Global strategy and plan of action on public health, innovation and intellectual property

Implementation 2021–2023
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Acknowledgements

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1 Background

Following a two-year negotiation process, the Sixty-first World Health Assembly adopted, in May 2008, resolution WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, for the period 2008–2015. In the following year, the Health Assembly adopted resolution WHA62.16 (2009), in which it finalized the list of stakeholders responsible for the implementation of each element and sub-element, established progress indicators for each element, and proposed time frames in which the specified actions should be accomplished (1).

Concerned about the pace of implementation, the Sixty-eighth World Health Assembly in 2015 decided in resolution WHA68.18 to extend the time frame of the plan of action from 2015 until 2022 and to undertake an overall programme review. In 2017, the report of the review panel recommended a way forward, including details of what elements or actions should be added, enhanced or concluded in the next stage of implementation until 2022 (2).

This summary of progress responds to the request to the WHO Secretariat to draw up a detailed implementation plan and establish a mechanism to support implementation and monitoring of the global strategy and plan of action in line with the recommendations of the review panel (2). Additionally, in 2022, in resolution WHA75.14, the World Health Assembly decided to extend the time frame of the plan of action on public health, innovation and intellectual property from 2022 to 2030 (3). An implementation plan for the GSPA-PHI for the biennium 2024-26, with progress indicators, will be published online.
2 Progress made in implementing the recommendations of the overall programme review panel

2.1 Prioritizing research and development needs

WHO’s Global Observatory on Health Research and Development (hereinafter the “Observatory”) and Global Malaria Programme have developed and implemented an approach to prioritize research and development for malaria (a Type III disease, namely one that is overwhelmingly or exclusively incident in developing countries). The experience gained and the feedback received on the report related to this prioritization approach informed the development of new initiatives for monitoring and prioritization of research and development by the Global Malaria Programme. An interactive analysis of the malaria vaccines that are in the clinical phase of development was conducted and published by the Global Malaria Programme in 2022 (4). Other reviews of health products in the pipeline and the development of desired product profile characteristics for new products are also underway in several areas of malaria control, including therapeutics and vector control.

The Observatory continues to provide up-to-date information and analyses to support the prioritization of research needs and to identify gaps, and regularly updates its narrative reports on research and development priorities (5). The Emerging Technologies, Research Prioritization and Support (EPS) unit serves as a dedicated Unit for the development of prioritized research agendas across all disease areas. The Observatory has developed guidance for WHO staff on taking a systematic approach to undertaking research priority-setting exercises (6). In 2022, in collaboration with the Antimicrobial Resistance Division, the Observatory published a new analysis of bacterial vaccines in development against drug resistant pathogens (7), in addition to two updated reviews of antibacterial products in the preclinical and clinical phases of development (8,9). In addition, the Observatory continues to add newly developed WHO target product profiles, which are now available for over 30 indications, including for products and diagnostics for Buruli ulcer, COVID-19, HIV/AIDS, human African trypanosomiasis, leishmaniases, mycetoma, onchocerciasis, scabies, and yaws (10). In April 2021, the Director-General established WHO’s Science Council, comprising international experts from a broad range of disciplines to provide guidance on WHO’s science and research strategy and facilitate the adoption of new ideas and opportunities in research and innovation to improve global health. In 2022, the Science Council worked off the workshop held in late 2021, to develop their recommendations to accelerate equitable access to genomics technologies for global health. The Science Council gathered in person in Geneva in July 2022, when the report was officially launched (11). In April 2023, the Science Council published a draft report on mRNA technology for improving global health, for public consultation (12). The Science Council gathered for its second in-person meeting in July 2023. The next Science Council report will focus on information technology and digital health, including components of implementation science and equitable access to emerging technologies (13).
2.2 Promoting research and development

The Observatory continues to serve as WHO’s authoritative source of global information and strategic direction on research for health. It does so by serving as a global analytical and information-sharing mechanism to promote and disseminate relevant information and the results of analyses on health research and development, and to help to coordinate efficient and equitable priority-setting for new investments in health research based on public health needs. This activity, supported by the active engagement of groups of diverse stakeholders, including the Science Council, serves to promote evidence-informed decisions on new investments in health research based on public health needs in a coordinated and equitable manner.

The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases supports, since 2008, a Clinical Research and Development Fellowship programme (CRDF), with the objective to create a critical mass of clinical research and development leaders in low- and middle-income countries, to tackle neglected tropical diseases. For example, 19 fellows have worked on the different study phases in adults and children, in the development of the RTS,S/AS01 (RTS,S) malaria vaccine, that WHO recently recommended for its widespread use. The CRDF scheme also contributed to responding to epidemics and during the COVID-19 pandemic, the CRDF programme helped building health system resilience with 74% of trained Fellows involved in clinical research, mostly as clinical trial managers (14).

