

**WORKSHOP ON DIFFERENTIAL PRICING
AND FINANCING OF ESSENTIAL DRUGS**

**BACKGROUND NOTE PREPARED
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Introduction

The purpose of this note is to provide participants in the WHO-WTO Secretariat Workshop of 8-11 April 2001 on differential pricing and financing of essential drugs with some background information and to suggest some issues that may be relevant for discussion in the various sessions. By differential pricing is meant the adaptation, in some measure, of prices to the purchasing power of consumers in different countries.

This note focuses primarily on issues relevant to the World Trade Organization (WTO). These include issues of the impact of tariff and non-tariff barriers to trade on access to essential drugs in poor countries and the impact of patent protection on prices of essential drugs (Session I). In regard to Session III, the paper provides information which may be relevant to assessing the extent to which differential pricing of essential drugs can assist in balancing the need to make existing drugs affordable to those who need them in poorer countries with preserving the incentives for inventing and developing new and better treatments provided for in the TRIPS Agreement. With regard to Session V, the paper seeks to provide information that will help identify ways of providing for the market segmentation necessary to make differential pricing work, while at the same time respecting WTO and other international trade rules and ensuring consistency with competition law and policy.

The paper should be read in conjunction with the background paper prepared for the Workshop by the consultants to the WHO, which focuses more on public health issues.

Session I - Access to essential drugs in low-income countries: key issues

This first session of the Workshop will set out the context for the later discussion on differential pricing and financing of essential drugs. While the session will address the full range of problems affecting access to essential drugs in poor countries, this background paper focuses on three particular issues with the aim of helping put into perspective the significance of the price of essential drugs as an impediment to access and the relevance of patent protection and of the TRIPS Agreement in this connection. These issues are:

- the relative importance of manufacturers' prices *vis-à-vis* other relevant factors and components of price;
- the impact of patents on the prices of essential drugs; and
- the role of the TRIPS Agreement in patent law changes in poorer countries.

1.1 Relative importance of price *vis-à-vis* other relevant factors

The WHO estimates that, although the number of people with access to essential drugs has doubled in the last 20 years, one-third of the world's population still lacks such access, with this figure going up to over 50 per cent in Asia and Africa (WHO, 2000). The WHO Medicines Strategy for 2000-2003 puts affordable prices as one of the four factors that affect access to medicines, the other three being rational selection, sustainable financing and reliable health and supply systems.

The importance of reliable health and supply systems is highlighted by a study (World Bank, 1993) that estimated that in many African countries inefficiencies in drug selection, procurement and waste may have led to only 12 per cent of the tax money allocated to the purchase of drugs being effectively utilised. Reliable health and supply systems and infrastructure are required in order to ensure the efficient distribution of drugs wherever they are needed and their effective use.

Under the WHO Medicines Strategy, the purchase of essential drugs should be based on sustainable and equitable financing. This can be done either through government revenues or social health insurance. An unsustainable financial burden on consumers in poor countries, in addition to limiting access, can contribute to less efficient use, since it can lead to poor or erratic consumption of essential drugs. As is to be examined in the next session, external financial support on a sustained basis may be necessary for the poorer developing country governments.

Under the Medicines Strategy rational selection of drugs is to be based on a national essential drugs list and on treatment guidelines that help select the optimal, cost-effective treatment for diseases common to the country. This would imply that it is not always necessary to use the most expensive drugs or brands available in the global market if there are cheaper and effective substitutes. Nevertheless, affordable prices are important for improving access of poorer countries to essential medicines. Once a drug is rationally selected out of all the possible candidates, the price at which it can be procured is a critical determinant of the number of patients that can be treated in a country in any given time-period. Financial resources, whether domestic or external, are not unlimited and given these budgetary constraints, the final procurement prices can be decisive in this respect.

1.2 Components of the retail price

The final retail price of a drug has several components: producer's cost, tariffs and taxes, and distribution margins at the wholesale and retail levels. Unfortunately, data on distribution margins and taxes on pharmaceutical products in developing countries are not systematically collected and published. According to the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), wholesale and retail margins can be as high as 150 to 200 per cent in some developing countries (IFPMA, 2000a). According to WHO sources, distribution margins and taxes can constitute up to 80 per cent of the consumer price, with some of the highest margins among developing countries being found in Ghana and Cameroon. There are developing countries with lower margins. A comparison of a sample of wholesale and retail prices for new drugs in India puts retail margins at 25 per cent (Watal, 2000). In developed countries, the corresponding figure for distribution margins and taxes as a proportion of final price is often in the order of 40 per cent.

On the other hand, detailed information on tariffs exists. According to this data, average tariffs on final pharmaceutical products are generally low or moderate in the developing world with the exception of two countries, India and Tunisia, where they are 30 and 20.6 per cent respectively. For active ingredients that go into the manufacture of pharmaceuticals, six developing countries have average tariffs in the range of 20 to 30 per cent, *viz.* Burkina Faso, Pakistan, Tanzania, India, Kenya and Tunisia.¹

The producer's cost includes R&D costs, production costs, marketing costs and profits. The research-based pharmaceutical industry is distinguished from others by relatively high R&D costs, marketing costs and profit margins. Risks are high even though patents support high margins for new, innovative drugs because only a small proportion of chemical entities tested reach the market and of these only a few are best sellers. Consequently, R&D expenditures have to be recovered from the relatively few commercially successful products. Moreover, it is sometimes claimed that a combination of lengthy regulatory approval periods, high up-front R&D costs, high marketing costs and high risk limit entry into the research-based industry and thus help explain the relatively high profit margins observed.

The substantial difference that often exists between manufacturing costs and ex-factory price is influenced also by demand-side factors. It is a third party, generally a physician, who decides which drug the patient should purchase, although self-medication may occur more commonly in developing countries. Pharmaceutical companies usually incur heavy marketing costs to convince

¹ Internal study by the WTO and UNCTAD Secretariats.

physicians to prescribe their products. Physicians tend to be less price sensitive than the final consumers. Also, at least in developed countries, rarely does the patient bear the full cost of the medicine. This is generally covered by an insurance company or by the government through some form of social security. Moreover, the more affluent the consumer, whether in a developed or a developing country, the more willing they will be to pay a high price to alleviate suffering from an illness or disease condition. All these factors make for lower price sensitivity of consumers of pharmaceutical products as compared to other products, at least in developed countries (Scherer, 2000).

