtual formats to improve global reach and cost efficiency. A total of 64 learning solutions were delivered across all regulatory functions and prequalification product streams, reaching a total of 1978 learners worldwide as of December 2025 (excluding e-learning) with a strong focus on trainees from the African and the Western Pacific regions. Women accounted for 56% of trainees, and a high proportion of participants were early- and mid-career professionals, supporting long-term sustainability of regulatory expertise.

Fig. 46. Number of regulatory professionals trained

1978*

- Assessors (30%)
- Inspectors (17%)
- Vigilance staff (16%)
- Lab analysts (16%)
- Male (44%)
- Female (56%)

*As of 11 December 2025, excluding e-learning trainees

Fig. 47. WHO Rotational Fellowship Programme

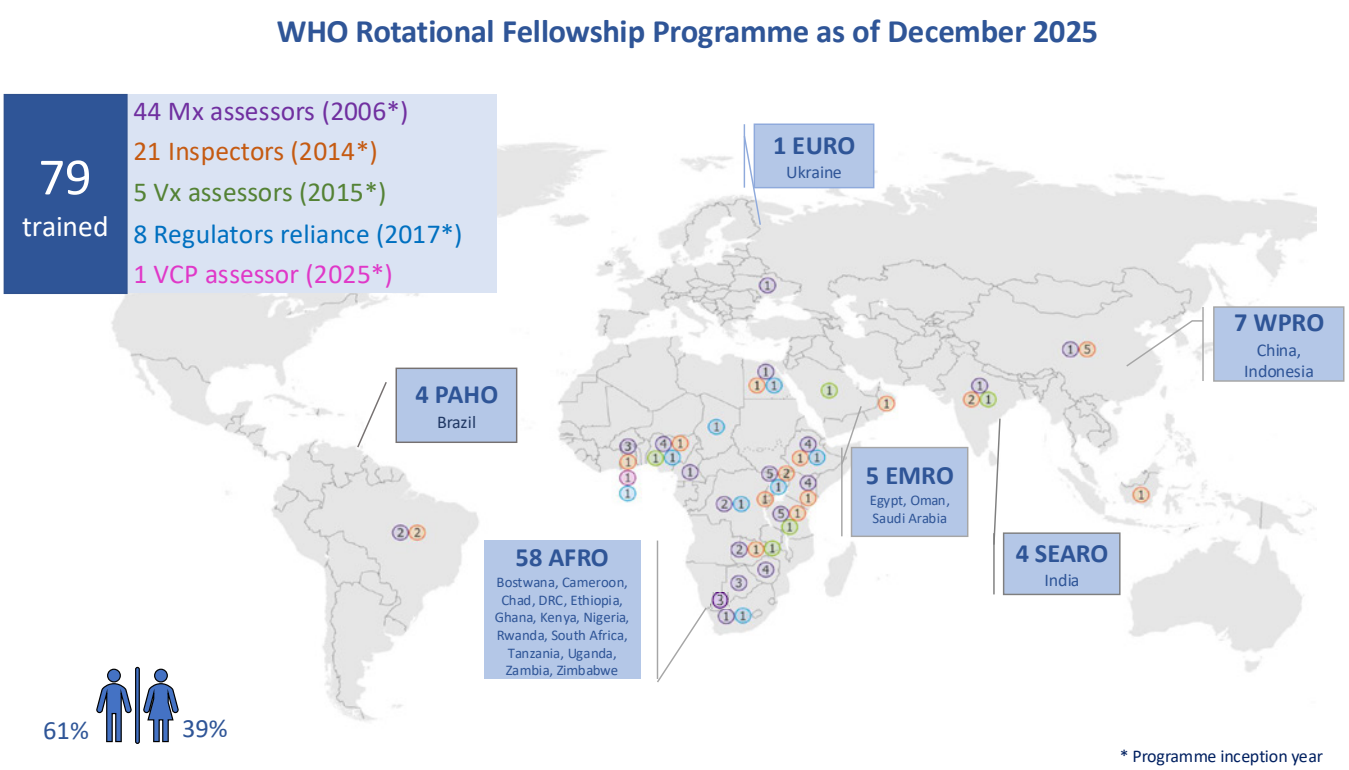


Fig. 48. Global reach of RPQ training in 2025 (size of circle reflecting number of learners)

