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## **REPORT OF THE WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS\***

**World Health Organization and World Trade Organization Secretariats**  
Norwegian Foreign Affairs Ministry, Global Health Council  
8–11 April 2001, Høsbjør, Norway

This workshop was jointly convened by the WHO and WTO Secretariats, hosted and financially supported by the Norwegian Ministry of Foreign Affairs, co-financed by the Netherlands Ministry of Foreign Affairs and organized and planned with the assistance of the Global Health Council. This report seeks to describe the work done at the workshop, summarizing the principal issues identified and points made. It has been prepared by and under the responsibility of the WHO and WTO Secretariats.

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\* Background papers for the Workshop are available from the World Health Organization ([http://www.who.int/medicines/docs/par/equitable\\_pricing.doc](http://www.who.int/medicines/docs/par/equitable_pricing.doc)) and the World Trade Organization ([http://www.wto.org/english/tratop\\_e/trips\\_e/wto\\_background\\_e.doc](http://www.wto.org/english/tratop_e/trips_e/wto_background_e.doc)).

## **Executive summary**

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

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

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

## **Access to essential drugs**

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

## **Financing of health care and essential drugs**

The point was made that, even with low prices, substantially expanding access to essential medicines will require additional domestic and international financing for the purchase of essential drugs as well as for building effective health and supply

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

### **Differential pricing is necessary and feasible**

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

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

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

*Ways of giving effect to differential pricing* — A variety of options was put forward and discussed to carry forward the concept of differential pricing. These included creating the right conditions and leaving it to the market, the bilateral negotiation of price discounts between companies and governments, the use of regional or global bulk purchasing, the impact of moral suasion, the role of voluntary and, where necessary, compulsory licensing, and the establishment of a flexible, global differential pricing system. The role of donations was also considered. There was

discussion of the respective pros and cons of these approaches. Some argued that a global mechanism could be difficult to manage and have undesirable, unintended consequences while some others took the view that it would not be sufficient to rely on individual initiatives focusing on a limited number of drugs and countries. Some felt there is need for greater international cooperation to support differential pricing.

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

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

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

*Political feasibility* — There appeared to be a common view that preferential prices in developing countries should not be a factor in pricing in developed countries. Differential pricing policies hinge critically on the political acceptability of lower prices in poor countries. It was suggested that, in a climate of increasing international scrutiny of prices and growing direct and indirect reference pricing schemes, the industrialized countries may need to make undertakings not to use differential prices meant only for poor countries as benchmarks for their own price regulation systems or policies. A more difficult point was how to forestall differential prices being used in

the political process in these countries. Some felt that this required political leadership, advocacy efforts and public education. Part of this will be the need to reassure public opinion that lower prices in poor countries do not mean higher prices in rich ones or a greater burden on national health budgets. Also, consideration must be given to whether differentially priced products may be seen as a form of unfair competition by local industries in developing countries and possibly subject to recourse to anti-dumping relief.

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

#### **The role of intellectual property rights**

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

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

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

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

## REPORT OF THE WORKSHOP

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

This report summarizes the principal issues identified and points made. It cannot, by its very nature, provide a complete record of the totality of what was a rich discussion. The programme for the workshop can be found annexed to this report as can be a list of the participants. Presentations made at the workshop will be available through WHO and WTO web sites where texts have been provided.

### **1. Access to essential drugs in developing countries**

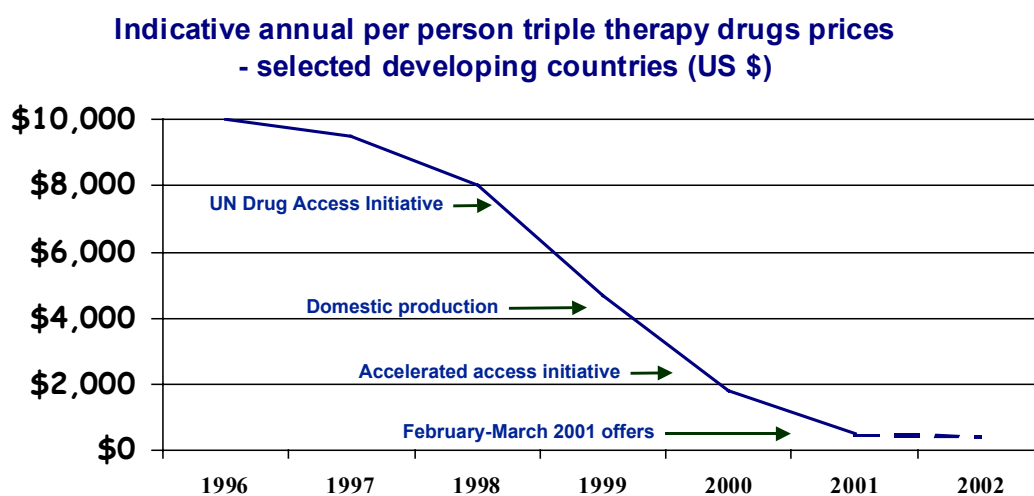
It was noted that the World Health Organization, UNAIDS and several other UN agencies identify four components of an “access framework”, each of which was felt to be necessary for ensuring access to essential drugs in developing countries: rational selection; affordable prices; sustainable and adequate financing; and reliable health care and supply systems. The point was made that any effort to expand and secure access to essential drugs should ensure that all four “legs of the access table” are adequately addressed. This includes the provision of local health services, adequately staffed, equipped, managed and financed, and oriented to local needs and priorities, as well as efficient and tariff and tax-free distribution systems. Participants assigned differing degrees of importance to the individual factors influencing access to care, but all recognized the complexity of the access puzzle, and its variability from one setting to another. Countries’ health and drugs supply systems — public, NGO and private — need to offer services of reasonable quality which respond to local needs. And priorities need to be considered carefully — between health and other demands, within the health sector, and among competing demands for drugs. WHO’s essential drugs concept is widely used by countries to set evidence-based priorities for cost-effective drugs selection.

It was widely noted that the price of essential drugs does matter, especially to poor people and to poor countries. At the same time, the price of drugs alone does not determine who gets access to health care and in the words of one speaker “price is a necessary but not sufficient condition” to improve access to essential drugs in poor countries. Nevertheless, it was noted that the world’s poor spend a large part of the income devoted to health care on buying drugs privately. The private sector (which includes NGOs and “quality health centres” as well as “quacks”) provides from 50 per cent to 90 per cent of drugs by value, paid out of the patient’s pocket. As a result, spending on drugs dominates household spending for health in developing countries.

It was noted that effective drugs exist to combat the principal components of the global burden of disease — HIV/AIDS, tuberculosis, malaria, and depression and suicide. However, in many poor countries expenditure to meet basic drug needs fell short of the earlier WHO recommendation of at least \$2 per head per year. With personal incomes frequently less than \$2 a day, there was considerable agreement that half the world’s population are too poor to pay for many of the drugs they need from their own resources even at the lowest possible prices. Organized, sustainable health financing is required, from domestic public health and social security budgets where national resources are adequate, and reinforced by international assistance in poor countries.

