



TECHNICAL SYMPOSIUM

Access to Medicines: Pricing and Procurement Practices

Summary and key issues

On July 16, 2010, the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) organized a joint

Technical Symposium on Access to Medicines: Pricing and Procurement Practices

hosted by the WTO in Geneva. It was the first in a series of trilateral Symposia that WHO, WIPO and the WTO are organizing in Geneva and set out several themes for continuing cooperation. Its purpose was to gather experiences in the pricing and procurement of medicines as important determinants of access and to examine how and where to obtain information on access to medicines, medicines prices and availability. It provided an opportunity for participants from governments, international and philanthropic initiatives, civil society and industry, to share experiences, take stock of the present situation and examine future needs.

This report summarizes the key issues presented and provides an overview of the detailed and sometimes technical information presented. For further details and copies of the presentations given, please refer to the website of the Symposium.^{1 2 3}

Box 1: Some key issues

- Prices are one important factor determining access to medicines.
- Prices can be influenced by procurement practices, marketing policies (differential pricing – different prices in different markets, mark ups – profit margins added to the cost), tariffs, taxes or other government charges.
- Prices vary from country to country, within countries, and between the public and private sectors.
- Exploring policy options depends on reliable data. Organizations, such as WHO, HAI, the Global Fund and UNICEF make price information available.
- Procurement procedures and decisions are also influenced by selection and quantification of medicines.
- A competitive and transparent procurement process is one important element of access to affordable medicines. Adequate and sustainable financing is also critical.
- Information on relevant intellectual property rights is generated by the intellectual property system. Searching and retrieving the information, particularly in respect of low and middle income countries, is a challenge.
- WTO Members' reporting obligations in relation to their respective trade policies can provide useful information on factors affecting medicines prices.

THE POLICY CONTEXT

Access to health depends to a large extent on prices that have to be paid for pharmaceuticals. Strategies for procuring reliable and affordable supplies of medicine are therefore important factors in determining how easy or difficult it is for patients, especially in poorer countries, to receive the treatment they need. The access to medicines framework includes four key components:

- rational selection;
- affordable prices;
- sustainable and adequate financing; and
- reliable health care and supply systems.

Within these four pillars, different determinants play a role, including the legal framework, intellectual property, procurement and competition policies, taxes and tariffs, as well as regulatory matters ensuring the quality, safety and efficacy of medicines. Practical experiences relating to these factors contribute to a better understanding of the impact of procurement practices on prices and to eventually improving access to medicines.

The policy debate can build on a wealth of information resources providing solid factual data on health, intellectual property and trade. However, data relevant to access are not always readily available. How can policy makers and practitioners obtain an overview about the available data, about who is collecting which kind of data and about where such information can be retrieved? There is value in partnership, dialogue and policy coherence within the international system. The systematic flow of practical information may guide and support international cooperation and contribute to an effective response to the challenges of public health.

This strictly factual and empirical approach is distinct from the broader policy setting. In the Doha Declaration, WTO Members have stressed the importance of intellectual property in the development of new medicines and of the flexibilities provided for in the TRIPS Agreement to enable access to such medicines. WTO Members have agreed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. The Symposium aimed to pull together the practical information that is readily available. It did not intend to establish any link with or to have an impact on the ongoing policy debate on the use and functioning of flexibilities available under the TRIPS Agreement.

Box 2: The health perspective

Improving access to medicines is a priority. International systems aim at creating benefits and improving access, but still face gaps in health outcomes between wealthy and poor countries. The WHO has a vast practical expertise in the area of essential medicines, regulatory questions, procurement and pricing and many other factors affecting access to medicines. Price can be an absolute barrier to access to medicines by the poor. The organization of a country's pharmaceutical sector, its capacity for efficient and impartial procurement and the government's procurement practice, quality control, regulation, and enforcement, availability of staff, delivery systems, and the existence of health insurance schemes affect access to medicines, both originator and generic medicines. Looking at facts about prices and procurement practices is therefore essential.

RELEVANT FACTORS IN PRACTICE AND SOURCES OF INFORMATION

Improving access to essential medicines is a complex challenge for all actors involved. Many different factors define the level of access, such as financing, prices, distribution systems, appropriate dispensing and use of essential medicines. Information about these factors is widely collected by different actors and much information is published in the internet. The systematic use of this information contributes considerably to achieving greater transparency and awareness about the issues in the context of procurement and prices.

