2022 annual report

Department of Regulation and Prequalification
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The World Health Organization (WHO) Department of Regulation and Prequalification holds a unique role in the global health ecosystem. RPQ provides essential guidance, supports WHO Member States, and facilitates collaboration among stakeholders to regulate medical products throughout their lifecycle. This document highlights are successes in 2022 and reflects our unwavering dedication to building effective and efficient regulatory systems worldwide. This is a mission that is critical to supporting national regulators as they protect the public, enable timely access to quality products, and encourage innovation.

In 2022, we made significant progress in implementing our strategic priorities. Our achievements were driven by a clear vision and a strategic approach, guided by four primary objectives.

Firstly, we have strengthened country and regional regulatory systems. This was achieved by implementing regulation in an increasing number of countries through reliance and national regulatory authority networks. We enhanced regulatory convergence through the wider implementation of WHO quality standards. National regulatory capacity was bolstered to ensure the quality of medical products, and that the pharmaceutical sector capacity was fortified, particularly in countries manufacturing products for low- and middle-income countries (LMICs) and local supply. Additionally, safety surveillance systems were strengthened to support and safeguard the uptake of new or innovative products by LMICs, and efforts to improve the prevention, detection, and response to substandard and falsified medical products were intensified.

Secondly, we increased regulatory preparedness for public health emergencies, supporting 19 countries as they adapted regulatory requirements to address public health emergencies. Our diligent work in this area has ensured that countries can respond more swiftly and effectively to public health emergencies, enhancing global health security.

Thirdly, we have strengthened and expanded WHO prequalification and product risk assessment processes. We increased and expanded WHO’s prequalification lists and developed new pathways to prequalification listing along with new risk-based approaches to support time-limited procurement. The range of products eligible for prequalification was broadened, ensuring access to more quality medical products.

Lastly, we increased the scope and impact of WHO’s regulatory support activities. We ensured that WHO’s regulatory support capacity and resources were sufficient to implement the RPQ’s strategic plan for 2019–2023. Additionally, efforts to improve the targeting and alignment of WHO regulatory support activities were intensified, ensuring that resources were utilized where they were most needed.

As we look to the future, we remain committed to our mission. The coming year will be pivotal as we complete the final year of our Thirteenth General Programme of Work and the RPQ’s 2019–2023 Action Plan. We will continue to build on our achievements, striving to enhance regulatory systems worldwide, protect public health, and promote innovation.

I would like to personally express my gratitude to the Bill & Melinda Gates Foundation, Unitaid, United Nations Children’s Fund (UNICEF), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance for their invaluable partnership and funding. Additionally, I extend my heartfelt thanks to the broader community of RPQ staff, stakeholders, partners, and funders who have worked closely with us.

Finally, two important messages.

First, to thank all staff, external partners and collaborators for their unequivocal commitment to the COVID-19 pandemic response. Without this commitment and personal engagement, which was beyond duty and fully dedicated, it would have been difficult to have our response align across more than 150 Member States.

Lastly, but not least, our immense gratitude and recognition of Dr Mariângela Bastista Galvão Simão, for her leadership as our Assistant Director-General throughout this difficult year. As she leaves for a merited retirement, she will always be recognized as the leader that steered our Division on the pathway to success, always with public health and people as the frontline priority.

Together, we celebrate our achievements and remain committed to advancing global health.

Rogério Gaspar
Director
Department of Regulation and Prequalification
Acknowledgements

WHO’s Department of Regulation and Prequalification gratefully acknowledges the support provided by Belgium, Bill & Melinda Gates Foundation, China, European Commission, Fleming Fund, Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Japan (funding through the United Nations Development Programme), the Netherlands, the Swiss Agency for Development and Cooperation, UNICEF, Unitaid, the United States Food and Drug Administration, Uppsala Monitoring Centre, Sweden, and Wellcome.

WHO would also like to thank the WHO Collaborating Centres worldwide for their contribution to WHO’s work to strengthen regulatory systems and harmonization and ensuring the availability of quality-assured medical products for purchase by Member States and international procurement.

Abbreviations

API  active pharmaceutical ingredients
        current good manufacturing practice (virtual)
CRP  collaborative registration procedure
EUL  emergency use listing
FPP  finished pharmaceutical product
GBT  Global Benchmarking Tool
IVD  in vitro diagnostic
KPI  key performance indicator
LMICs  low- and middle-income countries
NRAs  national regulatory authorities
PQ  prequalification
SF  substandard and falsified
SP  strategic priority
SRAs  stringent regulatory authorities
VCP  vector control product
Vx  vaccines
WHO  World Health Organization
WLA  WHO-Listed Authority
2022 at a glance

- **6 countries** achieved a stable, well-functioning and integrated regulatory system (ML3/ML4)
  - The Republic of Korea ML4 (medicines and vaccines)
  - Singapore ML4 (medicines)
  - Nigeria ML3 (medicines)
  - China, Egypt and South Africa ML3 (vaccines).

- **>2000** vaccine and biopharmaceutical manufacturers trained from over 80 countries on WHO standards and requirements to achieve quality and compliance.

- **4 new countries** with safety surveillance systems in place to detect, investigate, manage and share safety data on medicines and vaccines
  - Burundi, Central African Republic, Guinea-Bissau, Yemen.

- Expanded in vitro essential diagnostics list
  - including tuberculosis and hepatitis B virus nucleic acid tests and finalized technical specification series for hepatitis C nucleic acid tests, hepatitis B virus immunoassays and hepatitis B virus surface antigen rapid diagnostic tests.

- **Improved access to diabetes treatment and care**
  - with the prequalification of human insulin products and development of technical specification series for haemoglobin point-of-care tests, glucose meters and test strips.

- **Technical Advisory Group on Local Production and Technology Transfer of Health Products**
  - established with nine members spanning eight countries.

- **50%** of the world population covered by a functional regulatory system.

- **1st time** prequalification of generics therapeutics for COVID-19 and tuberculosis.

ML = maturity level
34 countries submitted reports to WHO’s Global Surveillance and Monitoring System; with 8 alerts issued on substandard and falsified medical products. The System works with Member States to improve the quantity, quality, and analysis of accurate data on substandard and falsified medical products, and to use that data to prevent, detect, and respond to such products.

97 on-site, 61 desk-review, and 5 remote prequalification inspections conducted for sites that manufacture or test medical products.

3 countries (Ghana, the Islamic Republic of Iran and the United Arab Emirates) supported with ecosystem assessments for sustainable local production.

104 websites in the Vaccine Safety Net include 4 new Member State websites (Greece, Israel, Kenya and South Africa); 43% of websites are from non-high-income countries.

The Vaccine Safety Net aims to counter vaccine misinformation and support countries to build credible, WHO-validated websites for sharing vaccine safety information.
Progress towards strategic priorities in 2022

WHO’s Regulation and Prequalification Department builds effective and efficient regulatory systems worldwide to assist national regulators as they protect the public, enable timely access to quality products and encourage innovation (1).

This work is essential if WHO is to achieve its “triple billion” targets, the foundation of the organization’s Thirteenth General Programme of Work (2019–2023). To meet its targets, WHO must ensure that by 2023 (relative to 2018) (2):

- **1 billion** more people are benefiting from universal health coverage;
- **1 billion** more people are better protected from health emergencies;
- **1 billion** more people are enjoying better health and well-being.

The Regulation and Prequalification Department’s work is critical for meeting the second and third targets. In 2022, the second-to-last year for both WHO’s Thirteenth General Programme of Work and 2019–2023 Action Plan, the department made considerable progress in implementing its strategic priorities. Here, we share some of its most important achievements.