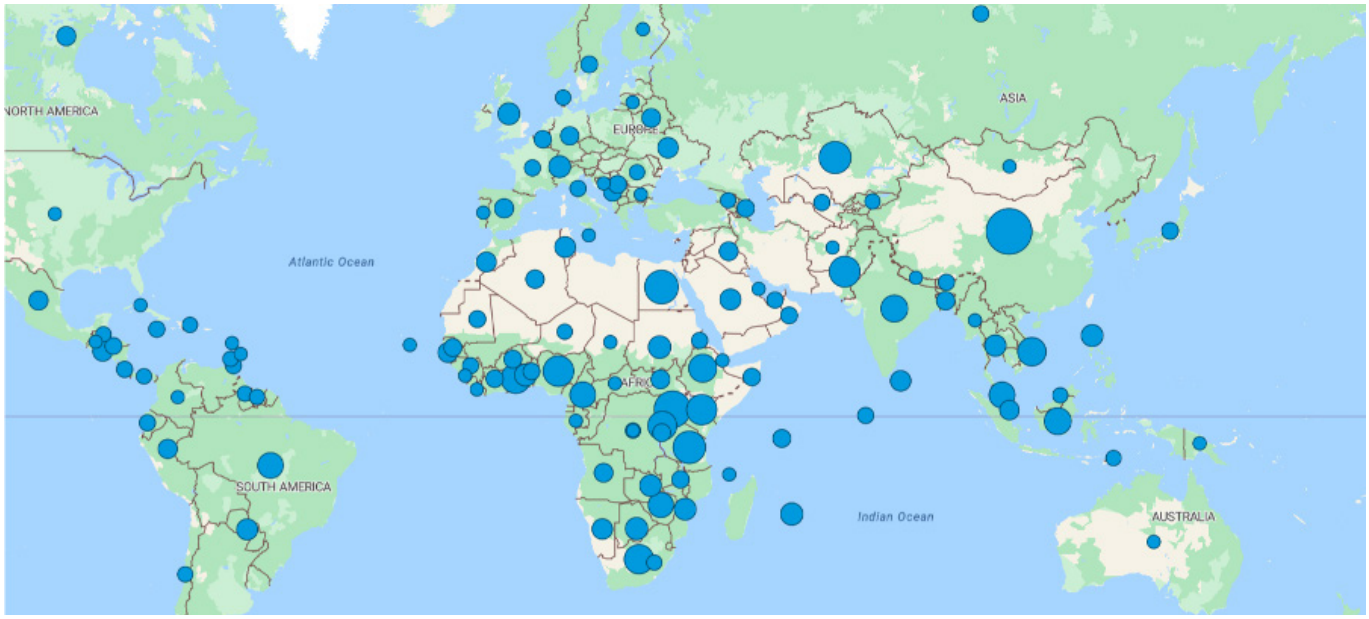
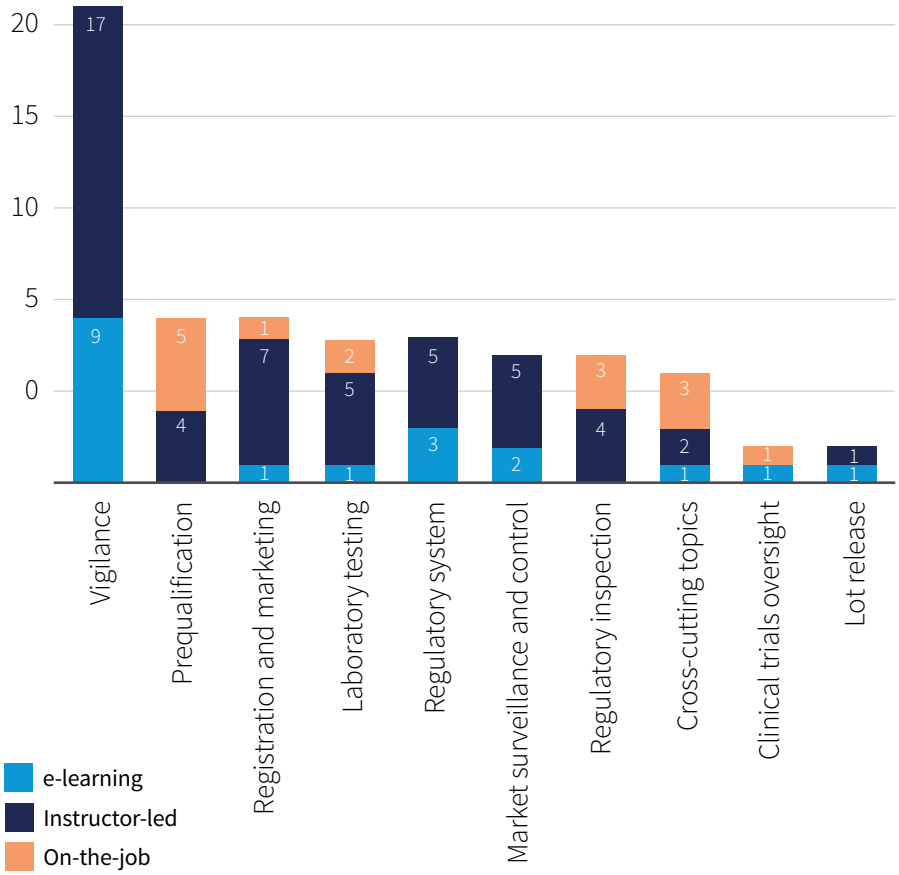


