



World Health
Organization



FAIR PRICING FORUM

INFORMAL ADVISORY GROUP MEETING

WHO Headquarters, Geneva

22 - 24 November 2016



FAIR PRICING FORUM

INFORMAL ADVISORY GROUP MEETING

WHO Headquarters, Geneva

22 - 24 November 2016

© **World Health Organization 2017**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>). Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition". Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules>).

Suggested citation. Fair Pricing Forum: Informal Advisory Group Meeting. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This is a report of the proceedings of the informal WHO Advisory Group meeting on fair pricing that met on 22-24 November 2016 at WHO headquarters in Geneva, Switzerland. The meeting was to discuss challenges in the current system of pricing medicines and provide advice to WHO on how to move forward with organizing a Fair Pricing Forum. The group discussed a number of background papers that were produced for the meeting. This report provides a summary of the deliberations. A list of attendees and the meeting agenda are included as appendices.

INTRODUCTION

A key aim of the UN Sustainable Development Goals is to attain universal health coverage, including access to essential medicines. Lack of access can be due to many different reasons, but one essential condition is that medicines have to be affordable for those who need them. This is a challenge particularly for new medicines coming to the market, but also in cases where companies have monopolist market positions for older treatments. Recent controversies in the United States—for example, the overnight 5,000% increase in the price of pyrimethamine and the price increases for epinephrine injection, USP, sold under the trade name EpiPen—are only some of the most recent manifestations of a growing problem. Another challenge is how national health systems can cope with the overall expenditure. The global market for prescription medicines is expected to increase by one-third over the next five years, reaching almost US\$ 1.5 trillion by 2021¹. Yet national health budgets are buckling under the strain of paying for new treatments. The breakthrough therapies to treat hepatitis C, for example, are so expensive—for a single course of treatment in most developed countries, sofosbuvir costs more than US\$ 50,000—that they have created serious health budget problems, even in the wealthiest countries in the world leading to situations where access is restricted on account of cost.

The time is ripe to rethink how medicines are priced and what tools governments have to make sure that essential medicines are affordable to patients and the health system. At the other side of the spectrum, shortages of in-principle cheap generic essential medicines are increasing. While there are many different reasons for shortages to occur, it is

¹ Quintiles IMS (2016) Outlook for Global Medicines Through 2021: Balancing Cost and Value,

important to maintain a market for these products. Unsustainably low prices can drive high-quality manufacturers out of the market in the long run, jeopardizing the continuity of supply.

A 'fair pricing' model for medicines could respond to these challenges while providing space for innovation for health technologies to address existing unmet needs. To explore strategies for achieving fair prices, the WHO will convene a global dialogue among relevant stakeholders at a public Fair Pricing Forum in spring 2017. The objectives of the 2017 Fair Pricing Forum are as follows:

- To start a process with all relevant stakeholders (including patients and third party payers) to exchange experience with the current price setting and pricing systems and discuss options that could lead to a fairer price setting and pricing system that is sustainable for health systems and for innovation;
- To have a preliminary discussion about the wanted but also unwanted consequences of the current business model including ideas about possible alternative business models;
- To identify the price related factors that contribute to shortages of essential medicines;
- To identify suitable measures and approaches for countries to remedy shortages of essential medicines that may be due to low profit margins;
- To provide a platform for these discussions and provide relevant background research;
- To expand current networks of payers to include other relevant players and countries to facilitate better exchange of experience;
- To identify areas for action with the current innovation and pricing system, including the need for transparency of prices paid, research and development (R&D) costs, production costs, and profit margins.

WHAT IS A FAIR PRICE?

The Advisory Group discussed the definition of “affordability” from the Lancet Commission’s report, *Essential Medicines for Universal Health Coverage*,² the “ability to purchase a necessary quantity of a product or level of a service without suffering undue financial hardship.” With respect to medicine sales, the undue hardship can fall on individuals, employers, or governments, depending on who pays for the medicines. The Advisory Group explored different benchmarks for what might be considered “undue hardship” for each of these groups.

