

**Informal Consultation on the Global Strategy and Plan of Action on
Public Health, Innovation and Intellectual Property**

3 December 2020

Summary report

1. In response to World Health Assembly decision WHA73(11), the Director-General convened an informal consultation of Member States on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) on 3 December 2020 to discuss the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (2018) as “not emanating from the global strategy and plan of action on public health, innovation and intellectual property” and the “recommendations of the review panel on promoting and monitoring transparency of medicines prices and actions to prevent shortages” referred to in paragraph 3 of decision WHA73(11). More than 100 representatives of Member States participated in the consultation via Zoom.
2. In her opening remarks, **Mariângela Simão**, Assistant Director-General for Access to Medicines and Health Products, drew attention to the rich and long history of the GSPA-PHI, adding that it provides an agreed common response to the areas of interface between public health, innovation and intellectual property which are now, more than ever, part of a global agenda on access to health. She highlighted that the COVID-19 pandemic brings to surface even more some of the common issues for which a common, global response is needed. She underlined the recurrent nature of some of the problems that low-, middle-, and high-income countries face regarding access to affordable, safe, quality-assured, and efficacious health technologies and emphasized that short-, mid- and long-term solutions are required. The consultations are expected to trigger collective dialogue in the spirit of collaboration around areas of the GSPA-PHI overall programme review where broad consensus is yet to be met, points raised in governing bodies meetings such as funding for R&D, and the linkages between costs for development and final prices. Deeper discussion during the consultations around the recommendations of the review panel on promoting and monitoring transparency of medicines prices and actions to prevent shortages will also provide input and guidance to assist the Secretariat in preparing the report on progress made in implementing decision WHA71(11) to the Seventy-fourth World Health Assembly in 2021, through the Executive Board at its 148th session.
3. As former Chair of informal consultations on the GSPA-PHI, **Maria Nazareth Farani Azevêdo**, Ambassador, Permanent Mission of Brazil to the United Nations in Geneva, was invited to deliver additional opening remarks. In her remarks, she reflected on the importance of the access to medicines agenda for the sustainability and resilience of health systems, noting that access to affordable, safe, efficacious, and quality medicines is key to achieving universal health coverage, adequate levels of preparedness, and responding to health emergencies. She stated that

comprehensive and timely implementation of the GSPA-PHI would be a major contribution to reaching those key goals and fulfilling promises of higher standards of health and well-being for all. Noting that COVID-19 has added to the importance of ensuring equitable access to vaccines, therapeutics and diagnostics, catalyzing initiatives such as COVAX, ACT-A and C-TAP, she called on participants to build upon such momentum to move ahead on implementation of the GSPA-PHI as a cross-cutting enabler to many public health initiatives. She emphasized the GSPA-PHI as a remarkable asset for addressing present challenges where affordability hinders the access to health both in poor and developed countries as well as emerging challenges, such as the steep costs of cutting-edge treatments that involve, for example, gene and cell-based therapies. She encouraged the Secretariat to move ahead as a matter of urgency with the implementation plan recalling decision, WHA73(11) which reiterated to the Director-General the need to allocate necessary resources for the implementation of the recommendations of the review panel addressed to the WHO Secretariat.

4. In presenting ongoing work by the WHO Secretariat, **Erika Dueñas** provided an update on the final “Implementation Plan 2020 -2022 to Guide Further Action on the Prioritized Recommendations of the Review Panel Addressed to the Secretariat” published on the WHO website, noting that comments received from Member States were incorporated in the final version. She explained the next steps on implementation and monitoring from the WHO Secretariat, including several deadlines for activities indicated in the recommendations for 2020, 2021 and 2022. Resource requirements were estimated in USD 16.9 million between 2020-2022 for full implementation of the prioritized actions. **Nicole Homb** reviewed the purpose, content, and process of the GSPA-PHI Member State Survey¹ and also presented preliminary results on recommendations germane to the informal consultation.