The Regulation and Prequalification Department played a critical role in ensuring that the regulatory framework was in place to make COVID-19 vaccines available swiftly worldwide.
Strategic priority 1

Strengthen country and regional regulatory systems

Strengthening the regulatory systems of countries and entire regions is part and parcel of the Regulation and Prequalification Department’s work. All three units – the Prequalification Unit, the Regulation and Safety Unit and the Local Production Assistance Unit – reported significant accomplishments in this area in 2022.

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

In 2021, the Regulation and Prequalification Department played a critical role in ensuring that regulatory frameworks were in place to swiftly make COVID-19 vaccines available worldwide. This work alongside that of other public health organizations averted an estimated 5 million COVID-19-related deaths in 2021 alone (3). Although the COVID-19 pandemic transitioned from being an acute global public health emergency to the world’s “new normal” in 2022, it continued to shape the department’s work. The work of the COVID-19 Vaccines Global Access (COVAX) initiative’s partners continued to facilitate access to COVID-19 vaccines globally and the department further coordinated the facilitation of the relevant regulatory approvals. The department also reflected on lessons learned during the pandemics and identified areas for improvement to enhance impact.

The Regulation and Prequalification Department continued work on the collaborative registration procedure (CRP). This was launched in 2013 to promote reliance and facilitate in-country registration to mitigate national regulatory authorities (NRAs) duplicating work already done by WHO or other regulatory authorities.

In 2022, the Prequalification Unit prepared reports for 23 prequalified in vitro diagnostics (IVDs), all of which were shared with NRAs within the target timelines. As a result, seven new IVDs were registered under the programme in 2022, exceeding the RPQ's target of five new IVD registrations. The Regulation and Safety Unit signed CRP agreements with 27 new countries for medicines and vaccines, bringing the total number of Member States signatories with CRP agreements to 59 for medicines and 49 for vaccines (4). CRP agreements were also signed with 13 new countries for IVDs, bringing the total number of agreements for this product type to 26 (4). Foundational steps were taken during 2022 to investigate options for the implementation of CRP for VCPs, laying the groundwork for initiation of a pilot programme.

As an illustration of WHO CRP work, 73 medicines were submitted through CRP for medicines during 2022, while 53% of registrations for prequalified CRP medicines were processed within 90 calendar days, which is a considerable acceleration compared to standard timelines.
At the same time, the Regulation and Safety Unit continued its work establishing the WHO-Listed Authority (WLA) framework. This programme facilitates identification of NRAs that consistently perform high-quality work. In 2021, the Regulation and Prequalification Department introduced the world to this concept, publishing the definition of a WLA and a supporting policy brief (5). In 2022, the Regulation and Safety Unit published interim operational guidance, as well as a manual for evaluating and publicly designating NRAs as WLAs (6). It also shared a list of 57 transitional WLAs (7). In December 2022, the Regulation and Safety Unit began evaluating the first three WLA candidates – the NRAs of Singapore, Switzerland and the Republic of Korea – as part of its ongoing pilot programme.

In 2022, the Regulation and Safety Unit improved implementation of the concept of reliance through the launch of an e-learning platform, as well as personalized training sessions for assessors from 20 countries and technical support for the implementation of facilitated registration pathways in three countries: Bangladesh, Bhutan and Timor-Leste. The Unit also supported eight new countries as they implemented a risk-based approach for regulating IVDs: Angola, Cabo Verde, Cameroon, Comoros, Côte d’Ivoire, the Democratic Republic of the Congo, Rwanda and Zimbabwe. In addition, it welcomed four new members (Finland, Pakistan, Philippines and Singapore) to the WHO Network of National Control Laboratories for Biologicals, for the exchange of best practices, promoting reliance and exchange of quality and technical information on prequalified vaccines. These new members bring the total number of National Control Laboratories for Biologicals, including those located in low- and middle-income countries (LMICs), to 47 (Fig. 2) (4), helping to support vaccine lot release and monitoring in Member States through the recognition of the responsible NRA’s lot release by recipient countries.

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**Fig. 2.** Cumulative number of members of the WHO Network of National Control Laboratories for Biologicals that are located in LMICs by region

<table>
<thead>
<tr>
<th>Year</th>
<th>WHO Regional Office for Africa</th>
<th>WHO Regional Office for the Americas</th>
<th>WHO Regional Office for Europe</th>
<th>WHO Regional Office for South-East Asia</th>
<th>WHO Regional Office for the Western Pacific</th>
<th>% of members located in LMICs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>27</td>
<td>7</td>
<td>2</td>
<td>12</td>
<td>2</td>
<td>37%</td>
</tr>
<tr>
<td>2019</td>
<td>16</td>
<td>3</td>
<td>4</td>
<td>14</td>
<td>4</td>
<td>45%</td>
</tr>
<tr>
<td>2020</td>
<td>12</td>
<td>12</td>
<td>14</td>
<td>14</td>
<td>5</td>
<td>48%</td>
</tr>
<tr>
<td>2021</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>47%</td>
</tr>
<tr>
<td>2022</td>
<td>7</td>
<td>7</td>
<td>3</td>
<td>16</td>
<td>5</td>
<td>47%</td>
</tr>
</tbody>
</table>

LMICs: low- and middle-income countries

Source: WHO data
Strategic priority 1.2: Increase regulatory convergence through wider implementation of WHO quality standards

In 2022, the Regulation and Prequalification Department facilitated regulatory convergence by supporting regional and international cooperation for all product streams, including the African Medicines Regulatory Harmonization programme, the African Medical Devices Forum, the African Vaccine Regulatory Forum, the Global Harmonization Working Party, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, the International Pharmaceutical Regulators Programme, the International Medical Device Regulators Forum, the Association of Southeast Asian Nations Pharmaceutical Product Working Group, the Asia-Pacific Economic Cooperation, the WHO Paediatric Regulatory Network, as well as various other regional networks and initiatives.

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

The WHO’s Global Benchmarking Tool (GBT) is used to assess the maturity level of an NRA. Only those which have reached maturity level (ML) 3 are eligible for the performance evaluation required to be considered for WLA status. ML3 is also one of the prerequisites for the evaluation of vaccines under prequalification. In 2022, the Regulation and Safety Unit achieved a record number of benchmarking assessments performed (4). Nine Member States, including China, Egypt, Kenya, Nigeria, the Republic of Korea, Rwanda, Saudi Arabia, South Africa and Türkiye, were evaluated, and 19 additional countries were supported to perform self-benchmarking (4), a preliminary assessment that typically precedes formal benchmarking.

In 2022, the Regulation and Safety Unit recognized three new countries as always including well-functioning and integrated regulatory system (i.e. an NRA of) Maturity Level 3 or above: Egypt, Nigeria (for importing vaccines) and South Africa. Three more countries were re-assessed and deemed to have stable and well-functioning regulatory systems. These included China, the Republic of Korea and Singapore (please see details below), bringing the total number of countries with an NRA ML3 or above to 57, up from 50 in 2018 (Fig. 3).

GBT assessments performed in 2022 also allowed the Regulation and Safety Unit to recognize the achievement of seven countries (Bangladesh, Egypt, Indonesia, Nigeria, the Republic of Korea, Singapore and South Africa) that improved their Maturity Level for any of the nine regulatory functions assessed. Of these, six benchmarked countries achieved pharmacovigilance scores of three or four (4), while all benefited from the support of the Regulation and Safety Unit.

