

Differential pricing of essential drugs¹

In the growing debate over the prices of pharmaceutical products to treat HIV/AIDS and other illnesses around the world, a number of suggestions have been made for ways to make key life-saving medicines more affordable and more widely available, especially in lower-income countries. One of the solutions under discussion is “differential pricing.” Also called “equity pricing” or “preferential pricing,” it refers to the process of charging different prices in different markets according to each country’s ability to pay.

That approach was the focus of a workshop held in Norway in April 2001, with 80 experts from 21 nations participating in an event that had been organized by the World Health Organization (WHO), the World Trade Organization (WTO), the Norwegian Foreign Ministry, and the Global Health Council, which is an international health care advocacy organization based in the United States of America. The workshop was intended to raise and discuss issues rather than to reach final conclusions on them. Strategies were discussed for drugs to treat a range of illnesses, including HIV/AIDS, malaria, and tuberculosis. Two reports issued before the meeting—one from WHO and the other from WTO—presented many of the policy issues that the workshop participants discussed and debated.

Differential pricing is already being used for vaccines, contraceptives, condoms, and some medicines. Price reductions have been achieved through such strategies as high-volume purchasing, reliable and adequate financing, public advocacy, negotiation, and market competition. And while some countries have been able to arrange lower drug prices with individual pharmaceutical producers on an ad hoc basis, differential pricing is intended as a more systematic approach to obtaining price reductions.

Differential pricing could allow companies that make patented drugs to recover most of the costs of research and development in richer markets and at the same time to sell or license production at lower prices in lower-income countries. This could be a win-win solution, provided that consumers in richer countries do not face higher prices as a result.

In order to expand the differential-pricing approach to additional medicines in more developing countries, no single formula will be appropriate, according to the WHO and WTO reports. Instead, a wide mix of options are possible and will be needed.

Key words: Drug costs, drug industry, economics.

¹ Based on: 1) Watal J. Workshop on differential pricing and financing of essential drugs. Geneva: World Trade Organization; 2001. Available from: <http://www.wto.org>. Accessed 12 April 2001; 2) World Health Organization. More equitable pricing for essential drugs: what do we mean and what are the issues? Geneva: WHO; 2001. Available from: <http://www.who.int/medicines/docs/pagespublications/doclist.htm>. Accessed 12 April 2001; and 3) World Health Organization. WHO/WTO workshop on pricing and financing of essential drugs. Experts: affordable medicines for poor countries are feasible. Geneva: WHO; 2001. Available from: <http://www.who.int/inf-pr-2001/en/pr2001-20.html>. Accessed 12 April 2001. (Press Release WHO/20, 11 April 2001).

Priority health problems and products for differential pricing

As international organizations, individual countries, and others work on differential pricing, priority should go to the products that address the heaviest burden of disease in developing countries. Currently, these priorities are likely to be HIV-related drugs, drugs for multidrug resistance tuberculosis, antimalarials, antibiotics for resistant strains of sexually transmitted infections, and antibiotics for bacterial pneumonias, bacterial meningitis, and other common childhood illnesses for which resistance to first-line drugs has developed.

Key pharmaceuticals for differential pricing could be identified through an international process or through individual national processes, with each approach offering some advantages. A national approach might allow greater responsiveness to local conditions. However, given the frequent similarity of morbidity patterns among countries within a particular region, an internationally determined list would offer the benefits of pooled procurement and easier production logistics.

The list of products addressed by differential pricing will be dynamic. A number of factors could affect the list, including changing patterns of disease, antimicrobial resistance patterns, development of new therapeutic options, and the impact of price competition when key pharmaceuticals come off patent. Guidance in identifying priority products could come from the WHO Model List of Essential Drugs, WHO treatment guidelines, and national lists of essential drugs.

Cost-effectiveness should be taken into consideration in order to direct both domestic and international funds to those treatments that achieve the greatest health impact on poor populations for a given expenditure. Cost-effectiveness calculations would be dependent on price levels and could change dramatically over time.