Fig. 49. Learning solutions

64 learning solutions (all regulatory functions and prequalification)



6 new training offers in 2025 addressing critical needs

- Crisis communication for regulators: substandard-falsified medical products
- Risk management plan assessment
- Method validation and verification (WHO TRS 1052 Annex 4): training and clinic
- Determination of ethylene glycol and diethylene glycol by Thin-Layer Chromatography in oral liquid medicines, using the tiered approach of the International Pharmacopoeia
- PQT/MED Training for African Assessors and EMP-TC Members under AMRH and the future African Medicines Agency (AMA
- GCP inspection: coached audit
- PQ VCP rotational fellowship

Regulation and Prequalification Rotational Fellowship Programme

The unique WHO arrangement of rotational fellows has been an important component of regulatory capacity-building offering regulators (with some initial pre-exposure to prequalification) further hands-on experience with a wide range of prequalification and regulatory-related activities. Since 2006, the Department of Regulation and Prequalification has accommodated 79 fellows from 22 countries including from four regional economic communities. The programme expanded this year to assessors of vector control products.

Focus on alignment, streamlining and new technologies

The mandate of the Department of Regulation and Prequalification supports a transition from prequalification towards achievement of functional national and regional regulatory capacities worldwide. Throughout 2025, WHO continued to invest in more rapid regulatory pathways through strengthening regulatory reliance, convergence and harmonization, matched with focus on streamlining operational procedures and introducing new technologies, to enhance efficiency and effectiveness of its operations.

Aligning WHO's normative and prequalification processes

Ensuring access to quality-assured, safe and effective health products is central to WHO's mandate and requires two distinct and complementary processes: the normative process, which develops recommendations on the use of health products, and the prequalification process, which independently assesses product quality, safety and performance. Traditionally, these processes have been conducted sequentially. Building on an interim approach introduced during the COVID-19 pandemic, WHO is currently engaged in the development of a synchronized and parallel assessment process, for a broader range of products beyond emergency contexts. The new procedures are being developed under the coordination of a WHO working group across 16 departments and are currently being piloted in the area of diagnostics. Once finalized in 2026, the new aligned assessment procedures will have positive impact on operational efficiency and contribute to a more rapid regulatory pathway.

Alignment, streamlining operational procedures and new technologies will continue to enhance efficiency and effectiveness.