Prices

Prices of medicines can be influenced by procurement practices, marketing policies such as differential pricing (different prices are set in different markets), mark ups (the profit margins companies or dealers add to the cost), border measures such as tariffs or other government charges. Prices can vary from country to country and between the public and private sectors. Purchasing in large quantities does not necessarily ensure the best price. Prices may rather be influenced by trust and reliability on the demand and on the supply side. Buying in large volumes or grouping of orders may, however, contribute to making orders and the expectation of payment more credible.

WHO is engaged in making existing drug price information widely available to improve equity in access to essential medicines in health systems and to provide support to Member States⁴. The WHO web site on Medicines Price Information⁵ provides links to a broad range of information resources from the WHO and WHO Regions^{6 7 8}, Member States^{9 10}, organizations^{11 12}, such as Health Action International (HAI)¹³ and the WHO/HAI Medicines prices survey¹⁴, as well as information in respect of certain diseases, such as HIV/AIDS¹⁵, Malaria¹⁶ or Tuberculosis^{17 18}.

The available data resources and methods allow researching of price information in respect of certain countries or regions and certain pharmaceuticals, generic or originator products. These databases permit comparison and analysis of prices of different categories of medicines and of prices for the same product in different regions. They facilitate the evaluation of policy or programmatic actions at global, regional or national levels. The WHO/HAI Project on Medicine Prices and Availability, Affordability & Price Components¹⁹ endeavors to increase price transparency and provide guidance on pricing policy options. The data on medicine prices and availability, affordability of treatments and components in the supply chain resulting from such surveys are made available through a website^{20 21}. Analyses have shown that in some countries medicines are free, but nevertheless not easily available to the poor. In some cases, good procurement prices are not always passed on to patients, but reach the market with considerable surcharges. Public sector prices and private sector prices may differ in some countries, but not in others. In May 2008, HAI and WHO published the 2nd Edition of a manual²² to collect and analyze medicine prices (patient prices and government procurement prices) and availability, treatment affordability and all price components in the supply chain from the manufacturer to the patient (taxes, tariffs, mark-ups, etc.). The first and important step in exploring the policy options is to have reliable data available. Such data provide the solid basis for preparing any action to reduce prices and improve the availability and affordability of essential medicines.

SELECTION AND QUANTIFICATION OF MEDICINES

Beyond prices, procurement procedures and decisions are influenced by selection and quantification of medicines. It has to be determined which medicines are needed in what quantity.

To serve national authorities as a guide to identify their own priorities in respect of needed medi-

cines and considering the respective particularities of the country, the WHO has established a Model List of Essential Medicines²³. Essential medicines are those which cover the priority health care needs of a population. The medicines on the WHO Model List of Essential Medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness which does not necessarily mean absolute cost. The Model List does not create a global standard. It is prepared by a WHO Expert Committee²⁴ and updated every two years. Intellectual property protection is not a criterion for inclusion of a medicine into this list. Experience has shown that on average only a small percentage of the medicines contained in the list is protected by patents in different jurisdictions.

WHO prequalification²⁵ aims at supporting decision making on the purchase of quality assured priority medicines. The application of unified standards of quality, safety and efficacy and the cooperation with laboratories and staff from national regulatory authorities, quality control laboratories and manufacturers aims to ensure quality of medicines. The WHO prequalification is transparent since it publishes both positive and negative outcomes to applications for prequalification as well as suspension and withdrawals from the list as needed. The list of prequalified medicinal products²⁶ is used to guide decisions of medicines procurement agencies.

The decision about quantities requires specific data to estimate the expected medicines use based on morbidity and past consumption. WHO recommends²⁷ a systematic long term observation of experience, short term reactions to crises, and subjective impressions of the quantities needed.

PROCUREMENT POLICIES

The way in which medicines are procured has an impact on prices and accessibility of medicines.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)²⁸ does not procure medicines itself but provides extensive funding for procurement. The Global Fund's Procurement and Supply Management Policy and Principles²⁹, assist the recipients of funds in applying good procurement practices when procuring with funds received from the Global Fund. The Procurement and Supply Plan submitted by the prospective recipient of funds has to comply with the Global Fund's Procurement and Supply policies, including clinical and quality criteria and the applicable

national regulations, e.g. be authorized by the national drug regulatory authority. The implementation of the plan and the performance of the project will be closely monitored.