What is a fair price? And how is such a fair price to be achieved? The questions are easier asked than answered, and intersect areas of ethics, politics, and public health. What seems fair to sellers may appear unfair to buyers, and vice-versa. The ultimate aim, however should be a price that assures that new medicines are affordable to all patients and health systems, allows for a reasonable profit margin (also allowing for investment in innovation), and assures a stable supply of generic medicines.

The economic concepts of consumer and producer surplus should be considered with respect to the question of fair pricing. Consumer surplus refers to the welfare that accrues to consumers when a product is priced below their willingness to pay for it. For example, if a consumer would have paid US\$ 5 for a medicine but finds it is available on the market for US\$ 1, the consumer enjoys US\$ 4 worth of consumer surplus. Analogously, if a manufacturer is willing to make and sell a medicine for US\$ 1 but is able to sell it to consumers for US\$ 5, the producer enjoys US\$ 4 worth of producer surplus.

Framing the discussion around economic surplus enables the disaggregation of two questions. First, what is the size of the surplus that exists in the medicine market? Because it is costly to develop, register, manufacture, and distribute medicine, manufacturers often suggest that the surplus is small in comparison to the risks of failure in the development and the investment. Critics doubt that assertion, and point to data suggesting a mismatch between R&D costs and the large profits in the pharmaceutical industry.

² Wirtz, V.J., et al. (2016), *Essential medicines for universal health coverage*. The Lancet.

Second, what is the distribution of surplus between consumers and producers? The nature of medical need means that demand for medicines is relatively inelastic. As a result, manufacturers will often have market power to set high prices for essential medicines particularly in monopoly situations—implying that manufacturers acquire a large share of any surplus. However, high prices limit the number of people who can purchase a medicine and restrict surplus overall, and consumer surplus in particular; on ethical, human rights and efficiency grounds, there is a strong case that the overall surplus (and that distributed to consumers) should be increased through lower prices that in turn improve access to needed medicines.

In general, the group felt that more work is needed to understand what constitutes a fair price and how a framework could be developed to define that price. Better information about the costs of pharmaceuticals—in particular, R&D investments and the costs of manufacturing medicines using good manufacturing standards—need sustained attention.

WHAT DOES IT COST TO PRODUCE A GENERIC MEDICINE?

Most of the medicines on the WHO Essential Medicines Lists were not or are no longer patented and can be procured from a variety of manufacturers. While vibrant competition does exist for some of these medicines, there is a dwindling supply of quality manufacturers for others. Prices also vary enormously between countries for some products. Taken together, price disparities and medicine shortages raise questions about the health of the generic market.

For generic medicines, the major cost driver is the expense of manufacturing—most significantly, the costs of synthesizing the active pharmaceutical ingredient (API), registration and distribution. The Advisory Group discussed preliminary results of a study on estimating the manufacturing costs of medicines on the essential medicines list. Minimum costs were estimated based on data on Indian exports of the API, which are available from the database www.indiainfodrive.com. The data suggest that the price of production for most generic medicines is low, although the Advisory Group emphasized the importance of basing cost assumptions on API that meets stringent safety and quality standards.

The costs of production were then compared with publicly available databases of medicine prices from India, South Africa, and the United Kingdom. That comparison suggests that government procurers often pay many times more than the cost of production for generic medicines. Countries likely pay more than they have to for different reasons, one being lack of good information about what other countries pay. Price transparency could therefore be one way to reduce high generic prices. Lower costs for generics might also drive down prices for patented medications in the same therapeutic area. With this in mind, countries could reduce their medicine expenditures substantially if they were to optimize their procurement systems (see procurement strategies section).

At the same time, the Advisory Groups discussed the importance of not underestimating the costs of production. The production process is complex, and includes the need to maintain and renew factories, to comply with good practices in manufacturing API, and to adhere to environmental standards. Manufacturing costs also depend on the type of API with respect to water solubility, stability, and the types of excipients used. The WHO and lead author will review the draft study and study design in full recognition that prices can be too low as well as too high.

IS THERE A LINK BETWEEN SHORTAGES AND LOW PRICES?

