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MORE EQUITABLE PRICING FOR ESSENTIAL DRUGS: WHAT DO WE MEAN AND WHAT ARE THE ISSUES?

Background paper for the WHO-WTO secretariat workshop on differential pricing and financing of essential drugs, Høsbjør, Norway, 8-11 April 2001[*]

NOTE TO READERS: This paper is in two parts. Part A provides background information on the state of health systems in developing countries and the factors determining access to care. It clarifies what is meant by differential pricing of essential drugs, briefly reviews related experiences, and draws some lessons from these.

Part B is structured around a set of ten questions and offers, as the title indicates, "A framework for discussion". The options and issues identified are meant to serve as a starting place for the development of principles and action plans for differential pricing of key pharmaceuticals for priority health problems in low income countries. These principles and options should not be taken as recommendations or conclusions by the World Health Organization.

[*] Prepared by the WHO secretariat.

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Executive Summary

Health systems and access to essential drugs in the least developed countries

Serious illness is a major reason why poor populations remain trapped in poverty. Where public health services and insurance are inadequate, health care and medicines costs push households further into debt and dependence. In countries hit hardest by diseases such as malaria and HIV/AIDS, economic development has ceased altogether. Yet much of this illness burden is avoidable: effective prevention and treatment exists.

In marked contrast with the industrialized countries, health care in the least developed countries is predominantly financed privately. Drugs are typically the principal component of a poor household's health care spending. Though reliable data on drugs spending in low income countries are still scarce, indications are that 50–90% of out-of-pocket spending is for drugs, depending on the level of health care. Drug prices, in the context of a patient in a low income country health care setting, thus figure very highly as a factor influencing access to care. Furthermore, drugs prices for newer medicines in low income countries are sometimes equal to or higher than those in developed countries.

Access to essential drugs: four factors, five groups of actors

WHO and its partners recognize four key factors which influence access to drugs: rational selection and use, affordable pricing, sustainable financing, and reliable health and supply system. Many different actors have roles to play in making these factors into enabling forces, rather than obstacles. Five actors are of particular importance in this context:

- The **governments of developing countries**, overall stewards of each country's health system, are responsible for its performance and regulation.
- **Governments in industrialized countries** may use technical and financial assistance to support the domestic policy of many developing countries directly, and indirectly.
- The **pharmaceutical companies** develop, produce and market medicines, with research-based and generic companies each playing crucial roles.
- **Consumer groups and non-governmental organizations** have played an important role as advocates of patients' interests, in both developed and developing countries. NGOs are sometimes major health service providers in low income countries.
- **International agencies and foundations** - including WHO, UNICEF, UNAIDS, UNFPA and the World Bank - also play a role in supporting better access to essential drugs.

Differential pricing of essential drugs: what do we mean?

Differential pricing - also referred to as "equity pricing" or "preferential pricing" - refers to the concept that essential drugs prices should in some way reflect countries' ability to pay as measured by their level of income. The goal of differential pricing is to help ensure that price is not a barrier to low income countries securing access to essential drugs for their populations, price being one of the four essential components of access to essential medicines.

Experience to date with differential pricing: lessons for the future?

Though definitive conclusions are not possible from the brief overview of experiences with differential pricing, the following observations are suggested by these experiences. It will be important during the workshop to confirm or modify these observations to draw lessons for future work.

- Long term and sustainable reduction in the burden of disease is the criterion on which pricing and other access initiatives should be judged.
- Experience with contraceptives and vaccines points to the importance of bulk purchasing, even for on-patent drugs. Prices of 1% to 5% of high income market prices have been achieved. Scale economies in manufacturing and product uniformity have also aided differential pricing. For vaccines,

two broad price bands, one for IDA-eligible low income countries, and one for the rest of the world, has emerged as the most feasible approach.

- Recent experience with drugs for major communicable diseases has shown that advocacy, negotiation and competition have contributed in different degrees to lower prices for second-line TB drugs and antiretrovirals.
- Achieving market segmentation is more of a challenge with drugs than vaccines, and its effective working depends on action by governments, regulatory agencies and donors as well as manufacturers.
- Consumer and public interest groups have played an important role in publicizing price as an access barrier, and in increasing price information.

Framework for dialogue: questions, principles and options

The second half of the paper addresses the following ten questions, with draft principles and options as a framework for dialogue:

1. **Priorities -** *Which health problems and products should be priorities for differential pricing?* Burden of disease and comparative safety and efficacy of alternative treatments - standard criteria for selecting essential drugs for national lists - are primary considerations. Cost-effectiveness analysis may contribute to decision-making. Diagnostics for common health problems should also be considered.

2. **Target countries -** *Which countries should benefit?* If national income criteria are used, then the choice of countries could range from the 33 countries (654 million people) in the Low category of the Human Development Index to the 78 countries (2,326 million people) which are IDA-eligible (GNP less than $885).

3. **Mechanisms -** *How can differential pricing be achieved in the context of international agreements?* Differential pricing can be achieved through normal market mechanisms, negotiated price discounts, or licensed competitive production. Each of these options can be pursued within international agreements, national law, and available safeguards.

4. **Price reduction -** *What else will contribute to lower prices?* Adequate and sustainable domestic and international financing, therapeutic competition, concentration of demand through pooled procurement arrangements, improved distribution efficiency, elimination of tariffs and taxes, better governance, and other factors can each contribute to achieving the best possible prices.

5. **Target price -** *Should a "target price" be set for individual products?* Setting a target price, though technically difficult and perhaps undesirable to some stakeholders, can be invaluable in negotiation, other price reduction strategies, and in monitoring progress. Possible benchmarks include marginal cost of production, existing therapeutic alternatives, a specified level of developed country prices (e.g. under 5%) , or a ratio of annual treatment cost to per capita GNP.

6. **Financing -** *How could differentially priced drugs be financed?* Increased domestic public financing, expanded social health insurance, greater employer health spending, use of debt relief resources, and substantial increases in international donor funding for the poorest countries could each contribute.

7. **Purchasing and distribution** - *Who should purchase and distribute differentially priced drugs?* Potential purchasers include public sector national health services, non-governmental organizations, private health services, and private pharmaceutical supply channels. International purchasing funds can play an important role in achieving better prices and attracting donor funding.

8. **Preventing diversion** - *How can diversion away from intended countries and populations be prevented?* Preventing diversion to unintended markets, especially back-flow to high income countries, will be critical to the long-term viability of differential pricing schemes. Manufacturers' market segmentation technology, purchaser undertakings, and regulation all have roles.

9. **Ensuring political support -** *How can developed countries be persuaded not to demand the same low prices?* Adding a high volume, low margin market in developing countries would not be expected to raise prices in developed countries. Advocacy and public awareness are needed.

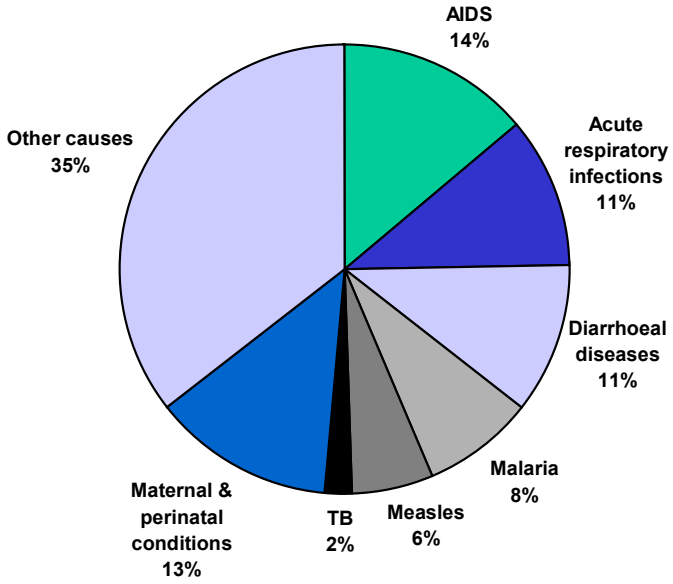
10. **Sustainability and dependability -** What mechanisms are needed to ensure sustained and dependable differential pricing? Existing discretionary decisions by individual companies could be supported by tax or other financial incentives, international agreements on differential pricing for low income countries, monitoring and publication of companies' performance on differential pricing.

