

WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS

World Health Organization and World Trade Organization Secretariats
Norwegian Foreign Affairs Ministry, Global Health Council
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Executive Summary of Report*

The workshop brought experts together to explore the often complex questions involved in ensuring access to existing essential drugs at prices affordable in poor countries and adequate financing for this purpose, while providing adequate incentives for R&D into new drugs. In addition to individual academic, legal and consultancy experts, the perspectives of governments, manufacturers from both the research-based and generic industry, non-governmental organizations concerned with health, and intergovernmental organizations, were heard in presentations and discussions. The principal focus at the workshop was on two main topics: differential pricing and financing of essential drugs.

While it was not the purpose of the workshop to seek agreed conclusions, there seemed to be a large measure of common thinking among participants on two central points:

- First, that differential pricing could, and should, play an important role in ensuring access to existing essential drugs at affordable prices, especially in poor countries, while allowing the patent system to continue to play its role of providing incentives for research and development into new drugs.
- Second, that while affordable prices are important, actually getting drugs, whether patented or generic, to the people who need them in poor countries will require a major financing effort, both to buy the drugs and to reinforce health care supply systems, and that for these countries most of the additional financing will have to come from the international community.

Access to essential drugs

There was recognition of the wide range of obstacles to adequate access to essential drugs in poor countries, including issues of financing, pricing, supply, selection and distribution. The price of drugs alone does not determine who gets access to health care. Nevertheless, it was noted that the health expenditure of the world's poor is largely devoted to buying drugs, often through private outlets. So the price of essential drugs matters to poor people and to poor countries. However, it was also noted that low-priced drugs, or even those made available free of charge, are often not being sufficiently used. Locally available health services, adequately staffed, equipped, managed and financed, and oriented to local needs and priorities, as well as efficient distribution systems and tariff and tax-free treatment for drugs are some of the other factors that play an important role in enabling access on the basis of medical need. Participants assigned different importance to the individual factors influencing access to care, but all recognized the complexity of the access puzzle, and its variability from one setting to another.

* Background papers for the Workshop are available from the World Health Organization (http://www.who.int/medicines/docs/par/equitable_pricing.doc) and the World Trade Organization (http://www.wto.org/english/tratop_e/trips_e/wto_background_e.doc). The full report of the Workshop and papers presented at the workshop should be available shortly.

Financing of health care and essential drugs

The point was made that, even with low prices, substantially expanding access to essential medicines will require additional domestic and international financing for the purchase of essential drugs as well as for building effective health and supply systems. This is important not only for newer drugs, such as the anti-retrovirals, but also for essential generic drugs such as many of those for treating tuberculosis, malaria, diarrhoeal disease and respiratory infections. Mobilization of domestic resources in middle-income developing countries is an important way of improving access, but in poor countries financing needs will have to be primarily met by the international community. It was not the purpose of the workshop to estimate what these needs were nor to explore the most suitable modalities for meeting them, but there was a common view that there was a need for a massive upward shift in the level of international health aid.

Differential pricing is necessary and feasible

By differential pricing is meant the adaptation of prices charged by the seller to the purchasing power of governments and households in different countries. The workshop heard that more widespread and sustainable differential pricing can be feasible provided the right legal, technical and political environment can be secured.

Economic feasibility – It was explained that differential pricing can be feasible where there are substantial fixed costs, and variable or marginal costs of production are relatively low. While there is perhaps greater scope where patented products are concerned, because of the high level of sunk R&D costs, differential pricing can also be feasible for non-patented products. Some leading economists explained how differential pricing can be in the interests of both consumers in poor countries and manufacturers, while not adversely affecting consumers in richer countries, provided markets can be effectively segmented. This entails prevention of diversion of low-priced products into high-income markets (a technical issue) and a readiness on the part of consumers in such markets to accept sustained price differences (a political issue). They also showed how differential pricing can help reconcile the twin objectives of affordability of existing essential drugs and providing incentives for research and development into new drugs, by support for R&D costs being shared according to ability to pay.

Differential pricing is already practised, but in a limited manner – Several manufacturers already, independently of each other, offer heavily discounted prices and donations to certain poor countries for selected drugs. Experience with vaccines, contraceptives and drugs for tuberculosis presented at the workshop shows that low prices can be made available for poor countries, both for patented and non-patented products. Reductions of 90 per cent or more below developed country prices have been achieved through bulk purchasing, competitive tenders and skilful negotiation. The point was made that generic competition has also been shown to bring prices down.

Ways of giving effect to differential pricing – A variety of options was put forward and discussed to carry forward the concept of differential pricing. These included creating the right conditions and leaving it to the market, the bilateral negotiation of price discounts between companies and governments, the use of regional or global bulk purchasing, the impact of moral suasion, the role of voluntary and, where necessary, compulsory licensing, and the establishment of a flexible, global differential pricing system. The role of donations was also considered. There was discussion of the respective pros and cons of these approaches. Some argued that a global mechanism could be difficult to manage and have undesirable, unintended consequences while some others took the view that it would not be sufficient to rely on individual initiatives focusing on a limited number of drugs and countries. Some felt there is need for greater international cooperation to support differential pricing.