The Advisory Group reviewed data on shortages of certain essential medicines, low prices, and low profit margin. Without multiple competitors, relatively minor disruptions to the market—manufacturing problems, unexpected spikes in demand, temporary shortage of quality raw materials—can lead to supply-side shortages. In countries with shortage registries, such as Brazil, the United States, and Italy, manufacturers have reported shortages or permanent discontinuation of products on account of “commercial reasons” or “business problems,” though detailed information is not publicly provided. For vaccines, a few examples were shared of shortages—in particular, vaccines for *Bacillus Calmette-Guérin* (BCG) and Yellow Fever—that may be linked to the low profitability of these vaccines, partly as a result of fluctuating demand. However, no specific investigation was made into any link between shortages and low profit margins, this could be an area for future research.

The Advisory Group discussed research on the stability of the markets for many essential medicines. Preliminary results were presented of a supplier analysis in Brazil and South Africa for low-price essential antineoplastics, anti-infectives, and anesthetics that are frequently in shortage across the globe. The analysis noted that 18 of the 26 products analyzed in South Africa and 13 of the 39 products analyzed in Brazil had two or fewer suppliers for at least 1 year since 2009—a signal of unstable markets. Additionally, the presence of a large multinational entity in a product market seems to be associated with more supplier participation over time. Production lines for a medicine with low profitability and smaller markets may be converted to produce a different medicine that is demanded at higher volumes and higher prices.

The Advisory Group provided a number of suggestions for further research on the effects on low price on availability. First, it was suggested that WHO link new data on the production costs of essential medicines that are frequently in shortage with their procurement price and supplier trends. This analysis could identify the role that price plays in medicine shortages. The Advisory Group also suggested qualitative interviews with pharmaceutical manufacturers to better understand their market strategy for low-priced medicines. Finally, the Advisory Group noted a need for additional research into the business environment for API manufacture, in particular ways to create incentives for the promotion manufacturing of APIs in shortage. The advantage of lower-cost production in low- and middle-income countries has led the API manufacturing sector to shift to India and China. Consolidation or closure of API manufacturing firms creates a reliance of a few API manufacturers to supply a global market. Thus, operational decisions about production quantity and capacity or quality issues with API may have an effect on a medicine's availability in the global market.

WHAT DOES IT COST TO DEVELOP A NEW MEDICINE?

One of the major cost components for new medicines is the investment into R&D. For patented medicines, the Advisory Group recognized that medicine prices must be sufficient to cover R&D investment, including the costs of R&D into medicines that fail to secure final approval. Given the difficulty of identifying new compounds and proving their efficacy, that risk of failure is substantial: according to data from the Pharmaceutical Research and Manufacturers of America (PhRMA), for every medicine that receives FDA

approval, between 5,000 and 10,000 compounds will be investigated and 250 will begin preclinical testing. As a result, innovation in the pharmaceutical sector depends on intensive and expensive R&D. Indeed, PhRMA estimates that it spends 13 times more per employee on R&D than manufacturing industries overall. However, industry also benefits from research carried out by publicly financed universities and research institutes, and tax breaks on R&D.

Yet there is a notable lack of robust data and transparency on R&D costs. As the European Commission concluded in 2008, “[t]he costs of bringing a new medicine to market is subject to wide debate and a variety of estimation.” The Advisory Group discussed a review of the available studies, which offer estimates of average medicine development costs (adjusted to 2014 dollars and taking into account the cost of capital) that range from US\$ 180 million to US\$ 2.6 billion—a ten-fold difference.³

In part, the difference reflects methodological differences between studies. The highest estimates of R&D costs, for example, focus on the costs of developing new chemical entities, which account for about one-quarter of medicine approvals. Costs will generally be lower to develop a variant of an older medicine—perhaps a different mode of administration (e.g., oral versus injection) or a combination product. Similarly, some of the lowest estimates of medicine development costs come from product development partnerships that target neglected diseases.