In collaboration with the Prequalification Unit, the Regulation and Safety Unit performed inspections of 11 medicines quality control laboratories and supported the prequalification of two new medicine quality control laboratories in Ghana and Pakistan contributing to strengthened national regulatory capacity (4). Prequalified quality control labs comply with the following standards: Good Practices for Pharmaceutical Quality Control Laboratories, Good Practices for Pharmaceutical Microbiology Control Laboratories, and relevant parts of WHO’s Good Manufacturing Practice (GMP) guidelines.

Once prequalified, these laboratories can participate in WHO’s Prequalification Programme in quality monitoring projects, which assess the quality of medicines procured by United Nations agencies.
**Fig. 3. Current levels of maturity of national regulatory systems – WHO Global Benchmarking Tool (for medicines and vaccines: as of December 2022)**

<table>
<thead>
<tr>
<th>Regulatory System Level</th>
<th>October 2018</th>
<th>November 2020</th>
<th>December 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>ML1 (With some elements of regulatory system)</td>
<td>100 countries</td>
<td>100 countries</td>
<td>98 countries</td>
</tr>
<tr>
<td>ML2 (Evolving national regulatory system)</td>
<td>44 countries</td>
<td>41 countries</td>
<td>39 countries</td>
</tr>
<tr>
<td>ML3 (Stable, well-functioning and integrated)</td>
<td>50 countries</td>
<td>53 countries</td>
<td>57 countries</td>
</tr>
<tr>
<td>ML4 (Advanced level of performance and continuous improvement)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ML**: (regulatory system) maturity level

**Vaccines produced in countries with weak regulatory systems, i.e. ML1/ML2, are not eligible for WHO Emergency Use Listing or Prequalification**

**GOAL of World Health Assembly Resolution 67.20**

In 2022 alone, six countries achieved ML3/ML4 in medicines and vaccines regulatory systems:
- Republic of Korea ML4 (medicines and vaccines)
- Singapore ML4 (medicines)
- China ML3 (vaccines)
- Egypt ML3 (vaccines)
- Nigeria ML3 (medicines)
- South Africa ML3 (vaccines)
Strategic priority 1.4: Strengthen pharmaceutical sector capacity, especially in countries that manufacture products for LMICs and/or local supply

In 2022, the Local Production and Assistance Unit, serving as the World Local Production Forum Secretariat, began organizing the second forum, to be held in the Netherlands in November 2023. The first World Local Production Forum, held virtually in June 2021, convened ministers and delegates from more than 100 countries, as well as heads of United Nations agencies, academics, representatives from international organizations and other stakeholders who are active in local production and technology transfer. It is intended that this forum would maintain momentum by providing a global platform for stakeholders to discuss key opportunities and challenges in promoting local production and technology transfer.

Following a recommendation issued in the first World Local Production Forum in 2022, the Local Production Assistance Unit established a Technical Advisory Group on Local Production and Technology Transfer of Health Products (10) to provide strategic and technical advice to WHO aimed at promoting and strengthening sustainable local production and technology transfer.

The Local Production Assistance Unit, which will serve as its Secretariat, published a call in August 2022 for experts to serve as members of the group. To date, nine members from eight countries representing a variety of disciplines, including economics, law and pharmaceutical manufacturing and supply, have joined. The Local Production Assistance Unit also convened three meetings and webinars to foster partnerships and promote local production. One of these meetings was the Regional Vaccine Manufacturing Workshop for WHO’s South-East Asia and Western Pacific regions, which was organized in collaboration with the regions’ authorities and with technical support from the Coalition for Epidemic Preparedness Innovations. The workshop, which brought together roughly 300 manufacturers, regulators and government ministries and agencies, explored the landscape of vaccine production capacity, gaps and challenges in these regions and examined ways to improve vaccine development, production capacity and efficiency. The Unit also convened eight meetings and webinars promoting WHO’s work on local production.

In 2022, the Local Production Assistance Unit delivered three capacity building activities to strengthen Member States’ understanding of WHO and international standards, and improve their capacity for sustainable local production of quality health products. These activities included the annual Virtual Current Good Manufacturing Practice (cGMP) Training Marathon for Vaccine Manufacturing and a virtual workshop on Vaccine Common Technical Document/ Chemistry Manufacturing and Controls Requirements. More than 2000 vaccine and biopharmaceutical manufacturers from over 80 countries across all six WHO regions were trained on WHO standards and requirements to achieve quality and compliance (4). Furthermore, in 2022 the Unit published a document, Virtual cGMP Training Marathon for Vaccine Manufacturing: Questions and Answers, which featured answers to over 325 questions from participants in the 2021 activity (11). Of note, 30% of participants in the 2021 cGMP training marathon returned for the 2022 cGMP training marathon or the workshop on Vaccine Common Technical Document/ Chemistry Manufacturing and Controls Requirements, indicating their confidence in the quality of the Unit’s programming (4).
In addition to organizing meetings to support local production, in 2022 the Local Production Assistance Unit supported three countries with ecosystem assessments for sustainable local production: Ghana, the Islamic Republic of Iran and the United Arab Emirates (4). To do so, the Unit used its Situational Analysis Tool, a standardized approach for collecting evidence. With this information:

- Member States can use the results to prioritize actions to mitigate the gaps that hinder them from achieving quality, sustainable production, as well as to develop holistic national roadmaps; and
- WHO is empowered to provide tailored support and capacity-building to Member States to help them reach the standards required to submit an application for product prequalification assessment.

In 2022, the Local Production Assistance Unit also developed an electronic version of this tool, which it piloted in seven countries throughout WHO’s Africa, South-East Asia and the Eastern Mediterranean regions.

In 2022, the Local Production Assistance Unit provided specialized, on-site technical assistance to manufacturers in WHO’s African Region, WHO’s Eastern Mediterranean Region, WHO’s South-East Asia Region and WHO’s Western Pacific Region (regarding GMP, chemistry manufacturing and controls/common technical document standards for vaccines, training on vaccine dossier requirements, etc.), including to manufacturers seeking prequalification/EUL for eight medicines, five vaccines, and two IVDs. Finally, the unit updated the WHO Guidelines on Technology Transfer in Pharmaceutical Manufacturing to support Member States with technical guidance on transferring and absorbing technologies in accordance with current GMP standards and regulatory expectations.

Strategic priority 1.5: Strengthen safety surveillance to support and safeguard LMIC uptake of new or innovative products

In 2022, the Regulation and Safety Unit assisted four new countries (Burundi, Central African Republic, Guinea-Bissau and Yemen) to implement safety surveillance systems that would detect, investigate, manage and share safety data on medicines and vaccines. It also launched active surveillance on the safety of the antiviral drug, Molnupiravir, in Bangladesh, Egypt, Jordan and the Philippines. Used to treat mild and moderate COVID-19 in adults at risk for hospitalization and progression to severe illness, Molnupiravir is the first oral medicine approved under an emergency use listing (EUL) to treat non-severe COVID-19. Monitoring adverse events associated with its use will provide evidence with which NRAs can make sound regulatory decisions.

In 2022, the Regulation and Safety Unit also supported four countries (Argentina, Brazil, Pakistan and the Philippines) to carry out investigations regarding the safety of medicinal products in special populations, such as pregnant women and neonates. The Unit also introduced a new indicator for measuring vaccine safety system performance, no more limited to childhood immunization but expanding to immunization over the life course, aligning with the Immunization Agenda 2030 (IA2030): one serious adverse event per million population (as opposed to the previous indicator of 10 serious adverse events per 100,000 surviving infants).