While the workshop was not specifically about HIV/AIDS, many participants addressed the situation regarding access to drugs to treat this condition, given the scale of the pandemic and the size of the gap between their prices and the means to pay for them in poor countries. It was noted that within the year prior to the workshop, a combination of corporate responsiveness, domestic production, and competition have led to substantial reductions in the price of HIV/AIDS drugs (see Figure 1). The point was made that this makes them more affordable for both domestic and international procurement, thus making mobilization of additional financial assistance the principal limiting factor to improved access to treatment.

**Figure 1. The decline in anti-retroviral prices**



Source: Presentation by Dr J. Quick

Nevertheless, participants were generally of the view that, even at these low prices, many developing country governments and most of the world’s poor cannot afford these HIV/AIDS drugs and the related health care system demands. It was noted that the scaling up of the order of magnitude of the number treated in poor countries from thousands to millions was a major challenge.

Even with reduced prices, rates of uptake of the drugs involved have sometimes been low. In discussion several possible reasons for this were identified: low levels of discount, recent date of the offer, under-recognition of the role of NGOs and the private sector in drugs supply, human and financial capacity constraints in the health



system. The sometimes “leaky safety net” of public health care systems is, in many poor countries, a smaller provider of first-contact care than the total provision by networks of private for-profit, not-for-profit and employer-based care. For this reason, it was suggested that differential prices not be restricted to the public sector, but cover also not-for-profit providers and employers of large numbers of low-income workers.

The point was also made that the same problems of under-utilization of existing essential drugs can be seen for many relatively inexpensive generic products. In this regard, it was noted that most essential drugs are not under patent protection anywhere. Important exceptions are anti-retrovirals for HIV/AIDS and drugs for resistant tuberculosis.

In discussion on the role of government in health, attention was drawn to the need for overall regulatory and standard-setting functions for all components of a country’s health system, both public and private. It was noted that governments have a special role in relation to essential drugs, given the unusual character of demand and supply in the market for drugs. Public purchasing of essential drugs is necessary on behalf of poor populations. To achieve public health objectives in such countries, essential drugs have to be made available to individuals by public health authorities or NGOs on the basis of need, not ability to pay.

Participants noted that some components of the retail price of drugs in developing countries are local. Tariffs, taxes and local distribution costs, in particular, can double the manufacturers’ selling price. So lower prices call for government and distributors’ actions, as well as those of manufacturers. It was noted that, although customs tariffs in most developing countries were low or moderate, below 20 per cent, developing countries had not committed themselves in the WTO to zero duties on pharmaceuticals as had most OECD countries. Some drew attention to harmful trade policies in some developing countries that affected price. An example was given of an anti-dumping action taken against generic imports on the grounds that low prices harmed domestic industry.

A problem of access to which attention was drawn is that in some countries some essential drugs have not been approved by the local drug regulatory authorities and therefore could not be imported and marketed. A specific aspect that was mentioned is that problems can arise where local approval depends on prior approval of the drug in a major market and yet that drug has not been submitted for approval in that market. There was also discussion as to whether production and process standards required in developed countries may not at times be unnecessarily strict when applied in a developing country context and lead to higher costs than necessary.

Speakers also drew attention to the complex pattern of stakeholder interests involved in the debate on improving access — developing and developed country governments, international organizations, NGOs, and manufacturers of both generic and patented drugs, together with experts in trade and health policy.

## **2. The role of financing in ensuring access to essential drugs**

It was widely accepted that, even with lower prices, substantially expanding access to essential medicines, including but not limited to the anti-retrovirals, will require additional domestic and international financing for the purchase of essential drugs as well as a significant investment in building effective health and supply systems.

It was noted that the mobilization of domestic resources is an important way of improving access to essential medicines. For this to be done more effectively, there is need to give greater priority to health in the budgets of developing countries. The view was expressed that some countries would benefit from diverting expenditure from defence for this purpose. The presentations made on two middle-income countries, Brazil and Thailand, demonstrated the impressive results that can be obtained through domestic mobilization.

Between 1995 and 2000 Brazil implemented a programme of universal and free anti-retroviral treatment which increased access to 92,000 patients, achieved a 40–70 per cent reduction in mortality, 60–80 per cent reduction in morbidity, and avoided 234,000 hospitalizations. The average price of locally made anti-retrovirals fell by 72 per cent over a five-year period. The point was made that this programme had been cost-effective given the resulting savings of costs that would otherwise have had to have been borne.

In Thailand user fees constituted one-third to one-half of public expenditure on drugs while the balance is taken out of tax revenues. Over 80 per cent of Thailand's population have some degree of health insurance protection against the full costs of needed care. The view was expressed that in many middle-income countries enhanced domestic resource mobilization combined with the untying of aid, differential pricing and, in respect of patented products, the use of the flexibility in the TRIPS agreement may prove sufficient.

However, for poor countries, domestic resource mobilization is limited by the level of economic growth and incomes and a debate confined to ways of mobilizing domestic resources alone would be misdirected. The point was made that health systems are under-financed in poor countries, with many such countries having a per capita public health expenditure of less than two per cent of their gross domestic product or \$6 per person per year. For these poor countries, even with differential pricing and the strongest political commitment to increasing public health expenditures, external assistance is critical to improving access to essential medicines.

A range of figures for the increased international aid flows that would be necessary were put forward. It was estimated that to tackle only the three major communicable diseases (HIV/AIDS, malaria, tuberculosis) massive increases in external assistance to poor countries are needed. This assistance needs to cover health system development requirements as well as treatment costs. Rough estimates given at the meeting ranged from an additional US\$12–15 billion per year to a more moderate sum of \$4.5 billion. These figures were compared with the existing, rather modest flows of official development assistance devoted to public health.

Some felt that the estimated financial requirements for TB drugs or HIV/AIDS drugs were too high, for example because HIV-positive persons have been shown to benefit from anti-retroviral treatment only later in the illness. But others considered that not enough was set aside for developing the necessary health system capacity. There was also some discussion of the requirements for financing research and development of drugs for neglected diseases in situations where the patent system by itself would not provide adequate incentives. There was a general view that more detailed work is needed to obtain better estimates of external financial requirements to tackle the health crisis in poor countries.

The need for a massive increase in the level of international health aid was widely expressed. The point was made that this could be the best investment that could be made in the future of poor countries, especially those in Sub-Saharan Africa. The view was expressed that, now that prices of HIV/AIDS drugs have been reduced to a fraction of their previous levels, the main constraint to getting them to HIV/AIDS patients is finance; and that, without such finance, price discounts will benefit a relatively small number of people compared to the number in need.

The workshop was informed of plans on the part of some countries or regional groupings to increase their commitment to this form of aid. However, the point was made that there needed to be a greater degree of international cooperation and coordination, both in order to maximize the usefulness of the aid and in order to ensure proper burden-sharing amongst donor countries. In regard to the latter point, it was suggested that account should also be taken of differing degrees of public support in donor countries for medical research, especially that of relevance to tropical diseases. Various ideas were put forward, including the creation of a global trust fund and in regard to the possible role of bodies such as the UN, WHO, UNAIDS, the World Bank and UNICEF.

