World Health Organization

FAIR PRICING FORUM JOHANNESBURG

11 - 13 April 2019

Fair Pricing Forum
2019 Meeting Report
Johannesburg, South Africa
11-13 April 2019

WHO/MVP/EMP/IAU/2019.09

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Introduction

In 2017, WHO convened the first Fair Pricing Forum in Amsterdam, The Netherlands, to enable stakeholders to discuss options for a fairer pricing system for pharmaceuticals.

The second Forum, held 11-13 April 2019 in Johannesburg, addressed the following objectives:

- To share experiences in employing regulatory and non-regulatory measures for achieving 'fair' prices for pharmaceutical products that are affordable to patients and healthcare systems while incentivizing enterprise, efficiency and innovation
- To explore tools, approaches and system factors that could facilitate affordable and sustainable pricing of pharmaceutical products
- To identify areas of actions that would support countries in achieving fairer pricing of pharmaceutical products

The Forum was hosted by the South African National Department of Health together with WHO, and attended by representatives from Member States, non-governmental and patient organizations, and the innovator and generic pharmaceutical industry (full list of participants available in Annex A). The Forum consisted of a series of participatory workshops, followed by plenary and parallel panel discussions on key issues of current interest, and concluded by a plenary discussion on key learnings and commitments for further action (See agenda and speaker affiliations in Annex B). Additional information and meeting presentations are available at https://www.who.int/medicines/access/fair_pricing/en/.

Key Takeaways and Next Steps

The second Fair Pricing Forum achieved the following outcomes:

- Exchange of experiences in achieving better access through pricing measures
- Enabling networks for sharing of information relating to tools and approaches that could be used to achieve more affordable and sustainable prices
- Enhanced understanding of the merits and challenges of pricing and financing approaches that might bring about fairer pricing
- Common understanding and shared commitment towards the areas of actions identified for supporting countries in achieving fairer pricing.

Participants acknowledged difficulties in defining a price that is truly fair, but also that it is most important to think practically about what fairness means in practice and how all stakeholders can work together to achieve it. To that end, a set of technical working groups 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. These working groups will have focused terms of reference and concrete deliverables, with an established process for nomination and representation.

Stakeholders are invited to provide feedback by 15 September 2019 on these next steps towards achieving a fair pricing system. Further instructions are available at https://www.who.int/medicines/access/fair_pricing/en/.

Summary of proceedings

Plenary Session: Fair pricing in practice

Fatima Suleman moderated the opening plenary on the topic of "fair pricing in practice," an attempt to unpack the definition of fair pricing and its interplay with affordability. Suerie Moon noted that fairness can be considered from either the buyer's or seller's perspective, with a price floor needing to cover the cost of supply and price ceiling above which there would be a loss of access. Between the floor and the ceiling, there is a "fair pricing zone" that could accommodate concepts such as rewarding higher value medicines, differential allocation of certain cost components, and pricing of generic medicines.

Thomas Cueni acknowledged that finding the right balance between affordability and innovation is challenging, and that industry is open to new models of ensuring affordability in resource-constrained settings. However, this must be accompanied by a clear process from governments for attaining UHC, including regulatory clarity and efficiency.

Salmah Bahri shared the experience of Malaysia relating to the situation where products disappeared from the market when the incentives for industry were perceived to be inadequate. She also presented the challenges of using value-based approaches for pricing when the true value of a medicine in the real world would only emerge over time and therefore subject to considerable uncertainties at the time of pricing. These include predicting patient uptake and the extent of upfront payment.

During the subsequent discussion, the need for reliable international information on prices was emphasized, as this would enable countries to be better informed about the actual prices of medicines in different markets. However, such an approach would necessitate not including countries with much lower GDP per capita in external referencing pricing baskets and not parallel importing from such countries.

Parallel Session 1: Improving transparency

Moderator Jacqui Miot set the scene regarding transparency in South Africa, where the government has set a generic substitution policy, established a pricing committee, defined a single exit price and dispensing fee, and have no confidential discounts. Reaching this point was not a speedy process with various legislative and regulatory challenges, however via stakeholder engagement and constant updating of data and information, the pricing committee has achieved an important degree of certainty and consistency.

Luca Li Bassi discussed the draft World Health Assembly resolution on transparency of markets for health products and its potential to support decision-making on pricing and reimbursement, improve capacity to negotiate, enhance market efficiency by promoting competition, improve international benchmarking, better allocation of health resources, establish clear lines of accountability and confidence in public institutions, and facilitate dialogue.

Richard Torbett acknowledged alignment on the ultimate end goal of access, but polarization on a complex debate often fails to account for nuanced or unintended consequences such as price convergence undermining access to medicines in poorer countries, rewarding inefficiencies in

development instead of value, disincentivizing high-risk research, or establishing policy barriers to differential pricing.

Andrew Hill discussed his recent research comparing cost of production and medicine prices, to demonstrate how much countries can save by paying better prices and maximizing use of generics. Such an initiative may require a re-evaluation of cost-effectiveness for patented medicines versus generic alternatives.

Gaëlle Krikorian discussed the MSF example of access to pneumococcal vaccine, where some low- and middle-income countries pay higher prices than high-income countries. She argued for price transparency by asserting that “countries cannot negotiate fair medicine prices blindfolded.”

During the discussion, participants and panelists focused mainly on various elements of price and cost transparency, and the availability of data and potential impact of such transparency initiatives. The complexity of the research and development system was acknowledged but seeking transparent information may be a potential solution. A key concern was jeopardizing access in low-income countries, suggesting that perhaps a global system of differential pricing could be piloted for select molecules before advancing to further transparency.