In the absence of better information from the pharmaceutical industry, the WHO’s most recent figures—which are based on a study by TDR, the Special Programme for Research and Training in Tropical Diseases—may offer a starting point. In connection with the R&D pipeline for medicines to treat emerging pathogens with epidemic potential, the WHO has estimated that R&D costs range from US\$ 58.4 million (for a simple-repurposed medicine that can immediately begin Phase II trials) to US\$ 743 million (for new chemical entities to treat poorly understood diseases). These estimates exclude the capital costs of investing

³ See Morgan, S., et al., *The cost of drug development: A systematic review*. Health Policy, 2011. **100**(1): p. 4-17.; DiMasi, J.A., *Briefing: Cost of Developing a New Drug*. 2014, Tufts Center for the Study of Drug Development. (http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf, accessed 15 December 2016).

in new medicines instead of pursuing alternative investments; if those costs were included, the WHO figures would be considerably higher.⁴

The bottom line, however, is that more clarity is needed on the costs of R&D. The Advisory Group discussed the possibility of insisting on greater transparency from the pharmaceutical industry. For orphan drugs, for example, manufacturers must compile medicine-specific data on R&D investments in order to claim tax credits. Manufacturers could make that information—and other information about R&D investments—public.

The Advisory Group also discussed the connection between R&D investments and prices. The group was skeptical of the common claim that increasing R&D investments are directly responsible for recent price increases. Economic theory suggests that a seller will usually fix the price at whatever level the market will bear, without regard to the sunk costs associated with previous R&D investments. Recent experience underscores the point. An inquiry from the U.S. Congress into sofosbuvir, concluded that the pricing decision was not related to the costs of R&D, but “focused on maximizing revenue—even as the company’s analysis showed a lower price would allow more people to be treated.”⁵

R&D investment is made, not only by pharmaceutical manufacturers, but there is also significant investment by governments, academic institutions and not for profit organizations. A study in the United States noted that public sector research institutions contributed to approximately 21% of medicines involved in new-drug applications to the FDA between 1990 and 2007.⁶

The Advisory Group also considered research into the costs of medicine registration in different countries. Registration costs range widely across jurisdictions, from almost nothing in some countries (e.g. Bhutan) to more than US\$ 2 million in the United States. In general, fees are roughly proportional to gross domestic product (GDP), with lower fees for generic registration fees. Fees are not, however, the only costs associated with

⁴ World Health Organization, *An R&D Blueprint for action to prevent epidemics: Funding & Coordinating models for preparedness and response*. 2016, World Health Organization. (http://www.who.int/csr/research-and-development/workstream_5_document_on_financing.pdf, accessed 15 December 2016)

⁵ Committee on Finance United State Senate, *The Price of Sovaldi and its Impact on the U.S. Health Care System*. 2015, U.S. Government Publishing Office: Washington. ([http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](http://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf) , accessed 10 November 2016)

⁶ Stevens et al. (2011). *The role of public-sector research in the discovery of drugs and vaccines*. The New England Journal of Medicine.

regulatory procedures. Preparation of the dossier for each authority, translation, local agents and other related costs, including good manufacturing processes (GMP) certification and inspection, must also be considered.

Market dynamics in the pharmaceutical industry may also influence pricing decision. One common strategy to fill the R&D pipeline of major players is to acquire smaller companies that have, or are about, to bring to the market a few new medicines. In the recent past, companies have increasingly paid above market value for the acquisition of smaller companies with products on the market or in the R&D pipeline. Escalating acquisition prices may translate into substantial price increases for the acquired company's medicines, whether or not those increases are justified by R&D investments.

PRICE TRANSPARENCY

The Advisory Group heard research about the possible consequences of the lack of price transparency surrounding medicines. Although the advertised "list price" for a medicine often does not reflect its actual price, particularly given the global proliferation of rebates over the past two decades, medicine manufacturers rarely share detailed data about the true price at which they sell their medicines. Indeed, many of the most prominent medicine-price databases include only the list price and therefore offer a misleading picture. The obscurity of medicine prices hinders national efforts to negotiate effectively with manufacturers.