### **3. Differential pricing**

By differential pricing is meant the adaptation of prices charged by the seller to the purchasing power in different countries. It was widely agreed that differential pricing could and should play an important role in ensuring access to existing essential drugs at affordable prices, especially in poor countries and, in doing so, could help reconcile affordability with incentives for research and development. There was considerable agreement that the general objective of differential pricing should be to obtain the best possible prices in poor countries for essential drugs. This was generally seen to be both desirable and feasible.

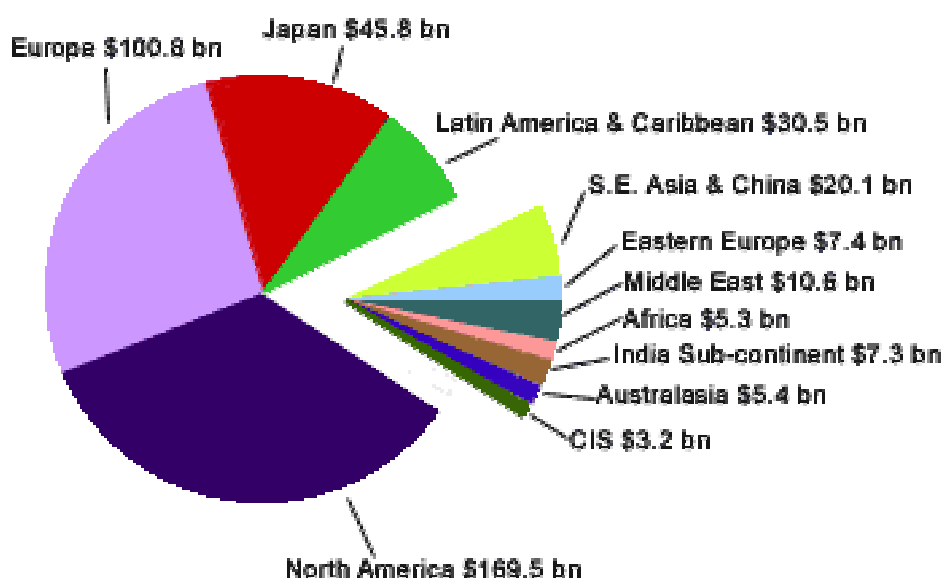
#### **3.1 Economic feasibility of differential pricing**

The workshop heard presentations by a number of leading economists who indicated that, given the right conditions, differential pricing can be in the interests of both consumers in poor countries and manufacturers, while not adversely affecting consumers in richer countries and maintaining incentives for research and development. In theory it would be in the interests of producers to relate prices inversely to price sensitivity in each market, provided the markets can be separated. Since prices in developed country markets are generally set already at what the

market will bear or by government, a move towards differential pricing involving lower prices in developing countries should have no adverse effects on prices in developed country markets. On the other hand, as a general rule, differential pricing should lead to lower prices in poor countries, given the greater price sensitivity of consumers in such markets. The alternative to differential pricing is the setting of internationally uniform or nearly uniform prices (to the extent that government regulation permits), which likely would be established at the levels that the market can bear in the rich countries and thus be much higher than the optimal price in poor countries. It was suggested that such pricing is neither equitable nor efficient.

It was pointed out that poor countries collectively represent a very small share of the global pharmaceutical market (Figure 2). In practice, therefore, a large part of the R&D and other fixed costs are already allocated mostly to high and middle-income countries, another reason why differential pricing should be feasible.

**Figure 2. Countries most in need of differential pricing constitute a small part of the world pharmaceutical market by value**

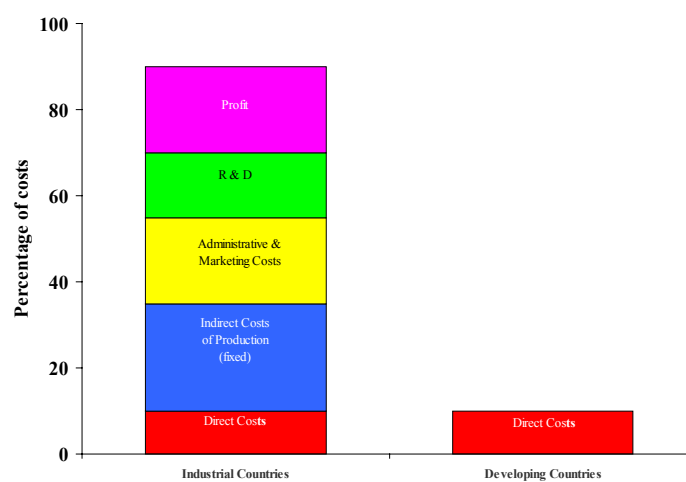


Source: [www.ims-global.com/insight/report/global/report.htm](http://www.ims-global.com/insight/report/global/report.htm)

It was noted that a number of conditions have to be in place in order for differential pricing to be feasible. One is that the fixed costs of the producer have to be substantial in relation to marginal production costs and the producer must have the necessary degree of market power to be able to allocate those fixed costs differentially between different consumers. Fixed costs include R&D costs, many marketing and administration costs and fixed production costs (see Figure 3). What is a fixed cost and what is a marginal cost — and therefore the degree of differential pricing feasible — depends to some extent on whether additional demand can be met through existing unused capacity or requires investment in new capacity. The point was made that, while the scope for differential pricing is generally greater where patented products are concerned because of the high sunk R&D costs, the importance of other fixed

costs means that differential pricing may also be feasible for non-patented products. Practical examples of this were given in the workshop’s discussions, for example in the fields of vaccines and contraceptives.

**Figure 3. Differential pricing is economically feasible because of the nature of pharmaceutical cost structures**



Source: Presentation by Dr J-F Martin

A second condition is that differential pricing requires market segmentation. It was pointed out that this entails prevention of leakage of low-priced products into high-priced markets (a technical issue), and a readiness to accept sustained price differences by consumers in high-income markets (a political issue). The way in which these conditions can be met are further explored in later sections of this report.