Parallel Session 2: Improving information sharing

Vinzent Rest presented several cross-country initiatives in which Austria is participating, namely BeNeLuxA, the Pharmaceutical Pricing and Reimbursement Information (PPRI) network, and the EURIPID price database, noting that the voluntary provision of information by the member countries has contributed to the success of each network. The main challenges encountered are lack of political commitment, legal barriers, and lack of resources, with the lesson learned that dialogue between stakeholders is essential.

The PIEMEDS price database in the WHO Western Pacific Region was presented by Socorro Escalante, whereby information on procurement price is provided on a voluntary basis by the Member States. The main challenges cited are the high turnover at the Ministry level causing changes to focal points and delays in obtaining data. However, the database has improved procurement practices in some countries that compare prices between countries before purchase.

Johanna Fihman presented the market information for access (MI4A) initiative, which helps to enhance understanding of global vaccine demand, inform discussion and decision making, and inform on the market to influence global market analysis and supply. Countries provide a landscape on their immunization programmes on a regular basis where information on procurement and supply are extracted. There has been strong engagement from 150 countries that maintain data flow and reporting, with quality check and masking system to guarantee confidentiality to avoid issues with negotiated price disclosure.

Parallel Session 3: Garnering purchasing power through pooled procurement

The session provided an opportunity to discuss different approaches to pooled procurement, exploring opportunities and challenges related to large-scale multi-country pooled procurement,

procurement across a limited number of countries and national-level pooled procurement. Across the range of experiences, common themes emerged related to benefits for payers, suppliers, and patients of pooled procurement, in addition to critical lessons for ensuring successful implementation.

Key benefits from pooled procurement on a multi-national level for countries included improved pricing, as well as consolidated technical support in product selection and assessment, quality assurance, timely and continuous supply and payment, and financial stability through access to credit for payment. Multi-country pooled procurement also had substantial benefits for suppliers particularly related to reliable and rapid payment and the limited transaction costs of contracting and negotiating agreements. Challenges to multi-national pooled procurement included maintaining transparency especially where this may risk raising prices, the ability to effectively forecast demand across countries, as well as approaches for tiered pricing and negotiations for sole-supply products.

Lessons for multi-country procurement on a more limited scale included the importance of managing the heterogeneity between countries, including different language and legal frameworks. On a national level, it was demonstrated that substantial savings can be achieved through a comprehensive and coordinated pooled purchasing strategy, including prioritizing line items by linking to an essential medicines list and concurrently establishing electronic procurement monitoring system.

It was emphasized that pooled procurements go beyond supply-side aggregation of demand to achieve low prices, and that further actions to improve systems and regulatory and legal frameworks are required to enable effective pooled procurement. Pooled procurement initiatives should include strategies to implement procurement legislation, regulatory harmonization and necessary regulation to create the space for effective competition.

Discussants noted that governments should seek opportunities for multinational collaboration to participate in pooled procurement, but this should be done under a clear strategy that addresses country requirements including language, supply arrangements and legal frameworks. Governments could also develop and enhance existing national pooled procurement, ensuring that major supply-side, system and legal and regulatory frameworks are addressed.

Participants recommended that WHO should continue to support countries through sharing information and knowledge exchange on best procurement practice and extending the scope of procurement support beyond medicines to include diagnostics and products for vector control. Participants also discussed potential benefits of pooled procurement to the pharmaceutical industry, including reduction in transaction costs and financial stability, and recommended further open discussion and information sharing, particularly around improving traceability and documentation for line items.

Parallel Session 4: Emerging approaches

This session explored several emerging approaches to tackle high drug prices and their potential applicability as sustainable solutions for both higher- and lower-income countries. Valérie Paris discussed the OECD challenges for policy makers related to high-priced medicines, along with existing and emerging strategies to cope with such prices. She discussed

the importance of horizon scanning in updating spending projections, setting clear criteria and rules to manage budget constraints, addressing uncertainties on clinical benefits, and the role of competition authorities in off-patent markets.

Wilbert Bannenberg then focused on legal options for challenging unfair pricing practices for therapies, which was defined as a necessary treatment unaffordable to patients or health systems, resulting in unreasonable and socially unacceptable profit margins. In addition to existing policy mechanisms to control unfair medicine prices, he founded the Pharmaceutical Accountability Foundation in the Netherlands to challenge the issue of unfair pricing in court and ensure medicines are available in a sustainable and socially acceptable manner.

Douglas Clark then presented the recent drug pricing reforms in Canada, including the creation of the Patented Medicines Pricing Review Board (PMPRB) to manage costs and balance competition policy objectives by strengthening patent protection for manufacturers to incentivize pharma R&D in Canada as well as ensuring consumer protection from unreasonably-priced patented medicines. Although Canada is unable to leverage national buying power in the same way as other countries, the PMPRB regulates ceiling prices for all medicines in Canada and assesses new medicines for level of therapeutic benefit relative to existing therapies.

James Love suggested possible mechanisms for a transition to delinking the costs of R&D from the price of the medicine. Such an approach would aim to reduce barriers for access, create competitive prices for health products, and potentially save governments money while more efficiently targeting subsidies and incentives. It would also modernize the approach to market entry rewards via an innovation fund of a fixed size with a multi-year coopetition among suppliers of innovations for shares of the fund. The transition approach would progressively decrease the maximum monopoly patent term allowed, with corresponding progressive increases in market rewards for entry.

Parallel Session 5: Intellectual Property and Pricing

This session focused on intellectual property and trade as key elements to getting access to medical technologies. Marumo Nkomo discussed proposed reforms to the Patent Law in South Africa that seeks to strike a balance between IP and trade and economic development and potential alternative ways of stimulating innovation. He noted that no element of access can be modified in isolation, and the importance of public engagement in progressing reforms.

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