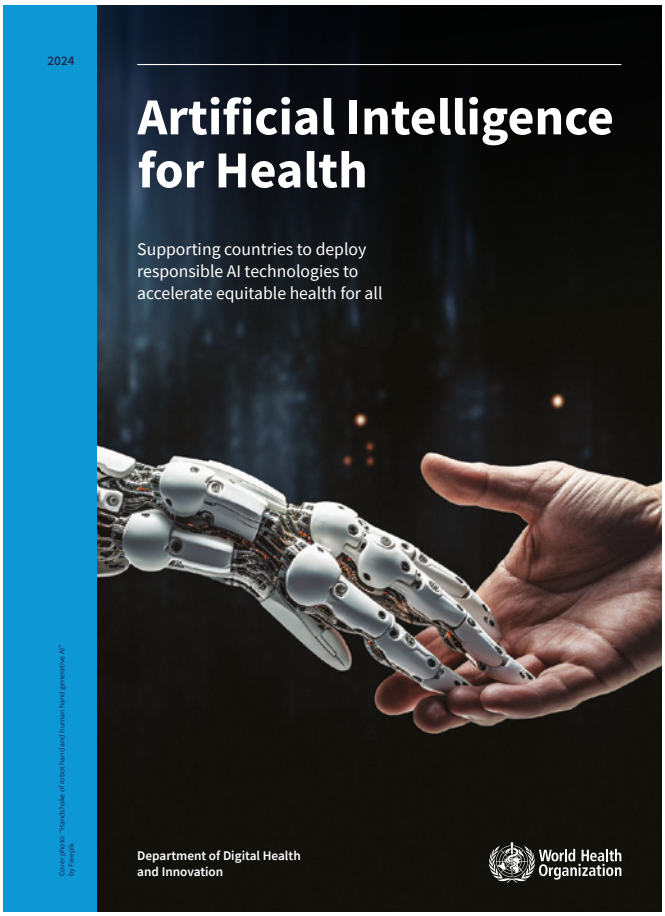
Digitalization and artificial intelligence in the health sector

There is a growing consensus that the strategic and innovative use of digital and cutting-edge information and communications technologies will be an essential enabling factor towards ensuring the achievements of the Sustainable Development Goals. In 2005 the World Health Assembly adopted a resolution urging Member States 'to consider drawing up a long-term strategic plan for developing and implementing eHealth services' and in 2020 WHO launched its first Global Strategy on Digital Health 2020–2027, with a subsequent strategy for 2028–2033 under discussions. WHO is actively promoting digital health initiatives to enhance global health outcomes through the integration of digital technologies into health systems, including for its own operations.

WHO also supports a science-based adoption of Artificial Intelligence with the goal to ensure that its advancements contribute to global health in a way that is safe, ethical, and equitable, with appropriate governance and regulation. Whilst WHO recognizes the immense potential of Artificial Intelligence to revolutionize health, it is also aware that technology progresses rapidly and that regulatory frameworks often struggle to keep pace with these developments. WHO is therefore actively engaged in developing guidance on governance, ethical standards and regulations to address emerging opportunities and challenges, mitigate risks, safeguard public health.

The digital backbone for WHO prequalification, ePQS supports more efficient workflows, improved data integration and stronger alignment of regulatory support activities. Integration between the portal and the WHO website is currently being rolled-out

Fig. 50. Publication on artificial intelligence for health



The electronic prequalification system portal: ePQS

In 2025, WHO advanced the digital transformation of prequalification processes through the successful launch and early adoption of the electronic Prequalification System. The external portal went live for applicants in May 2025, enabling manufacturers to submit and manage prequalification applications through a secure, role-based platform, across 13 product types and 48 application types. Feedback from applicants during the initial roll-out has been positive, with a steady increase in registrations and use. The portal supports secure submission of applications, responses and supporting documentation, provides real-time visibility on application status and enables differentiated access for applicants, national regulatory authorities and external experts. ePQS also enabled, for the first time, submission of dossiers in electronic Common Technical Document (eCTD) format. Use of both the ePQS portal and eCTD format remained voluntary in 2025 with transition to mandatory use planned for early 2026.

A future electronic regulatory system strengthening Portal: eREG

Building on the experience and functionalities of the ePQS, WHO is also in the early stages of exploring the development of a complementary electronic portal for regulatory system strengthening, eREG, to track, monitor and improve efficiency and effectiveness throughout regulatory strengthening processes. This work is in its early stages, and will include a needs assessment, collaboration with the WHO Information Technology Department.