A competitive and transparent procurement process based on prequalification is key for the Global Fund. Reporting is mandatory. The data obtained through the Price and Quality Reporting System³⁰ are published and provide a solid source of information about prices, suppliers and quality of tested products.³¹ This information can contribute to building up procurement capacity and improving access to health by obtaining better value for money.

Experiences from some WHO regions show some advantage in centralized procurement. Centralized procurement is able to create economies of scale resulting in low transaction costs and better leverage in pricing negotiations and contract terms. Centralized procurement is an option for different levels, be it the public sector or the private sector, and be it in a district, a region or even between countries. A common feature of centralized procurement is the goal to streamline procurement procedures and improve the capacity in the acquisition of medicines, to advance quality assurance and to negotiate competitive prices by consolidating demand and achieving economies of scale. Experience has also shown that merely buying in greater quantities does not automatically lead to decreased prices. A greater impact on prices results rather from adherence to good procurement practice, safe, reliable and prompt payment mechanisms and effective quality assurance.

INTELLECTUAL PROPERTY INFORMATION

Information about the scope and legal status of intellectual property rights regarding specific technology and products in given markets can help to design business strategies and can help to assess which products can be produced and marketed without running the risk of intellectual property infringement.

Procuring agencies are interested in knowing whether medicines can be bought and distributed without conflict with intellectual property rights holders. Information about the rights holders may indicate opportunities for licensing.

Intellectual property rights are territorial rights and pharmaceutical products, their ingredients, their use, combinations of medications etc. can be covered by several patents, with potentially different scope and effect in different countries. Information about intellectual property rights is

Box 3: The intellectual property perspective

New pharmaceuticals are the result of innovation. Innovation and access to innovation are a core concern of the intellectual property system. How is innovation encouraged? How to ensure that medicines reach the patient? Procurement practice asks for comprehensive and reliable information about intellectual property rights covering medicines and the impact of these rights on the purchase and distribution of medicines. Most of the relevant information is produced within the intellectual property system and administered in patent offices. The challenges are, especially in developing countries, to make such information accessible in a practicable and user friendly way and, to overcome language barriers.

generated and administered in all patent offices. While some intellectual property offices offer a wealth of information in electronic form over the internet, other offices do not have such information infrastructure in place and may lack administrative capacity to administer or make available the relevant data. Additional barriers to accessing the information result from different languages used.

WIPO is committed to make intellectual property information available. On June 1, 2010, WIPO launched WIPO Gold³², the Global Intellectual Property Reference Resource, a portal to all existing WIPO services.

WIPO's gateway to patent information is the PATENTSCOPE[®] portal³³. PATENTSCOPE[®] allows a full text search³⁴ in international patent applications published under the Patent Cooperation Treaty³⁵. However, international patent applications are not granted patents and for procurement purposes one needs information about patents in force in the relevant jurisdictions. It is important to search for respective information in national patent databases³⁶.

A number of national and regional offices provide information about national patent proceedings building on international applications³⁷. As of September 2009, PATENTSCOPE[®] gives increasingly access to national patent collections³⁸.

To address the particular challenge of searching patent documents in different languages, WIPO has launched the Cross-Lingual Information Retrieval (CLIR)³⁹. This facility opens up a new way of carrying out multiple linguistic searches of patent databases in different languages and will significantly enhance access to patent information

throughout the world. The search query in one language will be translated at best into several other languages by special software which has been developed by WIPO. CLIR has extensive coverage in English, French, German and good coverage for Japanese and Spanish. The next languages to be considered are Chinese and Portuguese.

TRADE INFORMATION

The international trade system is largely shaped by the various Agreements that form the basis of the WTO. A joint study by the WHO and WTO Secretariat "WTO Agreements & Public Health"⁴⁰ illuminates the public health relevance of WTO Agreements. The multilateral trade system provides a wealth of data and factual information relevant for procurement and access to medicines.

Certain elements of the international trade system have direct impact on prices of medicines and influence the capacity of governments, health care providers and consumers to access medicines. Such factors relate, on the one hand, to trade between countries, such as tariffs, import licenses and restrictions, and, on the other hand, include a country's internal factors, such as standards, regulation, procurement policies, competition policies and intellectual property settings. Information available about those factors is largely based on WTO Members' reporting obligations.

Tariffs are custom duties on merchandise products. Tariffs raise revenue for countries through charging the importation of goods. From a public health perspective, tariffs on medicines increase the costs for pharmaceuticals. A study prepared for the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH)⁴¹ has therefore concluded that pharmaceutical tariffs should be eliminated. WTO databases⁴² allow searching and analyzing detailed information on tariffs applied by WTO Members⁴³.