Attention needs to go to not just pharmaceuticals but also to diagnostic products. For many major health problems, such as HIV/AIDS, diagnostics play a key role in ensuring accurate diagnosis, proper drug therapy, and overall quality of care.

Which countries should benefit

Differential pricing for key pharmaceuticals should clearly be made available to low-income countries, but there are a variety of ways to define "low income." Using the criterion of "lowest income" (a gross national product (GNP) of less than US\$ 350 per capita) would limit the benefits to 26 countries with a population of 450 million. However, benefits could be extended to 86 countries

with 3.7 billion inhabitants by using a broader definition, of countries that either are eligible for assistance from the International Development Association (maximum per-capita GNP of US\$ 885) or that have at least half of their populations living on less than US\$ 2 per day. In between those two limits a variety of other criteria could be used, with corresponding numbers of countries and persons either being included or excluded.

Using any one of those kinds of criteria would effectively establish two pricing tiers, one for low-income nations and another for all other countries. An alternative would be a systematic multi-tier approach, based on national income "bands" or ranges. Regardless of whether just two levels or more than two levels are established, there is likely to be some amount of price variation within each of the levels, as has been true with the international vaccine market.

Besides level of income or economic development, other criteria could be considered. They might include a demonstrated commitment to improving health outcomes, the burden of disease for specific priority health problems, and other national performance indicators for health system development or pharmaceutical sector development. While they could contribute to improved health outcomes, such additional criteria could also greatly complicate the implementation of differential pricing.

Differential pricing and international agreements

Any mechanism to achieve differential pricing will need to be consistent with national legislation and with international agreements on trade and other issues, such as WTO's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). To achieve this objective, there are four primary options, according to the WHO report.

One option is for the product's patent holder to be the sole producer of the medicine and also the initiator of differential pricing. This is the current situation in countries implementing the WTO TRIPS agreement and where the patent holder chooses to remain the single source supplier. With this alternative there is a potential for a high-volume low-margin market, which would allow pricing close to the marginal cost of production. However, since this approach is noncompetitive, it may not achieve the lowest possible prices.

A second alternative is nonexclusive voluntary licensing. This incorporates technology transfer, geographic restrictions, and the payment of royalties to the patent holder. This type of arrangement encourages price-lowering competition. It depends on

having a sufficient market—purchase volume times price—to support competitors. Controls are needed to ensure that licensed producers do not produce for direct or indirect sale in markets other than the intended ones.

Another option is nonexclusive compulsory licensing with the payment of royalties to the patent holder. It may be used for local production as well as importation, provided that production in other countries is legal. However, this approach may entail protracted and resource-intensive legal disputes between the patent holder and the applicant. In addition, there is no obligation on the part of patent holder to transfer technology. As is the case with voluntary licensing, controls are needed to keep products within the intended markets.

A fourth alternative is a waiver of rights by the patent holder for specific countries or regions. One research-based company has already initiated this approach for Africa. As with voluntary licensing, controls are needed to keep products within the intended markets.

Factors that contribute to lower prices

A number of factors can help achieve the best possible price for essential drugs. For example, it is important to ensure adequate and sustainable financing, through domestic and international sources. Also needed is prompt and reliable payment by the procurement agency, whether is a public, private, or not-for-profit entity.

Maximizing therapeutic and generic competition is another consideration. Therapeutic competition can be increased by ensuring that treatment guidelines and essential drug lists make use of the latest information on comparative efficacy and cost-effectiveness. Generic competition among off-patent drugs can be encouraged through an established set of policy instruments and strategies. Competition with on-patent drugs can be encouraged through nonexclusive licensing arrangements.

In low-income countries the private-sector selling price of a drug may be as much as five times the producer or importer price due to the effects of multiple middlemen, taxes, pharmaceutical import duties, distribution charges, and pharmacy and drug seller charges. Therefore it is key to reduce these distribution costs through improved efficiency, elimination of taxes and tariffs, and the promotion of reasonable dispensing charges

Better pricing can also come from concentrating demand and increasing volume through pooled procurement arrangements. Depending on the volumes and the sources of the products, procurement can be done on a national, regional, or international basis.