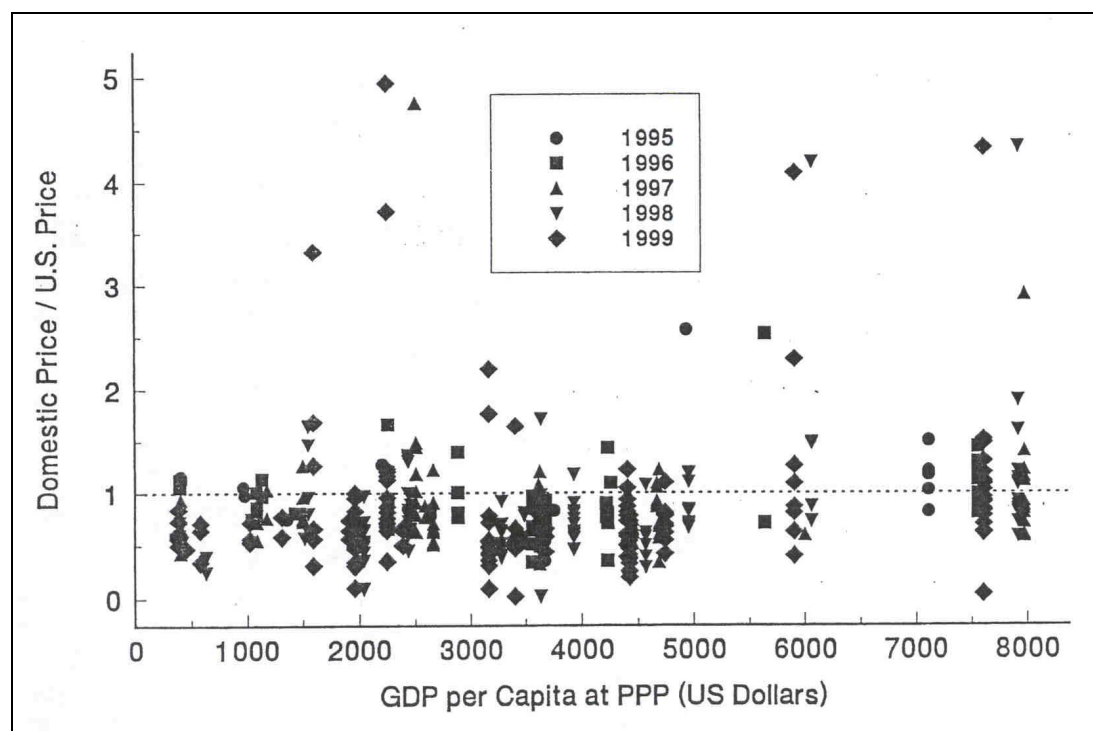
A related point is that it was suggested that, operationally, firms would be more ready to engage in differential pricing if conditions in their “core markets” in the developed countries could be secured. In this regard, the point was made that excessive price regulation in such markets could adversely affect the scope for differential pricing in poor countries. It was also observed that developing country suppliers may not have the benefit of such “core markets”. A further factor cited as encouraging differential pricing is the existence of significant prospects of larger volume sales in low-priced markets than would otherwise be reached.

Among the points that came up in the discussions and which were the subject of differing views are whether, for patented products, a form of differential pricing known as “Ramsey pricing”, or socially optimal pricing, would be conducive to maximizing global efficiency as well as promoting equity in international pricing and whether differential pricing was better promoted through the transparency or confidentiality of the lower prices that it led to.

The workshop considered the question of why, if differential pricing is in the interests of producers, there is not more evidence that it has been applied. Indeed, pricing evidence for the years 1995–1999 (and thus prior to recent discounts) from several developing countries for HIV/AIDS drugs presented at the workshop points to only a weak relationship between the income levels of countries and pharmaceutical prices (Figure 4). The reasons put forward by way of explanation were the preoccupation of producers with the dominant developed country markets; the fear of trade diversion and/or political, regulatory or psychological feedbacks into developed country markets; and little effort until recently on the part of developing country consumers to extract low prices.

**Figure 4. Ratio of domestic to US prices for selected AIDS drugs show a weak relationship with per capita income among low and middle-income countries**

Domestic to US price ratios for selected AIDS drugs, in relation to per capita income, low and middle income countries.



Source: Presentation by Professor F.M. Scherer

### 3.2 Differential pricing in practice

Several existing mechanisms by which low prices are achieved for essential drugs, vaccines and other health commodities in developing countries were presented at the workshop. Several manufacturers already independently offer heavily discounted prices and donations, to certain poor countries for selected drugs. Experiences with both patented and non-patented products presented at the workshop show that reductions of 90% or more below developed country prices can be possible through bulk purchasing, competitive tenders and skilful negotiation. A participating generic

manufacturer noted that it too implements a policy of price reductions for poor countries. It was said that an important body of available experience had been built up, and that this had happened through a combination of volume purchasing, corporate responsibility and market forces.

**Global bulk purchasing** schemes exist which are able to offer prices to developing countries well below those in industrialized countries. UNFPA, the largest public sector purchaser of contraceptives, obtains reductions of up to 99 per cent of the US market price for some contraceptives and sells at a standard low price to developing countries (see Table 1).

**Table 1. Contraceptive price reductions through UNFPA procurement practices**

Item	Unit	UNFPA Price	US Price	Percent reduction
Oral Contraceptives — generic (off-patent)	Cycle	0.175	30.00	99.4%
Oral Contraceptive — single-source (on-patent)*	Cycle	0.364	34.00	98.9%
Condom	Piece	0.025	0.50	95.0%
Intrauterine device	Piece	0.430	350.00	99.9%
Injectable contraceptives	Dose	0.675	65.00	99.0%
Spermicides	Tablet	0.060	1.20	95.0%
Hormonal contraceptive implants	Set	23.000	393.00	94.1%

\* Example of third generation oral contraceptive  
Source: Presentation by Mr C. Saunders

UNICEF's supply division also obtains major price reductions through large volume purchasing. In addition to volume purchasing, competitive bidding and direct negotiation with suppliers for long-term agreements were identified as routes to lower prices. The point was made that, for manufacturers, this has sometimes opened access to markets which were not previously considered, and enhances their public image through concessionary pricing. **Regional bulk purchasing** funds such as that of the Gulf Cooperation Council, and ACAME (African Association of Central Medical Stores) have also negotiated price reductions of up to 30 per cent on some drugs.

**Several company initiatives** involving individual companies (acting independently of each other) negotiating discounts on a product-by-product and country-by-country basis have also led to lower prices. More recently, some of these initiatives have been opened to groups of countries, rather than applied on a country-by-country basis. The representative of one company described how the anti-malarial product Coartem/Riamet was planned from early in its product life to be packaged, branded, registered and priced differently in low and high-income markets. The point was made that this product may anticipate some important steps which companies can take to prevent backflow of products from low to high-income markets. Several examples of **corporate donations** were presented, with some involving open-ended commitments in terms of time and quantities.

Amongst the points made about experience with the above programmes, in particular donations, was that their success depended importantly on effective partnership with the public authorities, political will on their part, the availability of dependable local distribution and health care systems and the education of providers and patients. It was noted that the rate of uptake of the drugs offered at substantially lower prices or free of cost was sometimes low, reflecting factors such as the lack of adequate financing, constraints of health system capacity, lack of up-to-date information on such offers or under-utilization of the private sector or NGO delivery systems.

The merits and demerits of donations were the subject of some discussion. One view was that donations suffer from the disadvantage that they are not always sustainable or generally available and could come with conditions which might reflect an imbalance of negotiating power between donors and recipients. Another view was that in situations where even a low price is too high, donations are to be preferred where possible and that the notion that donations are unacceptable because they reflect an imbalance of power, if carried to its logical conclusion, would rule out philanthropic activity in general. More general views were also exchanged on the issue of conditionalities. There were differences of view about the extent to which conditions are attached to existing programmes, for example for HIV/AIDS drugs. It was suggested that, if any conditions are to be attached to the supply of differentially-priced products, they should be minimal and worked out openly with the participation of all stakeholders.

Among the factors that were mentioned as influencing the extent to which reduced prices can be obtained under existing programmes are the volume, duration and standardization of purchases, the patent status of the product, its importance in high-income markets, competitive pressure on the supply side, the buyer's monopsony power, the use of transparent, competitive and corruption-free procurement procedures, negotiating expertise, and the existence of technical or legal obstacles to trade diversion. It was observed that these presentations showed that more widespread and sustainable differential pricing is economically, legally, and technically feasible with the right mix of consistent and mutually supportive strategies.