1.3 Impact of patents on prices of essential drugs

Patents provide the patent owner with the legal means to prevent others from making, using or selling, importing or offering for sale the new, patented drug for a limited period of time. The TRIPS-compatible 20-year term of a patent runs from the time of filing of the application. In the case of pharmaceutical products, which are subjected to lengthy procedures that verify safety and efficacy, the effective patent life may only be an average of 11 or 12 years² (CBO, 1998). Generally, innovations can be protected through secrecy, lead time or through patents. In the pharmaceutical sector it is patents that are especially crucial in appropriating the returns to R&D (Levin *et al*, 1987). This is because once the originator, breakthrough drug is produced through lengthy and relatively expensive R&D processes, the time, capital and effort involved in copying it is often minimal. Patents, however, do not prevent competition from "me-too" drugs or other (therapeutic substitutes) that treat the same disease condition. Indeed, few patented drugs have no effective substitutes and this affects originator firms' strategies on introductory prices. Those facing greater therapeutic competition at entry tend to price their products lower (Lu and Comanor, 1998).

There is evidence from nations which encourage generic substitution that average pharmaceutical product prices fall sharply when generic entry occurs after patent expiry. One study done in the United States showed that the average generic substitute's wholesale price was 60 per cent of the previously patented drug's price with just one generic entrant, 29 per cent with 10 entrants, and 17 per cent with 20 entrants (Caves *et al*, 1991). This, however, may not be the case in Europe and Japan as the United States sees a much greater impact on original brand sales for reasons of both policy and market size. Indeed, market size is found to be such an important determinant of generic entry that the patent system has been characterized as 'a risk-smoothing device': the more successful a product is in terms of generating revenue to the original firm, the more likely it is to attract generic competition on patent expiry; conversely, the less successful products see profits maintained for a longer time (Hudson, 2000).

A question is how important are patents in the context of improving access to essential medicines in poorer countries. Of some 300 drugs currently listed by the WHO on its Model List of Essential Drugs, recent estimates are that less than five per cent or fewer than 20 are under patent protection anywhere in the world.³ While it is true that affordability is itself a criterion in deciding which drugs are classified on this list and, consequently, some patented drugs that many consider essential are not part of the WHO list, the fact that the vast majority of drugs deemed essential are in the public domain everywhere needs to be taken into account in assessing the impact of patent protection for access to essential drugs.

²See <http://www.cbo.gov> for Chapter IV of the report. OECD, 2000 (p. 18) cites a 1993 study that estimates average effective patent life to be 9.7 years in the US, 6.4 years in Germany, 8.7 years in the UK, 13 years in France and 7-8 years in Japan.

³ Of course this figure is constantly changing as products fall out of patent protection and new drugs are added to the list.

Another way of examining the impact of patent protection is to estimate the proportion of drugs on the market, both essential and non-essential, that may be affected. Redwood has calculated the proportion of drugs on respectively the Indian and Brazilian markets that would have been covered by TRIPS-level product patent protection had such protection been available in those countries prior to TRIPS implementation. His estimates, by sales value at the then current prices, were 10.4 per cent of the total Indian pharmaceutical market as of June 1993 (Redwood, 1994) and 13 to 15 per cent of the Brazilian pharmaceutical market as of November 1994 (Redwood, 1995). Even in developed countries, off-patent drugs constitute a high proportion of the total pharmaceutical market. For instance, of the 200 top selling prescription drugs in the US in 1994, 95 per cent were off-patent (Dukes, 1998).

Some economists have attempted to simulate the likely price effects of the introduction of product patents for this 'patentable' segment of the pharmaceutical market in Argentina and India. The results of these studies are highly sensitive to the methodologies used and assumptions made. But what is striking is that in each of the three studies that rely on more detailed data the average effect on prices, using the assumptions which yield the highest impact, is in the order of 200 per cent (Challu (1991), Fink (2000) and Watal (2000)). Changing the assumptions, the average price effect has been estimated as less than 30 per cent (Watal, 2000). Fink (2000) shows that the availability of therapeutic substitutes could contain such price increases to as low as 12 per cent or to a maximum of 68 per cent. Of course, within these averages there are dispersions for individual products. Earlier studies, using less detailed data, arrived at price increase estimates of up to 67 per cent (Maskus and Eby-Konan (1994), and Subramanian (1995)).

Often predictions of higher prices with the introduction of product patents are made on the basis of a comparison of drug prices between countries that do and do not offer pharmaceutical patent protection. It is not clear whether these comparisons consider other demand and supply side factors, notably differences in purchasing power, market structure, distribution margins, tariffs, taxes and exchange rate fluctuations, that may also account for these price differences. Sometimes such comparisons are also factually incorrect as in the case of price comparisons between India and Pakistan (UNDP, 1999 and OXFAM, 2001), both of which excluded pharmaceuticals from patent protection in the relevant period.

1.4 Impact of the TRIPS Agreement on patent protection of pharmaceuticals

The TRIPS Agreement represents an attempt at the multilateral level to achieve the difficult task of balancing the public health interest in providing incentives for research and development into new drugs with the public health interests of making existing drugs as accessible as possible. On the one hand, it provides for pharmaceutical inventions to be protected for at least 20 years (counted from the date of filing of the patent application) and, on the other, it provides for transition periods and a number of forms of flexibility in relation to the basic rights conferred by a patent, including provisions on limited exceptions, compulsory licensing, government use, anti-competitive practices and exhaustion. It also recognizes that governments can use policy measures outside the field of intellectual property to address issues of access to and prices of drugs. Further details can be found in the Annex to this paper.

With regard to the estimates of the impact on prices of the introduction of product patent protection that are described in the previous section of this paper, it is important to note that these estimates are based on the presumption of the existence of full and unqualified patent rights and do not take into account the forms of flexibility in relation to these rights provided for in the TRIPS Agreement. Clearly, the existence of these types of provisions in national legislation and their possible use can have an effect on the terms on which patented products are made available.

Frequently, commentators write as if developing countries in general did not provide product and process patent protection for pharmaceuticals prior to TRIPS and will have to make this change as a result of TRIPS. In fact, as of January 1995, the date of entry into force of the TRIPS Agreement, fewer than 20 developing and least-developed country WTO Members excluded pharmaceutical products from the grant of patents⁴, and virtually all provided for process patent protection. Under TRIPS, these developing countries were allowed up to January 2005 to introduce pharmaceutical product patent protection (the least-developed countries among them have until 2006 with the possibility of an extension). Since the entry into force of the WTO Agreement, Argentina, Brazil, Guatemala, Morocco and Turkey have introduced product patent protection for pharmaceuticals and Paraguay has notified the WTO of its intention to do so by January 2003.⁵ Thus, even of those developing countries entitled to the transition period allowed under TRIPS of up to 2005 for the introduction of product patent protection for pharmaceuticals, not all are availing themselves of the full period.