5. Panel 1 on “Transparency of pricing of health products and elements throughout the value chain” began with a presentation by **Kiu Tay** on behalf of the WHO Secretariat. Kiu presented recommendations relating to promoting price transparency included in the September 2020 “WHO Guideline on Country Pharmaceutical Pricing Policies.” He noted that the Guideline Development Group made two conditional recommendations on promoting price transparency, including that countries improve the transparency of pricing and prices through 1) sharing the net transaction prices of pharmaceutical products with relevant stakeholders, within and external to the country; disclosure of prices along the supply and distribution chain; reporting publicly the R&D contributions from all sources and communicating pricing and reimbursement decisions to the public, and through 2) a clear description of pricing approaches and their technical requirements. **Fatima Suleman**, Co-Chair of the WHO Guideline Development Group on Country Pharmaceutical Pricing Policies and Director of the WHO Collaborating Center for Pharmaceutical Policy and Evidence Based Practice at the University of KwaZulu-Natal elaborated three justifications by the Guideline Development Group to support their recommendations on promoting price transparency, namely 1) overall balance of effects favors the policy, 2) urge stakeholders to take the necessary steps in line with WHA72.8, and 3) serve multiple purposes for improving pricing policies. **Anban Pillay**, Deputy

¹ https://www.who.int/medicines/innovation/gspa-review/member_state_questionnaire-gspa-phi.pdf?ua=1

Director-General Department of Health in South Africa shared national experiences on transparency of pricing of health products from an implementation perspective. He highlighted the need for political support and noted that South Africa has specific legislation relating to transparency. He supported the Guideline Development Group's recommendations, drawing specific attention to the need to disclose prices along the entire supply and distribution chain, noting that net transaction price rather than manufacturing price must be shared. He cautioned the principle of alternative reimbursement models, noting their potential to undermine transparency. He emphasized that the system must reward low prices in order to incentivize competition on prices. **Nora Kronig Romero**, Global Health Ambassador, Switzerland, shared national experiences using the example of vaccines. She remarked on the important role of the rule of law in providing a protective environment for all stakeholders. She highlighted issues of infrastructure and logistical challenges, noting vaccine cold chain storage as a particular challenge for low-income countries. Regarding price transparency, she reiterated Switzerland's steadfast support, noting the country's strong regulation and legal obligation for price transparency. In Switzerland, the prices of medicines for rare diseases present a challenge to the social contract around health insurance schemes. She emphasized the need for international cooperation around issues of price differentiation and shortages as well as Switzerland's commitment to play a role in facilitating discussions with private sector in her country. **Sonia Caldeira**, National Authority of Medicines and Health Products INFARMED, Portugal, presented the Portuguese experience on the topic. She outlined the country's pharmaceutical pricing policies and reviewed the Health Technology Assessment process (pharmacotherapeutic assessment, pharmacoeconomic assessment, negotiation and managed entry agreements, decision, monitoring, and reassessment) for pricing and reimbursement. She concluded by sharing steps the country is taking toward promoting and achieving greater transparency in pharmaceutical policies.

6. Panel 2 on "The concern with shortages to health products" began with a presentation by **Lisa Hedman** on behalf of the WHO Secretariat. Lisa presented WHO's activities to support Member States on shortages and stock outs of medicines and vaccines. WHO will work to expand the use of the WHO Shortages Notification Portal; reinforce national capacity to use data to detect and report and to respond with short/medium term solutions via sharing and training on best practices, including regulatory reliance, and; identify chronic, long-term shortages for strategic intervention. **Claudia Chamas** of FIOCRUZ, Brazil, elucidated the challenges that remain despite progress in the field of access to medicines over the past decade. Highlighting that all regions of the world face problems with regular access to medicines, vaccines and other health products, she reflected that inequitable access affects the poorest more severely. She reflected that the COVID-19 crisis has brought to light longstanding vulnerabilities in the availability and supply of health products, noting the concerns and risks of patients of shortages. She called tackling the global problem of access with the seriousness it requires to ensure the right to health and other fundamental human rights. **Valerie Jensen**, Food and Drug Administration, USA, presented an overview of FDA's role in mitigating and preventing drug shortages. She outlined the notification requirements under section 506C of the FD&C Act and FDA regulations and described the current challenge of increasing new shortages