Finally, in 2022 the Regulation and Prequalification Department helped counter vaccine misinformation by supporting four countries to build credible, WHO-validated websites for sharing vaccine safety information: Greece, Israel, Kenya and South Africa. With the addition of these four new websites, the total number of member websites in the WHO-initiated Vaccine Safety Net is now 104, 43% of which are hosted from non-high-income countries (4).
Strategic priority 1.6: Improve prevention, detection and response to substandard and falsified medical products

In 2022, the Regulation and Safety Unit supported nine countries as they expanded, refined and enhanced their local surveillance and monitoring systems to better detect substandard and falsified medical products, and supported 44 countries as they conducted risk-based post-market surveillance in their supply chains.

It also helped one country develop a national strategy to both detect and prevent substandard or falsified medical products in their supply chains. Based on this work, as well as additional requests from other countries, the Unit also commenced work to develop a handbook for the development, implementation and monitoring and evaluation of substandard and falsified national action plans.

Implementation of WHO’s Global Surveillance and Monitoring System helps to improve the quality and accuracy of data gathered about substandard and falsified medical products, and to use that data to prevent, detect and mitigate the risk of those products. In 2022, 34 countries submitted reports to the system. Compared with the geographical distribution of reporting countries in 2018, the distribution in 2022 was significantly more balanced, with almost all regions contributing between 15% and 20% of reports (Fig. 4), a finding that reflects the Regulation and Safety Unit’s work with Member States to encourage reporting worldwide. As a result of Member State participation in 2022, the Regulatory and Safety Unit issued eight alerts on substandard and falsified medical products, including COVID-19 products and cough syrups, which had claimed the lives of more than 300 children.

Fig. 4. Recorded incidents on the Global Surveillance and Monitoring System by WHO regions 2018–2022, average
Strategic priority 2

Increase regulatory preparedness for public health emergencies

In 2022, RPQ’s Regulation and Safety Unit supported 19 countries as they adapted regulatory requirements to address public health emergencies, of which three were low-income countries and 10 LMICs.

While this number was lower than in previous years due to the Unit’s focus on the GBT and WLA programmes, support from the Unit, combined with the efforts of Member States, resulted in improved regulatory preparedness (as measured by performance on the emergency preparedness–related indicators of the GBT) for public health emergencies in six countries, including Bangladesh, Egypt, Nigeria, Saudi Arabia, South Africa and Türkiye.
Strategic priority 3

Strengthen and expand WHO prequalification and product risk assessment processes

In 2022, the Prequalification Unit continued to strengthen and expand the scope and number of prequalified products which include medicines, vaccines, in vitro diagnostics, immunization devices and cold chain equipment, and vector control products (VCPs) (Fig. 5).

By the end of 2022, more than 1580 prequalified health-improving products across 13 therapeutic areas were available in LMICs (4). The Prequalification Unit contributed to this total by prequalifying 55 new finished pharmaceutical products (FPPs), eight active pharmaceutical ingredients (APIs), eight vaccines and eight IVDs. In addition, one vaccine and 10 IVDs received EULs, and the Unit accepted changes to a further 346 FPPs and 136 API prequalified products. It should be noted the number of products prequalified reflects an increased number of assessments. For example, in 2022 the Unit processed 71 IVD change requests, performed 49 IVD assessments and prequalified eight IVDs. In the same manner, the Unit performed four new VCP assessments and accepted 34 VCP changes to existing products, as well as two new sources and 13 changes for active ingredients for formulation in VCPs. In addition to assessments, in 2022, the Prequalification Unit also performed 97 in-person, 61 desk review and five remote inspections of sites that manufacture or test medical products.

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

In 2022, the Prequalification Unit engaged regulators and manufacturers in the Prequalification Programme through online webinars, trainings, targeted technical support and pre-submission meetings for medicines. Overall, the Regulation and Prequalification Department invited 42 regulators to join assessments of COVID-19 vaccines, resulting in a strengthened network of assessors. In addition, more than 30 medicine assessors from LMICs participated in each of the six bi-monthly medicine assessment sessions. The PQ Unit also delivered two webinars for manufacturers on COVID-19 therapeutics – particularly antivirals – in collaboration with the Medicines Patent Pool and International Federation of Pharmaceutical Manufacturers and Associations.

The Unit increased the capacity of its IVD programme in 2022, listing one new lab as a prequalification evaluating laboratory for IVDs and the audit of the first laboratory for tuberculosis IVDs (listed in 2023). In addition, it implemented prequalification performance evaluations for IVDs at two new evaluating sites. The Unit also identified 16 new IVD assessors, nine of which performed at least one assessment in 2022. To build the capacity of its relatively new programme for vector control products, the Unit developed a video to explain its evaluation process for this type of product. That video is now available on the WHO website in five languages (13).

The Unit enhanced its engagement with stakeholders of the VCP community with the launch of the biweekly Wednesday webinar programme, allowing for an hour to discuss any questions stakeholders may have in an open forum. Additionally for VCPs, the conclusion of the product review of insecticide-treated nets leading to the publication of the draft WHO Guideline on Prequalification Assessment of Insecticide-Treated Nets and open consultation to further clarify for stakeholders the principles for prequalification assessment as a progression for the enhancement of WHO evaluation of VCPs.
In 2022, the Prequalification Unit prequalified its first human insulin products that can be stored at temperatures of up to 30°C for four weeks before they are opened. This facilitates the use of these essential medicines in LMICs (14). Several first-time generic therapeutics, including Molnupiravir capsules and a combination of Nirmatrelvir + Ritonavir for the treatment of COVID-19 were prequalified as were Rifapentine/Isoniazid tablets, Linezolid paediatric formulation and Delamanid tablets for use in the treatment of tuberculosis. To further strengthen and expand the prequalification lists, the Prequalification Unit updated its Expressions of Interest for HIV/AIDS, malaria and COVID-19 products by including new medicines, and prepared to include in its scope the first tuberculosis skin tests. The prequalified lists of IVDs for infectious diseases was also expanded to include tuberculosis and hepatitis B virus nucleic acid tests and finalizing the finalizing the technical specification series for hepatitis C nucleic acid tests, hepatitis B virus immunoassays and hepatitis B virus surface antigen rapid diagnostic tests. The technical specification series for haemoglobin point-of-care tests, glucose meters and test strips were developed and published for public comment.
Strategic priority 3.3: Develop new pathways to prequalification listing and new risk-based approaches to support time-limited procurement

In 2021, the Regulation and Prequalification Department co-developed a novel coordinated scientific advice procedure with WHO’s Science Division. This procedure allows developers of medical products to obtain advice from WHO about appropriate ways to collect evidence about a medical product’s risks and benefits, with the goal of achieving a WHO policy recommendation and a prequalification listing. In 2022, the Prequalification Unit continued to receive requests from medicine manufacturers to participate in the coordinated scientific advice procedure, and completed five of these in the areas of malaria, leprosy and tuberculosis medicines and one coordinated scientific advice procedure for malaria vaccine.

Through its Expert Review Panel service to procurers, the department assisted in procurement decisions of first-time generics, including Rifapentine, Bedaquiline and Pretomanid products as these progressed towards prequalification.

In addition, the Prequalification Unit agreed to expand the WHO Expert Review Panel for Diagnostic Products to include neglected tropical diseases and vaccine preventable diseases. The Expert Review Panel for Diagnostic Products reviews the risks and benefits associated with the procurement and use of IVDs that:

- are not prequalified and have not yet undergone a stringent regulatory assessment by a founding member of the International Medical Device Regulators Forum; but
- may have a high public health impact.

The Panel’s work helps procurers, such as Unitaid and the Global Fund to Fight AIDS, Tuberculosis and Malaria, to decide whether to purchase products in advance of the completion of a stringent review process.