2.3 Building and improving research capacity

The UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases continues its research capacity strengthening activities in clinical research and implementation research to identify bottlenecks and break through barriers to life-saving interventions. This is achieved through a considerable effort to build in-country capacity and institutional competences to address local research needs through transdisciplinary approaches, including communities, researchers, implementers and policy makers such as regional training centres initiative, the postgraduate programme, with eight universities contributing to build the critical mass, the Structured Operational Research and Training (SORT-IT) programme and the Social Innovation for Health Initiative (SIHI). Recent developments include the opening of a postgraduate training centre in Senegal as a hub for improving support to French speaking African countries.

The Secretariat provides support to national and regional regulatory networks, such as the African Vaccine Regulatory Forum, in order to strengthen vaccines regulatory functions and systems in Africa. The Forum, an informal capacity-building platform aimed also at improving the regulatory oversight of interventional clinical trials being conducted in Africa, received support from the Secretariat for implementation of its joint reviews guideline including a training manual for inspection of clinical trial sites, and for development of its compassionate use guide. The Secretariat also provided specific support to the Forum for COVID-19 response activities, including the development of training material for the use of its MedNet and DataForm platforms for joint reviews. In December 2019, the Secretariat reactivated the Paediatric Regulatory
Network, a global network providing a platform for exchange of regulatory information on paediatric medical products to support the availability of quality-assured medical products for children. The membership in the network grew from 13 national regulatory authorities in 2019 to 35 in 2020.

In 2022, the WHO-National Control Laboratory Network for Biologicals successfully pursued membership agreements and gained new members, thereby increasing the number of participating national regulatory authorities and national control laboratories to 47. Confidentiality Agreements with manufacturers allowed for sharing of lot release date with the network members. An advocacy workshop for National Control Laboratories for Biologicals was held for countries in the EURO region. Additional national regulatory authorities have agreed to participate in the Collaborative Procedure for Accelerated Registration for prequalified products, for both medicines and vaccines, for a total of 61 participating countries and one regional network (15). The Collaborative Procedure is designed by the Secretariat to facilitate assessments and accelerate national registration of WHO’s prequalified products. In 2020, 94 products were registered under the Procedure in 16 countries.

In early 2022, WHO published a technical document on international standard terminologies on traditional Chinese medicine (16). It also published two benchmarks for training in Ayurveda (17) and Unani medicine (18) and two benchmarks for the practice of Ayurveda (19) and Unani medicine (20). In February 2022, the Secretariat supported the Member States to convene a meeting to evaluate the role of traditional Chinese medicine in the treatment of COVID-19 (21). During the period 2020–2022, WHO-SEARO funded a study to assess the facilitators and barriers to deliver Ayush services during and for COVID-19, in 10 states of India. The study entitled “Assessment of integration of Ayush into the public health system for combating COVID 19” was undertaken as a collaborative project between Government of India and Public Health Foundation of India. WHO organized field-joint missions of the Regional Expert Advisory Committee on Traditional Medicine for COVID-19 Response (REACT), Centre for Diseases Control and Prevention (Africa CDC), the African Union Commission for Social Affairs (AUC) and the European and Developing Countries Clinical Trial Partnerships to the following countries to monitor the clinical trials being conducted: Madagascar (February 2022), Uganda (February-March 2022), Democratic Republic of Congo (DRC) (March 2022), Nigeria (April 2022), Ghana (April 2022) and South Africa (June 2022). A meeting between WHO and REACT was held in Republic of Congo in July 2022 to discuss the findings from the country missions to fast-track research and development and local manufacturing of traditional medicine-based therapeutics for COVID-19. On April 19, 2022, the WHO Global Centre for Traditional Medicine was launched in India. The Centre has a strategic focus on evidence and learning, data and analytics, sustainability and equity, and innovation and technology to optimize the contribution of traditional medicine to global health and sustainable development. Membership of national/regional regulatory agencies in WHO’s International Regulatory Cooperation for Herbal Medicines network expanded to 47 in 2021. The Secretariat facilitated capacity-building of 43 government officials through virtual interregional training on traditional,

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1 Ayush systems refer to Ayurveda, Yoga, Naturopathy, Unani medicine, Siddha medicine, Homeopathy and Sowa-Rigpa.
complementary and integrative medicine in November 2021 and the next annual workshop is planned for November 2022.