Also important is ensuring prompt delivery with minimal losses, through better governance and management efficiency. Such improvements promote confidence on the part of donors, suppliers, and the country's citizens. To achieve this goal, political commitment, solid management skills, and a realistic assessment of local supply options are required.

Paying for differentially priced products

Purchases of key pharmaceuticals can be supported by both domestic and international sources. Domestic public financing can certainly be a key component. Governments can also encourage large-scale employers to increase their funding for health care, including for essential drugs.

Another possibility are development loans from the World Bank and regional development banks. This may be most appropriate in cases where eradicating or substantially reducing the prevalence of certain diseases is associated with significant development gains.

Another option are tax deductions for drug donations or other forms of company grants to developing countries. For example, the United States of America already has tax incentives for corporate donations. Recently, the Government of the United Kingdom announced that it will allow tax deductions for the entire value of drugs donated toward "treatments that are genuinely needed" in poor countries. Nevertheless, such drug donations should be consistent with long-term solutions and should not undermine public health policy objectives.

Purchasing and distributing differentially priced drugs

Differential pricing should reinforce health systems that improve services for poor people through such mechanisms as fair financing, responsiveness, the use of all effective delivery channels, and high quality of care.

Differential pricing should first benefit the public sector in target countries, including national health services and health insurance programs directed at lower-income populations. Nevertheless, providing differential prices just to the public sector can exclude many poorer persons who do not have access to public sector services.

Nongovernmental organizations (NGOs) and other nonprofit health care providers can participate in purchasing and distributing differentially priced drugs. Many such organizations provide efficient, quality health care for the urban poor and lower-income rural populations. Providing differ-

entially priced essential medicines to these organizations can help them sustain their services.

Private employers and health insurance schemes in economic sectors with large numbers of low-income employees can also be involved. Providing access to differentially priced essential medicines to employers who are already providing health services will reinforce the role of employers in meeting health care needs. Supporting coverage of low-income households through employer health services also reduces the demands on public services.

Private sector retail channels are another option. In many developing countries, private pharmacies, licensed drug sellers, and informal channels constitute the primary source of essential medicines, even for poor and rural populations.

Preventing diversion away from intended countries and populations

Regulatory, legal, product presentation, and other mechanisms should be used to ensure that products sold at differential prices benefit the intended countries and populations and are not diverted to other nations and groups.

For example, pharmaceutical technology can be applied to support market segmentation by using different brand names, packaging, and dosage forms. Such differentiation already exists among generic and brand name products in the same market as well as among those produced in different regions of the world. However, differentiation using these measures could be misperceived as differences in product quality.

Another option are export controls in the target countries. These measures can stop diversion close to the source, but they place additional burdens on governments and systems in low-income countries.

Import controls in countries that are not target countries are another possibility. High- and middle-income countries have more resources that they can use to control imports. However, this approach requires efforts by a large number of countries that do not benefit from lower prices or from the production and sale of differentially priced products.

Persuading developed countries not to demand the same low prices

Methods must be found to prevent lower-priced drugs from finding their way into markets in high-income countries. This may be difficult given that health care payers around the world are keenly aware of rising health care costs, including for pharmaceutical products. Further, lower prices in

developing countries could come to be considered reference points for price controls in industrialized countries.

Part of the answer to those pressures could be global and national advocacy for differential pricing. In both developing and developed countries, this will require support from governments, companies, nongovernmental organizations, international agencies, and other entities.

Another option is to ensure that differentially priced products are sufficiently different so that they can not reasonably be compared, such as through differences in packaging and dosage form.

Ensuring sustained and dependable differential pricing

Low-income countries and the international community want to expand access to key pharmaceuticals regardless of which company produces particular drugs. Companies, on the other hand, want to respond to the market without being restricted or directed by international or national agreements over which they may have limited control.

In trying to balance these interests, one alternative is to leave differential pricing entirely at the discretion of individual companies. While this approach may be the least cumbersome and involve the least intrusion into private business, it is not predictable and may not be sustainable in terms of equitable access for low-income countries.