The Prequalification Unit also created new, more efficient regulatory pathways. A procedure for parallel guideline development and prequalification for COVID-19 therapeutics was developed and implemented, resulting in prequalification of the first Nirmatrelvir + Ritonavir product at the same time as the publication of an updated COVID-19 living treatment guideline. Also developed was an innovative regulatory pathway for Nirmatrelvir + Ritonavir generic products (used to treat mild-to-moderate COVID-19 in adults at high risk of progressing to severe disease), whereby Nirmatrelvir tablets are evaluated using the full assessment route, while the abridged route/cross-referencing is used for Ritonavir products that are prequalified or approved by SRAs. Finally, a new API master file-like pathway for human insulin was implemented to facilitate the prequalification of new insulin products.

This year, for the first time, the Prequalification Unit called for applications from licensed manufacturers of snake antivenom immunoglobulin products. Those manufacturers interested in having those products evaluated for potential listing by WHO and recommended for procurement were encouraged to submit applications to the Prequalification Unit. A total of 17 expressions of interest were received, and are currently under assessment.

Strategic priority 3.4: Expand the range of products eligible for prequalification

Currently, the Prequalification Unit is conducting pilot prequalification of biotherapeutic products, including human insulin. In 2022, four virtual workshops on the quality of small molecules and biotherapeutic medicines were conducted for manufacturers and regulators. The Unit also convened two manufacturer webinars on COVID-19 therapeutics, with an emphasis on antivirals, in collaboration Medicines Patent Pool and the International Federation of Pharmaceutical Manufacturers and Associations.
Strategic priority 4

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

Throughout 2022, the Regulation and Prequalification Department worked to strengthen WHO’s regulatory support activities, making substantial progress in collecting fees to make its operations more sustainable, and channeling medical product manufacturers to a new, streamlined electronic prequalification system.

Strategic priority 4.1: Ensure that WHO’s regulatory support capacity and resources are sufficient to implement RPQ’s Strategic Plan 2019–2023

The Department received support from the following contributors and partners (Table 1):

- **Government and intergovernmental organizations** Belgium, China, the European Commission (Directorate-General for International Partnerships), France, Germany, Japan, the Netherlands, Norway, Sweden, Switzerland, the United Kingdom, the United States
- **Foundations and nongovernmental organizations** Bill & Melinda Gates Foundation, Wellcome Trust
- **International agencies and global health initiatives** GAVI Alliance, Global Fund to Fight AIDS, Tuberculosis and Malaria, United Nations Children’s Fund, United Nations Development Programme, Unitaid

China, France and Japan contributed technical expertise and country experience through the secondment of national professional staff and the placement of junior professional officer.

The percentage of prequalification fees invoiced/received in 2022 was 103% of the US$ 20 million target, whereas actual fees received were 90% of the target. This represents the Unit’s best performance ever for both metrics. The fees collected in 2022 represents a 566% increase over the amount collected from fees in 2016 and the new fee model does not appear to have negatively impacted the prequalification pipeline. Despite this increase, the amount collected from fees in 2022 still falls short of the annual US$ 20 million target. Some of the most significant reasons of revenue loss in 2022 were fee waivers and reductions, withdrawals or de-listings of products, fee waivers for vaccines and other health products used in public health emergencies, including the COVID-19 pandemic.

Strategic priority 4.2: Improve targeting and alignment of WHO regulatory support activities

To better align its services with the needs of manufacturers, in 2021 the Prequalification Unit launched its electronic prequalification system for FPPs, APIs, vector control products, quality control laboratories and manufacturing site inspections. By the end of 2022, with the exception of data for vaccines and immunization devices, the unit had migrated all data to the electronic prequalification system. The Prequalification Unit also launched a website with improved structure and search tools, to better target its support activities for medical product manufacturers (15).
Table 1. The Regulation and Prequalification Department implemented a total budget of US$ 38,775,070 in 2022.

<table>
<thead>
<tr>
<th>Funding source</th>
<th>US$</th>
<th>% budget, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prequalification fees</td>
<td>9,942,663</td>
<td>26</td>
</tr>
<tr>
<td>Government and intergovernmental organizations</td>
<td>4,878,857</td>
<td>13</td>
</tr>
<tr>
<td>Foundations and non-governmental organizations</td>
<td>9,220,110</td>
<td>24</td>
</tr>
<tr>
<td>International agencies and global health initiatives</td>
<td>14,480,785</td>
<td>37</td>
</tr>
<tr>
<td>Assessed contribution (core funding from WHO Member States)</td>
<td>252,655</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total budget</strong></td>
<td><strong>38,775,070</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Way forward

Despite the ongoing challenge of the COVID-19 pandemic, in 2022, the Regulation and Prequalification Department made substantial progress toward implementing its strategic priorities.

The department’s work is critical to ensuring that people worldwide enjoy better health and well-being, and are better protected from public health emergencies. Investing in the activities of the Regulation and Prequalification Department provides a good return on investment with every US$ 1 invested in the Prequalification Programme resulting in savings of roughly US$ 30–40.

The department has ambitious plans for 2023 and beyond. For example, plans are in place to perform assessments of all 57 transitional WLAs by 2027. In addition, as approximately 70% of Member States currently have NRAs that do not meet the GBT requirements for a stable and well-functioning regulatory system; many of these Member States will require the department’s support in the coming years. Finally, providing local production assistance and facilitated introduction of quality-assured medical products will be a major focus for the Regulation and Prequalification Department as it works to build stable, efficient and equitable ecosystems for medical products in all regions of the world.

References


Annexes

Annex 1. Achievements by strategic priority and unit

Strategic priority (SP) 1: Strengthen country and regional regulatory systems

SP 1.1: Implement regulation in an increasing number of countries through reliance and NRA networks

- Collaborated with mature NRAs to conduct desk review inspections
- Prepared CRP reports for 22 prequalified IVDs, all reports shared within key performance indicator timelines
- Evaluated three NRAs as candidates for WHO-listed authorities as part of ongoing pilot programme (Singapore, the Republic of Korea, Switzerland)
- Signed CRP agreement with 27 new countries for medicines and vaccines (21 new countries for SRA CRPs, 11 new countries for PQ CRPs, 13 new countries for CRP-IVDs)
- Improved implementation of the concept of reliance in three countries: Bangladesh, Bhutan, Timor-Leste

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

- Six new countries with a stable and well-functioning regulatory system status (NRA ML3 and above): China, Egypt, Nigeria, the Republic of Korea, Singapore and South Africa
- Seven countries with improved regulatory status (for any of the nine regulatory functions): Bangladesh, Egypt, Indonesia, Nigeria, the Republic of Korea, Singapore and South Africa
- Supported prequalification of two new medicines quality control labs: Ghana and Pakistan
- Benchmarked nine countries using GBT: China, Egypt, Kenya, Nigeria, the Republic of Korea, Rwanda, Saudi Arabia, South Africa and Turkiye
SP 1.4: Strengthen pharmaceutical sector capacity especially in countries that manufacture products for LMICs and/or local supply

• Organized World Local Production Forum
• Convened three meetings/webinars to foster partnership and promote local production
• Held eight meetings/webinars promoting WHO’s work in local production
• Supported three countries with feasibility assessments/situational analyses for local production (per request by Member States)
• Provided technical support to Member States for resolution on strengthening local production
• Delivered three capacity building activities to build Member States’ understanding of WHO/international standards and capacity for sustainable local production of quality health products
• Promoted and/or facilitated technology transfer for one technical product
• Performed seven vaccine manufacturing site inspections, 32 medicines manufacturing site inspections (finished product and active pharmaceutical ingredient manufacturing sites) in LMICs
• Provided prequalification/EUL-related specialized technical assistance for eight medicines, five vaccines and two IVDs

SP 1.5: Strengthen safety surveillance to support and safeguard uptake of new or innovative products by LMICs