2.4 Promoting transfer of technology

The Secretariat updated guidelines on the transfer of technology in pharmaceutical manufacturing and will present them for endorsement to the forthcoming meeting of the Expert Committee on Specifications for Pharmaceutical Preparations. WHO-UNCTAD joint webinars were organized on investing in high-quality local vaccine production for COVID-19.

WHO supported the efforts of the Secretariat of the World Trade Organization (WTO) on more effective implementation of Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on health-related technology transfer. Discussions took place with least-developed countries on the broader development and policy context of technology transfer with a focus on three specific fields of technology transfer, namely the fields of health, agriculture and the environment.

In response to the Solidarity Call to Action, the COVID-19 Technology Access Pool (C-TAP) was established by WHO and receives support from the United Nations Development Programme (UNDP), Unitaid, the UN Technology Bank and the Medicines Patent Pool. C-TAP was launched to facilitate timely, equitable and affordable access to COVID-19 health products through the sharing of intellectual property, knowledge, and data with quality-assured manufacturers to scale up production around the world.

Several technologies have now been licensed to C-TAP. The Spanish National Research Council (CSIC) and the United States National Institutes of Health (NIH) have shared their technologies with C-TAP for the development of COVID-19 diagnostics, vaccines and therapeutics. The technology received from CSIC has been sublicensed to Biotech Africa to promote access in low- and middle-income countries (22). Medigen Vaccine Biologics Corp has shared with C-TAP a worldwide license for a COVID-19 vaccine based on the COVID-19 spike protein sequence that Medigen licensed from the US National Institutes of Health (NIH). This is the first transparent, global, non-exclusive license for a COVID-19 vaccine and the first health technology developed by a private company and included in C-TAP (23). The University of Chile shared with C-TAP a worldwide license for a system for quantification of neutralizing antibodies (NAbs) against SARS-CoV-2. This diagnostic can be used in facilities using heightened control measures similar to Biosafety Level 2 (BSL-2) laboratories (24). All licenses are worldwide, non-exclusive, and transparently available on the C-TAP website (25). C-TAP and its supporting partners continue to negotiate with public and private partners for new licenses and to grant sublicenses to the technologies already in C-TAP to manufacturers.

Since the establishment of the first COVID-19 mRNA vaccine technology transfer hub in South Africa, in June 2021 (26), WHO and its partners have supported the development of such technology, that has concluded the pre-clinical study phase. The 15 partners have all received training at the hub in South Africa on the laboratory scale manufacturing process (27). The medicine Patent Pool, as WHO’s implementing partner, undertakes facility assessments at each receiving partner to define tailored technology transfer
strategies and plans, while the hub and the first technology recipient in South Africa are upgrading their facilities to GMP standards.

2.5 Managing intellectual property to contribute to innovation and public health

In September 2023, in their third meeting since the onset of the COVID-19 pandemic, the Directors-General of WHO, WIPO and WTO agreed to shift the focus of trilateral cooperation from the response to the COVID-19 pandemic to increasing and broadening support for more effective and sustainable use of TRIPS flexibilities to increase access to health technologies and to be better prepared for future pandemics (28).

WHO, WIPO and WTO published updated information notes on “Integrated health, trade and IP approach to respond to the COVID-19 pandemic” in October 2021 and May 2023 (29,30). These information notes map the challenges posed by the COVID-19 in relation to the integrated health, trade and intellectual property framework set out in the second edition of the Trilateral Study on “Promoting Access to Medical Technologies and Innovation” (31). The updates contain developments up to May 2023, including on the impact of COVID-19 on health systems and responses at the global level, policy challenges, meeting the demand for health technologies and medical services, international trade, intellectual property aspects, international initiatives to support research and development and equitable access, regulatory responses, transparency and mapping the way forward.

Within the existing trilateral collaboration framework between WHO, WIPO and WTO, the COVID-19 Technical Assistance Platform website was created as a one-stop shop for the three organizations to make available their expertise in public health, IP and trade matters in a coordinated and systematic manner to help Member States address the COVID-19 pandemic (32). The Platform also facilitates the provision of tripartite technical assistance on the pathways for accessing vaccines, medicines and technologies, including through coordination between members facing similar challenges to facilitate collective responses.