Improving transparency of medicine prices would help countries in their tendering and negotiation strategies. Some steps have been made in the right direction. For vaccines, the WHO's Department on Immunization, Vaccines, and Biologicals has created a database called V3P that aims at collecting and disseminating vaccine price and procurement information.⁷ The database allows countries to improve their decision-making regarding new vaccine introduction, to increase their market knowledge and negotiating power, and to guide their procurement choices. The WHO's Global Price Reporting Mechanism (GRPM) compiles information on medicine prices that are used to treat HIV, tuberculosis, and malaria. However the prices in the GRPM database are the international transaction prices and not those paid by end-users at country level. End-user prices for

⁷ V3P: Vaccine Product, Price and Procurement. Available at: www.who.int/immunization/v3p.

antiretroviral drugs are typically lower than those reported because of subsidies. For other medicines, in contrast, end-user prices are often higher than international transaction prices, owing to tariffs, taxes, transportation costs and other mark-ups. The V3P and GPRM databases could provide the foundation for future efforts.

COUNTRY EXPERIENCES

The advisory committee also heard reports about the policies and practices surrounding medicine prices in specific countries, including Brazil, Chile, Colombia, South Africa, and Thailand. Global experience was illuminating on many fronts. Brazil, for example, has regulated prices to secure competitive prices for the medicines that it procures. By one estimate, medicines in Brazil cost six times less than medicines in the United States. At the same time, Brazil does not regulate prices in the market for medical devices. As a result, prices for medical devices in Brazil are often many times higher than the prices for the same medical devices elsewhere. Other countries face similar price disparities between the cost of medicines and medical devices: stents in India, for example, are especially expensive.

The WHO Regional Office for the Western Pacific offered another perspective on the problem. Geography can complicate efforts to distribute medicines where they are needed, especially for small island states or countries like Indonesia, which consists of hundreds of islands. As a result, mark-ups multiply throughout the supply chain, increasing prices. Many countries in the region lack the leverage of a large market, or skilled negotiators who can effectively bargain with companies over medicine prices, respond to arguments and evaluate data brought forward by companies. It was suggested that there was a need for more collaboration in the Western Pacific region to enable the exchange of procurement experience and to improve procurement practices.

Procurement difficulties are not confined to low- and middle-income countries, however. WHO Regional Office for Europe reported that European countries generally face difficulty in refusing to buy expensive, low-value medicines. Although some countries do from time to time refuse to cover some medicines, most have not made it a priority, in part because of political pressure from hospitals and the elderly. Moreover, in those countries where residents purchase private, government-regulated health insurance, insurers often

lack the market power to negotiate effectively with manufacturers. As elsewhere, European countries would benefit from better international cooperation on medicine-procurement strategies.

VALUE-BASED PRICING

In discussing alternative pricing models, the Advisory Group considered value-based pricing, where a medicine's price is set to reflect its therapeutic value, not what the market will bear. Value-based pricing has certain virtues. It may, for example, reduce prices for new medicines that do not add value over existing treatments. Value-based pricing may also encourage medicine manufacturers to focus their R&D on medically important interventions.

But value-based pricing also presents difficulties. Most importantly, it is insensitive to questions of affordability. A high-priced medicine can impose a severe fiscal burden, even if it is considered cost-effective, according to a particular methodology, as recent experience with the new hepatitis C treatments suggests. If value-based pricing is used to justify extracting the full willingness-to-pay of the consumer, it also results in all surplus being distributed to the producer rather than also being distributed to the consumer. The Advisory Group also appreciated the difficulties associated with identifying the "value" of a particular medicine. This uncertainty raises questions about whether value-based pricing can yield its promised benefits, particularly when it is considered in isolation from total cost.

ORPHAN DRUGS

The Advisory Group also considered orphan drugs, which are developed to treat rare conditions. Manufacturers can command exceptionally high prices for orphan drugs: in 2015, the median price of an orphan drug in the United States was US\$ 100 000⁸. Orphan drug laws—which exist in the United States, the EU, Japan, and elsewhere—confer special regulatory advantages, tax incentives, and an extended period of market exclusivity for orphan drugs. The laws aim to stimulate investment to find treatments for rare conditions that might not otherwise be sufficiently profitable due to small market size. However,

⁸ EvaluatePharma, Orphan Drug Report. 2015, Evaluate. (<http://info.evaluategroup.com/rs/607-YGS-364/images/EPOD15.pdf>, accessed 16 November 2016)

manufacturers may be able to take advantage of the orphan drug laws without making substantial R&D investments. An existing medicine already in widespread use for one indication may be repurposed and receive orphan drug approval to treat a rare disease. Manufacturers may also secure a series of orphan drug approvals for indications that are for a sub-group of a larger patient population. Additionally, they may encourage the off-label use of orphan drugs. The Advisory Group acknowledged that the current system may encourage companies to redefine and artificially create orphan designations, contributing to the proliferation of orphan drugs.