• Four new countries with safety surveillance systems in place to detect, investigate, manage and share safety data on medicines and vaccines: Burundi, Central African Republic, Guinea-Bissau and Yemen
• Supported four countries to build and develop credible, WHO-validated websites for sharing vaccine safety information: Greece, Israel, Kenya and South Africa

• Supported four countries to investigate safety of medicinal products in special populations (pregnant women, neonates, etc.): Argentina, Brazil, Pakistan and Philippines
• Introduced a new indicator for measuring vaccine safety system performance

SP 1.6: Improve prevention, detection and response to substandard and falsified (SF) medical products

• 44 countries conducted risk-based post-market surveillance in their supply chains
• One new country with national strategies or plans to strengthen prevention, detection and response for SF medical products
• Supported nine countries to expand, refine and enhance local surveillance and monitoring system for SF medical products
• 34 countries reported to the Global Surveillance and Monitoring System on SF medical products

Strategic priority 2: Increase regulatory preparedness for public health emergencies

SP 2.1: Strengthen national and regional regulatory procedures for risk-based evaluations during public health emergencies

• Six countries with improved regulatory capacity preparedness for public health emergencies: Bangladesh, Egypt, Nigeria, Saudi Arabia, South Africa and Türkiye
• Assisted and supported 19 countries to adapt their regulatory requirements to effectively address public health emergencies
Strategic priority 3: Strengthen and expand WHO prequalification and product risk assessment processes

SP 3.1: Improve efficiency, capacity and awareness of the Prequalification Programme

- Increased efficiency in most areas, despite unprecedented challenges due to COVID-19 pandemic
- Helped build capacity of regulators and manufacturers through online webinars, trainings and targeted technical support, and pre-submission meetings (medicines)
- Enhanced PQ capacity-building through networks of experts/assessors from all regions
- Invited 42 regulators from WHO regions to join assessment of COVID-19 vaccines
- Commenced face-to-face medicines assessment sessions in September 2022
- Achieved most Prequalification Unit key performance indicators for medicines for 2022 (see Annex 2)
- Audited and listed two new labs as PQ evaluating laboratories for IVDs. Audited first tuberculosis lab.
- Implemented PQ performance evaluations for IVDs in two new evaluating sites
- Identified 16 new IVD assessors, nine of whom performed at least one assessment
- Performed 48 assessments for IVDs (16 PQ and 32 EUL) and processed 71 IVD change requests
- Developed video to explain WHO evaluation of vector control products (video is on website, in five languages)

SP 3.2: Strengthen and expand WHO’s prequalification lists

- Prequalified 55 medicines, including COVID-19 therapies and first-time generic products
- Prequalified first human insulin products
- Accepted 319 FPP and 135 API changes to prequalified products
- Prepared to launch prequalification of tuberculosis skin tests under medicines PQ assessment team
- Updated expressions of interest for HIV/AIDS, malaria and COVID-19 with inclusion of new medicines
- Expanded prequalification of diagnostics to include TB NAT assays and hepatitis B virus NAT assays
- Finalized PQDx technical specification series for hepatitis C virus NAT, hepatitis B virus immunoassays and hepatitis B virus surface antigen rapid diagnostic tests
- Developed PQDx technical specification series for haemoglobin point-of-care tests, glucose meters and test strips and published for public comments
SP 3.3: Develop new pathways to prequalification listing and new risk-based approaches to support time-limited procurement

- Continued to receive requests from medicines manufacturers for coordinated scientific advice procedure (more than five procedures completed)
- Prepared new abridged assessment pathway for non-marketed biotherapeutic products
- Prepared new API Master File-like pathway for human insulin
- Developed and implemented procedure for parallel guideline development and PQ process in place for COVID-19 therapeutics
- Developed an innovative path for nirmatrelvir + ritonavir generic products whereby nirmatrelvir tablets are assessed using full assessment route while using abridged route/cross-referencing to ritonavir products approved by SRAs/prequalified
- Agreed upon expansion of WHO Expert Review Panel for Diagnostic Products to neglected tropical diseases and vaccine preventable diseases

SP 3.4: Expand the range of products eligible for prequalification

- Delivered four virtual workshops on quality of small molecules and biotherapeutic medicines to manufacturers and regulators
- Delivered two manufacturer webinars on COVID-19 therapeutics, especially antivirals, in collaboration with medicines patent pool and International Federation of Pharmaceutical Manufacturers and Associations

Strategic priority 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 the strategic plan

- Improved management of overall budget, including PQ fees

SP 4.2: Improve targeting and alignment of WHO regulatory support activities

- With exception of vaccines and immunization device data, all data was migrated to electronic prequalification system
- Launched PQ website with better structure and search tools
Annex 2. Key performance indicators (KPIs) for SPs

Table A2.1. Summary of KPIs for the Prequalification Unit across three areas showing 2022 targets and figures achieved (2019–2022)

<table>
<thead>
<tr>
<th>Prequalification Unit KPIs</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines: finished pharmaceutical products (FPPs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FPPs PQed</td>
<td>61</td>
<td>62</td>
<td>46</td>
<td>55</td>
<td>35</td>
</tr>
<tr>
<td>FPPs registrations under CRP*</td>
<td>64</td>
<td>109</td>
<td>119</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>% FPPs PQed ≤ WHO target for full assessment (270 days)</td>
<td>26%</td>
<td>36%</td>
<td>58%</td>
<td>29%</td>
<td>50%</td>
</tr>
<tr>
<td>% FPPs PQed ≤ manuf target time for full assessment (450%)</td>
<td>68%</td>
<td>72%</td>
<td>45%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>% FPPs PQed ≤ total target time for full assessment (720 days)</td>
<td>54%</td>
<td>51%</td>
<td>34%</td>
<td>47%</td>
<td>50%</td>
</tr>
<tr>
<td>% FPPs PQed ≤ WHO target time for abridged assessment (100 days)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>% FPPs PQed ≤ manuf target time for abridged assessment (80 days)</td>
<td>100%</td>
<td>100%</td>
<td>67%</td>
<td>83%</td>
<td>50%</td>
</tr>
<tr>
<td>% FPPs PQed ≤ total target time for abridged assessment (180 days)</td>
<td>100%</td>
<td>100%</td>
<td>83%</td>
<td>100%</td>
<td>50%</td>
</tr>
<tr>
<td>% of FPPs post-PQ change 1st actions ≤ target time: major variation (90 days)</td>
<td>100%</td>
<td>86%</td>
<td>100%</td>
<td>100%</td>
<td>80%</td>
</tr>
<tr>
<td>% of FPPs post-PQ change 1st actions ≤ target time: minor variation (60 days)</td>
<td>91%</td>
<td>98%</td>
<td>90%</td>
<td>94%</td>
<td>80%</td>
</tr>
<tr>
<td>% of FPPs post-PQ change 1st actions ≤ target time: immediate notification (45 days)</td>
<td>88%</td>
<td>100%</td>
<td>95%</td>
<td>93%</td>
<td>80%</td>
</tr>
</tbody>
</table>

*An increasing number of COVID-19 submissions are competing for available assessment resources. Also noted are an increased number of assessment rounds due to rushed and incomplete responses from manufacturers (possibly linked to COVID-19 restrictions in China and India since 2020).
## Prequalification Unit KPIs