Part A: Context and experience

1. The context: disease burden, health systems and access to essential drugs in low income countries

"Despite the long list of successes in health achieved globally during the 20th century, the balance sheet is indelibly stained by the avoidable burden of disease and malnutrition that the world's disadvantaged populations continue to bear…Reducing the burden of that inequality is a priority in international health. Furthermore, it can be done –the means already exist".[1] In Africa and South-East Asia prompt diagnosis and treatment could save an estimated four million lives each year. Two thirds of all deaths of children under 15 are due to seven diseases for which effective prevention and treatment exist.[2] Put simply, people are dying because the drugs they need are not available to them. The opportunities for rapid health gain through better access to available health technology are immense.

Figure 1. Two out of three deaths among children and young adults in Africa and South East Asia are due to seven causes - Ages 0 – 44



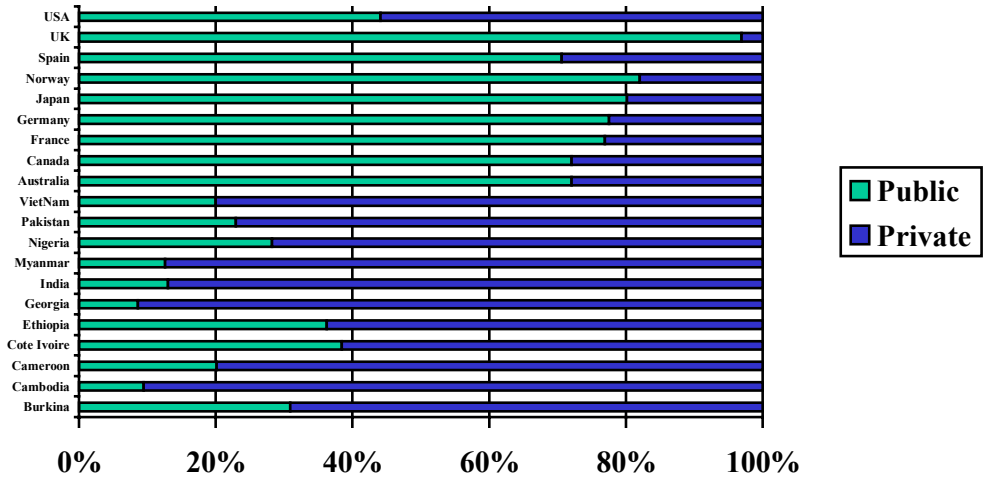
Source: Communicable Diseases, World Health Organization, 1999

Despite their poverty, some low income countries, such as Senegal and Nicaragua have performed relatively well in meeting the health needs of their populations. Yet the world's poorest people too often are served by the most poorly performing health systems[3]. In the low income countries* as a group, health outcomes are below what is attainable, and health systems are unresponsive and unfairly financed.

A major factor in this poor performance lies in the way health care is financed in low income countries. In marked contrast with the industrialized countries of the OECD, health care in low income countries is predominantly financed privately. The following figure shows dominance of private finance for health in eleven low income economies and the importance of public finance in 9 OECD countries. The top part of the figure shows the situation in OECD countries, the bottom part the situation in developing countries.

* For alternative classifications of countries based on income level or stage of development see table in Part B, Section 2.

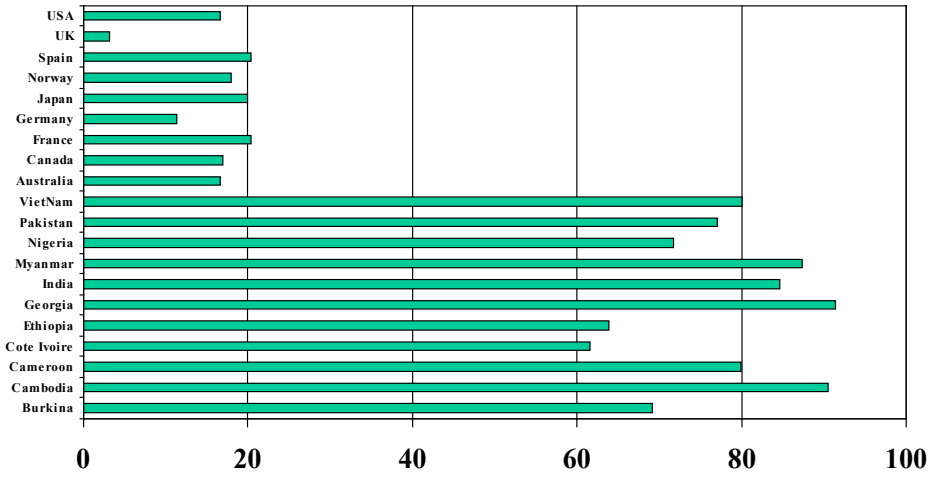
Figure 2 : Public and private shares in health financing differ in high and low income countries



Source: World Health Report, 2000

By far the most common private finance mechanism is out-of-pocket payment, made at the time people seek care, rather than as a prepayment scheme. Figure 3 shows, for the same group of 20 countries, that out-of-pocket payment in the industrialized group seldom exceeds 20% of total while it exceeds 90% in some low income countries. Protection by social insurance coverage is very low, covering less than 8% of Africa's population[4], and publicly subsidized health services (where patients commonly pay for prescribed medicine) are geographically skewed towards principal urban centres.

Figure 3: Out of pocket payment as % total health expenditure is more important in low income countries

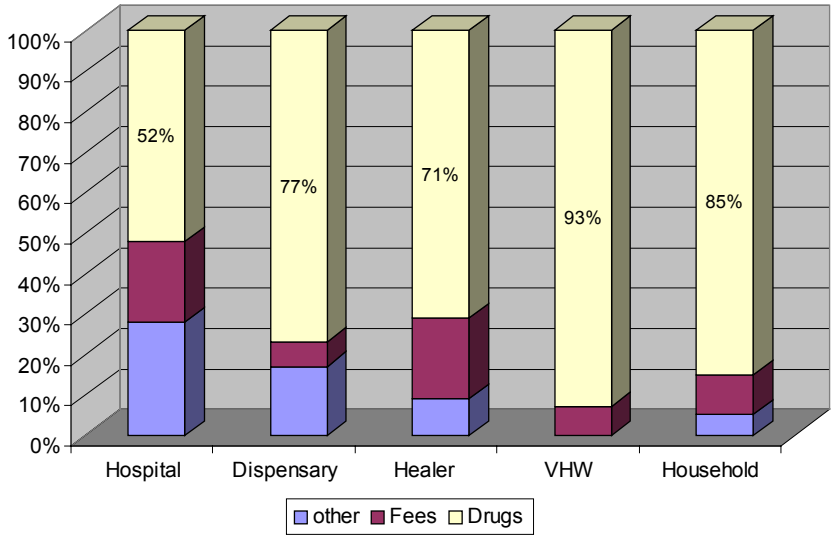


Source: World Health Report, 2000

Out of pocket payment for health care tends to be both inequitable and inefficient when it plays a major role in health financing. Evidence on the distribution of the health financing burden shows that the burden of payment for health care falls heavily on the poorest households at the time when a family member is sick. Drugs are typically the principal component of a poor household's health care spending.