WHO, WIPO and WTO agreed to organize practical capacity-building workshops at the technical level to enhance the flow of updated information on current developments in the pandemic and responses to achieve equitable access to COVID-19 health technologies (33). The first in the series of workshops, titled “WHO, WIPO, WTO Workshop on Innovation in, and Access to, COVID-19 Technologies”, was held on September 27, 2021 to discuss technology transfer and licensing as specific IP policy options. The workshop, held virtually, conveyed information to enhance knowledge and understanding of how IP, know-how and technology transfer work in practice, not only vis-à-vis medical technologies but also for related products and services. This was aimed at strengthening the capacity of policymakers and experts in member governments to address the pandemic accordingly (34). A second workshop in this series, titled “WHO-WIPO-WTO Workshop: Innovation and Access to diagnostics for COVID-19 and beyond”, was held on October 28, 2022, providing information on practical capacity-building for increasing access to in vitro diagnostics, including a
review of the landscape of in vitro diagnostics for COVID-19, understanding relevant regulatory processes, considering relevant intellectual property and trade issues, and providing a forum for the exchange of experiences and views to help the Secretariats of the three organizations to respond to the capacity-building needs of their members (35).

On 28 February 2022, WHO, WIPO and WTO jointly organized a workshop focused on access and use of information resources for COVID-19 response (36). The purpose of the workshop was to enhance understanding of the characteristics, potential uses and limitations of particular information sources related to the pandemic. Points raised for future consideration included the connection of various data resources, the importance of coherent information across resources, the utility of expanding resources to include data related to other diseases and how to leverage or improve resources to prepare for future pandemics.

The 10th WHO-WIPO-WTO Trilateral Symposium was hosted by WHO on 14 November 2023 (37), as a public event in hybrid format open to government representatives and other interested stakeholders, on the topic of climate change and human health.

WHO monitors coverage and use of existing and new user-friendly databases of patent status and licensing information for key health technologies. WHO has launched the Technology Access Pool database as a global one-stop shop for dynamic information on selected therapeutics, diagnostics, vaccines and other health products (38). The database includes information on clinical trials, scientific publications, regulatory status, manufacturers, patent status, licensing agreements, and other publicly available data. WHO continues to promote the development of user-friendly databases. WHO and Unitaid published in April 2023 a technical briefing document explaining some of the legal instruments that Member States may use to promote public health and access to key COVID-19 therapeutics, in the framework of their multilateral trade obligations and rights and according to their national legislations and level of development (39).

2.6 Improving delivery and access

The Secretariat has developed and shared good practices on evidence-based methodology for selection of all major health product types. WHO launched a digital version of the Model List of Essential Medicines and the Model List of Essential in vitro Diagnostics. In March 2020, WHO published a guidance manual on how to update a national essential medicines list (40). It also published, in July 2021, a guidance document for countries on methods for developing and updating national lists of essential in vitro diagnostics. A webinar to help countries to develop national essential diagnostics lists was held in October 2021. WHO has also published a how-to guide on institutionalizing health technology assessment mechanisms. A global survey on health technology assessment processes in Member States has been developed, pilot-tested, and implemented. The survey website, with detailed methods and a database of country results, has been published online (41).

In September 2020, WHO published an update of the WHO guideline on country pharmaceutical pricing policies. The guideline includes evidence-informed recommendations for the promotion of price transparency of pharmaceutical products.
In April 2021, WHO convened the third Fair Pricing Forum, with promoting and monitoring transparency in medicine prices being a major theme. To ensure greater adoption of the pricing guideline’s recommendations, WHO also published 10 plain-language summaries and a handbook containing 12 country case studies of pricing policies. In addition, WHO has been hosting monthly webinars on various topics in pharmaceutical pricing policies and created an online community of practice for discussion and collaboration. In collaboration with the Noncommunicable Diseases Department of the WHO Regional Office for Europe, MHP conducted three national surveys of the availability and affordability of NCD medicines and started updating the new Country Assessment Platform (CAP) MEDMON tool for surveys and further monitoring. WHO is currently piloting the tool in two countries. WHO has published a report on access to insulin in 2021 entitled: “Keeping the 100-year-old promise: making insulin access universal”, identifying critical barriers to and potential solutions to improve access to insulin. WHO is in process of developing new methodologies to analyze publicly available price information and has updated the database of national price information sources. WHO is developing methodology guidance for tracking pharmaceutical spending at the country level.

The Secretariat provided support to Member States for strengthening national regulatory capacity and regional harmonization activities. Since 2021, nine additional national regulatory authorities have been benchmarked (total of 33 to date) while 38 additional national regulatory authorities completed self-benchmarking (total of 58 to date) using the WHO Global Benchmarking Tool. To date, 57 (29%) of WHO’s 194 Member States are operating at either Maturity Level 3 (stable, well-functioning and integrated regulatory system) or Maturity Level 4 (advanced level of performance and continuous improvement). In accordance with resolution WHA67.20 (2014) on regulatory system strengthening for medical products, the Director-General launched the WHO network for regulatory system strengthening called the Coalition of Interested Parties (CIP) Network, and the CIP web platform. The CIP web platform is a secure, central repository for sharing confidential information related to collaborations between NRAs and CIP members. It is worth mentioning that with strategic support to strengthening regulatory capacity, the NRAs of Nigeria, Egypt, China and South Africa achieved Maturity Level (ML) 3, commensurate with a stable, well-functioning and integrated regulatory system.