In those countries that did not provide product patent protection for pharmaceuticals on 1 January 1995, TRIPS obligations do not affect those drugs which were no longer "new" for patentability purposes on that date.⁶ That is to say, the TRIPS rules do not prevent such drugs from being freely copied in these countries.

When analysing the possible impact of the TRIPS Agreement in those developing countries that will be obliged by its provisions to introduce patent protection for pharmaceutical products, it is necessary to take into account the extent to which new medicines were previously competitively priced. It is not clear that this has been the case in all the countries concerned.⁷ Competitive pricing might not emerge if there are other non-patent related factors that restrict entry and competition, the most important being absence of a domestic generic drug industry or policies to facilitate generic imports from the cheapest sources. Not all developing countries have had such capabilities or policies in place.

Further, there is evidence that the presence of a higher number of local generic manufacturers does not necessarily mean lower local prices. According to 1999 IMS Health retail store sales data, Argentina, with five and eight local generic sellers respectively for two of the drugs involved in the HIV/AIDS triple therapy (zidovudine, lamivudine and saquinavir), had the highest weighted mean annual dosage cost for these drugs out of the 18 developing countries for which data was available, at US\$10,929 per person per annum. Brazil and India, with one seller each in the retail sales market, had the lowest cost, at US\$5,019 and US\$5,466, respectively.⁸

⁴ To the best knowledge of the WTO Secretariat, these countries were Angola, Argentina, Bangladesh, Brazil, Cuba, Egypt, Guatemala, India, Kuwait, Madagascar, Morocco, Pakistan, Paraguay, Qatar, Tunisia, Turkey, United Arab Emirates and Uruguay.

⁵ IP/Q/PRY/1.

⁶ Inventions cease to be "new" for patentability purposes once they have been disclosed or otherwise overtaken by the "prior art" (knowledge already in the public domain). Disclosure generally takes place as a result of publication of the patent application 18 months after its first filing. Judging by patent expiry dates in the US, patents for almost all HIV/AIDS anti-retrovirals currently marketed were filed well before 1995.

⁷ The oft quoted statistics comparing prices in India and Pakistan may well be an illustration of this.

⁸ Borrel and Watal, forthcoming. On the other hand, Argentina had fourteen anti-retrovirals available through its retail stores compared to seven and five in Brazil and India, respectively as of that date. It is important to note that, according to this data, the number of patients who received a full year's treatment of any single anti-retroviral through retail sales was two per cent of all HIV infected persons in Argentina and about 0.001 per cent of those in India. The data excludes purchases by government or charities for free or other distribution. Trends in the first half of 2000 show reductions in these costs but 1999 is the last calendar year for which data is available with the authors.

1.5 Some issues for discussion

- (1) What are the important factors that obstruct access to essential drugs in poor countries and what is their relative significance?
- (2) How important are tariff and non-tariff barriers in final prices of drugs in developing countries? What role can multilateral trade agreements play in the reduction or removal of these barriers in the developing world?
- (3) To what extent do patents give effective market power to introduce and maintain high prices and to what extent is this the case for essential drugs in poor countries?
- (4) To what extent is the price of non-patented drugs a hindrance to adequate access to essential drugs?
- (5) Assuming that essential drugs can be made available at prices that are affordable (with the aid of external financial assistance when necessary), what conditions need to be put in place to ensure that they actually reach those in need and are effectively used?

Session II - The role of financing in ensuring access to essential drugs

The subject of this session is the role and the relative importance of sustainable financing in improving access to essential drugs in poorer countries. This note looks in turn at:

- Current expenditures on pharmaceuticals and source of financing in poorer countries.
- Assessment of resources required to purchase essential drugs.
- Grants or donation of drugs by pharmaceutical companies.

2.1 Current expenditures on pharmaceuticals and source of financing in poorer countries

In developing countries private expenditures on the purchase of medicines constitute up to 70-90 per cent of total pharmaceutical expenditures as compared to an average of about 40 per cent for the group of OECD countries (WHO, 1997 and OECD, 2000). Much of the problem of access to essential drugs lies in the inadequate purchasing power of most people in low-income countries. According to the World Bank, "a sixth of the world's people produce 78 per cent of the world's goods and services and receive 78 per cent of the world's income — an average of US\$70 a day. Three-fifths of the world's people in the poorest 61 countries receive six per cent of the world's income — less than US\$2 a day".⁹

Not surprisingly, of the total global sales of pharmaceutical products, sales to the developing world constitute about one-fifth and sales to sub-Saharan Africa only about one per cent (Balance *et al*, 1992). Projections of the world pharmaceutical market for the year 2002 reveal a similar picture (www.imshealth.com). It is likely that most of these sales are targeted at the richest 10 per cent of the population in developing countries. According to the World Bank, there is generally greater inequality in the distribution of incomes in poorer countries than in the developed ones. The richest 10 per cent of the population in developing countries can have as much as 30-50 per cent of the country's income or consumption as compared to 20-30 per cent in developed countries.¹⁰

⁹See <http://www.worldbank.org/data/wdi2000/worldview.htm>.

¹⁰See http://www.worldbank.org/data/wdi2000/pdfs/tab2_8.pdf.

2.2 Assessment of resources required to purchase essential drugs

At this low level of purchasing power, it is clear that essential medicines will have to be distributed at very low cost for the majority of the world's population. Earlier annual per capita cost estimates of US\$1 or US\$1.60 for the provision of essential drugs sufficient to treat 85 per cent of illnesses in Africa (World bank, 1993) do not appear to have considered the cost of the more expensive drugs required for treating the HIV/AIDS pandemic. Notwithstanding differential pricing by pharmaceutical companies in poorer countries, additional financial assistance would seem necessary if basic needs are to be met. It is not clear how much can be raised domestically, especially by highly indebted nations.

At the lowest-priced offer made public to date, the cost of triple therapy drugs for treating one disease condition, HIV/AIDS alone, would be about a dollar a day.¹¹ At cost estimates of US\$500 per person per year for purchase of these medicines for Africa alone for the supply of HIV/AIDS drugs, Attaran and Sachs (2001) concluded that US\$7.5 billion per year would have to be forthcoming and that most of that would have to come from the rich country donors. Current total bilateral official development assistance amounts to only some US\$78 million per annum for all HIV/AIDS activities (including education, information and communication) in all developing countries.