Though reliable data on drugs spending in low income countries are still scarce, the data in Figure 4 show that 50-90% of out-of-pocket spending is for drugs, depending on the level of health care.

Figure 4: Private spending for health is dominated by drugs, Burkina Faso, 1995



Sauerborn,R.; Nougtara,A.; Borchert M; Hien M; Benzler J; Koob E; Diesfeld,H.J. The economic costs of illness for rural households in Burkina Faso. Trop.Med.Parasitol: (46) 54-60, 1995.{ID:51}

WHO's own estimate for Burkina Faso is that just under 70% of total health spending is out-of-pocket[I] which puts total household drugs spending in that country for 1997 at US$3 to US$5.40, or between $35 million and $63 million. A similar calculation for India (out-of-pocket about 85% of total health spending) puts annual average household spending for drugs at $16, and total household spending for drugs at $16 billion.

Drugs prices, in the context of a patient in a low income country health care setting, thus figure very highly as a factor influencing access to care. Getting care means buying drugs more often than having a consultation with a qualified health worker. These drugs come from a variety of providers, licensed, unlicensed, traditional and modern. Unmediated by prepayment, prices, which are sometimes higher than those in richer countries, fall wholly on sick persons and their relatives. Illness and injury are common causes of indebtedness and deeper poverty[5]. Public and private foreign assistance, though an important part of the global picture, often has little impact on the everyday life of poor people as they seek care.

2. Access to essential drugs: four factors, five groups of actors

Essential drugs and key pharmaceuticals

The established definition of essential drugs is as follows: *Essential drugs are those drugs that satisfy the health care needs of the majority of the population, they should therefore be available at all times in adequate amounts, and in the appropriate dosage forms, and at a price that individuals and the community can afford*[6].

For the purpose of this paper and the WHO-WTO workshop, however, the term "essential drugs" is used in a more broad sense and does not specifically refer to the drugs on the WHO Model List of Essential Drugs. In Part B of this paper, in particular, the phrase "key pharmaceuticals" for priority problems is employed[7]. This helps to keep discussion open-ended and to include new generations of safe and effective drugs which deal with major disease problems.

Access factors

WHO and its partners recognize four key factors which influence access to drugs: rational selection and use, affordable prices, sustainable financing, and reliable health and supply systems[8]. Many different actors have roles to play in making these factors into enabling forces, rather than obstacles.

- **Rational selection and use** requires defining what drugs are most needed and ensuring that they are used as intended. This involves 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, training and supporting health professionals in effective use of the drugs, and promoting rational use by consumers.
- **Affordable prices** depend on, among other things, transparent price information for healthcare providers and consumers, competition among quality generic drugs for off-patent drugs, negotiation and therapeutic competition for on-patent drugs, use of TRIPS safeguards as needed[9], reduced duties and taxes, improved distribution, and promotion of reasonable dispensing margins.
- **Sustainable financing** requires reliance on all viable financing mechanisms, including public revenues, social health insurance, better use of out-of-pocket spending, and international financing through grants, donations, and loans under appropriate circumstances.
- **Reliable health and supply systems** are needed to ensure continuous availability and assured quality of essential medicines. Supply system improvements are central to health sector development. Many countries have made progress through a creative and efficient mix of public, private, and NGO roles in pharmaceutical supply systems. Effective drug regulation, including drug quality assurance for both imported and locally produced drugs, is vital.

Key actors

The **governments of developing countries**, overall stewards of each country's health system, are responsible for its performance and regulation. Many governments are implementing far-reaching reforms, designed to improve access to services of good quality from both public and private providers. Effective regulation of drugs purchasing and distribution, and of tax policy towards essential drugs, are also government responsibilities. Public budgets for essential drugs could be increased, as these are often key inputs in the most cost-effective interventions for better health. Some governments have come together in purchasing groups in order to achieve better prices by economies of scale (e.g. Eastern Caribbean Islands, and Arab Gulf countries). Other public tasks are to ensure that the costs of health care are shared among the population in rough proportion to people's disposable income – fair financing – and that the health system responds to legitimate expectations.

Governments in industrialized countries may use technical and financial assistance to support the domestic policy of many developing countries directly, and indirectly through the incentives they can

give to manufacturers to produce appropriate products and make them available at affordable prices. Governments, whether in industrialized countries or in low and middle income countries such as India and Brazil, have to balance economic and health policy interests in their dealings with manufacturers. Most industrialized countries employ a variety of drug price control policies[10].

Manufacturers' principal role is in discovering, making and selling effective drugs for major health problems. The most powerful incentives are in the large markets of the high income countries, and product development history reflects this. Only 13 of 1233 new drugs that reached the market between 1975 and 1997 were approved specifically for tropical diseases[11]. Manufacturers' influence over prices reflects the degree of competition for "therapeutic equivalents": prices tend toward the lowest achievable when there are five or more competing products ("rule-of-fives"). In non-competitive situations, such as patent protection confers for a defined period, price can be set (or negotiated) according to what markets will bear. Recent levels of profitability of the research-based pharmaceutical sector, differences in prices between different national markets, and the gap between price levels and affordability of HIV/AIDS drugs in the worst affected parts of the world, have brought drugs prices into growing prominence.

Consumer groups and non-governmental organizations are long-term major supporters of the essential drugs concept - with its focus on equity and access - both through their advocacy and through their use of the model list of essential drugs in emergency relief and health development work. In many developing countries, particularly in sub-Saharan Africa, public interest NGOs play a significant role in the provision of health care. NGOs have drawn attention to the fact that some drugs prices are higher in low income than in richer countries. Most recently, some of these groups have conducted campaigns to highlight concern about pressure on developing countries not to draw on TRIPS compliant safeguards, and on the possible impact of new international trade agreements (such as TRIPS) on drug prices and access.

International agencies and private foundations also play a role in supporting better access to essential drugs. This is part of WHO's mandate as the global health agency, of the WTO in promoting open trade, the World Bank in making grants and loans available as a central part of its Population and Human Resources lending, UNICEF and UNFPA as global purchasing bodies for vaccines, contraceptives and some drugs, and UNAIDS representing the rights and needs of people living with HIV/AIDS everywhere. The Rockefeller Foundation, the Gates Foundation and several other private foundations are also very active on issues of access to essential medicines.

Progress towards improved access, through a focus on financing and differential pricing, will thus involve actions by each of these broad groups, working in a coordinated manner toward a defined goal.