VOLUNTARY AND COMPULSORY LICENSING

Finally, the Advisory Group reviewed data on voluntary and compulsory licenses. A medicine's patent holder can issue a voluntary license to enable a different company to manufacture and distribute the medicine. Voluntary licenses have been used in the distribution of anti-retroviral HIV medications and, more recently, for the new hepatitis C treatments. Although the benefits of those voluntary licenses can be large, the Advisory Group noted that the existence of a voluntary license is no guarantee that the medicine covered by that license will go to market. It is therefore crucial that agreements include a number of licensees and a large enough market. License agreements are also usually restricted to a set of countries included in the licensed territory, and many middle-income countries can be excluded.

The World Trade Organization's Trade Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) offers countries another option to secure access to essential medicines where these are patented and not available or affordable. Under TRIPS, countries are permitted to issue compulsory licenses under certain conditions that should be further defined in national legislation. The reasons for issuing such licenses can include unaffordable prices of medicines. Compulsory licenses enable the government to either import the medicine or have it locally manufactured by another company. The originator is still entitled to adequate remuneration, such as a reasonable royalty.

To date, compulsory licenses have been used only by a small number of countries, mainly for antiretrovirals for HIV treatment and for cancer therapies. The Advisory Group discussed the reasons for the limited use of compulsory licenses to date, which include

inconsistency with broader trade objectives, national intellectual property policies, and opposition from patent-holders and certain governments, which may exercise diplomatic or economic pressure to discourage their use.

CONCLUSION

The Advisory Group's discussions confirmed that the prices of essential medicines have appropriately become a matter of global concern. The prices of some medications where companies hold an exclusive market position are unaffordable for health systems and patients. At the same time, the prices of some generic medicines are too low to assure a stable, high-quality supply. The current system for setting medicine prices must be reformed to make it fairer and more sustainable. Increasingly, even the pharmaceutical industry is recognizing this challenge. The CEO of Allergan, for example, has publicly criticized "aggressive or predatory price increases."⁹ Other pharmaceutical companies have similarly addressed affordability concerns and hope to increase predictability, reduce out-of-pocket spending, and transform the medicine-pricing system.¹⁰

"Fairness," however, is a subjective term and needs to be further defined. Although the discussion demonstrated that a range of factors influence medicine prices, it confirmed that more transparency around production and R&D costs would move the discussion forward. At the heart of the question is how to allocate between producers and consumers any surplus that arises when a medicine is purchased. Willingness to pay was considered a problematic starting point for a variety of reasons, including the access problems in which such an approach may result. While value-based pricing may have some merit, value-based pricing systems tend to be complex and are insensitive to questions of affordability.

The Advisory Group also heard concerns that medicine-by-medicine, country-by-country negotiations are resource-intensive and duplicative. Overall, the group felt that more solidarity among payers would make it harder for industry to use negotiations with one

⁹ Allergan (2016) *Our social contract with patients*.(<http://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients>, accessed 10 November 2016)

¹⁰ Novo Nordisk. *Our position on pricing and affordability*. 2016. (<http://www.novonordisk-us.com/whoweare/about-novo-nordisk/our-position-on-pricing-and-affordability.html>, accessed 10 November 2016); Beasley, D. (2017) *Pharma company executives debate drug pricing increases*.(<http://www.reuters.com/article/us-usa-healthcare-drugpricing-idUSKBN14W2T6>, accessed 16 January 2017)

country to set a high benchmark against which all other countries must negotiate. With respect to new medicines coming on the market, the Advisory Group discussed the idea of setting up an international network of health technology assessment (HTA) agencies under the auspices of WHO that would systematically provide assessments for all new treatments. Those assessments could, in turn, be made available to all countries. The Group also took note of the various subregional European initiatives on pooling demand or procurement.