<table>
<thead>
<tr>
<th>Medicines: active pharmaceutical ingredients (APIs)</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2022</th>
</tr>
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<tbody>
<tr>
<td>APIs PQed</td>
<td>19</td>
<td>13</td>
<td>10</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>% APIs PQed ≤ WHO target time for full assessment (270 days)</td>
<td>93%</td>
<td>64%</td>
<td>0%</td>
<td>38%</td>
<td>40%</td>
</tr>
<tr>
<td>% APIs PQed ≤ manuf target time for full assessment (540 days)</td>
<td>100%</td>
<td>73%</td>
<td>50%</td>
<td>88%</td>
<td>50%</td>
</tr>
<tr>
<td>% APIs PQed ≤ total target time for full assessment (900 days)</td>
<td>100%</td>
<td>64%</td>
<td>50%</td>
<td>88%</td>
<td>50%</td>
</tr>
<tr>
<td>% of APIs post-PQ change 1st actions ≤ target time: major variation (90 days)</td>
<td>91%</td>
<td>93%</td>
<td>57%</td>
<td>40%</td>
<td>80%</td>
</tr>
<tr>
<td>% of APIs post-PQ change 1st actions ≤ target time: minor variation (60 days)</td>
<td>90%</td>
<td>100%</td>
<td>59%</td>
<td>26%</td>
<td>80%</td>
</tr>
<tr>
<td>% of APIs post-PQ change 1st actions ≤ target time: immediate notification (45 days)</td>
<td>92%</td>
<td>89%</td>
<td>34%</td>
<td>24%</td>
<td>80%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vector control products (VCPs)</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCP PQedb</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Specifications completed (technical materials and formulations)</td>
<td>7</td>
<td>14</td>
<td>18</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>Study protocol reviews completed</td>
<td>8</td>
<td>14</td>
<td>9</td>
<td>6</td>
<td>Not defined</td>
</tr>
<tr>
<td>Determinations of pathway (number completed)</td>
<td>67</td>
<td>32</td>
<td>50</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Change Submissions completed</td>
<td>-</td>
<td>20</td>
<td>33</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Proportion VCP PQed ≤ WHO target time (365 days)</td>
<td>67%</td>
<td>75%</td>
<td>100%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Proportion of VCP post-PQ reportable change 1st actions ≤ target time (90 days)</td>
<td>-</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

¹Further considerations needed to determine KPIs due to 3 processes used for assessment:
2020 – 4 PQed, 5 rejected/withdrawn
2021 – 3 PQed, 2 rejected at screening, 2 withdrawn following assessment

**CRP**: Collaborative Registration Procedure | **manuf**: manufacturing | **PQ**: prequalification | **PQed**: prequalified
Table A2.2. Summary of KPIs for the Prequalification Unit across two areas showing 2022 targets and figures achieved (2019–2022)

