First meeting of the Technical Advisory Group on Pricing Policies for Medicines (TAG-PPM), 27 November 2023
Executive Summary

The Technical Advisory Group on Pricing Policies for Medicines (TAG-PPM) held its first meeting virtually on 27 November 2023. This document summarizes the discussion.

Background

Universal health coverage encompasses the right to safe, quality-assured, effective, and affordable medicines, as stated in Sustainable Development Goal 3.8. However, inconsistent availability and poor affordability are hurdles for both health systems and patients.

WHO has increasingly been requested by Member States for technical input on matters relating to pricing and affordability of health products. These include the WHO Roadmap for Access to Medicines, Vaccines, and Other Health Products and World Health Assembly Resolution 72.8 on Improving the transparency of markets for medicines, vaccines, and other health products. Most recently the Expert Committee on Selection and Use of Essential Medicines recommended the establishment of a working group “to provide advice to WHO on policies and rules to make highly priced essential medicines more affordable and accessible” (p.5).

While WHO convenes the biennial Fair Pricing Forum to discuss the affordability and transparency of prices and costs, there is a recognized need for technical advice to improve equitable and affordable access via evidence-based pricing and other policies.

To this effect, the Technical Advisory Group for Pricing Policies for Medicines will support WHO to scale up the implementation of WHO mandates and guidelines, according to national contexts, to strengthen pricing policies, transparency of markets, and affordable access.

In its capacity as an advisory body to WHO, the technical advisory group has the following functions:

1. to provide evidence-based technical advice to guide efforts to increase affordable access to essential and priority medicines and health products;
2. to advise WHO on the implementation of medicines pricing policies, emerging evidence, and good practices for improving the affordability of essential medicines;
3. to advise WHO on methods for measuring availability and pricing of medicines, and the impact of interventions to make medicines more affordable;
4. to advise WHO on further research, country support, and international collaboration needed to improve the transparency of markets for medicines; and
5. to advise WHO on stakeholder engagement to improve the affordability of medicines.
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Meeting Objectives

The objectives of the meeting were to officially launch the TAG-PPM, familiarize TAG members with WHO's work on medicines pricing and affordability, and discuss the proposed 2024 workplan, including potential inputs to a revised procedure for selection of WHO Essential Medicines.

Meeting Participants

Out of 17 appointed TAG members, 16 participated in this first meeting and quorum was reached. The meeting was chaired by Andrew Gray and Sabine Vogler, who have been appointed Co-chairs for the TAG-PPM for the coming two years.

All TAG-PPM members provided their declaration of interest in advance of the meeting, which were assessed by the WHO Secretariat. It was assessed that all members could fully participate in all sessions.

A detailed list of participants is included in Annex 1.

Summary of discussion

Introduction and Operations of TAG-PPM

Director HPS welcomed TAG members and highlighted their vital role in supporting WHO to scale up the implementation of WHO mandates and guidelines, strengthen pricing policies, transparency of markets, and affordable access.

TAG-PPM members provided a brief overview of their professional expertise. The WHO Secretariat provided an overview of the TAG-PPM procedures and operations, including TAG responsibilities and inviting observers to future meetings.

The WHO Secretariat provided an overview of WHO's current work on Affordability and Pricing, and proposed areas where the TAG-PPM Workplan could augment that work going forward.

Key areas of TAG-PPM input for the next biennium include:

- advise on how economic assessment criteria could be incorporated in future updated procedure used by the WHO Model EML Expert Committee;
- advise WHO in its research efforts to assess the impact of price transparency on the affordability and availability of medicines;
- advise on systematic methods of capturing information from existing price databases and networks, and how to regularly use such data to support policy/decision making;
- review standards developed by WHO on pricing definitions and methodology of price comparisons.

In the longer term, WHO requests TAG-PPM input on the following:

- advise on how to promote good practices and develop country capacities for implementing national pricing policies, improve public payer capacity for price negotiations;
- review approaches and recommend strategies on country-driven global tiered pricing or single price approaches in line with the notions of broad access and fairness (and other alternative methods to external reference pricing);
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- identify issues for further discussion by the broader stakeholder group at the Fair Pricing Forum, other opportunities for partnerships or stakeholder collaboration;
- advise on strategies on how payers should manage uncertainty in determining pricing and reimbursement of health products approved under accelerated approval schemes or via surrogate endpoints.

TAG-PPM requested clarification on the technologies within their remit. In the near term, the TAG-PPM will focus only on medicines, although the Terms of Reference could permit work on other essential health products in the future. The Secretariat will also coordinate efforts with the newly-formed Technical Advisory Group on Market Access for Vaccines (TAG-MI4A) and Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV) to determine potential synergies in promoting access to essential health products.

TAG-PPM suggested that there is a potential gap that WHO should address regarding benchmarking and price comparisons, given the lack of updated international medical products price guides. The Secretariat acknowledged the current lack of data and potential need to update various methodologies. WHO will produce a new guidance on price comparisons and will be looking into Big Data sources to potentially provide global comparators. TAG-PPM input will be sought regarding price comparison methodology and sources.

