

WHO Fair Pricing Forum, 2020-21 Milestones

Background

In 2017 and 2019, WHO convened Fair Pricing Forums to enable stakeholders to discuss options for fairer pricing of pharmaceuticals. At the 2019 Forum in Johannesburg, participants acknowledged the difficulties in defining a “fair price”, particularly on what fairness means in practice, and how such notion could be put to actions by all stakeholders.

Following the 2019 Forum, stakeholders were invited to provide feedback on the next steps towards achieving fair pricing, through an online survey conducted between 15 August and 30 September 2019. The survey generated over 50 responses from stakeholders across government, industry, NGOs, academia, and individuals. Survey respondents considered the working definition of “fair pricing” (feedback considered in the recent commentary at www.bmj.com/fair-pricing). Survey respondents were also invited to suggest potential research topics pertinent to achieving fair pricing. With consideration to the suggested topics, WHO will convene two technical working groups in 2020 to determine policy options that are achievable in the short and medium term. The working groups will report to the 2021 Fair Pricing Forum.

This document outlines the 2020 milestones for the 2021 Fair Pricing Forum, including:

- Terms of reference, nomination, and milestones for the technical working groups; and
- Planning milestones for the 2021 Fair Pricing Forum.

Scope of work

The technical working groups will focus on the following two topics:

1) Exploring pricing approaches sensitive to health systems’ ability to pay and to the need for achieving universal coverage of pharmaceutical products

Evidence shows that medicine prices are not always commensurate with the medicine’s true clinical value, or a country’s needs, demand and purchasing power. This has resulted in unaffordable prices that impede universal access to pharmaceutical products with well-established efficacy and safety, particularly for patients in low- or middle-income countries.

This working group will examine what characteristics of healthcare systems and medicines should be considered in a pricing approach, with a view to ensuring the overarching public health objective of “health for all” is met. Based on the characteristics identified, the working group will identify technical options to ensure the pricing approach is sensitive to the health systems’ ability to pay and the true clinical value of the products. This group will also examine factors that would enable or impede the operation of such pricing approach(es) from various perspectives, including scientific, political, legal and commercial.

2) Aligning incentives for research and development for pharmaceuticals

Governments and multilateral institutions, working with stakeholders, have implemented a range of policy incentives to stimulate the R&D of medicines, including for rare disease,

neglected tropical disease and antimicrobial resistance. These incentives include research grants, R&D tax credits, flexibility for regulatory and reimbursement approval, and longer market exclusivity. Other measures include guiding development towards innovations with desired characteristics by defining targeted therapeutic profile, and through advance market commitment, guaranteeing a viable market for a product upon successful development. While price signals could stimulate innovation, high prices make medicines unaffordable and prevent its full benefit from being realised. It is also important to recognize that market dominance could encourage wasteful spending, distort investment and eventually stifle innovation.

This working group will explore different models for incentivising health innovation. The models should consider mechanisms that would meet, inter alia, public health objectives, clinical values, sustainable financing, good governance and timeframe. This group will also examine factors that would enable or impede the operation of such models from various perspectives, including scientific, political, legal and commercial.

Terms of Reference

Terms of Reference for both groups are in Annex A.

Each Working Group shall have up to 12 members, who serve in their personal capacities to represent the broad range of disciplines, institutional and professional affiliations, and with deep technical expertise relevant to the topic areas. For each group, 6 experts will be identified through WHO Regional Offices (one per region per group) and the remaining 12 (6 per group) will follow a call for nominations on the website: www.who.int/medicines/access/fair_pricing/en/.

All declaration and management of conflicts of interest will follow WHO's policies. Each working group should meet in-person at the initiation and conclusion of the work, with monthly interim meetings via WebEx. In-person meetings may take place at a WHO office or hosted by a WHO Collaborating Centre.