and persistent shortages and introduced the responsibilities of the US Interagency Drug Shortage Task Force. She explained the key findings from the FDA Drug Shortage Report which identified three root causes for drug shortages and offered three recommendations for enduring solutions. She concluded by outlining next steps relating to current legislative and related FDA initiatives.

7. Remarks on the relationship between the GSPA-PHI and the current fight against the pandemic were delivered by **Philippe Duneton**, Executive Director, Unitaïd. Philippe Duneton began by relating the GSPA-PHI to the core business of Unitaïd's operations to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively. He highlighted the importance of specific elements of the GSPA-PHI such as "Building and improving research capacity" for adapting products to the realities of countries. He highlighted the continued relevance of recommendations relating to transfer of technology and management of intellectual property, noting the experience and achievements of the Medicines Patent Pool (MPP) to cover more than 20 million people with more than USD 1.5 billion in savings. He emphasized that access requires an end-to-end solution from what is needed, what should be developed, the quality of it, creating the demand at the country and scaling up. As co-convener, with Wellcome Trust, of the ACT-A therapeutics pillar, and in working closely with FIND and the Global Fund on the diagnostics pillar, he highlighted the importance of access-oriented thinking at the fore of acceleration efforts. He noted the involvement of the Unitaïd-funded MPP in ACT-A and the COVID-19 Technology Access Pool (C-TAP) and emphasized requisite industry support for increasing capacity of production at low cost through voluntary mechanisms such as MPP and C-TAP.
8. Discussion amongst Member State participants reaffirmed the importance of international instruments, such as the GSPA-PHI and resolution WHA72.8 on 'Improving the transparency of markets for medicines, vaccines, and other health products,' for promoting access to medicines. It was acknowledged that the COVID-19 pandemic has renewed global discussion and the need for collective action on global public goods for health to address global systemic health inequities. Concerns about the lack of transparency of the price of medicines, vaccines, and other medical products was noted as a key factor hindering effective implementation of policies aimed at promoting affordable access to medicines. Furthermore, critical weaknesses in supply chains highlighted by the pandemic have led to shortages of medicines and other health products. The importance of the Doha Declaration on the TRIPS Agreement and Public Health was brought to the fore as an instrument in support of Member State measures to protect public health, including the use of flexibilities recognized by the declaration and other related World Trade Organization instruments. As an immediate next step to ensure equitable access to COVID-19 related health technologies, Member States were encouraged to join C-TAP and promote collective sharing of related knowledge, intellectual property and data.
9. In her concluding remarks, **Mariângela Simão**, Assistant Director-General for Access to Medicines and Health Products, complimented panelists and participants for their constructive contributions to the dialogue. She concluded with some reflections from the discussion and highlighted actions the Secretariat will be taking in the coming months:



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- The recommendations of the GSPA-PHI overall programme review remain relevant to the contemporary circumstances and even more relevant than ever before within the context of the COVID-19 pandemic;
- Lessons learned as a result of the pandemic in taking the GSPA-PHI forward include, for example, that there are distinct contextual differences between countries with and without manufacturing capacity as well as those with small markets versus large markets;
- A renewed collaborative spirit which is unpinned by the GSPA-PHI provides an opportunity to address the access to medicines agenda more holistically, within the context of COVID-19 and beyond;
- Key actions to facilitate increased manufacturing capacity, voluntary sharing of intellectual property, data and knowledge, and licensing, for example, through C-TAP, are essential to concretely bring results on implementation of the GSPA-PHI;
- The WHO Secretariat will publish a summary report of the consultation on the WHO website as well as the final GSPA-PHI implementation plan.