Communication and advocacy

Department annual report

The Department of Regulation and Prequalifcation report, published annually in the beginning of each year, provides stakeholders with a consolidated view of strategic priorities, progress and achievements on the key performance indicators presented in the Strategic Action Plan, and ultimately the overall impact of WHO's work in the area of regulation and prequalification. Engagement metrics from recent editions continued to demonstrate strong readership, with open rates consistently exceeding standard benchmarks, confirming sustained interest from a global audience.

Department newsletter

Throughout 2025, the Department of Regulation and Prequalification continued to issue monthly newsletters in all six WHO official languages, serving as a regular communication channel highlighting key milestones, publications, technical guidance and convenings across all regulatory and prequalification streams – with links to related content on the WHO website.

Other communication tools and resources

Technical teams continue to use targeted communication tools tailored to specific stakeholder groups, including:

- Wednesday webinars hosted by the Prequalification Vector Control Team, providing regular technical updates and stakeholder engagement;
- Quarterly newsletters from the Prequalification of In Vitro Diagnostics Team, offering insights into progress, priorities and new developments;
- Social media communication through regular LinkedIn posts supporting timely dissemination of information on activities, tools, resources and events;
- Visibility and recognition of department contributors on WHO website.

Way forward

Facing challenges with solutions

2025 was a period of significant upheaval in the global economic and geopolitical environment, with profound implications for multilateralism, humanitarian action and development and consequent shifts across the global health ecosystem.

2025 also brought a firm commitment from WHO Member States, through the WHO Executive Board and the World Health Assembly, to a continued increase in assessed contributions and a clearer path toward sustainable financing. In addition, WHO Member States approved the historic Pandemic Agreement in May 2025, marking a milestone in strengthening international collaboration for pandemic preparedness and response.

Quality and safety have remained at the core of WHO's mission since its Constitution entered into force in 1948. WHO's work to ensure quality and safety has continued to evolve in line with emerging therapeutic needs, changing health conditions, and in response to increasing expectations from external partners. Despite evolving organizational contexts and structures, quality and safety remain a central organizational priority, as reflected in the WHOs 14th General Programme of Work and the new WHO organizational structure.

The Department of Regulation and Prequalification is adapting swiftly to this new reality by aligning with the updated organizational structure, focusing on critical functions, transferring selected responsibilities to other departments and discontinuing others, and streamlining and re-engineering core procedures to improve efficiency and resource mobilization. In particular, the Department of Regulation and Prequalification will leverage the use of external institutional and human resource capacity, including broader engagement with existing and new WHO Collaborating Centers and non-state actors in official relations; further drawing on the use of the scientific and technical expertise within its networks, advisory groups and task forces; and expand opportunities for secondments, rotational fellowships and other human resource arrangements with Member States.

While the transition from reliance on prequalification toward fully functional national and regional regulatory systems is expected to be time limited, WHO will continue to require sustained investment and collaboration from key global health partners.

The challenges of 2025 have driven changes that will shape WHO's work for years to come. The department is making the necessary adjustments to respond to a rapidly evolving global public health agenda and enters 2026 with confidence in a more resilient and productive way forward, with focus on better alignment between the three levels of the Organization.

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Annexes

Annex 1. Key performance indicators

The following table outlines the key performance indicators for the department in 2025, all of which were reported on an annual basis.