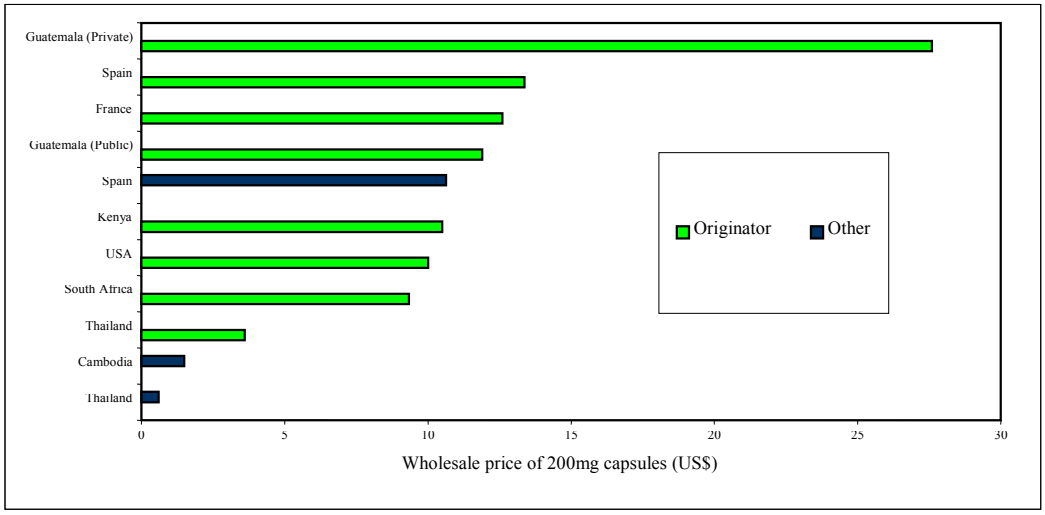
3. Differential pricing of essential drugs: what do we mean?

As with many other commodities, retail price differences, sometimes substantial, for the same drug exist within and between countries. The US General Accounting Office has drawn attention to price differences between the US, Canada and the United Kingdom.[12,13] For selected generic tuberculosis drugs, Laing and McGoldrick[14] have shown a 95-fold international price difference for ethambutol 100mg between the private sector in the US and the tender price in Zimbabwe, and a 27-fold variation for rifampicin and isoniazid 150/100mg combination tablets, between the public sectors in South Africa and India.

Figure 5 shows that drugs are not necessarily priced lower in low income countries or in countries with a higher incidence of the infection. The wholesale price of fluconazole, an antifungal used in the treatment of cryptococcal meningitis associated with full blown AIDS and usually resulting in death if not treated, shows variations unrelated to national income.

International price comparison in the field of pharmaceuticals is subject to many pitfalls[15], and retail prices, in particular, are often a far-distant relation to manufacturer's selling price (MSP). Import duties, taxes, wholesale and retail mark-ups, both formal and informal, can double the price of a drug between manufacturer and consumer. For the purpose of the WHO-WTO workshop discussions, the relevant price is MSP, not retail price but domestic and foreign assistance should recognize the importance of bringing these local additions to MSP under scrutiny and control.

Figure 5. Wholesale prices of originator and generic fluconazole in developing and developed countries.



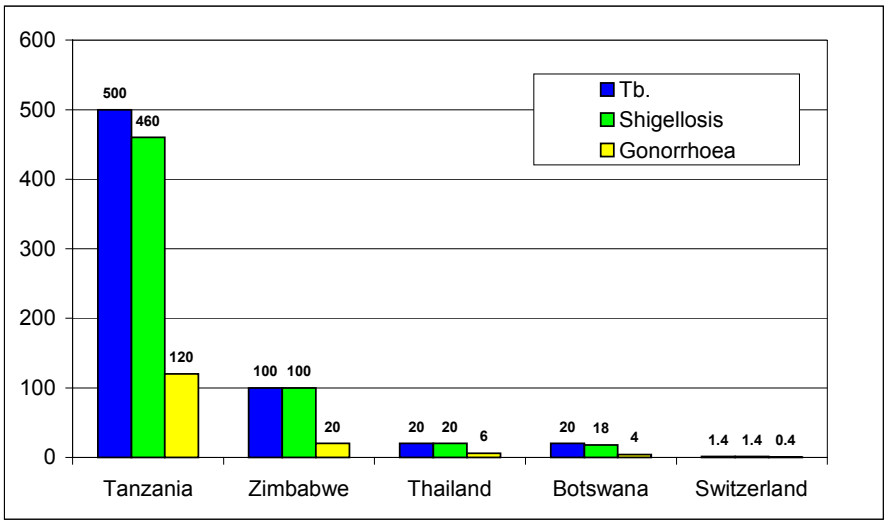
Source: C. Pérez-Casas, HIV/AIDS Medicines Pricing, Report (www.accessmed-med.org).

Establishing a policy of differential pricing means setting lower manufacturers' selling prices for the target group of low income countries than are charged in other markets. As now with vaccines, this means a single differential, creating a two tier market between richer countries where prices are set as currently and low income countries in which a substantially lower price is charged. The term "tiered pricing" is used in describing differential pricing regimes for vaccines. It is also used to describe the practice of setting prices according to individual markets for commercial purposes. To avoid possible confusion between these two uses, this term is not used in this paper.

WHO's Director-General has publicly called for movement toward "equity pricing" and this means exactly what has just been described. For convenience at this workshop, the terms "equity pricing" and "differential pricing" will be used interchangeably. Both mean a significantly lower manufacturers' selling price for a selected number of essential drugs for low income countries.

Several approaches to defining levels of differential prices are discussed in the "framework for dialogue" section. An easy and useful gauge of "affordability" is the ratio of cost of treatment (drugs price per episode for acute or per month for chronic conditions, for defined conditions) to average income or earnings. In Figure 6 this relationship is shown in terms of the number of hours, at local wage rates in different countries, required to pay for the full treatment course for three conditions, using uniform prices. The ratio of treatment costs to earnings or income in industrial countries should be regarded as setting an upper limit to affordability in low income countries, which lack financial risk-sharing through insurance or well developed subsidy schemes.

Figure 6: Cost of treatment in working hours, three conditions in five countries.



An alternative approach would be to express treatment costs in relation to annual per capita spending for health (all sources), for which the annual World Health Report now publishes estimates. However, per capita annual income is probably an easier figure for most people to relate their own situation with than per capita spending for health.

4. Experience to date with differential pricing: lessons for the future?

4.1. Vaccines

An extensive project is in operation to supply vaccines at special prices for use in low income populations.[16] Differential pricing has been implemented, with prices as low as 1% of those applicable in the US. Special provision has been made for independent quality control.

In 1994, UNICEF and WHO developed a strategy for targeting assistance for vaccines to countries based on their income level and population size.[17] The first step was the development of a grid to differentiate countries that were capable of producing their own vaccines from those unable to produce or purchase vaccines, according to their GNP/capita, total population size and total GNP. UNICEF overlaid the grid with a series of four bands that divided the world from poorest to richest nations having varying degrees of capability to develop their own vaccine programmes. The "banding" strategy was intended in part to encourage vaccine producers to apply differential pricing policies for traditional and newer vaccines.[18] In practice, two price bands are now being used: a low price for the IDA-eligible countries, and a higher price for the rest of the world. The former Children's Vaccine Initiative and its successor the Global Alliance for Vaccines and Immunizations have proposed market segmentation for the very poorest countries only.

In UNICEF's 1996-1997 tender for vaccine supply, it requested that new vaccines be supplied at prices which developing countries could afford; in exchange manufacturers were offered a series of new options.[19] For example, the tender proposed to offer a single buyer from private industry a large market made up of a host of small markets in the poorest developing countries. Further, it offered to limit supply of low-price vaccines to the neediest countries. Finally, UNICEF offered to guarantee long-term (up to four years), large volume (i.e. 3 million doses per month) purchases of traditional paediatric vaccines and the bundling of its guaranteed purchase of traditional vaccines with the supply of new vaccines. The tender also indicated that bids would be ranked not only according to price but

also according to other value criteria (i.e. immediate priorities and future priorities related to vaccines in development). These initiatives have contributed importantly to the growth in the global vaccine market over the last decade.