The proposed timeline for these activities is as follows:

- Q1 2020: Call for nominations for the Technical Working Groups (February)
 Member State information session (13/14 February)
 Constitute Technical Working Groups (March)
- Q2 2020: Convene Technical Working Group meetings, assign workstream research
 Secure host for 2021 Fair Pricing Forum
- Q3 2020: Send Save the Date for 2021 Fair Pricing Forum
 Working Group interim check-in/realignment
- Q4 2020: Working Group inputs to Fair Pricing Forum Agenda
- Q1 2021: Working groups to distribute draft background papers and Forum inputs
- Q2 2021: Fair Pricing Forum (indicative)

Annex A: Terms of Reference for Fair Pricing Working Groups

As requested by World Health Assembly Resolution 72.8 (2019), the Organization is convening its biennial Fair Pricing Forum in 2021. The meeting convenes Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products.

WHO is convening a set of two (2) technical working groups that will focus on specific areas of pricing to determine what is achievable in the short- and medium-term, reporting to the next Fair Pricing Forum in 2021.

The 2020 Fair Pricing Working Groups will focus on the following 2 topics:

- 1) Exploring pricing approaches sensitive to health systems' ability to pay and to the need for achieving universal coverage of pharmaceutical products**
- 2) Aligning incentives for research and development for pharmaceuticals**

Functions

Each Working Group shall have the following functions:

- 1) To prepare an analysis on one of the Fair Pricing topics outlined above, taking into consideration a broad set of determinants, and accounting for the impact on affordability of existing medicines and the potential for future innovation.
- 2) Based on these analyses, to provide advice to WHO on areas of further research and/or discussion needed at the Fair Pricing Forum.

Composition

1. Each Working Group shall have up to 12 members, who shall serve in their personal capacities to represent the broad range of disciplines, institutional and professional affiliations, relevant to each technical working group. In the selection of the members, consideration will be given to attaining an adequate technical distribution of expertise, geographical representation and gender balance.
2. Members of each Working Group, including Co-Chairs and Rapporteurs, shall be selected and appointed by WHO. The Chair's role includes:
 - to chair Working Group meetings;
 - to liaise with the WHO Secretariat between meetings.
3. Members of each Working Group, including the Chair, shall be appointed to serve for a period of one year (i.e., the duration of this project). Their appointment and/or designation as Chair may be terminated at any time by WHO if WHO's interest so requires or as otherwise specified in these TORs or letters of appointment.
4. Representatives from inter-governmental organizations, as well as nongovernmental organizations in official relations with WHO, may be invited by WHO to participate in Working

Group meetings as observers. Upon invitation of the Chair, they may present the views and policies of their organizations and contribute to the discussions in the Working Group. They will not participate in the process of adopting the final decisions or recommendations of the Working Group

5. Members must respect the impartiality and independence required of WHO. In performing their work, they may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of real, potential or apparent conflict of interest. To this end, proposed members/ members will be required to complete a declaration of interest form and confidentiality undertaking, and their appointment will be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

Operation

1. Each Working Group shall meet up to two times in-person between March 2020 and March 2021, plus the Fair Pricing Forum slated for Q2 2021. WHO shall provide any necessary scientific, technical and other support for each Working Group. WHO may convene additional meetings, including through teleconferences and videoconferences, on an ad hoc basis, as decided by the Assistant Director General of the responsible Division.
2. Members are expected to attend meetings. If a member misses two consecutive meetings/calls, WHO may end his/her appointment as a member of their respective Working Group. WHO may decide to appoint a member in replacement of that member.
3. Reports will be submitted by each Working Group to WHO (the Assistant Director-General of the responsible Division). Members usually take decisions by consensus as per WHO Regulations. All recommendations or opinions from the Working Groups are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the Working Groups. WHO also retains full control over the publication of the reports of the Working Groups, including whether to publish them.
4. Information and documentation to which members may gain access in performing Working Group related activities will be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. Working Group members shall not purport to speak on behalf of, or represent, the Working Group or WHO to any third party. All proposed members will be required to sign an appropriate confidentiality undertaking and provisions on ownership.
5. Remuneration: Participation in the Technical Working Groups is on a voluntary basis. Each member receives a travel and per diem allowance for participation in in-person meetings.