Table A1. 2025 key performance indicators

REG/ PQ	Indicator	Annual target	2025 achieved	2024 achieved	2023 achieved	Frequency of measurement
REG	Number of countries NRAs evaluated as candidate for WLAs	6	6	31	3	Annual
REG	Number of new countries operating under a signed CRP agreement for medicines and vaccines	5	9	1	SRA CRP: 10 PQ CRP: 6	Annual
REG	Number of countries with FPP registered under the CRP agreement at or below the target time	5	26	11	SRA CRP: 8 PQ CRP: 9	Annual
REG	PQ-CRP: Proportion of PQ products registered through CRP at or below the target time (90 days)	60%	53%	69%	58%	Annual
REG	SRA-CRP: Proportion of products registered at or below the target time (90 days)	40%	67%	46%	35%	Annual
REG	Number of countries with a risk-based approach for regulating IVD medical devices	2	2	1	6	Annual
REG	Number of countries implementing regulation through the concept of reliance and network	2	3	5	4	Annual
REG	Number of new members of the WHO National Control Laboratory Network for Biologicals	3	3	5	5	Annual
REG	Number of countries with stable and well-functioning regulatory status (NRA ML 3 and above)	1	1	3	2	Annual
REG	Number of countries with improved regulatory status (could be one of the eight regulatory functions)	5	5	6	9	Annual
REG	Number of medicines QC laboratories suppported to be PQed	3	5	3	3	Annual
REG	Number of countries benchmarked using the GBT	4	6	1	5	Annual
REG	Number of countries with safety surveillance systems in place to detect, investigate, manage and share safety data on medicines and vaccines	1	1	3	6	Annual

REG	Number of countries supported to build and develop credible and WHO-validated websites for sharing vaccine safety information	5	5	7	5	Annual
REG	Number of countries supported to investigate safety of medicinal products in special populations (pregnant women and neonates, etc.)	4	4	10	8	Annual
REG	Number of countries supported to establish active market surveillance system for IVDs	2	3	0	2	Annual
REG	Number of countries conducting risk-based post market surveillance in their supply chains	5	8	4	11	Annual
REG	Number of countries with national strategies or plans to strengthen prevention, detection and response for SF medical products	3	3	1	5	Annual
REG	Number of countries supported to expand, refine and enhance local surveillance and monitoring system for SF medical products	10	18	33	8	Annual
REG	Number of countries reporting to the GSMS reporting system on SF medical products	5	6	14	22	Annual
REG	Number of countries with improved regulatory capacity preparedness for public health emergencies	4	4	4	2	Annual
Vaccines						
PQ	Vx PQed (Presentations)	10	9 (13)	12 (16)	7(9)	Annual
PQ	Vx registrations under CRP	35	1	1	0	Annual
PQ	%Vx PQed < WHO target time for full assessment (270 days)	70%	67%	100%	100%	Annual
PQ	%Vx PQed < manuf target time for full assessment (450 days)	RO	67%	80%	100%	Annual
PQ	%Vx PQed < total target time for full assessment (720 days)	70%	50%	80%	80%	Annual
PQ	%Vx PQed < WHO target time for abridged assessment	70%	0%	80%	100%	Annual
PQ	%Vx PQed < manuf target time for abridged assessment	RO	50%	85%	100%	Annual
PQ	%Vx PQed < total target time for abridged assessment (180 days)	70%	50%		100%	Annual
PQ	%Vx post-PQ reportale change 1st actions < target time (90 days)	80%	27%		72%	Annual

Medicines: Finished Pharmaceutical Products (FPPs)						
PQ	FPPs PQed	40	32	48	46	Annual
PQ	FPPs registrations under CRP*	80	114	105	76	Annual
PQ	% FPPs PQed ≤ WHO target for full assessment (270 days)	50%	91%	76%	77%	Annual
PQ	% FPPs PQed ≤ manuf target time for full assessment (450 days)	RO	86%	68%	66%	Annual
PQ	% FPPs PQed ≤ total target time for full assessment (720 days)	50%	86%	66%	63%	Annual
PQ	% FPPs PQed ≤ WHO target time for abridged assessment (100 days)	90%	100%	100%	100%	Annual
PQ	% FPPs PQed ≤ manuf target time for abridged assessment (80 days)	RO	100%	100%	86%	Annual
PQ	% FPPs PQed ≤ total target time for abridged assessment (180 days)	70%	100%	100%	100%	Annual
PQ	% of FPPs post-PQ change 1st actions ≤ target time: major variation (90 days)	80%	100%	100%	80%	Annual
PQ	% of FPPs post-PQ change 1st actions ≤ target time: minor variation (60 days)	80%	100%	98%	93%	Annual
PQ	% of FPPs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	80%	99%	92%	88%	Annual
Medicines: Active Pharmaceutical Ingredients (APIs)						
PQ	APIs PQed	10	12	21	13	Annual
PQ	% APIs PQed ≤ WHO target time for full assessment (270 days)	40%	33%	44%	77%	Annual
PQ	% APIs PQed ≤ manuf target time for full assessment (540 days)	RO	75%	83%	100%	Annual
PQ	% APIs PQed ≤ total target time for full assessment (900 days)	50%	67%	44%	92%	Annual
PQ	% of APIs post-PQ change 1st actions ≤ target time: major variation (90 days)	60%	41%	58%	25%	Annual
PQ	% of APIs post-PQ change 1st actions ≤ target time: minor variation (60 days)	60%	61%	65%	64%	Annual
PQ	% of APIs post-PQ change 1st actions ≤ target time: immediate notification (45 days)	60%	60%	62%	49%	Annual