Another possibility is to develop an international agreement on differential pricing for low-income countries. This could provide consistency and predictability for both producing countries and beneficiary countries. However, private companies might consider it too much of an intrusion into their business.

Also possible is the creation of tax or other incentives for differential pricing. While providing a voluntary but structured approach, this depends on individual countries to develop their own legislation.

Additional challenges

For differential pricing to succeed, many other health care concerns will need to be addressed. The health care and drug supply infrastructures must be strengthened and improved for lower-cost drugs to be distributed and used effectively. Additional training and education for health care professionals may be required.

Rational selection and use of drugs is also key. It requires defining which drugs are most needed and ensuring that they are used as intended. This can be done through research and development of

needed new drugs, preparing evidence-based treatment guidelines, defining an essential drug list or list of key pharmaceuticals based on treatment guidelines, and promoting rational use by consumers.

Even if more drug prices fall, there is no assurance that poor communities can afford them. This is especially true for HIV/AIDS drugs. Reducing the cost to US\$ 500 per patient per year would still leave the products beyond reach in many countries, where total health expenditures can be as little as US\$ 10 or US\$ 20 per person per year. In these cases, sizeable amounts of external funding will be needed.

Both the WHO and the WTO will continue their discussions on differential pricing and related issues at upcoming meetings. In May the WHO will hold its World Health Assembly, and in June the WTO's Council on Trade-Related Aspects of Intellectual Property Rights (TRIPS) will hold a special discussion on intellectual property and access to drugs.

SINOPSIS

El precio diferencial de los fármacos esenciales

En el creciente debate sobre los precios de los productos farmacéuticos para tratar la infección por VIH/SIDA y otras

enfermedades, se han hecho varias sugerencias sobre la forma de costear y aumentar la disponibilidad los medicamentos claves que pueden salvar vidas, especialmente en los países de menores ingresos. Una de las soluciones propuestas es la del "precio diferencial", también llamado "precio equitativo" o "precio preferente", que se refiere al proceso de poner diferentes precios en diferentes mercados, dependiendo de la capacidad adquisitiva de cada país. Esta cuestión fue el centro de atención de un taller realizado en Noruega en abril de 2001, organizado por la Organización Mundial de la Salud (OMS), la Organización Mundial del Comercio (OMC) y otros grupos. Dos informes publicados antes de la reunión, uno de la OMS y el otro de la OMC, presentaron muchos de los temas políticos analizados y debatidos por los participantes en el taller. Según la OMS y la OMC no habrá una fórmula única que sirva para ampliar esta estrategia del precio diferencial a otros medicamentos en más países en vías de desarrollo. Para ello será necesaria una amplia gama de opciones posibles. Todavía quedan muchos temas políticos por resolver, entre ellos los problemas sanitarios prioritarios y los medicamentos que deberían incluirse en esta política de precios diferenciales, los países que deberían beneficiarse de ella, el precio diferencial y los acuerdos comerciales internacionales, cómo pagar los productos con precios diferenciales, cómo evitar que esos productos sean desviados de los países y poblaciones a los que están destinados, y cómo persuadir a los países desarrollados para que no demanden los mismos precios bajos.

International Congress of Nutrition

Dates: 27–31 August 2001
Location: Austria Center Vienna
Vienna, Austria

This congress will serve as a forum to discuss all aspects of the nutritional sciences. The motto for this congress, the 17th one, is "Modern Aspects of Nutrition — Present Knowledge and Future Perspectives."

The goal of the scientific program is to provide an update on issues in nutrition and food sciences and how these issues affect nutrition education, nutrition policy and programs, food security and safety, and nutrition practices to optimize global health through the prevention and treatment of disease. In addition to plenary lectures and theme-specific symposia, the congress will include workshops, poster sessions, and debate sessions on controversies in nutrition.

Among the groups helping to organize and support the congress are the International Union of Nutritional Sciences, the World Health Organization, the Food and Agriculture Organization of the United Nations, and the United Nations Children's Fund. The official language of the meeting is English, with no simultaneous interpretation provided. The registration fee is US\$ 404 if paid before 31 May and US\$ 495 after that date.

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