<table>
<thead>
<tr>
<th>Prequalification Unit KPIs</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2022</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Vx PQed (Presentations)</td>
<td>11 (17)</td>
<td>0</td>
<td>11 (13)</td>
<td>2 (2)</td>
<td>8 (9)</td>
</tr>
<tr>
<td>% Vx PQed ≤ WHO target time for full assessment (270 days)</td>
<td>75%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx PQed ≤ manuf target time for full assessment (450 days)</td>
<td>100%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>33%</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx PQed ≤ total target time for full assessment (720 days)</td>
<td>100%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>33%</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx PQed ≤ WHO target time for abridged assessment (100 days)</td>
<td>100%</td>
<td>n/a</td>
<td>50%</td>
<td>n/a</td>
<td>-</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx PQed ≤ manuf target time for abridged assessment (80 days)</td>
<td>100%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>-</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx PQed ≤ total target time for abridged assessment (180 days)</td>
<td>100%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>-</td>
<td>n/a</td>
</tr>
<tr>
<td>% Vx post-PQ reportable change 1st actions ≤ target time (90 days)</td>
<td>92%</td>
<td>n/a</td>
<td>85%</td>
<td>n/a</td>
<td>58%</td>
<td>n/a</td>
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<tr>
<td>IVDs</td>
<td>2019</td>
<td>2020</td>
<td>2021</td>
<td>2022</td>
<td>2022</td>
<td>2022</td>
</tr>
<tr>
<td>IVDs PQed</td>
<td>13</td>
<td>0</td>
<td>16</td>
<td>26</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>IVDs registrations under CRP</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>IVDs PQed / alt lab evaluation</td>
<td>23%</td>
<td>n/a</td>
<td>44%</td>
<td>n/a</td>
<td>67%</td>
<td>n/a</td>
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<tr>
<td>% IVDs PQed ≤ WHO target time for full assessment (350 days) with Lab Option 1</td>
<td>83%</td>
<td>n/a</td>
<td>36%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>% IVDs PQed ≤ manuf target time for full assessment (400 days)</td>
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<td>n/a</td>
<td>73%</td>
<td>n/a</td>
<td>100%</td>
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<tr>
<td>% IVDs PQed ≤ total target time for full assessment (720 days)</td>
<td>100%</td>
<td>n/a</td>
<td>45%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
</tr>
<tr>
<td>% IVDs PQed ≤ WHO target time for abridged assessment (100 days)</td>
<td>50%</td>
<td>n/a</td>
<td>20%</td>
<td>n/a</td>
<td>0%</td>
<td>n/a</td>
</tr>
<tr>
<td>% IVDs PQed ≤ manuf target time for abridged assessment (100 days)</td>
<td>50%</td>
<td>n/a</td>
<td>20%</td>
<td>n/a</td>
<td>0%</td>
<td>n/a</td>
</tr>
<tr>
<td>% IVDs PQed ≤ total target time for abridged assessment (360 days)</td>
<td>67%</td>
<td>n/a</td>
<td>20%</td>
<td>n/a</td>
<td>0%</td>
<td>n/a</td>
</tr>
<tr>
<td>% of IVD post-PQ reportable change 1st actions ≤ target time (90 days)</td>
<td>98%</td>
<td>n/a</td>
<td>100%</td>
<td>n/a</td>
<td>84%</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**CRP:** Collaborative Registration Procedure  |  **EUL:** Emergency Use Listing  |  **manuf:** manufacturing  |  **PQ:** prequalification  |  **PQed:** prequalified
<table>
<thead>
<tr>
<th>SP objective</th>
<th>Indicator</th>
<th>Baseline</th>
<th>Target 2022</th>
<th>Progress December 2022</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP1.1.1</td>
<td>Number of countries NRAs evaluated as candidate for WLAs</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>Republic of Korea, Singapore and Switzerland (ongoing pilots)</td>
</tr>
<tr>
<td>SP1.1.2</td>
<td>Number of new countries operating under a signed CRP agreement for medicines and vaccines</td>
<td>44</td>
<td>5</td>
<td>27</td>
<td>SRA CRP: 21 new countries including 5 countries for PQ CRP PQ CRP: 11 new countries CRP-IVDs: 13 new countries (baseline 26 countries)</td>
</tr>
<tr>
<td>SP1.1.3</td>
<td>Number of countries implementing regulation through the concept of reliance and network</td>
<td>15</td>
<td>2</td>
<td>3</td>
<td>Improved implementation of the concept of reliance: 3 countries (Bangladesh, Bhutan, Timor-Leste)</td>
</tr>
<tr>
<td>SP1.1.6</td>
<td>Number of new members of the WHO Network of National Control laboratories for biologicals</td>
<td>43</td>
<td>3</td>
<td>4</td>
<td>New members in 2022 are Finland, Pakistan, Philippines, Singapore</td>
</tr>
<tr>
<td>SP1.1.7</td>
<td>Proportion of FPP registration in countries under the CRP agreement at or below the target time</td>
<td>15</td>
<td>5</td>
<td>27</td>
<td>Progress due to advocacy work</td>
</tr>
<tr>
<td>SP1.1.7</td>
<td>Number of countries with a risk-based approach for regulating in vitro diagnostic medical devices</td>
<td>98</td>
<td>2</td>
<td>8</td>
<td>Angola, Cabo Verde, Cameroon, Comoros, Côte d’Ivoire, Democratic Republic of the Congo, Rwanda, Zimbabwe</td>
</tr>
<tr>
<td>SP1.3.1</td>
<td>Number of countries with stable and well-functioning regulatory status (NRA ML 3 and above)</td>
<td>54</td>
<td>2</td>
<td>6</td>
<td>China, Egypt, Nigeria, Republic of Korea, South Africa and Singapore</td>
</tr>
<tr>
<td>SP1.3.2</td>
<td>Number of countries with improved regulatory status (could be one of the nine regulatory functions)</td>
<td>16</td>
<td>5</td>
<td>7</td>
<td>Bangladesh, Egypt, Indonesia, Nigeria, Republic of Korea, Singapore and South Africa</td>
</tr>
<tr>
<td>SP1.3.3</td>
<td>Number of medicines quality control laboratories supported to be PQ-ed</td>
<td>53</td>
<td>2</td>
<td>2</td>
<td>Ghana and Pakistan. However, 4 labs were temporarily delisted either voluntarily withdrawing or due to non-compliance</td>
</tr>
<tr>
<td>SP1.3.4</td>
<td>Number of countries benchmarked using the GBT</td>
<td>28</td>
<td>5</td>
<td>9</td>
<td>China, Egypt, Kenya, Nigeria, Rwanda, Republic of Korea, Saudi Arabia, South Africa and Turkiye</td>
</tr>
<tr>
<td>SP1.5.1</td>
<td>Number of countries with safety surveillance systems in place to detect, investigate, manage and share safety data on medicines and vaccines</td>
<td>148</td>
<td>3</td>
<td>4</td>
<td>Gabon, Lesotho and Mauritania as associate members while Burundi, Central African Republic, Guinea-Bissau and Yemen as full members Focused support to study and investigate adverse drug reaction/ adverse event following immunization for Ghana, Indonesia, Iran, Lesotho, Nigeria, Republic of Korea</td>
</tr>
<tr>
<td>SP objective</td>
<td>Indicator</td>
<td>Baseline</td>
<td>Target 2022</td>
<td>Progress December 2022</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
<td>----------</td>
<td>-------------</td>
<td>------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>SP1.5.2</td>
<td>Number of countries supported to build and develop credible and WHO-validated websites for sharing vaccine safety information</td>
<td>90</td>
<td>5</td>
<td>4</td>
<td>Greece, Israel, Kenya and South Africa. Criteria for good information practices updated and endorsed by Global Advisory Committee on Vaccine safety and template of a vaccine safety website that complies with good information practices for Governments is being developed</td>
</tr>
<tr>
<td>SP1.5.1</td>
<td>Number of countries supported to investigate safety of medicinal products in special populations (pregnant women and neonates etc.)</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>4 countries in the WHO COVID-19 pregnancy cohort study: Argentina, Brazil, Pakistan and the Philippines and six countries will soon start data collection</td>
</tr>
<tr>
<td>SP1.5.3</td>
<td>Number of countries supported to establish active market surveillance system for IVDs</td>
<td>0</td>
<td>1</td>
<td></td>
<td>In planning phase in line with newly developed tools</td>
</tr>
<tr>
<td>SP1.6.1</td>
<td>Number of countries conducting risk-based post market surveillance in their supply chains</td>
<td>0</td>
<td>40</td>
<td>44</td>
<td>Data based on formal survey of countries in the African Region, results show approx. 56% of countries in Africa have formal surveillance systems. Data from other regions being collected</td>
</tr>
<tr>
<td>SP1.6.1</td>
<td>Number of countries with national strategies or plans to strengthen prevention, detection and response for SF medical products</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>Reflects countries actively supported by WHO, implementation planned for 2023. Plans to roll out support to at least two countries in 2023. Delays due to development of handbook to facilitate support</td>
</tr>
<tr>
<td>SP1.6.1</td>
<td>Number of countries supported to expand, refine and enhance local surveillance and monitoring system for SF medical products</td>
<td>0</td>
<td>10</td>
<td>9</td>
<td>Support being provided to Côte d’Ivoire, Egypt, Fiji, Gambia, Guinea, Senegal, Sri Lanka, South Africa and Uzbekistan. More countries planned based on institutional development plans following benchmarking</td>
</tr>
<tr>
<td>SP1.6.1</td>
<td>Number of countries reporting to the Global Surveillance and Monitoring System reporting system on SF medical products</td>
<td>26</td>
<td>31</td>
<td>34</td>
<td>Currently at more than 50% year-on-year</td>
</tr>
<tr>
<td>SP2.2.1</td>
<td>Number of countries with improved regulatory capacity preparedness for public health emergencies</td>
<td>10</td>
<td>2</td>
<td>6</td>
<td>Bangladesh, Egypt, Nigeria, Saudi Arabia, South Africa and Türkiye</td>
</tr>
<tr>
<td>SP2.3.2</td>
<td>Number of countries assisted and supported to adapt their regulatory requirements to effectively address public health emergencies</td>
<td>15</td>
<td>20</td>
<td>19</td>
<td>Algeria, Benin, Cameroon, Chad, Costa Rica, Côte d’Ivoire, Ecuador, El Salvador, Gabon, Guatemala, Honduras, Morocco, Niger, Panama, Peru, the Democratic Republic of the Congo, Senegal, Togo and Tunisia</td>
</tr>
</tbody>
</table>
Table A2.4. Summary table of Local Production Assistance Unit KPIs for 2022

**Global coordination and partnership**

<table>
<thead>
<tr>
<th>SP</th>
<th>KPI</th>
<th>2022 target</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4.2</td>
<td>Organize the World Local Production Forum (biennial)</td>
<td>1 per biennium</td>
<td></td>
</tr>
<tr>
<td>1.4.2</td>
<td>Number of meetings/webinars convened to foster partnership and promote local production</td>
<td>≥ 2</td>
<td>3</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Number of meetings/webinars promoting WHO’s work in local production</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

**Country support in local production and technology transfer**

<table>
<thead>
<tr>
<th>SP</th>
<th>KPI</th>
<th>2022 target</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4.1</td>
<td>Number of countries supported with feasibility assessments/ situational analyses for local production (per request by MS)</td>
<td>≥ 1</td>
<td>3</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Provide technical support to MS for resolution on strengthening local production</td>
<td>Report to World Health Assembly biennially</td>
<td>1st report in 2023</td>
</tr>
<tr>
<td>1.4.2, 1.3.5</td>
<td>Number of capacity-building activities to build MS’ understanding of WHO/international standards and capacity towards sustainable local production of quality health products</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Number of technical products in promoting and/or facilitating technology transfer</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**PQ/EUL-related specialized technical assistance**

<table>
<thead>
<tr>
<th>SP</th>
<th>KPI</th>
<th>2022 target</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4.2</td>
<td>Number of products provided with PQ/EUL-related specialized technical assistance for medicines</td>
<td>≥ 8</td>
<td>8</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Number of products provided with PQ/EUL-related specialized technical assistance for vaccines</td>
<td>≥ 4</td>
<td>5</td>
</tr>
<tr>
<td>1.4.2</td>
<td>Number of products provided with PQ/EUL-related specialized technical assistance for IVDs c</td>
<td>tbc</td>
<td>2</td>
</tr>
</tbody>
</table>

**Notes:**
- **IVD**: in vitro diagnostics
- **KPI**: key performance indicator
- **MS**: Member State
- **SP**: strategic priority
- **PQ/EUL**: Prequalification and Emergency Use Listing