World Health Organization

FAIR PRICING FORUM

INFORMAL ADVISORY GROUP MEETING

WHO Headquarters, Geneva

22 - 24 November 2016

World Health Organization

FAIR PRICING FORUM

INFORMAL ADVISORY GROUP MEETING

WHO Headquarters, Geneva

22 - 24 November 2016

WHO/EMP/IAU/2017.06

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

Printed by the WHO Document Production Services, Geneva, Switzerland

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 2021[1]. 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