4.2. Contraceptives

Various agreements have been concluded, particularly under the auspices of the International Planned Parenthood Federation, UNFPA and the Rockefeller Foundation, to supply hormonal (and other contraceptives) at very low prices to participating countries. Few of the products involved are patented, though several are expensive. Some countries are now able to obtain contraceptives for as little as 1% of US prices. It has been possible to avoid back-leakage to the US market.

In 1997, a US manufacturer planned to launch the three-month injectable contraceptive medroxyprogesterone (Depo-Provera) in Brazil with a high-price niche market strategy.[20] They intended to sell 100,000 units by 2001. The Futures Group International (TFGI), with the support of USAID, alternatively proposed that if the new contraceptive was priced at a similar price to a three-month cycle of pills, and if marketing was aimed at middle- and lower-income consumers, then 350,000 units could be sold by 2001. The company agreed to the price decrease and TFGI, with US$1 million from USAID undertook a direct-to-consumer marketing campaign in support of the product launch. As sales in 1997 exceeded expectations, projections for 2001 were increased to 520,000 units.

4.3 Drugs

Differential pricing

To ensure the supply of quality-assured drugs for the treatment of multidrug-resistant tuberculosis (MDR-TB) for DOTS-Plus pilot projects, an arrangement has, as of 2001, been concluded with one research-based company and several generic manufacturers to supply six classes of second-line anti-TB drugs (variously under patent, in non-patent monopoly and having generic status) at a standard price that is as low as 5% of what some countries are currently paying for an individual drug. Provisions have been included to prevent backflow of these preferentially priced drugs into high-price markets. Médecins Sans Frontières (MSF) has been designated the procurement agency for the short-term supply of these drugs, and the International Dispensary Association (IDA) will be designated for extended supply. WHO has worked closely with MSF and IDA to quantify global demand for these drugs and to negotiate agreements with manufacturers[21].

An anti-malarial, artemether-lumefantrin, produced by a European research-based manufacturer is now supplied at different price levels under two different names and with distinctive packaging for each. One brand name is marketed in industrialized nations to travellers at standard price, while the identical product, under a different brand name, is made available at about one fourth of the standard price to the private market in endemic countries. Currently, WHO and the manufacturer are developing an agreement to make the endemic country version available for the public and not-for-profit private sector in endemic countries at one fifth of the price for private market use. The low price version will be delivered in a distinctive packaging to improve patients' adherence to treatment, and will be supplied through the WHO supply system.

Initiatives on drugs for HIV/AIDS

Prior to very recent price reductions announced by individual companies, back in 1997 the Joint United Nations Programme on HIV/AIDS (UNAIDS) announced the UNAIDS HIV Drug Access Initiative. The pilot programme was a collaborative effort between three pharmaceutical companies and health officials in Chile, Côte d'Ivoire, Uganda and Viet Nam. In each country a nonprofit company served as a clearinghouse for placing orders and receiving drugs on behalf of the government. Drug price subsidies were negotiated individually between each country and the

pharmaceutical companies. UNAIDS donated US$1 million to help improve the infrastructure in each participating country in order to facilitate the distribution and proper use of treatments.

A preliminary report of the initiative in Côte d'Ivoire was published in 2000.[22] Although discounts were negotiated by UNAIDS on antiretrovirals, the cost of a month's supply nevertheless remained far too high for most people in Côte d'Ivoire. Consequently, a programme was designed to provide the medicines at subsidized prices ranging from 50 to 95 per cent of cost, according to each person's socioeconomic conditions, but the numbers having access remained tiny. The subsidies were supported by a special 'Solidarity Fund' established by the government which it hopes will be replenished by corporations, donor agencies and through special taxes.

The preliminary report on the UNAIDS initiative by the Uganda Ministry of Health[23] reported that access to antiretroviral therapy remained extremely limited due to the high cost and technical challenge of administering and monitoring the medications.

Finally, a review of the experiences with the four Drug Access Initiative countries indicated that considerable logistical and clinical experience had been gained, best practices for managing ARV care in resource-constrained settings were evolving, and important though modest progress had been made on reducing prices. The review concluded that the "hook" effect of antiretrovirals to promote wider access to a comprehensive care package should be strengthened, the feasibility and sustainability of the monitoring of antiretroviral therapy should be improved, the procurement and distribution of the HIV/AIDS drugs including antiretrovirals should be integrated into the national pharmaceutical structures, and a multipartite approach for funding should be advocated, involving other stakeholders than the governments and international donor community.[24]

In May 2000, five major research-based companies announced their intention to work with UNAIDS, WHO, and other UNAIDS partners to expand access to care and treatment for HIV/AIDS through the Accelerating Access Initiative. The combination of negotiation and competition which followed the announcement has led to major reductions in the price of several drugs for HIV/AIDS. At the time of the May 2000 announcement, one company began an initiative to provide courses of anti-AIDS drugs for use by African governments at $2 a day rather than the usual $16.[25] This was followed by negotiations with individual countries and price reductions by the five companies in the Initiative.

A competitive offer from a generic manufacturer in February 2001 to make triple therapy for treating HIV/AIDS patients in Africa available at $600 or less for a year's course was followed by additional offers from the research-based and generic industries. In March 2001 another research-based company agreed to make two of its HIV/AIDS drugs available at $1 per day and is making patent rights to one of the drugs available at no cost for treatment of HIV/AIDS in Africa. The net result of these various offers has been prices for triple therapy as much as 95% below the initial developed country price .

The Initiative was welcomed and expectations from countries were high[26], though the price reductions were initially criticized as "modest" in comparison with those secured in other fields, such as vaccines. Initial progress has been slow, as a precondition of participation is that countries have to develop HIV care strategies and action plans. At the same time, it can be argued that the initiative has started a chain reaction of price reductions that are already bringing the price of triple therapy well below $500 per year.

The largest example of sustained differential pricing for HIV-related drugs is from Brazil. Between 1996 and 2000 Brazil substantially increased large-scale production of antiretroviral drugs. By 2000 there were 11 local producers with two to six producers for each of 12 different ARVs or ARV combinations. Between 1996 and 2000 the average price reduction for domestically produced drugs was 73%, compared with 8% for single-source products.[27]

Donations

Well designed long-term donation programmes can make major contributions to better global public health, particularly when directed at time-limited needs such as disease eradication. At the same time, for many of the most common problems responsible for high disease burdens, donated drugs are unlikely to be a sustainable solution to meeting long-term country needs.

Corporate donation programmes have sometimes been an accompaniment to a uniform or global pricing strategy. Since 1987 Merck & Co Inc have made ivermectin available free of charge for the treatment of onchocerciasis. SmithKline Beecham has donated 500,000 doses of its meningitis vaccine to the WHO for use during epidemics in the African 'meningitis belt'. Glaxo SmithKline (then SmithKline Beecham) announced its commitment to support the global programme to eliminate lymphatic filariasis. GSK committed to the donation to WHO of the entire supply of albendazole, one of the drugs in the recommended two drug combination, for free supply to filaria endemic countries until the achievement of elimination. Subsequently Merck pledged to expand its ongoing Mectizan Donation Program for onchocerciasis to cover treatment of lymphatic filariasis in all African countries where the two diseases occur together.

In August 1999, Novartis signed an agreement with WHO and pledged to provide WHO with adequate quantities of antileprosy multidrug therapy (MDT) for all patients in the world until the end of 2005, together with funds for shipping and independent quality control.

In July 2000, Boehringer Ingelheim announced that it would offer nevirapine free of charge to any developing country with an operational system to administer the drug properly for the prevention of mother-to-child transmission of HIV, for a period of five years.