In 2000, the World Bank announced financial assistance of up to US\$1 billion for combating the HIV/AIDS pandemic. In sub-Saharan Africa alone, this assistance is to be of the order of US\$500 million in soft loans.¹²

Recently, the United Kingdom, in its capacity as the current chair of the G-7, proposed that a new global purchase fund for drugs and vaccines be created both for treatments that do not yet exist and for those that already exist and are urgently needed. Pharmaceutical companies were called upon also to accept increased responsibility in this regard.¹³

2.3 Grants or donation of drugs by pharmaceutical companies

Pharmaceutical companies have for long had programmes under which drugs are donated to developing country users (see list in IFPMA, 2000b). In addition, the private sector may well have been more generous than many individual donor governments in making grants for disease control, including for the distribution of essential drugs in poorer countries (Attaran and Sachs, 2001).

Tax deductions for drug donations or other forms of company grants to developing countries can be an incentive for such measures and entail a degree of public/private sharing of the burden entailed. The US already has tax incentives for corporate donations. The recent announcement by the Government of UK that it will allow tax deductions for the entire value of drugs donated toward "treatments that are genuinely needed" in poor countries is another example.¹⁴

However, it needs to be remembered that even donated drugs may be "too costly" for developing country governments. This is because of the cost of the infrastructure required to get donated drugs distributed and effectively used.

¹¹ It is not clear if these estimates are at non-loss making prices or not.

¹² See <http://www.worldbank.org/html/extdr/transcripts/ts112800.htm>.

¹³ See http://www.htm-treasury.gov.uk/press/2001/p19_01.html.

¹⁴ See *ibid*.

2.4 Some issues for discussion

- (1) What is the magnitude of the financing required to provide both generic and patented essential medicines to the world's poor, even in the context of differential pricing?
- (2) How much of this can be raised through domestic resources in developing countries?
- (3) How much of this requirement can realistically come from external assistance from donor governments?
- (4) To what extent should such assistance come in the form of grants and to what extent as loans? Can the process of debt relief play a role in this connection? Should an international fund for financing the purchase of essential drugs be established?
- (5) What can the private sector contribute towards the financing of essential medicines? How much of this burden should be borne by the pharmaceutical companies? Should generic drug manufacturers in developed and developing countries also contribute?
- (6) How economically/politically efficient is the provision of tax incentives for donations? How can the adoption of such measures be promoted?

Session III - Differential pricing: concepts and issues

3.1 The concept of differential pricing

We define differential pricing as the adaptation, in some measure, of prices to the purchasing power of consumers in different countries. In the context of access to essential medicines, this would mean that pharmaceutical companies would charge lower prices in poorer countries. Since such pricing relates prices to consumers' ability to pay, it can also be seen as addressing issues of equity and is sometimes referred to as equity pricing. Again, since such pricing divides consumers into different groups or tiers, it is sometimes called tiered pricing.

The principle of differential pricing is based on the economic concept of price discrimination. Price discrimination describes the situation where a profit-maximizing seller sells the same product to different consumers at different prices and where the price differences bear no relation to differences in supply cost but rather reflect the differing willingness and ability of consumers to pay. For this to happen, three conditions need to be fulfilled:

- the seller must have some control over price, i.e. some degree of market power;
- the seller must be able to identify and segregate consumers according to varying price sensitivities; and
- opportunities for re-sale from low-priced markets to high-priced markets must be constrained or, in other words, market segmentation must be assured.

The counterfactual to differential pricing is uniform pricing wherein the seller sets one price, adjusted for transport, distribution and other costs, for all consumers and markets. Under such pricing, the seller maximizes his profits against global demand or an aggregation of each market's demand. The seller will continue global sales up to the point where costs of producing and selling an additional unit of the product exceed revenues from such sales anywhere in the world.

If the conditions for price discrimination can be fulfilled, economic theory suggests that it would be more profitable for pharmaceutical companies to charge lower prices in highly price sensitive markets, such as the poorer countries, than in less price sensitive markets, such as the richer countries. The seller would continue sales in each segmented market up to the point where costs of producing and selling an additional unit of the product exceed revenues from such sales in that market. Compared to uniform global pricing, the additional volume from selling at a lower price in the more price-sensitive market would more than offset the lower unit margins received there.

3.2 The welfare effects of differential pricing

A key question is what is the allocation of the welfare effects of a move from global uniform pricing to differential pricing in markets characterized by the requisite degree of market power, i.e. who are the winners and are there losers from such a change. In analysing this, there are three groups who are primarily affected:

- the consumer in the less price-sensitive (richer) market;
- the consumer in the more price-sensitive (poorer) market; and
- the producers.

With regard to the latter group, the producers, economic theory would suggest that, where the conditions for price differentiation are met, they will benefit from adopting such pricing. Indeed, in an environment where prices are set by the market, it can be expected that as a general rule they will only engage in such pricing to the extent that it is beneficial. Thus, in principle, differential pricing should also enhance incentives for research and development into new drugs and, to this extent, be in the long-term interests of consumers, in rich and poor countries alike.

With regard to the short-term interests of consumers in terms of access to existing drugs, much depends on the extent to which uniform pricing takes into account demand in more price-sensitive as well as less price-sensitive markets. If it does, then differential pricing may lead to an increase in prices in the less price-sensitive (wealthier) markets, and thus a loss of consumer welfare there, while leading to lower prices and increased welfare in the more price-sensitive (poorer) markets. If, on the other hand, the uniform world price is set with only the conditions in the wealthier markets taken into account, there should be no increase in prices in those markets from a shift to differential pricing, but only a reduction in prices in the poorer markets. In this situation, a move from uniform pricing to differential pricing should yield unambiguously positive welfare effects; that is to say, it should be a win-win situation in that the welfare of the consumer in the poorer countries is enhanced, and that of the consumer in the rich countries is not adversely affected but may actually, in the long term, increase as a result of enhanced incentives to R&D.

An important question therefore is whether the global pharmaceutical market corresponds to the second of the two situations described above. There would appear to be good reasons to believe that it does and that, in practice, where uniform prices are set, they are set without significantly taking into account the more price-sensitive markets. The reality of the global pharmaceutical market is that sales in poorer countries constitute a very small part of total sales. Moreover, sales in those countries may well be targeted primarily at the more well-to-do segment of the population which has a lower degree of price sensitivity than the poor in those countries. Further, since in many developed countries prices are not set by the market but are subject to some form of price regulation, there is no reason to expect a market-driven effect on these prices from a shift to differential pricing.