In Vitro Diagnostics (IVDs)						
PQ	IVDs PQed	12	13	11	5	Annual
PQ	IVDs registrations under CRP*	5	38	36	7	Annual
PQ	IVDs PQed / alt lab evaluation	30%	31%	50%	60%	Annual
PQ	% IVDs PQed ≤ WHO target time for full assessment (350 days) with Lab Option 1	70%	67%	0%	0%	Annual
PQ	% IVDs PQed ≤ manuf target time for full assessment (400 days)	RO	57%	100%	100%	Annual
PQ	% IVDs PQed ≤ total target time for full assessment (720 days)	50%	71%	80%	0%	Annual
PQ	% IVDs PQed ≤ WHO target time for abridged assessment (100 days)	50%	50%	60%	0%	Annual
PQ	% IVDs PQed ≤ manuf target time for abridged assessment (100 days)	RO	0%	0%	33%	Annual
PQ	% IVDs PQed ≤ total target time for abridged assessment (360days)	50%	43%	20%	0%	Annual
PQ	% of IVD post-PQ reportable change 1st actions ≤ target time (90 days)	80%	100%	91%	100%	Annual
Vector Control Products						
Specifications						
PQ	New Specifications established for VCAI Source Materials	1	2	2	1	Annual
PQ	Specification Extension to New Manufacturers of VCAIs	3	5	3	11	Annual
PQ	VCAI Change assessments	3	4	2	4	Annual
PQ	Proportion of specification related assessments completed ≤ WHO target time (525 days)	80%	90%	86%	67%	Annual
Prequalification						
PQ	VCPs PQed	4	9	7	4	Annual
PQ	Protocol Reviews Completed	6	28	71	6	Annual
PQ	Change Assessments Completed	25	48	38	42	Annual
PQ	Proportion of Determination of Pathway submissions completed ≤ WHO target time (90 days)	90%	82%	93%	48%	Annual
PQ	Proportion of Study Protocol submissions completed ≤ WHO target time (90 days)	80%	100%	99%	100%	Annual
PQ	Proportion VCP PQed ≤ WHO target time (365 days)	80%	100%	67%	25%	Annual
PQ	Proportion of VCP PQed 1st actions ≤ target time (180 days)	80%	100%	100%	75%	Annual
PQ	Proportion of Minor Change submissions completed ≤ WHO target time (90 days)	80%	100%	100%	82%	Annual
PQ	Proportion of Major Change submissions completed ≤ WHO target time (210 days)	80%	100%	100%	57%	Annual
PQ	VCP Registrations under CRP	TBD	PILOT	2	PILOT	Annual

Immunization Devices (IMD)						
PQ	IMD PQed	50	21	22	37	Annual
PQ	% IMDs PQed ≤ WHO target time for full assessment (120 days)	65%	87%	86%	95%	Annual
PQ	% IMDs PQed ≤ manuf target time for full assessment (30 days)	RO	7%	6%	8%	Annual
PQ	% of IMDs post-PQ reportable change 1st actions ≤ target time (30 days)	70%	80%	80%	100%	Annual
Inspections						
PQ	% of planned and conducted inspections within 6 months (Mx-APIs and FPPs)	50%	91%	75%	73%*	Annual
PQ	% of planned and conducted inspections within 6 months (IVDs, Vx and VCP)	RO	Close to 100%	Close to 100%	100% (for IVDs), 71% (for VCP)	Annual
PQ	% of desk assessments completed within 90 days	70%	89%	77%**	44%	Annual
PQ	% of inspection reports sent to site within 30 days	80%	90%	80%	37%	Annual
PQ	% of CAPA reviews completed within 30 days	60%	94%	91%	74%	Annual
PQ	% of product quality complaints handled within 60 days	75%	100%	100%*	100%	Annual
PQ	Total number of inspections	150	186	152	157	Annual