A strategy used by some companies has been to maintain a fairly uniform price across countries, but for public health programmes to lower the effective price to programmes by combining "list price" sales with donations. For example, purchasing one unit at list price and receiving 2 units of a product as a donation. This approach provides less price transparency than differential or discount pricing.

4.4. Observations for more widespread differential pricing of essential drugs

It is not possible to draw definitive conclusions from the above brief overview of experiences with differential pricing. However, the following observations are suggested by these experiences. It will be important during the workshop to confirm or modify these observations to draw lessons for future work.

Indications of success

- The criterion by which any initiative should be judged is its long-term contribution to reducing the burden of disease on poor people and, thereby, contributing to long-term development.
- An initiative's contribution to countries' long-term ability to meet their own needs is also important.

Long-term experience with vaccines and contraceptives

- Global and regional bulk purchasing has played an important role in the vaccine and contraceptive experience with prices.
- Scale economies, product uniformity and a controllable supply chain were important factors in the development of vaccine differential pricing.
- Large institutional buyers such as UNICEF and UNFPA can negotiate a package of conditions even for on-patent drugs aimed at serving both the buyer and seller.

Recent experience with drugs for tuberculosis, HIV/AIDS, malaria

- Negotiation based on volume purchasing and some degree of competition has lowered prices for second-line TB drugs.

- Negotiated moves towards differential pricing for HIV-related drugs have thus far benefited relatively few people, but these initiatives are in their early stages.
- Recent antiretroviral price offers by individual companies show remarkably fast change; advocacy and competition appear to have contributed to recent rapid price decreases and at least one company is offering a patent waiver for Africa.

Achieving differential pricing

- Market segmentation is more of a challenge with drugs than vaccines, and its effective working depends on action by governments, regulatory agencies and donors as well as manufacturers.
- Consumer and public interest groups have played an important role in publicizing price as an access barrier, and in increasing price information.
- Two broad price bands – for low income countries, on the one hand, and the rest of the world, on the other – may be the most feasible approach to differential pricing for essential drugs.
- Long-term experience with pharmaceutical pricing indicates that the lowest prices generally are achieved only when there are five therapeutic alternatives or five competing producers of drugs of assured quality ("rule-of-fives" competition).

Part B: A framework for dialogue

The **goal of differential pricing** is to help ensure that price is not a barrier to low income countries securing access to essential drugs for their populations, price being one of the four essential components of access to essential medicines.

Differential pricing is intended as a more systematic approach to favour low income countries than is possible through ad hoc discounts offered at the discretion of individual companies. Differential pricing describes an intended outcome (lower prices for those most in need) that can be achieved through several possible mechanisms outlined below.

Questions, principles and options

The following pages pose 10 key questions concerning differential pricing. For each question, several options are presented and analysed. Within each section some options may be mutually exclusive. In general, however, the options presented could be adopted in various combinations. These ten questions suggest principles for guiding the development and implementation of a systematic approach to differential pricing for drugs needed for priority health problems. The questions are as follows:

1. Which health problems and products should be priorities for differential pricing?
2. Which countries should benefit?
3. How can differential pricing be achieved in the context of international agreements?
4. What factors will contribute to lower price?
5. Should a "target price" be set for individual products?
6. How would differentially priced products be financed?
7. Who should purchase and distribute differentially priced drugs?
8. How can diversion away from intended countries and populations be prevented?
9. How can developed countries be persuaded not to demand the same low prices?
10. What mechanisms are needed to ensure sustained and dependable differential pricing?

1. Which health problems and products should be priorities for differential pricing?

Principle

Differential pricing should be available for life-saving and life-extending drugs for priority health problems.

Options and issues

Issues and options to consider include the following:

1. **Burden of disease** - Priority should be given to ensuring differential pricing for products which address the greatest burden of disease in developing countries. Currently, priority products are likely to be HIV-related drugs; drugs for multi-drug resistance tuberculosis (MDR-TB); antimalarials; antibiotics for resistant strains of sexually transmitted infections, and antibiotics for common childhood illnesses for which resistance to first line drugs has developed (e.g., a growing percentage of bacterial pneumonias and bacterial meningitis).

2. **International list or individual country lists** - Should key pharmaceuticals for differential pricing be identified through an international process or through individual national processes? A national approach might allow greater responsiveness to local conditions. At the same time, there are distinct advantages in an internationally determined list when consideration is given to the relative similarity of morbidity patterns among countries within a region, the benefits of pooled procurement, production logistics, and other factors.

3. **Identification of specific products for differential pricing** - The list of products addressed by differential pricing will by its nature be dynamic. Factors affecting the list include changing patterns of disease, antimicrobial resistance patterns, development of new therapeutic options, and the impact of price competition when key pharmaceuticals come off patent. The WHO Model List of Essential Drugs, WHO treatment guidelines, and national lists of essential drugs provide reference points for identification of priority products. The process for updating the WHO Model List of Essential Drugs, currently under review, is moving toward a more systematic evidence-based approach which focuses first on burden of disease and comparative safety and efficacy of alternative treatments.

4. **Cost-effectiveness considerations** - Adding a cost-effectiveness criterion would help direct domestic as well as international funds to those treatments which could achieve the greatest health impact on poor populations for a given expenditure. Established mechanisms exist for cost-effectiveness analysis, though there continue to be different views on methods and assumptions used in these analyses. Cost-effectiveness calculations would clearly be dependent on price levels and could therefore change over time - perhaps quite dramatically.

5. **Diagnostics as well as pharmaceuticals** - For a number of priority health problems, including most notably HIV/AIDS, diagnostics have an important role in ensuring accurate diagnosis, proper drug therapy, and overall quality of care. In principle, the same process which is used to achieve differential pricing for key pharmaceuticals could be used for diagnostics.

2. Which countries should benefit?

Principle

Differential pricing for key pharmaceuticals* should be made available to low income countries.

Options and issues

Options - eligibility based on income level or development	Countries Affected	Population affected	Explanation
1. Lowest income countries	26 countries	450 million	GNP less than US$350 per capita. Used as a category of analysis in the *World Development Report 1999*
2. Countries Low on Human Development Index	33 countries	654 million	UNDP *Human Development Report 2000*
3. Least developed countries (LDC)	48 countries	629 million	Official classification system of the UN General Assembly based on a number of agreed criteria
4. IDA-eligible countries	78 countries	2,326 million	Criteria of the World Bank, International Development Association (IDA) include low GNP (current threshold US$885), lack of creditworthiness, and policies that promote growth and poverty reduction
5. IDA-eligible and/or high rates of poverty	86 countries	3,688 million	Countries which are either IDA-eligible and/or have 50% the population living on less than $2 per day

The least complex eligibility requirement would be to rely solely on one of the established income levels or development indexes listed above. Using any of the above criteria would establish effectively two pricing tiers, one for the low income and one for all other countries. Within the tier for "all other countries", considerable price variation can be expected, just as there is today.

A systematic multi-tier approach, based on national income bands is another option, (e.g., Band A under US $200, Band B US$200 to $350, Band C US$350 to $800, and so forth). Such a system has been long proposed for vaccines. In practice, however, the vaccine market has also tended to divide into two tiers: one tier for pooled procurement in developing country programmes and one tier for developed countries, with some degree of price variation within each tier.

In addition to a criterion based on income or national development, the following criteria could also be considered:

- Demonstrated commitment to improving health outcomes through an established criterion such as fair financing or a minimum per capita public expenditure on health or pharmaceuticals.
- Burden of disease for specific priority health problems.
- Other defined national performance indicators for health system development or pharmaceutical sector development.