Since early 2022, the WHO initiated a new advocacy approach to engage new Member States in the Collaborative Registration Procedure (CRP), in view of the relevancy of the programme during the COVID-19 pandemics for Member States to be able to accelerate the assessment and registration of medical products. The CRP is designed by the Secretariat to facilitate assessments and accelerate national registration of products prequalified by WHO (PQ CRP) or approved by SRAs (SRA CRP). Since early 2022, with a more personalized reach out and wider regional coverage twenty-one (21) new Member States initiated engagement in SRA CRP and PQ CRP. In 2022, the secretariat also developed and implemented a 5-step systematic approach when a Member State joins CRP for medicines and vaccines, to support the implementation of facilitated regulatory pathways in the countries, including CRP. Resulting from this activity, a significantly higher number of much-needed medical products have been submitted to and registered by member states using CRP, with the support of the
secretariat. For SRA CRP more than 200 submissions for 47 products were made to more than 40 Member States, and 107 products registrations have been granted. For PQ CRP more than 1450 submissions for about 300 medicines were made to more than 40 Member States and 800 registrations have been granted.

In April 2021, WHO published guidelines on Good Reliance Practices and Good Regulatory Practices following their adoption by WHO’s Expert Committee on Specifications for Pharmaceutical Preparations in October 2020. Both policy documents will help to streamline and support regulatory practices at global, regional and national levels. In June 2021, WHO issued a policy on the evaluation and designation of regulatory authorities as WHO-listed authorities (42). The WHO-listed authorities framework will replace the concept of stringent regulatory authorities.

The Access, Watch and Reserve (AWaRe) classification of antibiotics and the associated database were updated in 2023 (43). This update includes an additional 78 antibiotics not previously classified, bringing the total to 257. The WHO essential medicines list antibiotic book, published in December 2022, provides guidance on antibiotic treatment for more than 30 syndromes (44).

The Secretariat has provided technical support to nine Member States to integrate the provision of assistive products into their health services, with a focus on training of the primary health care workforce using WHO’s training in priority assistive products, which is due to be formally launched by the WHO Academy in 2022. The Secretariat surveyed the needs and priorities for assistive products within humanitarian response and is developing an essential assistive products list and manual for emergency response. In October 2021, WHO published 30 training videos for medical devices needed for oxygen-delivery systems; they will be uploaded shortly in the OpenWHO platform. The list of priority medical devices and its associated technical specifications as well as technical specifications for personal protective equipment for COVID-19 have been updated and translated into all six official languages of the United Nations.

2.7 Promoting sustainable financing mechanisms

G-FINDER tracks and reports global funding for research and development on neglected diseases, and Member States should commit themselves to provide information to G-FINDER (45). G-FINDER tracks public, private and philanthropic funding of basic research and product development for global health priorities. The focus of the project is neglected diseases. G-FINDER reported that the top public funders of research and development in 2020 were high income countries, providing 97% of the public sector total (46). Despite an increase in survey participation by low- and middle-income countries, funding from these countries reduced in 2020 (46). The G-FINDER database also includes data reported by researchers, although this may not represent the full funding of their institution or Member State.

2.8 Establishing a monitoring and accountability mechanism

The WHO Executive Board at its 148th session noted the implementation plan 2020–2022 to guide further action on the prioritized recommendations of the review panel
addressed to the Secretariat. To assess progress in implementation of the recommendations addressed to Member States, the Secretariat conducted a questionnaire to gather baseline information from Member States. The Secretariat presented preliminary results of the analyses of the responses during an informal consultation with Member States in December 2020 and the analysis has been published (47). A second survey was undertaken to provide further information on Member States’ progress in the implementation of the review panel recommendations. The survey included 33 detailed questions covering the eight Elements of the GSPA-PHI, and responses were received from 36 Member States, covering all six WHO regions and all World Bank income groups. A report of the survey results will be presented to Member States and will soon be available online.

Responding to the request made in resolution WHA75.14 (2022), WHO undertook in 2023 a review of the indicators included in the overall programme review of the GSPA-PHI, in consultation with Member States, as well as WHO regional offices and relevant teams in WHO headquarters, and developed proposed revisions to align indicators with the new term of validity of the plan of action (3), alongside a new implementation plan for GSPA-PHI for the 2024–26 biennium.
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