Finally, the Advisory Group discussed the Forum and future work that is needed. The background papers were considered useful for the discussion. Not all were considered equally relevant for the Forum, and the group encouraged WHO, in collaboration with the authors of the various background papers, to focus on the question of R&D and production costs, experience in procurement, and the different options to control and set prices. The group advised WHO to include experiences from low- and middle-income countries in the overall background paper instead of having separate country reports.

The Advisory Group also discussed whether to include vaccines and health products such as pacemakers or stents. The market for vaccines is significantly different as the oligopolistic positions of manufacturers are actually countered by monopsony power of buyers. The work on pricing in terms of transparency is more advanced than in the field of medicines which may allow some learning and the group thus considered it useful to include vaccines in the scope of work. With respect to other health products, lack of pricing transparency is a problem, but including them at this early stage would likely overburden the process. The Fair Pricing Forum will thus focus on medicines and vaccines, but may later expand and include other health products.

With respect to the design of the Forum as such, WHO is in discussions with the Dutch government, which will co-host the event in the Netherlands. With respect to participation, the Advisory Group recommended that the WHO include all relevant stakeholders—including member states, patient groups, industry and payers—but to allow participation on an invitation-only basis to avoid over- or underrepresentation of certain interest groups.

ANNEXES

Annex A. List of participants

Annex B. Meeting agenda

Annex A

Fair Pricing Forum: Informal Advisory Group Meeting

List of Participants

Date: 22-24 November 2016

Location: WHO/HQ, Geneva, Switzerland –Salle D, Main Building

Attendees

Claire Biot Agence Générale des Equipements et Produits de Santé (AGEPS) France
Andrew Briggs University of Glasgow & Memorial Sloan Kettering Cancer Center UK
Mateus R. Cerqueira Agência Nacional de Vigilância Sanitária (ANVISA) Brazil
Steffan Crausaz Pharmaceutical Management Agency New Zealand
Alessandra Ferrario London School of Economics and Political Science (LSE) Health UK
Sarah Garner National Institute for Health and Care Excellence, UK
Andrew Hill Pharmacology & Therapeutics University of Liverpool, UK
Isao Kamae Graduate School of Public Policy The University of Tokyo Japan
Anita Kotwani VP Chest Institute University of Delhi India
Suerie Moon Graduate Institute of Geneva Switzerland
Steven Morgan University of British Columbia Canada
Valérie Paris Organisation for Economic Co-operation and Development (OECD) France
Tanya Potashnik Patented Medicine Prices Review Board Canada

Tara Prasad Access to Medicine Foundation The Netherlands
Leandro Pinheiro Saftale Agência Nacional de Vigilância Sanitária (ANVISA) Brazil
Maximiliano Santa Cruz National Institute of Industrial Property (INAPI) Chile
Ad Schuurman National Healthcare Institute The Netherlands
Fatima Suleman University of Kwazulu-Natal South Africa
Kristin Svanqvist Norwegian Institute of Public Health Norway
Sabine Vogler WHO Collaborating Centre Austria

WHO Headquarter and Regional Office Staff

Nicholas Bagley Department of Essential Medicines and Health Products
Daniela Bagozzi Department of Essential Medicines and Health Products
Melanie Bertram Department of Health Systems Governance and Financing
Peter Beyer Department of Essential Medicines and Health Products
Tania Cernuschi Department of Immunization, Vaccines and Biologicals
Guillaume Dedet Health Technologies and Pharmaceuticals Europe Regional Office
Tessa Edejer Department of Health Systems Governance and Financing
Gilles Forte Department of Essential Medicines and Health Products
Martin Howell Friede Department of Immunization, Vaccines and Biologicals
Lisa Hedman Department of Essential Medicines and Health Products
Suzanne Hill

Department of Essential Medicines and Health Products
Swathi Iyengar Department of Essential Medicines and Health Products
Ryoko Miyazaki-Krause Department of Essential Medicines and Health Products
Rüdiger Krech Office of the Assistant Director-General, Health Systems and Innovation
Nicola Magrini Department of Essential Medicines and Health Products
Stephanie Mariat Department of Immunization, Vaccines and Biologicals
Martha Faith McLellan Office of the Director-General
David Newby Essential Medicines and Health Technologies Regional Office for the Western Pacific
Hanne Bak Pedersen Health Technologies and Pharmaceuticals Europe Regional Office
Inthira Yamabhai Department of Essential Medicines and Health Products