* See Section 2 above for a discussion of "essential drugs" and "key pharmaceuticals"

In principle these additional criteria may increase the chance that reduced prices will contribute to improved health outcomes. In practice, such additional criteria may substantially complicate implementation of differential pricing.

3. How can differential pricing be achieved in the context of international agreements?

Principle

Any mechanism to achieve differential pricing should be consistent with international agreements, national legislation, and the available safeguards.

Options and issues

Options – may be used in combination	Comments
1. Patent holder remains the sole producer of the medicine and initiator of differential pricing	• This is the current situation in countries implementing the WTO TRIPS agreements and where the patent holder chooses to remain the single source supplier • Potential for high volume low margin market may allow pricing close to marginal cost of production • Non-competitive and therefore may not achieve the lowest possible prices • Arrangements with low income countries depend on active involvement of affected countries and transparent methods of work
2. Non-exclusive voluntary licensing with transfer of technology, geographic restrictions, and payment of royalties to the patent holder	• Non-exclusive arrangement encourages price-lowering competition • Depends on having a sufficient market (defined in purchase volume times price) to support competitors • Transfer of technology component consistent with TRIPS obligations (Article 66) if licensed to a least developed country • Controls needed to ensure that licensed producers do not produce for direct or indirect sale in markets other than those intended
3. Non-exclusive compulsory license with payment of royalties to the patent holder	• Provisions already exist within the TRIPS agreement • May be used for local production as well as importation (provided production in other countries is legal). May involve protracted and resource-intensive legal disputes between patent holder and applicant • No obligation on the part of patent holder to transfer technology • As with voluntary licensing, controls needed to keep products within intended markets
4. Waiver of rights by patent holder for specific countries or regions	• Already initiated by one research-based company for Africa • As with voluntary licensing, controls needed to keep products within intended markets

Transparency in negotiated arrangements may be important to indicate if countries are being asked to modify aspects of their national health and medicines policies or to waive rights which they have under international agreements.

With both voluntary and compulsory forms of licensed competition the patent-holder retains intellectual property rights. For compulsory licensing the TRIPS agreement specifies that the patent holder, "shall be paid adequate remuneration in the circumstance of each case, taking into account the economic value of the license" (Article 31). Royalties in the pharmaceutical sector are well documented. Typical pharmaceutical sector royalties are 5% to 10%, but may vary considerably according to the nature of the license (product, process) and other factors.[28]

4. What factors will contribute to lower price?

Principle

All relevant factors should be explored to help achieve the best possible price.

Options and issues

Options	Comments
1. Ensure adequate and sustainable financing through domestic and international sources	• See previous question, above • Best prices can be obtained with prompt and reliable payment by procurement agencies (public, private, or not-for-profit)
2. Maximise therapeutic and generic competition	• Therapeutic competition can be increased by ensuring that treatment guidelines and essential drug lists are informed by 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 non-exclusive licensing arrangements (to achieve "rule-of-fives" competition)
3. Lower distribution costs through improved efficiency, elimination of taxes and tariffs, and promotion of reasonable dispensing charges	• In low income countries the private sector selling price of a drug may be two to 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
4. Concentrate demand and increase volume through pooled procurement arrangements	• Experience with large scale pharmaceutical procurement indicates that increased purchase volume, prompt payment, and predictable future demand are major factors in achieving price reductions • National, regional, and international procurement each have a role, depending on the volumes and sources of the products involved
5. Improve supply management through better governance, management efficiency, and a mix of public, private, and NGO supply functions	• Domestic public confidence, donor confidence, and supplier confidence are all increased when supply systems are able to ensure prompt delivery with minimal losses • Many examples now exist of supply system improvements; but political commitment, solid management skills, and a realistic assessment of local supply options are required
6. Create tax or other incentives for producers who actively engage in differential pricing for low income countries	• Tax incentives have been effective in encouraging drug development for orphan diseases and drug donations • Tax incentives may create unintended adverse consequences which would need to be carefully considered in advance

Most of the factors listed here are covered under component 4 of the WHO access framework, "reliable health and supply systems." As such, they are the focus of national efforts and a variety of efforts by bilateral development programmes, WHO, other UN agencies, and many local efforts. These factors are not a primary focus for the WHO-WTO workshop.

5. Should a "target price" be set for individual products?

Principle

Differential pricing should aim for the best possible price for each product.

Options and issues

Options	Pros	Cons
1. Do not attempt to establish a target price for individual products	• Requires no action	• With no target price there is no benchmark for negotiation, other price reduction strategies or for assessing progress
2. Use existing therapeutic alternatives as benchmarks for comparison	• The price of existing treatments is generally known and therefore this is a relatively non-complex and transparent approach	• Price comparisons with existing treatments could be quite misleading unless the treatments were equivalent in therapeutic effect
3. Use marginal cost of production plus a percentage for profit as a target price	• Seemingly a logical and fair approach to achieve best prices for low income countries without generating losses for producers	• Learning a manufacturer's actual marginal cost of production has proven difficult in practice, except perhaps where production is publicly-owned
4. Suggest a target price of under 5% of the quoted price in developed countries	• Quoted drug prices ("list price") in most developed countries are known; therefore this benchmark is observable • Experience has shown that developing country prices may fall to as low as 1% to 5% of the developed country price for a product	• Actual experience demonstrates widely variable prices changes over time and under full competition • Used on a large scale this approach would create an incentive for producers to increase stated launch prices, further reducing price transparency
5. Suggest a target price using cost-effectiveness analysis	• Established methods exist and a growing number of countries are using cost-effectiveness analysis for reimbursement purposes	• Treatments which are relatively cost-effective may still not be affordable by low income countries • Though established methods exist, there are a number of methodological debates
6. Suggest a target price based on per capita GNP or average daily wage	• An annual treatment cost of not more than the average annual per capita income for a country has been described as an "affordable" target for public expenditures on treatment • A total cost per outpatient visit equal to the daily agricultural wage has been suggested as an "affordable" maximum for out-of-pocket payments	• The higher the prevalence of a condition, the less feasible is such an approach

Establishing a realistic target price can be an extremely useful tool in negotiation as well as for monitoring progress in differential pricing.

The above methods vary in their information requirements, complexity, transparency and level of technical feasibility. Some are more dependent on national circumstances, which limits their use for setting a global target price. The feasibility and implications of using each of the above methods could perhaps best be explored through case studies of past price reduction experiences and through analysis of a few current price reduction efforts.

6. How would differentially priced products be financed?

Principle

Purchase of key pharmaceuticals should be supported by increased and sustainable domestic and international financing, using all viable health financing mechanisms.

Options and issues

Options - used in combination	Comments
1. Increase domestic public financing in target countries	• Within their limited public sector budgets, spending priorities vary greatly among low income countries • Countries which relatively under-spend on health could be encouraged and supported in giving higher funding priority to health
2. Encourage increased funding of healthcare, including essential drugs, especially by employers with large numbers of low-wage employees	• Healthcare benefits vary in different labour markets, but there are examples to build on of relatively large-scale employers in Africa and Asia who have found it in their interest to provide a level of primary health care
3. Substantially increase international donor funding and private foundation funding for essential medicines and other essential commodities for low income countries	• Investing in the health of poor people is an investment in development; the effectiveness of development assistance aimed at poverty reduction and economic development depends greatly on improving the health of the population being assisted
4. Expand efforts to direct debt relief funds to essential medicines and other essential commodities	• Inclusion of essential medicines in poverty reduction strategies
5. Consider use of development loans	• Use of development loans from the World Bank and regional development banks for funding recurrent costs such as drugs and other essential commodities is a matter of debate. The case is strongest for diseases in which eradication or substantial reduction in prevalence is associated with significant development gains
6. Drug donations	• The aim of differential pricing is not for pharmaceutical companies to subsidize medicines in developing countries through below cost price or on-going donations • Nevertheless, drug donations provide a form of in-kind financing which is welcomed by many countries, provided that such donations are consistent with long-term solutions and do not undermine public health policy aims

The question of financing for differentially priced drugs can only be addressed in the context of overall healthcare financing and in close connection with the question of who should purchase and distribute differentially priced drugs.