### **3.3 Giving effect to differential pricing**

A variety of ways for giving effect to differential pricing were put forward and discussed. The role of competition was discussed in relation to these techniques. There was wide support for the notion that essential drugs should be made available to poor countries at the most favourable price, which was variously referred to as a marginal cost or not-for-profit price. Differing views were expressed on the pros and cons of different modalities for differential pricing and their implications for securing favourable prices. These points are discussed below.

- *Leaving it to the market:* One view was that, if the right conditions were created, market forces would by themselves result in differential pricing by sellers as this would be in their own interest. However, some viewed this approach as reflecting unproven theory and pointed to the fact that there was no evidence that differential



pricing in favour of developing countries takes place systematically, despite the absence, in their view, of serious risks of trade diversion. Doubts were also expressed about whether market forces by themselves would result in the lowest possible prices for poor countries.

- *Bilateral negotiated discounts*: Drawing on experience, another modality discussed was discounted prices negotiated bilaterally between individual companies and countries. One view was that experience demonstrated that this is a practical and feasible way of implementing differential pricing. The point was made that the supplying companies themselves are the best judges of the maximum discounts that can be offered as such an assessment depends on confidential data on their product mix, profitability and costing. Another view was that given the unequal bargaining power and access to information between a poor country government and a pharmaceutical company, unfair conditionalities could be imposed and there is no way of verifying that the product is being offered on a not-for-profit basis or at the lowest possible price.

Various ways in which such a perceived imbalance of negotiating power could be addressed were discussed:

- One such instrument is the use of monopsony purchasing power, especially where a large volume is at stake. One concern expressed in this regard is that, just because a country is small, prices should not be less favourable than in large countries. The view was expressed that there should be no discrimination between equivalently placed developing countries in the provision of differentially-priced products.
- It was suggested that intergovernmental agencies could play a useful mediating role in such negotiations and, together with civil society groups, could exert influence by way of moral suasion.
- It was said that a country's negotiating position could be improved by the use of local or other generic companies to assess cost of production. Reference was made to the successful use of this technique in a number of cases.
- The pharmacoeconomic approach to price determination was also suggested. This brings together evidence of a new drug's likely cost and clinical effectiveness relative to the existing treatment alternatives. Product-specific information on R&D or production costs are not required in this approach. It was said that "value for money" prices can be identified and the method adapts easily to different economic settings such as particular low or middle-income country contexts. An example was presented illustrating how pharmacoeconomic analysis could be used to establishing a target price using data on the performance of a drug (drawn from clinical and epidemiological evidence of effectiveness) and information on GNP per capita (see Table 2).

- The potential impact of compulsory licences or the threat of compulsory licences was also mentioned (see below).

**Table 2. Example of indicative target monthly prices for a specific cardiovascular therapy, based on drug performance and GNP per capita**

Country	GNP per capita	Target Monthly Price
Armenia	\$500	\$0.20
Australia	\$20,511	\$8.07
Bangladesh	\$359	\$0.14
Belgium	\$24,088	\$9.47
Brazil	\$4,541	\$1.79
Canada	\$20,000	\$7.87
China	\$826	\$0.32
India	\$461	\$0.18
South Africa	\$3,112	\$1.22
USA	\$31,880	\$12.54

Source: Presentation by Dr D. Henry

- *Regional or global bulk purchasing:* Based on existing experience, it was suggested that, for certain diseases and products, regional or global procurement and distribution systems can be effective in implementing differential pricing. For contraceptives, vaccines, first-line drugs for tuberculosis, and most other essential drugs, competition is among off-patent generic equivalents and can be effective in lowering prices. Competition may also occur when there are several on-patent alternatives for the same therapeutic indication. Table 1 above illustrates savings of over 95% for an on-patent oral contraceptive subject to therapeutic competition. While it was recognized that regional or global bulk purchasing could help redress perceived imbalances of negotiating power and provide a channel for the use of international funding, it was suggested that it could negatively affect local manufacturing capacity if products were only bought from large global producers.
- *Voluntary licences:* The view was expressed that, wherever feasible, local production under voluntary licensing could be the most effective way of implementing differential pricing, while at the same time enabling the patent owner to be adequately compensated. It was seen as advantageous because it could promote competition, especially if applied on a non-exclusive basis, take advantage of potentially lower manufacturing costs in poor countries, could help reinforce such capacity, and facilitate transfer of technology. It was also suggested that it could help avoid trade diversion since products produced in poor countries could more easily be differentiated from the product on sale in developed countries and would require separate regulatory approvals for importation into such countries. It was noted, however, that it would only be feasible where there was sufficient local manufacturing capacity and markets.

The question arose as to the readiness of originator companies to engage in more widespread voluntary licensing, with such companies emphasizing its voluntary nature and the importance of a strong and effective intellectual property right regime for the transfer of technology. It was questioned whether voluntary licensing would necessarily lead to lower prices than direct supply of the market. The point was made that, normally, companies would prefer to supply the market and only licence to third parties in situations where this was not feasible. Another concern raised was the possible liability of originator companies for the quality of products produced under licence and the potential for parallel imports.

- *Compulsory licences:* It was argued that an important incentive for differential pricing, which could be relevant to any of the approaches set out above, was the existence of a credible possibility of the grant of a compulsory licence. It was pointed out that, subject to certain conditions, compulsory licensing and also government use without the authorization of the right holder are permitted under the TRIPS Agreement. There was some discussion as to the difficulty or not of meeting the procedural requirements attached to such authorizations and also of the technical feasibility of local production in some developing countries. The point was made that, under the TRIPS Agreement, compulsory licences could be given also for importation in situations where local production is not feasible. But concern was expressed that the availability of supply might be constrained by the limitation in the TRIPS Agreement that compulsory licensing should be predominantly for supply of the local market. Some participants warned of the possible negative effects of excessive resort to TRIPS safeguard provisions on local and global innovation, pointing to the trade-off between access to drugs today *vis-à-vis* access to newer and better drugs tomorrow.
- *Flexible global systems:* The view was expressed that the present approach, seen as a patchwork of individual initiatives focused on a limited number of drugs and countries, may not be adequate and there is a need for a more coherent global framework for differential pricing. It was said that such a framework would facilitate the mobilization of the funds necessary to ensure that differential pricing actually contributes to meeting the needs of the poor for access to essential drugs. Some argued that a global mechanism could be difficult to manage and have undesirable, unintended consequences while some others took the view that it would not be sufficient to rely on individual initiatives focusing on a limited number of drugs and countries.

Another modality for differential pricing that was mentioned is through the arrangements for the allocation of intellectual property rights under IAVI (the International AIDS Vaccine Initiative). This provides for public/private partnership arrangements under which private partners in the development of HIV vaccines retain full intellectual property rights in the OECD countries and IAVI retains march-in rights for HIV vaccines in developing countries in the event that the company partner is unable or unwilling to produce and distribute the vaccines to the developing world at accessible prices.

No single solution to achieving differential prices was identified; indeed it was remarked that a mix of mutually supportive strategies, geared to the circumstances of individual countries, is needed.