3.3 Why is differential pricing not more common?

If, as economic theory suggests, differential pricing can be a win-win situation which is good or at least not harmful to consumers and beneficial to producers, the question arises as to why it is not more commonly practiced. It might be helpful for the Workshop to explore this issue, since it may provide guidance as to what needs to be done to promote differential pricing. A number of possible explanations can be advanced. One of course is that there may not, in practice, be effective market segmentation between countries. For market segmentation to be effective for the purposes of differential pricing, it is necessary that not only should there be adequate means to prevent the diversion of the lower-priced product into the higher priced markets, but also an insulation of prices in the higher-priced market from any materially significant psychological or political effects that might flow from the existence of lower prices in the other markets. Another factor could be that the main market of interest in the poorer countries lies with the well-to-do minority and that it is difficult to adequately separate this market from the market represented by the poorer parts of the population. A third consideration may be that of administrative simplicity. These factors tending towards uniform prices, when combined with price controls in developed countries, may help explain the "anomaly" sometimes observed of higher prices in poorer countries.¹⁵

3.4 Ways of achieving win-win solutions with differential pricing

If indeed differential pricing can be generally welfare enhancing, the question arises as to how it should be given operational effect. Three main types of approach would appear to have been advanced:

- Establishing the right conditions and leaving it to the market.
- A combination of the above with negotiated price discounts and some degree of moral suasion.
- The establishment of a global system of differential pricing.

Where patented products are concerned, it may be recalled, when examining each of the above approaches, that under the legal environment in which the relevant markets work the supply of differentially priced products can be effected either through direct supply by the patent owner or through voluntary licensing. Subject to the conditions set out in the TRIPS agreement, compulsory licensing is also a possibility¹⁶.

3.4.1 *The market-driven approach*

Some economists (Danzon, 1997) have argued that, under the right market conditions, the prices charged for patented pharmaceuticals would be inversely related to the price sensitivity of the consumers in different markets and thus, differential pricing would resolve the dilemma that arises in the debate on prices of patented medicines for poor countries about how to ensure a fair allocation of joint R&D costs.

It is suggested in particular that this would be achieved if the conditions could be established for a form of price discrimination called "Ramsey pricing", named after an economist, Frank Ramsey (1903-1930). This theory is used to address the question of how utilities should allocate the burden of high fixed or sunk costs (for example those involved in establishing a telephone or electricity network) among different consumers so as to maximize welfare. Under Ramsey pricing the total

¹⁵ Price controls are, by and large, ineffective in poorer countries (Scherer and Watal, 2001).

¹⁶ As mentioned earlier in this note, this possibility can influence the terms of direct supply and of voluntary licensing.

revenue achieved by the seller would equal all costs plus normal profit. It is argued that this model can be effectively applied to the world of innovative pharmaceuticals, where the high sunk costs consist of research and development expenses. Indeed, under certain assumptions, notably those outlined in section 3.1 above together with that of competitive entry for therapeutic substitutes into the patented drug market, Ramsey prices would be approximately achieved in the long run. In this situation, it is suggested that the market outcome would be consistent not only with considerations of equity but also with those of efficiency since the global revenues generated would equal marginal cost of production plus a margin that just covers joint R&D costs and normal profits. It is claimed that a great advantage of Ramsey pricing is that outcomes consistent with the twin goals of efficiency and equity in the allocation of the joint R&D costs are automatically achieved if the requisite conditions are fulfilled.

An important question that arises is to what extent the Ramsey pricing logic applies in an imperfect world where there is price regulation of pharmaceuticals. Also, ideally Ramsey prices should be set for each market or group of consumers with different price sensitivities, both within and between countries. However, in practical terms, market segmentation within countries is more difficult than between countries. To what extent would Ramsey pricing work where there are income inequalities and possibly inadequate means to segment markets within countries?

3.4.2 Negotiated price discounts

The market approach outlined above can be combined with the negotiation of price discounts between buyer and seller. This type of an approach can have some advantages. The addition of a degree of monopsony purchasing power and the bulking of purchases can lead to better prices. Conditions on the use and distribution of the preferentially priced product can be negotiated with a view to safeguarding against diversion into higher-priced markets. The contracts and their terms can be either less transparent or presented in such a way as to minimize the risk of such discounted prices having repercussions on the acceptability of prices in the high price markets. A degree of moral suasion exerted by international public opinion can also influence the terms of such contracts.

3.4.3 Global system of differential pricing

Some commentators, when they talk of differential (or equity or tiered) pricing, seem to have in mind an approach under which prices would be set through some international regulatory mechanism. Exactly how this would work and who would be involved in setting and enforcing such prices is not very clear. Questions of acceptability and feasibility would need to be addressed. One of these is that of how to establish prices that strike the proper balance between ensuring affordable access to new drugs and making an appropriate contribution to R&D incentives.

3.5 Applicability of differential pricing to generic drugs

Much of the discussion of differential pricing is, implicitly or explicitly, about its application to patented products. This is because the patent system may lead to the degree of market power necessary for differential pricing to be feasible and also because of the public concern about the need to reconcile worldwide patent protection of pharmaceutical products with affordable access to essential drugs. One of the issues which the Workshop might wish to consider is the extent to which differential pricing can also be applied to non-patented drugs. This is an important question because, as indicated earlier in this paper, the vast majority of essential drugs are not under patent protection anywhere.

When considering this question, it is necessary to recall that there are a variety of situations under which non-patented drugs are produced and sold. They may be produced by the originator company and under the original brand name, after the expiry of the patent. They may be produced by another, "generic", company or even the originator company itself and sold under another brand

name. Finally, they may be produced by a company and sold, without any brand name, under the name of the active ingredient in the product. The degree of market power that may be enjoyed by the manufacturer will, other things being equal, vary according to the above. There may also be a variety of other factors which will affect the degree of competition on, and scope for entry into, any given market. Such factors can include trade and regulatory barriers, anti-competitive practices, corruption, etc. Thus, it should not be assumed that the conditions which would make differential pricing possible are necessarily absent where non-patented drugs are concerned. Indeed, it may be that session IV of the Workshop, which is looking at actual experience with differential pricing, will give some practical examples of the application of this concept to non-patented products, for example vaccines and contraceptives.

With regard to non-patented products, where the existence of market power does not have the underlying public policy purpose of providing incentives to research and development, the question arises as to whether promoting differential pricing or encouraging competition wherever possible is the optimal policy response.

3.6 Some issues for discussion

- (1) Is it accepted that, under the right conditions, differential pricing is welfare enhancing?
- (2) If differential pricing is good for producers, why is it not more common? What are the impediments to it and what needs to be done to remove them?
- (3) Can the market, under the right conditions, be relied upon to achieve satisfactory differential pricing or is there a case for some degree of moral pressure or regulation?
- (4) Is there a risk that differential pricing may lead to higher prices in developed countries? If so, what needs to be done to forestall this?
- (5) How can it be explained to public opinion in developed countries that differential pricing will not damage their interests, but may be advantageous if it leads to greater global incentives for R&D?