7. Who should purchase and distribute differentially priced drugs?

Principle

Differential pricing should reinforce health systems which increase services for poor people through fair financing, responsiveness, use of all effective delivery channels, and quality of care.

Options and issues

Options - may be pursued individually or in combination	Comments
1. Public sector – national health services and social health insurance programmes	• Differential pricing should benefit first the public sector in target countries, including national health services and health insurance programmes directed at poorer populations • Providing differential prices only to the public sector may help to strengthen public sector services • At the same time, limiting differential prices only to the public sector limits the benefit to the large proportion of poor populations not currently served by the public sector (over 80% in many countries)
2. Non-governmental organizations, mission essential drug services, and other not-for-profit (NFP) health care providers	• NFP health services provide up to 40% of curative care in parts of Africa and Asia, including healthcare for the urban poor as well as cash-poor rural populations • Providing differentially priced essential medicines to NFP health services could help to sustain these services, which often provide efficient, quality healthcare
3. Private employers and health insurance schemes in sectors with large numbers of low income employees	• In developing countries, healthcare benefits vary greatly among employers with large numbers of low-wage employees • Providing access to differentially priced essential medicines to employers who are already providing essential health services, including essential drugs, will reinforce the role of employers in filling the health care gap • Supporting coverage of low income households through effective employer health services also reduces the burden on public services
4. Private sector retail channels	• 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 • Whether or not differentially priced drugs are available through the private retail sector, efforts can be made to improve affordability through lower distribution costs, elimination of taxes and tariffs, and reasonable dispensing charges.

The choice of health care settings to which differential prices are extended will have an impact on the volume of drugs involved (broader inclusion and higher volumes likely leading to lower prices) and on problems of diversion (the narrower the share of a country's health services which are covered, the greater will be the pressure for diversion of differentially priced drugs from that sector).

Within countries, there may be two or more pricing tiers - for example, one for the public sector, one for institutional private sector health services, and one for the private retail market.

International purchasing funds, such as the Global Drug Facility being implemented for tuberculosis, offer a mechanism to concentrate demand and attract donor funding for key pharmaceuticals. Drugs purchased through such funds potentially could be supplied through any of the above domestic delivery channels.

8. How can diversion away from intended countries and populations be prevented?

Principle

Regulatory, legal, product presentation, and other mechanisms should be used to ensure that products sold at differential prices benefit the intended countries and population groups.

Options and issues

Options - may be used in combination	Pros	Cons
1. Use pharmaceutical technology to support market segmentation by using different brand names, packaging, dosage forms and other measures	• 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	• Differentiation using these measures could be misperceived as differences in product quality
2. Use regulatory mechanisms to ensure that differentially priced products registered in target countries are not registrable in other countries	• Regulatory differences already exist, with mutual recognition of marketing authorization far from universal	• Use of regulatory measures to segment markets and differentiate products could be viewed as counter to harmonization efforts
3. Purchaser undertakings	• Purchasers have a strong incentive to reduce diversion as a matter of good management, regardless of the source of their products • Support to purchasers to prevent diversion also improves supply system efficiency	• Purchasing undertakings alone may be insufficient to control diversion • Not all purchasing agencies in resource-limited settings may be able to meet all undertakings
4. Export controls in target countries	• Stop diversion close to source and are thereby more direct	• Place additional burden on governments and systems in low income countries
5. Import controls in countries which are not target countries	• High and middle income countries are better resourced to control imports	• Requires efforts by a large number of countries who do not benefit either from lower prices or from production and sale of differentially priced products

Considerable practical experience exists in this area, though much of it is in private companies, private enforcement agencies, and other non-public entities. Case studies presented earlier in this paper and cases presented during the meeting illustrate some of the possible approaches.

Import and export controls may be necessary to ensure the market segmentation necessary for differential pricing of designated drugs to succeed in the interests of all parties. For drugs not involved in differential pricing arrangements, however, the full array of purchasing strategies, including importing patented products legally marketed at a lower price in another country ("parallel" trade in the conventional sense) should remain open to countries.

9. How can developed countries be persuaded not to demand the same low prices?

Principle

Low income countries should not be expected to contribute the same share as high income countries to R&D, shareholder returns, and other pharmaceutical costs.

Options and issues

Options	Pros	Cons
1. Global and national advocacy for differential pricing	• With almost any scenario success will depend on support from governments, companies, non-governmental organizations, international agencies, and other bodies in both developing and developed countries	• Healthcare payers in countries at all levels of development are acutely aware of rising healthcare costs, including pharmaceutical costs • Consumer and other advocacy groups in high income countries may seek similar price reduces in those countries
2. Ensure that differentially-priced products are sufficiently different that they can not reasonably be compared (e.g., different production line, packaging, dosage form)	• High levels of such differentiation already exists among products marketed in different regions of the world	• Such pharmaceutical and regulatory differentiation can be misperceived as differences in product quality
3. Use refund mechanisms, sale-donation combinations, and other mechanisms to make price differences less apparent	• Has been used in previous programmes to increase access to HIV-related and other drugs	• Can be seen as non-transparent

Healthcare systems and consumers in developed countries would continue to pay prices based on the full cost of drug development, production, marketing, administration, and shareholder returns. But the aim of differential pricing is not for healthcare systems and consumers in high and middle income countries to subsidize differential prices in low income countries. Neither is the aim for pharmaceutical companies to subsidize medicines in developing countries through below cost price or on-going donations.

As indicated in the options and issues presented above, it is proposed that a variety of mechanisms be used to achieve the lowest possible prices for low income countries, to pursue adequate and sustainable domestic and international financing, and to ensure that differentially priced drugs reach the intended beneficiaries.

10. What mechanisms are needed to ensure sustained and dependable differential pricing?

Principle

Low income countries should benefit from differential pricing for key pharmaceuticals in a sustaind manner according to their health needs, whoever the individual manufacturer may be.

Options and issues

Options - some mutually exclusive, but most may be used in combination	**Pros**	**Cons**
1. Leave entirely at the discretion of individual companies	• Approach which is least cumbersome and involves the least intrusion into private business	• Not predictable and may not be sustainable from the perspective of equitable access for low income countries
2. Monitor and publish league tables of company participation in differential pricing	• Provides a transparent and voluntary approach • Provides a specific indicator for directing political encouragement	• Ranking of an individual company will depend in part on the fit between its particular product range and the burden of disease in developing countries
3. Develop an international agreement on differential pricing for low income countries	• Could provide consistency and predictability for both producing countries and beneficiary countries	• Could be viewed as intrusive into private business
4. Create tax or other incentives for differential pricing	• Provides a voluntary, but structured approach	• Depends on individual national legislation

Low income countries and the international community working to help improve the health of low income countries are interested in expanding access to key pharmaceuticals by securing the lowest possible prices for these drugs on a sustainable and predictable basis, regardless of which company produces particular drugs. Companies are interested in responding to the market and to expressed needs, without being restricted or directed by international or national agreements over which they may have limited control. These two different interests underlie the development and analysis of options for achieving the principle that low income countries should benefit from sustainable and predictable differential prices.

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