Analysis that distinguishes different categories of countries according to the access level shows that from 84 surveyed WTO Members with low to medium access (between 50% and 79% of the population) and very low access (less than 50% of the population) 75 WTO Members apply low tariff rates on medicines. Least developed countries (LDCs) tend to import medicines free of any duty and many LDCs have reduced or eliminated tariffs on imported medicines in the past years. However, a few LDCs maintain higher average tariff rates of up to 14%. Non-LDC national average tariff rates for medicines are generally fairly low, i.e. below 5%, but a few Members apply

Box 4: The trade perspective

Numerous aspects of trade policy have direct relevance to public health policy. Besides the political discussion and pertinent information about the WTO Member's positions through WTO documents, there is a wealth of data and factual information available resulting from WTO's notification mechanisms.

In particular, the Doha Declaration has helped to illuminate and clarify the flexibilities and policy options available under the TRIPS Agreement. It has served as a benchmark for multilateral cooperation and has been cited by WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and WIPO's Development Agenda. The Doha Declaration has led to the only amendment to WTO law since the WTO was established in 1994.

rates of up to 12%. There are some tariff peaks from 15% up to 35% especially in developing countries with domestic pharmaceutical industry.

WTO negotiations address reduction and elimination of tariffs and non-tariff barriers in various fora. The Uruguay Round negotiated the Pharmaceutical Sectoral Initiative aiming at full liberalization of over 6,500 pharmaceutical products and inputs covering an estimated 79% of global trade of these products. A number of WTO Members have liberalized their pharmaceutical sector under that initiative and committed to regular review of coverage for additional pharmaceutical products for tariff elimination. The non-agricultural market access (NAMA) Tariff reduction modalities⁴⁴ resulted in a significant drop in pharmaceutical tariffs in developed countries. Major developing country markets would also have to reduce pharmaceutical tariffs assuming that they do not choose to apply flexibilities on these tariff lines. The NAMA Sectoral initiative for Open Access to Enhanced Healthcare wants to reduce the cost of healthcare through the substantial elimination or reduction of tariffs and specific non trade barriers affecting the trade in medicines, medical devices and innovative medical technology products.

The Agreement on Technical Barriers to Trade (TBT)⁴⁵ recognizes protection of human health as a legitimate objective and provides a notification mechanism for proposed or modified technical regulations. 46% of the notified regulations aim at protecting health.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)⁴⁶ covers measures designed to protect human life from

food borne risks and plant/animal carried diseases. While there appears little connection with essential medicines and primary pharmaceutical products for human health, there is considerable information on medicinal food products such as tea or herbs and functional foods with nutritional additives.

The impact of the General Agreement on Trade in Services (GATS)⁴⁷ on trade in health services remains insignificant due to the low level of commitments in this sector that mostly only binds existing levels of market access. GATS leaves a high flexibility in defining obligations undertaken in a given service sector, whether or not to open the market to foreign suppliers at all, the scope and conditions of such opening and whether to bind it in GATS specific commitments. GATS also maintains the ability to regulate service quality and accommodate other domestic policy concerns and emphasizes the need for government regulations to protect the interests of its citizens.

Article 63 of the TRIPS Agreement⁴⁸ provides for extensive publication and notification obligations of WTO Members with the goal to achieve the greatest possible transparency on issues pertaining to the subject matter of the TRIPS Agreement. Members share information on their intellectual property laws, regulations and practices through notifications submitted to the TRIPS Council⁴⁹. For example regarding policy and legislative choices on the protection of clinical test data, 120 WTO Members have notified their legislative measures dealing with the protection of pharmaceutical or other test data. 59 WTO Members have notified specific legislation on pharmaceutical test data. 28 of them have notified other legislative measures covering protection of test data, e.g. unfair competition legislation, administrative practices to protection of

trade secrets in general. 61 WTO Members have notified more general protection referring to confidential information in general while some WTO Members adopted the text of TRIPS Article 39.3 directly. The Regional Trade Agreement database⁵⁰ is a means of monitoring data protection agreed in other fora.

COMPETITION POLICY AND INTELLECTUAL PROPERTY

Ensuring an adequate degree of competition throughout the supply chain of medicines generally, as well as in procurement procedures more specifically, has the potential to lead to lower prices and better value for money, thereby enhancing access to medicines.