While differing views were expressed, there seemed to be a wide view that more than one of the modalities mentioned above may need to be used, depending on the circumstances. Among the issues discussed were the role of competition in reducing prices, for example through voluntary licensing, and the relation of this to intellectual property regimes, the scope for incentives by developed countries for differential pricing and donations, and the constraints that competition law in many countries places on arrangements that involve concerted action among companies on how they compete with each other.

Achieving favourable prices - While there was wide support for the notion that essential drugs should be made available to poor countries at the most favourable price, which was variously referred to as a marginal cost or not-for-profit price, differing views were expressed as to how such a price should be determined. This question was considered important not only by developing country buyers but also by developed country donors who were concerned that, if large amounts of development funding were to be allocated for financing the purchase of essential drugs, the products would be bought at the lowest possible price. The approaches suggested included negotiation, perhaps aided by local cost of production calculations and large volume purchases; increased competition through voluntary licensing or eventually compulsory licensing or its possibility; and the development of target prices relating to therapeutic value through economic analysis.

Maintaining separate markets and preventing diversion – Participants accepted that markets for differentially priced drugs need to be tightly segmented to prevent leakage of differentially priced drugs to higher-income markets. A range of mechanisms that can be used for this purpose was discussed, including marketing strategies by manufacturers relating to the use of different trademarks and the presentation of products, stricter supply chain management by purchasing entities, the role of the drug regulatory authorities in high-income countries and export controls in poor countries and intellectual property-based rights to prevent parallel imports into the high-income countries. While these issues will require further study, there was a view that the available techniques, used in combination with each other with responsibility shared between the low-income and high-income ends, could ensure the degree of market separation necessary for differential pricing to be feasible.

Political feasibility – There appeared to be a common view that preferential prices in developing countries should not be a factor in pricing in developed countries. Differential pricing policies hinge critically on the political acceptability of lower prices in poor countries. It was suggested that, in a climate of increasing international scrutiny of prices and growing direct and indirect reference pricing schemes, the industrialized countries may need to make undertakings not to use differential prices meant only for poor countries as benchmarks for their own price regulation systems or policies. A more difficult point was how to forestall differential prices being used in the political process in these countries. Some felt that this required political leadership, advocacy efforts and public education. Part of this will be the need to reassure public opinion that lower prices in poor countries do not mean higher prices in rich ones or a greater burden on national health budgets. Also, consideration must be given to whether differentially priced products may be seen as a form of unfair competition by local industries in developing countries and possibly subject to recourse to anti-dumping relief.

What about middle-income countries and well-to-do populations in poor countries - Discussion recognized, but did not resolve, the questions of middle-income countries paying prices proportionate to their income levels and of possible prohibition of parallel trade between low and middle-income countries. The further question of whether the eligibility of the well-to-do segments in poor countries for differential prices would significantly affect its likelihood and, if so, whether it would be feasible to separate their markets from those of the poor in those countries was also raised. Some proposed that differential prices not be restricted to the public sector, but cover also not-for-profit providers and large employers.

The role of intellectual property rights

The point was made that differential pricing of essential drugs is fully compatible with the TRIPS Agreement and should not require countries to forego any flexibility they have under it. The need to find an appropriate balance in intellectual property rights systems between providing incentives for the development of new drugs and facilitating access to existing ones was also widely stressed. In this connection, many emphasized the importance of respecting the balance found in the negotiation of the TRIPS Agreement and the rights of developing countries to use the flexibility in it, including in regard to compulsory licensing and parallel imports, to respond to health concerns. It was noted that there was as yet relatively little experience with the use of these safeguard mechanisms. Concern was expressed about external pressure on countries to limit the use of these options. Some important reassurances were repeated in this connection. It was also noted that the TRIPS Agreement does not prohibit countries from aiding market segmentation through the prohibition of parallel imports, for example from poor countries to high-income countries. There seemed to be a wide acceptance of the view that the patent system, while a necessary condition for much R&D, was not a sufficient one to secure adequate R&D into the neglected diseases of the poor; and that additional measures of support for such R&D are necessary. Some participants warned of the possible negative effects on local and global innovation of excessive resort to TRIPS safeguard provisions.

Wider use of differential pricing and greater international funding: issues requiring further work

While the workshop contributed importantly to a better understanding of a number of key issues, many points were acknowledged to require further in-depth analysis and discussion. These included:

- The international funding required for ensuring effective access to essential medicines in poor countries and the most appropriate mechanisms for the mobilization and distribution of such funds.
- The most appropriate ways in which differential pricing can be given effect. Linked with this are questions of how the differential price at which products will be sold in poor countries can be determined, including how negotiation and competition should contribute, in ways compatible with international agreements, to achieving the most favourable prices, what constraints are imposed by competition law, and how to develop incentives for differential pricing.
- How to insulate in political terms pricing in developed countries from differential pricing in poor countries, including in regard to the use of reference pricing systems? Also, the best ways of securing effective separation of markets and preventing trade diversion, while taking into account international trade rules.
- How to treat middle-income developing countries and well-to-do populations in poor countries under differential pricing?