Excused Advisory Members

Peter Bach Director Memorial Sloan Kettering Centre for Health Policy and Outcomes, USA Replaced by Andrew Briggs
Adriana Platona Department of Health, Australia Replaced by Andrew Rintoul
Menno Aarnout International Association of Mutual Benefit Societies, Belgium
Javier Humberto Guzmán Cruz Director General of INVIMA (National Food and Drug Surveillance Institute), Colombia
Panos Kanavos London School of Economics, UK
Maurice-Pierre Planel Economic Committee of Health Products, France

Annex B

Fair Pricing Forum Informal Advisory Group Meeting

Meeting Agenda

Day 1 Tuesday, 22 November

- 08:30 - 09:00 Registration: Reception Main Building**
- 09:00 - 09:30 Welcome and introduction of participants**
- 09:30 - 10:00 Opening remarks *Suzanne Hill, Director EMP***
- Objectives of the meeting *Peter Beyer***
- Declaration of interests *Peter Beyer***

10:00 - 10:30 Tea/Coffee break

PAPER PRESENTATION# 1-6

For each paper: 15 minutes presentation and 30 minutes discussion

Moderator: Sue Hill

- 10:30 - 12:30 Current trends in medicine prices in high- and middle-income countries
*Faith McLellan***
- What is a fair price for medicines for all parties involved? *Suerie Moon***
- Discussion on the definition of "fair price"**

12:30 - 13:30 Lunch

Moderator: Steffan Crausaz

- 13:30 - 15:00 An assessment of different approaches by payers to set medicine prices and assess the value of a new treatment
*Steve Morgan***
- The costs of drug research and development
*Nicholas Bagley***

15:00 - 15:30 Tea/Coffee break

Moderator: Steffan Crausaz

15:30 - 17:00 What is the production costs for the medicines on the WHO Essential Medicines List?

Andrew Hill

Analysis of market authorization costs as a “potential barrier to entry” in countries with limited pharmaceutical markets

Steve Morgan

19.00 Dinner at Cafe de la Mairie

Day 2 Wednesday, 23 November

08:45 - 09:00 Summary of the previous day – *Peter Beyer*

PAPER PRESENTATION #7-14

Moderator: Hanne Bak Pedersen

09:00 - 11:00 How does confidentiality in price deals impact price setting and what are the actual procurement and patient prices?

Sabine Vogler

Fair pricing for vaccines: transparency as an option

Tania Cernuschi/ Stephanie Mariat

The role and impact of voluntary licensing and compulsory licensing

Inthira Yamabhai

11:00 - 11:30 Tea/Coffee break

Moderator: Hanne Bak Pedersen

11:30 - 13:00 Assessment of the role of venture capital and private equity investors in setting medicine prices

Peter Beyer

Analysis of impact of low prices on availability

Swathi Iyengar

13:00 - 14:00 Lunch

Moderator: Valérie Paris

14:00 - 15:30 The benefits and costs of promoting the development of new orphan drugs

Nicholas Bagley

Analysis of the price impact by various negotiation frameworks as well as strategic procurement

Alessandra Ferrario

15:30 - 16:00 Tea/Coffee break

Moderator: David Newby

16:00 - 17:30 What are the pros and cons that buyers of medicines have experienced when resorting to value-based pricing approaches?

Sarah Garner

Compilation of country studies in managing medicines prices

Fatima Suleman

Medicines price regulation in Brazil and drug shortage risk management

Mateus R. Cerqueira and Leandro Pinheiro Safatle

Day 3 Thursday, 24 November

Moderator: Peter Beyer

09:00 - 10:00 Feedback and input from regional offices

10.00 -13.00 Discussion on the Forum

- **Forum Style and agenda**
- **Participants**
- **Envisaged outcomes**
- **Report and Publications**
- **Way forward**

Closure - Director EMP