RO: Reported Only – targets are not set but the performance is reported retrospectively

Annex 2. List of advisory/steering committees and technical advisory/expert groups contributing to the work of the Department of Regulation and Prequalification

Table A2. List of key stakeholders contributing to the Department of Regulation and Prequalification's work

Name of advisory committee, technical advisory group or expert working group	Year established	# represented	Experts/membership
Active Pharmaceutical Ingredients Quality Assessment Group	2011	15	Brazil, Germany, Italy, Malawi, Malaysia, Portugal, Spain, Sweden, Switzerland, Uganda, the United Republic of Tanzania
Advisory Committee on Safety of Medicinal Products	2003	12	Australia, Canada, Colombia, Croatia, Egypt, Eritrea, Italy, New Zealand, Oman, Portugal, South Africa, the United States
Assessment Session for Vector Control Products	2017	24	Australia, Burkina Faso, France, Ghana, Hungary, Italy, Kenya, Malawi, Nigeria, Spain, Sri Lanka, Sudan, the United Kingdom, the United Republic of Tanzania, the United States
Bioequivalence Assessment Group	2001	7	Canada, Netherlands, Spain, Switzerland, Ukraine, Zambia, Zimbabwe
Biotherapeutic Product Assessment Group	2018	5	Canada, Italy
Clinical Assessment Group	2001	3	Canada, the United States
Finished Pharmaceutical Assessment Group	2001	31	Botswana, Brazil, Burundi, Cameroon, Canada, China, Egypt, Ethiopia, Germany, Ghana, Kenya, Namibia, Nigeria, Portugal, Rwanda, South Africa, Uganda, the United Republic of Tanzania, Zambia, Zimbabwe
Global Advisory Committee on Vaccine Safety	1999	12	Australia, Bangladesh, Canada, Germany, India, the Netherlands, Nigeria, Saudi Arabia, South Africa, Spain, the United Kingdom
Group for Preparation of WHO Public Assessment Reports	2005	19	Botswana, Brazil, Egypt, Ethiopia, Germany, Ghana, Italy, Kenya, Namibia, Nigeria, South Africa, Switzerland, Uganda, the United Republic of Tanzania, the United Kingdom, Zambia, Zimbabwe
Immunization Devices Specifications Working Group	2014	Approx. 15	Gates Foundation, PATH, Solar Electric Life Fund, Two experts from Kenya and the United States, UNICEF Programme Group, UNICEF Supply Division, WHO Expanded Programme on Immunization

Joint Meeting on Pesticide Specifications	2001	6	Belgium, Canada, Singapore, the United Kingdom, the United States
Member State Mechanism on Substandard and Falsified Medical Products	2012	194	All Member States
Programmatic Suitability for Prequalified Vaccines Standing Committee	2012	4	the United Kingdom, the United States
Steering Committee of the Member State Mechanism on Substandard and Falsified Medical Products	2012	12	Australia, Brazil, Ethiopia, India, Indonesia, Iran (Islamic Republic of), Israel, Oman, Republic of Korea, Rwanda (Chair), Serbia, the United States
Technical Advisory Group for Emergency Use Listing	2020	6	Australia, Canada, China (Hong Kong SAR), Nigeria, South Africa, Switzerland
Technical Advisory Group on Snake Antivenom Immunoglobulin Listing	2021	6	Australia, Spain, Sri Lanka, the United Kingdom
Technical Advisory Group WHO Listed Authority	2023	14	Australia, Brazil, China, Cuba, Egypt, Indonesia, Iran (Islamic Republic of), Italy, Nigeria, South Africa, Switzerland, Thailand, Zimbabwe
TSS Development Working Group	2015	Approx. 20	Changes every time

Department of Regulation and Prequalification

World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland

Email: regulation_prequalification@who.int
Website: https://www.who.int/teams/regulation-prequalification