Value Considerations for the WHO Model Essential Medicines List

WHO EML Secretariat provided an overview of the EML Expert Committee selection criteria revision process and potential TAG-PPM input. Price dynamics were initially a consideration for model EML listing in 1978 and removed from consideration in 2001. Now, price, intellectual property and budget impact are increasingly becoming points of discussion during the EML review. The EML committee reviews submitted dossiers of applications, which have largely focused on clinical effectiveness and the balance between clinical harms and benefits. Cost-effectiveness and associated resources required are requested in the application but responses to these questions vary, as have the EML Expert Committee approach to such information. Thus, clear information on affordability and price dynamics would be beneficial in supporting EML selection.

In response to questions from TAG-PPM members, the WHO EML Secretariat clarified that typically the EML core list includes minimum medicine needs for health system, whereas the complementary list typically includes essential medicines for priority diseases requiring specialized diagnostic or monitoring facilities, care, or training. Applications for the WHO Model EML are open, with applications typically submitted by WHO technical teams, NGOs, industry, or academia.

TAG-PPM noted that the primary impact of EML listing on price dynamics are for those products eligible for UN procurement. At the country level, the model EML is a global guidance for coverage, often used as a tool for prioritization, and sometimes used as an advocacy tool.

TAG-PPM requested additional information regarding the current role of price and cost in EML applications. When provided, applications typically include published cost-effectiveness data from high-income countries, which is of limited utility to the Expert Committee tasked with considering global impact. A basket of prices across income groups would likely be most useful, while noting the risk of making requirements too onerous for applicants as there are not sources readily available providing this information.
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TAG-PPM acknowledged the need for differing strategies and economic indicators for patented versus unpatented essential medicines, and whether this could be reflected in the application for the model EML. It would be important to understand, for example, the number of manufacturers of each medicine, where they operate, and how prices compare across manufacturers.

TAG-PPM reflected on the potential role of cost-effectiveness thresholds or the need for further coverage and affordability guidance beyond the WHO Model EML. WHO does not generally recommend a single cost-effectiveness threshold applicable globally, and as data availability on prices are different for each medicine there is no explicit threshold used for the WHO Model EML. Thresholds also frequently are ineffective for high-cost medicines used in oncology or in rare diseases. Other pharmaceutical pricing policies might be more effective in such cases.

Next steps

WHO Secretariat will incorporate the TAG-PPM discussion into a framework for incorporating affordability into model EML selection for discussion at an upcoming meeting.

TAG-PPM members invited to participate in the WHO Fair Pricing Forum to take place virtually from 6 to 8 February 2024 from 10:00 to 14:30 UTC each day.

WHO Secretariat to launch communication to TAG-PPM Members for setting up the next meetings, tentatively planned virtually for April 2024, followed by an in-person meeting in July 2024.
Annex 1. Meeting Participants

TAG-PPM Members:
Mohammad Al-Owairdhi, Saudi Arabia
Abeer Al Rabayah, Jordan
Yusi Anggriani, Indonesia
Zaheer Babar, Pakistan/New Zealand
Marcel Bahizi, Rwanda
Susi Geiger, Ireland
Andrew Gray, South Africa (co-chair)
Xiaodong Guan, China
Donald Light, United States of America
Steve Morgan, Canada
Nancy Njeru, Kenya
Nur’ain Shuhaila, Malaysia
Mariana Socal, Brazil
Netnapis Suchonwanich, Thailand
Rabia Sucu, Ukraine/Türkiye
Sabine Vogler, Austria (co-chair)

WHO Secretariat:
Adi Al-Nuseirat
Christine Berling
Tania Cernuschi
Allison Colbert
Johanna Fihman
Benedikt Huttner
Swathi Iyengar
Christina Liu
Filip Meheus
Lorenzo Moja
Clive Ondari
Rehab Rayan
Kiu Tay-Teo
Klara Tisocki
# WHO Technical Advisory Group on Pricing Policies for Medicines (TAG-PPM)

**First Meeting Agenda - 27 November 2023 - Virtual meeting**
*(Time: CET Central European Time)*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speakers</th>
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<tr>
<td>14:00-14:05</td>
<td>Welcome remarks</td>
<td>Yukiko Nakatani, Assistant Director General, Access to Medicines and Health Products</td>
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<td>14:05-14:10</td>
<td>Opening of inaugural meeting and presentation of chairperson</td>
<td>Clive Ondari, Director, Health Product Policy and Standards</td>
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<td>14:10-14:30</td>
<td>Introduction of TAG-PPM members</td>
<td>TAG-PPM members, moderated by TAG-PPM Chair</td>
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<td>14:30-14:40</td>
<td>Housekeeping rules and operations of TAG-PPM</td>
<td>Allison Colbert, Technical Officer, Affordability and Pricing</td>
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<td>14:40-14:55</td>
<td>Overview of WHO’s work on Affordability and Pricing and Proposed TAG-PPM Workplan</td>
<td>Klara Tisocki, Team Lead, Affordability and Pricing</td>
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<td>14:55-15:00</td>
<td>Break</td>
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