Session IV - Current experience with differential pricing

Some background information for this session is to be found in the note prepared by the WHO Secretariat with the aid of its consultants.

Session V - Market segmentation: techniques, actors and incentives

Whatever the approach taken to achieve differential pricing, actual and perceived market segmentation is an essential condition. This session seeks to examine different ways in which the diversion of low-priced products intended for poor country markets to other markets can be prevented. This will involve a discussion of what companies can do by themselves and what governments can do, in particular:

- Marketing strategies by manufacturers and contractual approaches.
- Governmental measures, particularly regulatory controls and export controls.
- The use of intellectual property rights.

In discussing these points, it is of course necessary to take into account competition law and international trade rules. The final sub-session is devoted specifically to consideration of the competition law questions that arise.

For market segmentation to be perfect, there must be no physical diversion of low-priced products to high-priced markets but also that there must be no perception of interdependence of price. If price in the high-income market is likely to be influenced even indirectly by the price in the low-income market, say through public opinion demanding lower prices, sellers would be reluctant to differentially price their product for fear of losing revenues in their more profitable high-income markets. It is suggested that these psychological or political linkages might be discussed primarily in subsequent sessions and session V focused on ways of avoiding product diversion.

5.1 Marketing strategies by manufacturers and contractual approaches

Manufacturers and sellers can, without any assistance from government, take several steps to ensure segmentation of markets. These include marketing strategies and contractual approaches such as purchase undertakings.

5.1.1 *Marketing strategies*

One way sellers of pharmaceutical products can try to segment markets to prevent diversion from low-priced to high-priced markets is through the use of different marketing strategies. One such strategy is to use a different brand name in different markets. For example, GlaxoSmithKline's well-known antiulcerant drug, Zantac, is called Zinetac in India. Another marketing technique used is to use a different colour or colour combination for the pill or capsule in low and high income countries. Differences in packaging or in language could also be used in some circumstances. Such strategies may help in preventing trade diversion as differently branded or packaged products may not have the required regulatory approvals in all markets. Also, they may not be recognized by consumers to be the same product. However, when there are large enough differences in price, middlemen may find it profitable to re-package drugs to suit different markets.

Another marketing strategy that may help to segment markets within a poor country would be to sell the preferentially priced product only to certain public health-care channels that are primarily used by the poor or located in certain poorer areas within the country. However, it would have to be considered whether, by itself, such a strategy would provide adequate safeguards against the diversion of the product into other markets.

5.1.2 *Purchase undertakings*

Another way in which market segmentation can be effected is through negotiating contractual commitments on the part of the purchaser of the preferentially priced product that the purchaser will ensure that the product is only used in the market for which it is intended. Such commitments may be only likely to be effective and credible where the purchaser is able to control directly the distribution of the product to the point of final consumption, such as might be the case with government or NGO-run hospitals or clinics. Of course, this is not just a legal matter since it is only with experience that trust in the effectiveness of such commitments will be built up.

5.1.3 *Ex-post reimbursement techniques*

A way in which markets within a country can be segmented is through ex-post reimbursement techniques. Such techniques enable the retail price to be uniform for all users, and thus minimize the risk of product diversion, while allowing for the effective price paid to be differentiated.

In the United States, in recent years health maintenance organizations (HMOs) and other specialized drug benefit managers (collectively called pharmacy benefit managers or PBMs) have instituted systems to obtain discounted prices on prescription drugs for their clients – usually an insurer, managed care company or employer. These discounts are paid directly to the client rather

than to the individual purchaser of the drug, thus eliminating the scope for arbitrage by traders. A European variation of this system was introduced by Germany in order to give discounted prices to the more price sensitive East Germans while not undercutting the West German market through parallel imports.¹⁷

This technique is of possible interest in two respects. One is that it offers a means of price differentiation within a jurisdiction. As has been noted earlier, a possible impediment to differential pricing in developing countries is the difficulty of separating the market of the well-to-do minority from that of the poor majority. Danzon (1997) has also raised the possibility of the payment of rebates by manufacturers directly to governments (or their surrogates) in countries where lower prices are appropriate.

5.2 Governmental measures

Since pharmaceutical products are extensively regulated in all countries, governments may be able to play a role in market segmentation.

5.2.1 *Role of regulatory authorities*

Even after a medicine is approved for marketing in one jurisdiction, extensive approval procedures are usually required to be followed before the medicine can be marketed in other jurisdictions. These procedures require not only the demonstration of the safety and efficacy of the product in that jurisdiction but also specific conditions with respect to the production, packaging and labelling of the product.

These regulation-driven obstacles to trade may be able, in practice, to contribute to the market segmentation necessary to make differential pricing work. For example, it is possible that a product authorized for marketing in a country enjoying a lower price would not have met the regulatory requirements for marketing approval in higher-priced markets. However, it has to be borne in mind that the deliberate use of such regulatory measures to restrict trade would likely give rise to questions about consistency with the WTO Agreement on Technical Barriers to Trade. This Agreement recognizes the right of countries to take measures which may restrict trade for legitimate public policy purposes, including for the protection of health, but requires that such measures not be a disguised restriction on trade nor be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries. Apart from running into possible legal problems with this Agreement, promotion of the deliberate use of health regulations as obstacles to trade would run counter to the public health interest of promoting competition in the market for pharmaceuticals and encouraging the development of international standards and conformity assessment systems.

The drug or medicines authorities, with the aid of customs administrations are perhaps the governmental agencies best placed to monitor imports of pharmaceuticals. This gives rise to the question as to whether these authorities in the developed countries can play a particular role in preventing trade diversion of products that have been put on the market in developing countries at lower prices. With regard to patented products, one way in which this might be done is through preventing parallel imports of patented products, that is to say imports without the authorization of the company that owns the patent in the country of importation, even if the product has been put on the market in another country by that company or with its consent. Governmental measures to restrict parallel imports have never been challenged as being inconsistent with WTO rules on trade in goods (for TRIPS rules see section 5.3 below).

¹⁷ This section has referred to Danzon, 1997, 28-29 and 89-90.

5.2.2 *Export controls*

Conceptually, it would also be possible for countries that are the recipient of preferentially priced products to restrict their export out of the country by giving the customs authorities the necessary legislative authority. Among the questions that this option gives rise to are those of feasibility and consistency with WTO trade rules.

In regard to the issue of feasibility, it has to be taken into account that customs infrastructure is generally more geared towards regulating imports than exports. Moreover, the countries that would be likely to be the recipients of preferentially priced essential drugs are those that are likely to have the least well-developed customs administrations.