The effect of intellectual property on competition has been described as dual in nature: on the one hand, intellectual property rights aim to protect business investments in order to foster innovation and enhance participation of those businesses and thus competition in relevant markets. On the other hand, intellectual property rights exclude competitors from using the protected innovation, trademark, etc. This, in turn, can reduce competition and, in certain circumstances, increase the potential for abuse of such rights. Hence, countries need to create an environment that ensures adequate and appropriate standards for competition, while also preserving the welfare benefits of intellectual property protection. A well-designed and applied competition policy can be an important tool to achieve this balance.

Considering the interface between intellectual property and competition, in particular in the pharmaceutical sector, is therefore an important matter for many policymakers⁵¹.

In WIPO's Development Agenda, Member States approved a project on Intellectual Property and Competition Policy (WIPO Document CDIP4/4⁵²) that seeks to promote a better understanding of the interface between intellectual property and competition policy, particularly in developing countries and countries with economies in transition through a series of activities aimed at collecting and scrutinizing recent practices, legal developments, jurisprudence and legal remedies available in selected countries and regions⁵³.

The currently inactive WTO Working Group on the Interaction between Trade and Competition Policy⁵⁴, between 1997 and 2003, produced extensive material on competition and intellectual property and reports of national experiences⁵⁵.

ARBITRATION AND MEDIATION

Disputes are often neglected matters. However, thinking about possible dispute resolution well in advance is essential for success. The WIPO

Arbitration and Mediation Center⁵⁶ promotes time and cost-effective resolution of commercial disputes involving intellectual property between private parties other than court litigation. Areas of Arbitration and Mediation cases that have been resolved include both contractual and non-contractual disputes, such as patent license agreements, research and development collaboration agreements, distribution agreements for pharmaceutical products, patent infringements, joint ventures, trademark coexistence agreements, research institutes and NGOs and universities (including spin-offs)⁵⁷.

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The Center serves as a resource for rules, contract clauses, and neutrals. It gives procedural guidance and offers tailored dispute resolution services, provides training and organizes conferences.

CONCERNS ADDRESSED

A number of political and practical concerns were addressed in the Symposium.

The major concern is making medicines affordable and available. Procurement agencies need to be efficient and must ensure buying at the best price for the required quality. In many, but not in all cases, generic medicines offer a lower price alternative. Ensuring availability of price information for example to healthcare providers, procurers and consumers is seen as a pre-condition for effective procurement results. Awareness about the relevant price factors is crucial. Solid data about taxes, tariffs, and other charges increase the factual basis for procurement decisions and contribute to building the relevant capacity of procurement agencies. Spending on originator and generic medicines, in the public and private sectors, are substantially lower if procurement and distribution procedures are more efficient, corruption-free and mark-ups are reasonable.

Certain concerns address a situation where medicines are available only from a single source and subject to high prices. Some see this situation as being intimately linked to patents. Since more and more countries are complying with the provisions of the WTO TRIPS Agreement, namely regarding patents on pharmaceutical products, there are concerns that the availability of generic products might decrease in the future. However, others see the existence of intellectual property rights not as a restriction, but rather as an indicator for a business opportunity that opens access to a product through a license agreement.

A key issue is adequate and sustainable financing of medicines supply to ensure that quality assured medicines are made available to patients lacking necessary financial resources. This requires safety nets for those that cannot afford to purchase even low priced necessary medication.

The intellectual property system is expected to provide needed information about products and potential providers of technology. Lack of capaci-

ty in dealing with the intellectual property regime at the national and international level and a lack of information about patents and intellectual property rights are recognized challenges.

Patent pools, such as the Medicines Patent Pool⁵⁸, have been seen as an innovative way in the context of public health of dealing with the complexity of patents for fixed dose combinations, especially for children's medicines, and to reduce prices through voluntary licenses.

A different set of concerns relates to measures to enforce intellectual property rights, in particular with respect to what is seen by some as their interference with the supply of affordable quality medicines, namely generic products. In particular, international procurement, parallel importation of pharmaceuticals and transit of medicines may be subject to border controls in certain jurisdictions. Such measures may slow down or even block access to medicines.

Among the topics mentioned for further work and study in the context of access to medicines, pricing and procurement practices were: the procurement and pricing of medicines, the role of competition policy, various factors affecting larger scale roll-out of patented medicines, and transparency and greater use of intellectual property information.

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