With regard to the impact of competition or antitrust law on ways of implementing differential pricing, it was explained during the workshop that under the national competition laws of many jurisdictions agreements between companies on how they compete are a *per se* offence, often criminal in nature. In many such jurisdictions, it is not a defence that the purpose of an agreement is to promote the public good. It was said that this would be a barrier to companies engaging in differential pricing through concerted action (i.e., an agreement between competitors). On the other hand, in general, competition law would not stand in the way of firms engaging in international price differentiation through actions independent of their competitors and not as part of any concerted arrangement to lessen competition. Issues might still arise under competition law provisions relating to predatory pricing or abuse of dominant position, if the tests applicable under such provisions are met. It was also emphasized that competition laws do not prevent legitimate discussion of public policy issues or consequential governmental actions duly authorized by legislatures.

In the discussion of ways of giving effect to differential pricing, the desirability of local generic production *vis-à-vis* that by the patent owner was discussed. One view was that, provided that a product is made available at an appropriate price, the patent owner should, wherever possible, retain control over supply, since this would optimize the balance between affordable access and incentives to research and development. Another view was that local production, for example under voluntary licences, could make an important contribution to the sustainability of differential pricing and could, through generating competition, lead to more favourable prices.

The point was made that generic companies in developing countries might have reason for concern about possible damaging competition from differentially priced products supplied by large foreign companies, especially if financed through international funds. It was pointed out that imports of such products from high-income markets could be liable to anti-dumping action if they caused or threatened material injury to the local industry. It was also suggested that local generic companies should be able to benefit from international funding for the purchase of essential drugs. Some participants from developing countries indicated that what was important to them was the price at which products could be made available rather than where they were produced and pointed to cases where they had used the threat of local production to secure more favourable import prices.

The importance of finding ways of ensuring that products are supplied to the poor at the most favourable possible price was highlighted not only from the perspective of the needs of poor countries but also from the perspective of donor countries. It was said that, if donor countries are to be ready to mobilize substantial resources to finance the purchase and distribution of essential drugs, they would want to be sure that such drugs are being purchased at the most favourable price.

A related point that was touched upon is the scope for donor countries to provide incentives to companies for donations or for supply at heavily discounted prices. It

was suggested that this needs further study and might call for international cooperation.

### **3.4 Maintaining separate markets and preventing diversion**

Participants accepted that markets for differentially priced drugs need to be tightly segmented to prevent leakage of differentially priced drugs to high-income markets. This is important not only for manufacturers but also for the poor country recipients, since otherwise a differentially priced product would not reach the people for which it is intended. The role that manufacturers, governments including regulatory authorities and purchasers could play in minimizing leakages out of the intended markets was discussed.

Presentations and discussions considered the following ways of achieving such market segmentation:

- *Marketing strategies by manufacturers* relating to the use of different trademarks and the presentation of products. The view was expressed that this technique could be helpful in preventing trade diversion and could also make cross-country price comparisons more difficult. However, it was also said that it may not always be appropriate to use more than one trademark and that, where price differences are large, repackaging may still be worthwhile.
- *Strict supply chain management* by purchasing entities. A number of companies indicated the importance they attach to effective supply chain management which could ensure that a differentially priced product is not diverted to persons other than those for which it is intended. The special features of the supply chain for vaccines was mentioned in this connection and it was said that, when it comes to anti-retrovirals, an assessment of the supply chain security has to be made on a case-by-case basis. A presentation was made indicating how, with the use of batch numbers, bar coding and dating methods, the flow of drugs through distribution channels can be effectively tracked and many forms of diversion minimized. It was explained that such arrangements require a sufficient degree of organization and accountability.
- *The role of drug regulatory authorities*. It was observed that essential drugs produced in developing countries and sold at differential prices, for example under voluntary licensing arrangements, can only be imported into developed country markets if they obtain authorization from the drug regulatory authorities in those countries. This would only be granted if an application was made and the relevant production standards met. It was suggested that a condition of the grant of a voluntary licence could be to undertake not to make such an application.
- *Import controls by the customs authorities*. The question was raised as to whether high-income countries would need some additional legal authority to prevent the import of products marketed elsewhere at differential prices. There was also some discussion of the special expertise that customs authorities have developed in preventing the import of counterfeit and other illicit products and the suggestion was made that full use should be made of this. However, the point was also made

that, even in the wealthiest countries who could devote the most resources to border controls, such controls are frequently less than fully effective. It was said that additional responsibilities to regulate, for example, parallel imports might require a major increase in the resources devoted to border control.

- *Export controls.* The question of whether export controls implemented by the customs authorities of the countries receiving differentially priced products can be an effective means of preventing diversion was touched upon. Further study is necessary to assess the extent to which this can be a credible mechanism in poor countries given the burdens entailed, the extent to which customs authorities in those countries already have the necessary legal authority and whether there are any international trade rule implications that need attention.
- *The use of intellectual property rights to restrict parallel imports.* Some participants said that, in order to provide the right conditions for differential pricing, it was important to have effective means of preventing parallel imports into developed country markets and also into middle-income country markets. There was some discussion of the extent to which patent law already gives the patent owner such rights in developed country markets. It was noted that doing so did not raise problems under the provisions of the TRIPS Agreement. The extent to which public authorities such as the drug regulatory authorities and the customs administration can play a role in the enforcement of such restrictions on parallel trade was also discussed. It was said that, at least in some jurisdictions, the powers of the customs authorities to prevent imports of infringing goods did not extend to parallel imports. It was also said that, whereas differential pricing requires restrictions on parallel imports into high-income countries and maybe in intermediate-income countries, poor countries should be left free to engage in parallel importing where this would help secure best-value products.

Many participants appeared to be of the view that the above mechanisms could effectively prevent diversion of differentially priced products, although further study is necessary into the legal and technical issues involved. It was said that, if there is agreement on the principle of preventing diversion, the international community and national governments should be able to work out how this could be done. It was suggested that more than one mechanism would be necessary and that the burden of preventing diversion should be a shared one between the low-income and high-income countries. It was said that, if the same differential prices could be offered in large, contiguous geographical areas, the problem of diversion would be thereby reduced.

### **3.5 Political feasibility**

There was a common view that preferential prices in developing countries should not be a factor in pricing in the developed countries. Differential pricing policies hinge critically on the political acceptability of lower prices in poor countries. Two aspects of this issue were analysed. One is the issue of price interdependency which results from the use of third country prices for the calculation of permissible domestic prices (usually referred to as reference pricing) and the other is the less tangible way in

which prices in one country can affect the acceptability of prices in another country, for example as mediated through the political process.

With regard to reference pricing, one presentation showed that, in parts of the world, market separability is breaking down. Price regulation of pharmaceuticals is increasingly based, either formally or informally, on international price comparisons and these are increasingly including, either directly or indirectly, developing country prices. Figure 5 shows countries which either use international price comparisons in their negotiations with manufacturers, or which are countries of reference for price purposes.

**Figure 5. A “web” of formal international price comparison has developed, much of it over the last five years**

Countries which use international price comparisons in their negotiations with manufacturers or which are countries of reference for price purposes.