In regard to the issue of consistency with the WTO rules on trade in goods, the starting-point is that as a general rule, the General Agreement on Tariffs and Trade (GATT) prohibits quantitative export restrictions. However, there are a number of exceptions to this provision. One (contained in Article XI:2(a)) allows export prohibitions or restrictions temporarily applied to prevent or relieve critical shortages of foodstuffs or other products essential to the exporting country. However, it should be noted that this clause can clearly only be used for temporary relief. Another provision, found in the general exceptions clause of the GATT (Article XX(j)), allows export restrictions essential to the acquisition or distribution of products in general or local short supply. There are a number of conditions attached. One is that the measure must be consistent with the principle that all WTO Members are entitled to an equitable share of the international supply of such products, and that any such measures which are inconsistent with the other provisions of GATT shall be discontinued as soon as the conditions giving rise to them have ceased to exist.¹⁸ This provision has not been the subject of any relevant GATT or WTO jurisprudence, for example in the context of dispute settlement.

5.3 The use of intellectual property rights

The use of intellectual property rights to effect market segmentation depends both on governmental measures to provide means of acquiring and enforcing intellectual property rights and on private actions to use such means. There are broadly two ways in which intellectual property rights can be used to segment pharmaceutical product markets: through licensing with geographical restrictions and through restrictions on parallel trade.

In regard to licensing, a patent owner (or owner of another type of intellectual property right) can license a third party to use the right in question subject to restrictions on the geographical area within which that licence is valid. Thus, a patent owner could contractually oblige his agent/licensee in a low-income country not to export to high-income countries. However, the reach of such contractual arrangements to persons which are not direct parties to the contract but which might come into possession of the preferentially priced product is very imperfect. Thus, there would appear to be limits to the extent to which such arrangements can be relied upon to prevent the undesired export of the product in question. The consistency of such arrangements with the national competition law in the jurisdiction in question could also be a factor; this is discussed in section 5.4 below.

¹⁸ It is also required that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.

A second way in which intellectual property rights can prevent the diversion of preferentially priced pharmaceutical products from low to high income markets is through intellectual property legislation that provides the legal means by which right holders can take action to prohibit imports, without their consent, of products incorporating their rights – in other words, to prevent parallel imports. In general, under intellectual property law, the rights of right holders are exhausted once the product has been put on the market by or with its consent. The question is whether the right holder can object to the importation by a third party of a product that has been put on the market *in another country* by or with its consent. When the intellectual property law of a country does not give this right to the right holder, the right holder cannot prevent imports of "grey market goods" or "parallel imports". However, where the rights of the right holder in the country of importation are not exhausted by its putting the product on the market in another country (but only when it has done so in the country of importation), then the right holder can use its intellectual property right to prevent such imports.

Thus, intellectual property law can provide a means by which companies can prevent the diversion of low-priced products intended for poor countries into developed country markets. However, there are a number of possible limitations to the use of this mechanism. One is that it depends on the existence of intellectual property rights in the products in question. It will thus likely be more useable for patented drugs than generic ones. Second, it depends on the intellectual property law in question giving right holders the right to prevent parallel imports; such rights tend to be stronger under patent law than trademark law. Third, it relies generally on a private right of action against individual importers (or sellers in the country of importation) and therefore may be burdensome and incompletely effective.

The TRIPS Agreement (Article 6) states explicitly that WTO Members practices in regard to the exhaustion of intellectual property rights cannot be challenged under the WTO dispute settlement system, provided that they do not discriminate on the basis of the nationality of the persons involved. It might also be noted that, to the extent that parallel importation is an infringing act, the TRIPS enforcement provisions only require civil judicial procedures and remedies to be available. The additional enforcement mechanism involving the assistance of the customs administration to prevent infringing imports only has to be applied in respect of counterfeit trademark goods and pirated copyright goods and explicitly excludes parallel imports. As regards criminal procedures, the TRIPS Agreement only requires them to be made available in respect of wilful trademark counterfeiting or copyright piracy on a commercial scale.

5.4 Competition policy considerations

National competition laws and related policies are another important factor that may have implications for the ability of pharmaceutical companies to engage in differential pricing favouring poor countries. As discussed below, there are several dimensions to this question, many of which are complex. While the following reflects on various aspects of the issues, clearly, firms contemplating initiatives relating to differential pricing in the pharmaceutical sector should be guided by their own legal counsel regarding possible risks associated with the application of national competition laws to such initiatives. Furthermore, in evaluating possible risks, it would be important to take account of the application of competition laws that exist in countries that would be the intended beneficiaries of differential pricing, in addition to other countries whose laws might be applicable in some circumstances.

A first issue to be considered is whether the mere act of charging lower prices in some countries as compared to others (i.e., international price discrimination) would raise issues under national legal provisions relating to price discrimination. Broadly speaking, although it would be important to consider the full range of legal provisions in the various countries affected, it appears that major competition policy jurisdictions such as the United States and (possibly) the European Community either do not apply certain legal provisions on price discrimination

internationally or are unlikely to deem the mere act of charging different prices to consumers in countries that constitute different markets for competition law purposes to be actionable under such provisions. For example, in the United States, the *Robinson-Patman Act*, which regulates discriminatory pricing practices, applies only to purchases involving commodities for use, consumption, or resale within the United States and has been specifically construed not to apply to sales for export.¹⁹ The European Commission, in its recent Issues Paper on Tiered Pricing, states that: "It is unlikely that there are antitrust concerns with regard to the principle of tiered pricing. Differential pricing only raises concerns if it amounts to discrimination [between] categories of consumers in the same relevant market."²⁰

Possibly in contrast to international price discrimination, the act of charging different prices to different classes of consumers within a particular country could well raise issues under national competition law provisions relating to price discrimination, depending on the specific content of those provisions and the facts at hand. Clearly, this would be an important factor to consider with regard to any such initiatives. On the other hand, it may also be borne in mind that, increasingly, competition agencies, in their analyses of particular cases and fact situations, are sensitive to the potential welfare-enhancing and pro-competitive effects of price discrimination. While this would not likely immunize conduct that is otherwise in violation of relevant laws, it might become a factor if, in particular cases, it is necessary to seek "comfort letters" or other assurances from relevant authorities regarding a particular course of action.

A related question is whether and, if so, under what circumstances differential pricing could give rise to issues concerning predatory pricing or abuse of a dominant position. Allegations of this nature might arise, for example, if the practice of differential pricing has the effect of eliminating or retarding the growth of pharmaceutical companies in the countries that are the intended beneficiaries of the practice and/or (possibly) third countries that are supplying or attempting to supply the markets of the beneficiary countries. Here, it would be important to consider the standards applicable to predatory pricing claims under the competition laws of the various affected countries. Typically, in jurisdictions with well-established competition regimes, establishing an allegation of predatory pricing requires proof of some or all of the following elements: (i) below-cost pricing; (ii) predatory or monopolistic intent; and (iii) a likelihood that the costs of below-cost pricing to the alleged predators can eventually be recouped through the charging of higher-than-competitive prices.²¹ A related question, not considered here but worthy of attention, is whether differential pricing policies could, in some circumstances, give rise to issues under the anti-dumping or other contingency trade remedy laws of the affected countries.