*Formal Price Referencing Today*

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Source: Presentation by Dr E. Schoonveld

At the workshop, it was not contested that developing country prices should not be used, either directly or indirectly, as references in developed country reference pricing systems. Indeed, the question was raised as to whether the more widespread use of differential pricing might not call for some kind of international agreement among developed countries to desist from such forms of reference pricing for the products involved.

A more difficult point in the workshop was how to forestall differential prices being exploited in the political process in developed countries. It was pointed out that such a difficulty had arisen a few years ago when concern had been expressed in the legislature of a major developed country about tiered prices for vaccines. Some felt that, political leadership, advocacy efforts and public education would be essential. Part of this effort would need to be directed at reassuring public opinion that lower prices in poor countries do not mean higher prices in rich ones or a greater burden on

national health budgets. Some felt that, without such a vigorous campaign and the understanding and support of industrialized country purchaser and consumer and other civil society organizations, any transparent scheme of lower prices for poor countries may be taken as setting price benchmarks for negotiations in better-off markets. The point was made that uncertainty regarding future pricing policy can itself be a considerable disincentive to investment in R&D.

### **3.6 Middle-income countries and well-to-do populations in poor countries**

The question of middle-income developing countries paying prices proportionate to their income levels was discussed. The view was expressed that such countries should not be excluded from differential pricing, especially since they often include large numbers of poor people. But such countries could be expected to pay a somewhat higher price than that in poor countries. It was suggested that the Human Development Index developed by the UNDP could be used as a reference point for this purpose. The point was also made that there would need to be measures in place to prevent the diversion of the lowest priced product intended for poor countries into middle-income developing countries and that the mechanisms discussed earlier for this purpose would need to be examined in this connection.

There was also some discussion of the situation of the treatment of the well-to-do populations in poor countries. One view was that, if such populations are also to benefit from differential pricing, it would act as a significant disincentive to differential pricing and could also aggravate any political repercussions in the high-income markets. Another view was that it would be difficult to segment a country's health system into separate parts for this purpose. This question overlapped with another one, namely whether the supply of differentially priced products should be limited to the public sector, should also be supplied to non-governmental organizations and possibly large employers, or should be generally available in recipient countries. Different reviews were expressed but this issue was not fully discussed.

## **4. The role of intellectual property rights**

The need to maintain and, if possible, enhance incentives for research and development into new drugs was widely recognized as was the importance of the intellectual property system for this purpose. It was recognized that this system needs to find an appropriate balance between providing incentives for the development of new drugs and facilitating access to existing ones. There seemed to be a wide acceptance of the view that the patent system, while a necessary condition for much R&D, was not a sufficient one to secure adequate R&D into the neglected diseases of the poor; and that additional measures of support for such R&D are necessary. It was pointed out that patents are not the only means of supporting R&D and that there were other means of international burden-sharing in this regard. Some concerns were expressed about the implementation of the existing patent system and the extent to which it was open to abuse, for example in regard to the grant of weak patents and the "evergreening" of pharmaceutical patents to delay generic competition.



The point was made that differential pricing of essential drugs is fully compatible with the TRIPS Agreement and should not require countries to forego any flexibility they have under it. The importance of respecting the balance found in the negotiation of this agreement and of the rights of developing countries to use the flexibility in it was widely emphasized. As indicated elsewhere in this report, particular attention was drawn to the rules of the TRIPS Agreement relating to compulsory licensing and parallel imports. It was noted that there was as yet relatively little experience with the use of these safeguard mechanisms. Concern was expressed about external pressures on countries not to incorporate these mechanisms into their national legislation or to avail themselves of them when already in national legislation. Some important reassurances were repeated in this connection. It was noted that developing countries may need technical assistance so that they can effectively implement these as well as other parts of the TRIPS Agreement. The decision of the Council for TRIPS to launch a debate on the relation between the TRIPS Agreement and health needs was welcomed.

#### **5. Wider use of differential pricing and greater international funding: issues requiring further work**

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

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

Despite the unresolved issues, the workshop brought a better understanding of the subjects discussed, bringing together for the first time all major interest groups concerned with the financing and pricing of essential drugs. It was intended to achieve a sharing of experience related to differential pricing and financing of essential drugs

while maintaining incentives for pharmaceutical innovation. Not surprisingly, wide differences of view were expressed by participants. Nevertheless, widely shared views on the need for enhanced financing and on the feasibility of differential pricing were apparent at levels ranging from abstract principle to operational detail. Many participants felt that they had learned from the exchanges, and left with a broader understanding of the issues involved in making further progress towards affordable essential health care.

## Annex 1. Participant List

<b>Name</b>	<b>Organization</b>
Applebaum, Harvey	Covington & Burling
Balasubramaniam, K	Consumers International
Bale, Harvey	IFPMA — International Federation of Pharmaceutical Manufacturers Associations
Bayer, Ron	Columbia University
Berkley, Seth	IAVI — International AIDS Vaccine Initiative
Bisonga, John	Customs and Excise Department, Kenya
Bloomer, Phil	Oxfam
Chidyausiku, Boniface	Zimbabwe
Cleves, Julia	UNAIDS
Correa, Carlos	University of Buenos Aires
Danzon, Patricia	Wharton School, University of Pennsylvania (Videoconference)
Faber, Gunter	GlaxoSmithKline
Fleet, Julian	UNAIDS
Fransen, Lieve	European Commission, DG Development
Haddad, Bill	CIPLA; U.S. Research and Development Corporation
Hardwick, Chuck	Pfizer, Inc.
Harper, Malayah	DFID, UK
Harrington, Mark	Treatment Coalition
Heimler, Alberto	Autorita Garante della Concorrenza e del Mercato
Henry, David	Newcastle University, Australia
Hessou, Pascal	ACAME
Hoekman, Bernard	World Bank
Itchner, Albert	Novartis
Johns, Desmond	South African Government
Jorge, Fabiana	Argentina, Generic Manufacturers Association
Kadama, Patrick	Ministry of Health, Uganda
Laing, Richard	Boston University
Love, Jamie	Consumer Project on Technology
McCullough, Keith	Vuna Healthcare Logistics
Martin, Jacques-François	Global Fund for Children's Vaccines
Medlin, Carol	Institute for Global Health
Miles, Cecile	Ranbaxy
Nightingale, Stuart	U.S. DHHS
Ochola, Dorothy	Uganda Improved Access to HIV/AIDS Drugs
Papovich, Joseph	U.S. Trade Representative
Pedersen, Hanne	UNICEF
Piot, Peter	UNAIDS
Redwood, Heinz	Author and Industry Consultant
Rovira, Joan	World Bank
Sachs, Jeffrey	Harvard University (Videoconference)
Saunders, Christian	UNFPA
Scherer, F.M.	Harvard University
Schoonveld, Ed	Cambridge Pharma Consultancy
So, Anthony	Rockefeller Foundation
Speaker, Mark	Bristol-Myers Squibb Co.
Steiger, William	U.S. DHHS
Stenvik, Are	Oslo University
Sturchio, Jeffrey	Merck & Co., Inc.
Teixeira, Paulo	Ministry of Health, Brazil
't Hoen, Ellen	Médecins Sans Frontières
Torongo, Mabel	International Pharmacy Federation
Vandoren, Paul	European Commission, DG Trade
Varet, Françoise	Government of France
Wanyanga, Wilberforce	COSMOS

Wecker, John  
Wilbulprasert, Suwit  
Wilder, Richard  
Wong, Clifford  
Woods, Guy  
Yamamoto Junii

Boehringer Ingelheim  
Ministry of Public Health, Thailand  
Powell, Goldstein, Frazer & Murphy  
Kaiser Permanente (retired); MedImpact Healthcare Systems, Inc.  
Lacuna Research, Ltd.  
Ministry of Health Japan

### **WHO Participants and Consultants**

Brundtland, Gro Harlem WHO  
Cassels, Andrew WHO  
Creese, Andrew WHO  
Dukes, Graham Consultant (International Journal of Risk and Safety in Medicine)  
Liden, Jon WHO  
Neira, Maria WHO  
Quick, Jonathan WHO  
Suzuki, Yasuhiro WHO  
Velasquez, German WHO

### **WTO Participants and Consultants**

Anderson, Robert  
Otten, Adrian  
Tran Wasescha, Thu-Lang  
Unqphakorn, Peter  
Watal, Jayashree

WTO Secretariat  
WTO Secretariat  
WTO Secretariat  
WTO Secretariat  
Consultant

### **Global Health Council**

Daulaire, Nils  
Hall, Sadhana  
Sorensen, Karen

Global Health Council  
Global Health Council  
Global Health Council

### **Norway**

Christiansen, Ottar  
Eckey, Susan  
Haralstad, Hilde  
Møgedal, Sigrun  
Riise, Anne  
Sydnes, Anne Kristin  
Tonseth, Didrik  
Walther, Arne

Norwegian Ministry of Foreign Affairs  
Norwegian Ministry of Foreign Affairs  
Norwegian Ministry of Foreign Affairs  
State Secretary for International Development, Norway  
Norwegian Ministry of Foreign Affairs  
Minister for International Development, Norway  
Norwegian Ministry of Foreign Affairs  
Norwegian Ministry of Foreign Affairs

## **Annex 2. Programme**

**Sunday, 8 April 2001, evening** — Registration

### **Reception and Buffet Dinner**

- Hosted by Anne Kristin Sydnes, Minister of International Development, Norway
- Recital Oystein Birkeland, cello and Vebjørn Anvik, piano

**Monday, 9 April 2001:**

### **Morning — Opening Session — Welcome and keynote remarks**

- Sigrun Møgedal (State Secretary for International Development, Norway)
- Gro Harlem Brundtland (Director General, WHO)
- Adrian Otten (Director, Intellectual Property Division, WTO Secretariat)
- Nils Daulaire (President and CEO, Global Health Council)
- Peter Piot (Executive Director, UNAIDS)

Overview of agenda and methods of work

### **Morning — Session I — Access to Essential Drugs in Low Income Countries: Key Issues**

- Role of government in health care: Patrick Kadama (Commissioner of Health, Uganda)
- Healthcare and pharmaceutical systems in developing countries: Richard Laing (Boston University)
- Tariffs and non—tariff trade barriers and access to essential drugs: Adrian Otten (WTO)
- A research-based industry perspective: Harvey Bale (IFPMA)
- Ensuring access to essential drugs — framework for action: Jonathan Quick (WHO)

### **Afternoon — Session II — The Role of Financing in Ensuring Access to Essential Drugs**

- Mobilization of domestic resources in developing countries:
  - Suwit Wilbulprasert (Ministry of Public Health, Thailand)
  - Paulo Teixeira (Ministry of Health, Brazil)
- External assistance and pharmaceutical financing:
  - Lieve Fransen (European Commission)
  - Françoise Varet (Government of France)
- Health financing and access to health care:
  - Jeffrey Sachs (Harvard University)

### **Afternoon — Session III — Differential Pricing: Concepts and Issues**

- Economic analysis:
  - Patricia Danzon (University of Pennsylvania)
  - F.M. Scherer (Harvard University)
- Conceptual issues:
  - Heinz Redwood (Industry Consultant)
  - Gunther Faber (GlaxoSmithKline)
  - Ellen 't Hoen (Médecins Sans Frontières)

### **Tuesday, 10 April 2001:**

#### **Morning — Session IV — Current Experience with Differential Pricing**

- Experience with vaccines: Jacques-François Martin (Global Fund for Children's Vaccines)
- Experience with contraceptives: Christian Saunders (UNFPA)
- Experience with generic drugs: Cecile Miles (Ranbaxy)
- Experience with HIV/AIDS-related drugs:
  - Dorothy Ochola (Uganda Improved Access to HIV/AIDS Drugs)
  - John Wecker (Boehringer-Ingelheim)
- Experience with access to essential medicines for tropical diseases: Maria Neira (WHO)
- Experience with drug donations:
  - Ivermectin: Jeffrey Sturchio (Merck & Co., Inc.)
  - Fluconazole: Chuck Hardwick (Pfizer, Inc.)

#### **Morning — Session V — Market Segmentation: Techniques, Actors and Incentives**

- Marketing strategies by manufacturers and contractual approaches:
  - Market segmentation and price differentiation: A Novel Approach: Albert Itchner (Novartis)
  - Purchase undertakings (including security and prevention of diversion): Keith McCullough (Vuna Healthcare Logistics)
  - Ex post reimbursement techniques: Clifford Wong (Kaiser Permanente, retired; MedImpact)
- Governmental measures:
  - Role of regulatory authorities: Guy Woods (Lacuna Research, Ltd.)
  - Export controls: John Bisonga (Customs and Excise Department, Kenya)

#### **Afternoon — Session V (continued)**

- The use of intellectual property rights:
  - Richard Wilder (Powell, Goldstein, Frazer & Murphy)
  - Carlos Correa (University of Buenos Aires)
- Competition policy considerations:
  - Harvey Applebaum (Covington & Burling)
  - Alberto Heimler (Autorita Garante della Concorrenza e del Mercato, Italy)

**Afternoon — Session VI — Purchaser Perspectives and Incentives for Differential Pricing**

- ACAME bulk purchasing of essential drugs: Pascal Hessou (ACAME)
- International procurement agency: Hanne Bak Pedersen (UNICEF)
- Incentives for differential pricing (tax, legal, other measures): Malaya Harper (Department for International Development, UK)
- A consumer perspective: K. Balasubramaniam (Consumers International)
- Market segmentation and international reference pricing: Ed Schoonveld (Cambridge Pharma Consultancy)

**Wednesday, 11 April 2001:**

**Morning — Session VII — Perspectives on Financing and Differential Pricing**

- A pharmaco-economic perspective: David Henry (Newcastle University, Australia)
- Public/private partnership: Seth Berkley (IAVI)
- A developed country consumer perspective: Jamie Love (Consumer Project for Technology)
- A pharmacy professional perspective: Mabel Torongo (International Pharmacy Federation)
- A generic manufacturer's perspective: Bill Haddad (Cipla)
- A developed country government perspective: Paul Vandoren (European Commission, DG Trade)
- A developing country government perspective: Desmond Johns (Government of South Africa)
- A research—based industry perspective: Mark Speaker (Bristol—Myers Squibb, Co.)

**Morning — Session VIII — Round—up Discussion**

Synopses of main points