Another important set of questions concerns the treatment under national competition laws of geographic territorial restrictions that are embodied in licensing agreements or other contractual arrangements relating to the manufacture and sale of pharmaceuticals. In reflecting on this issue, it is important to distinguish between contractual relationships that are horizontal in nature (i.e., involving entities that would have been actual or likely competitors in a relevant market, in the absence of the arrangement) and those that are essentially vertical in nature (i.e., involving firms that are not in direct competition with each other).²² While the former would be viewed with suspicion by most competition authorities, the latter are more likely to be subject to relevant exceptions or exemptions and/or to be tolerated under a "rule of reason" or case-by-case approach to the application of relevant

¹⁹ See U.S., Department of Justice and Federal Trade Commission, (1995a), footnote 12.

²⁰ See http://europa.eu.int/comm/trade/pdf/med_ip.pdf.

²¹ Generally, the latter element requires proof of the existence of substantial barriers to entry into the relevant market(s) since, without such barriers, any attempt to raise prices above costs would trigger entry by new competitors. In the case of patented medicines, the patents themselves might well constitute such a barrier.

²² U.S., Department of Justice and Federal Trade Commission, (1995b), section 3.3.

laws.²³ This recognizes that the latter type of restrictions often serve legitimate, pro-competitive purposes, for example by reinforcing incentives for the commercialization of products and preventing free-riding.²⁴ Broadly speaking, licensing or other arrangements through which firms combine their inputs or technology to make available products that would not otherwise be available in a particular market would tend to be considered as vertical in nature, and therefore subject to more permissive treatment. On the other hand, arrangements involving firms possessing technologies that are actual or potential substitutes in a market would likely be classified as horizontal in nature, and therefore be subject to stricter treatment. The latter could be the case, for example, where firms possessing competing technologies employ cross-licensing or similar arrangements to establish a *de facto* cartel.²⁵

Apart from territorial restrictions in licensing or other voluntary contractual arrangements, barriers to importation may arise through rights of action against parallel imports under relevant intellectual property laws that are enforceable in the courts. In most jurisdictions, claims asserted in relation to such rights would, presumably, be adjudicated under the relevant intellectual property doctrines rather than as a matter of competition law. In the European Community, however, the use of intellectual property rights to limit the movement of goods within the Community can in some circumstances be challenged under the competition provisions of the EC Treaty.

Finally, an issue that has been raised by industry representatives in the context of the current interest in differential pricing for pharmaceuticals is whether, if there is *concerted* action among companies to lower prices in poorer countries (i.e., through an agreement or joint commitment), this in itself could raise issues under provisions of national competition laws dealing with horizontal agreements or price fixing. This concern should not be swept aside lightly. Prohibitions of collective action by competitors on prices and other variables are at the core of all effective competition law regimes. Inter-firm arrangements that limit competition among firms that would otherwise be competitors in the supply of particular goods, services or technologies may be subject to strict or "*per se*" prohibition and heavy penalties. Nonetheless, the following factors would seem to be relevant to assessing the potential for issues to be raised in this area:

- international action on this issue seems less likely to raise concerns of this nature to the extent that it is aimed at encouraging greater use of international price differentiation by companies purely on an independent basis;
- in the case of those patented medicines in respect of which the patent-holder enjoys significant market power, by definition, the products involved are less likely to be in direct competition with products supplied by other firms; and
- in general, measures that have the effect or intention of making prices more transparent are not deemed to be anti-competitive *per se*. Nevertheless, it is recognized that increased transparency of pricing can sometimes be used by firms to engage in tacit forms of collusion through price signalling and related activities.

²³ More specifically, in the United States, vertical licensing restrictions are generally evaluated by the antitrust authorities under a *rule-of-reason* standard which recognizes that such restrictions often serve legitimate, pro-competitive purposes. Restrictions of this nature can nevertheless be deemed to violate antitrust law if they substantially foreclose access to a market or otherwise have demonstrable anti-competitive effects. The European Commission in its Issues Paper on Tiered Pricing points out that "as far as contractual clauses relating to parallel importation [are] concerned, Such measures would only raise competition concerns if they were to distort competition and affect interstate trade within the Community to an appreciable extent".²³ While implying that contractual restrictions on parallel imports are unlikely to be of concern in the majority of cases, this leaves open the possibility that such arrangements could be actionable in particular cases.

²⁴ See U.S., Department of Justice and Federal Trade Commission (1995b).

²⁵ See the discussion of relevant examples in U.S., Department of Justice and Federal Trade Commission, *ibid*.

In the light of the above, it is important to consider carefully whether any particular new arrangements or initiatives relating to pharmaceutical pricing could raise issues under national competition laws. If firms consider that possible initiatives relating to differential pricing could have this effect, they may wish to take advantage of programmes that are offered by competition authorities in many countries to obtain advisory opinions regarding the probable treatment of possible arrangements under relevant national laws. In addition, it is relevant to note that actions which are taken in order to comply with specific, validly-enacted government directives may enjoy limited immunity from national competition laws.

5.5 Some issues for discussion

Among the issues that might be discussed in this session are:

- (1) What are the most effective techniques for preventing diversion of low-priced products into developed country markets?
- (2) Will private action be sufficient, for example marketing strategies, contractual arrangements, use of IPRs, etc., or is the backing of governmental measures at the import and/or export end also necessary?
- (3) Is segmentation of markets within countries necessary to make differential pricing work and, if so, how can it be made effective?
- (4) Can the necessary segmentation of markets be achieved consistently with existing national competition law and international trade law?

Sessions VI-VII - Purchaser perspectives and incentives for differential pricing and other perspectives on financing and differential pricing

These sessions provide for a variety of perspectives on differential pricing and financing of essential drugs to be expressed. Some notes on some of the points that might be discussed follow.

One issue is the extent to which public opinion in the wealthier countries can accept preferential pricing of essential drugs in poor countries. A number of the speakers may wish to comment on this question, in particular those from consumer associations.

Another issue is what incentive measures can the governments in developed countries put in place to encourage differential pricing?

The reaction of the generic industry in poorer countries to differential pricing in their markets, in particular by large foreign companies, might be discussed. Is there a risk that they might regard such practices as a form of dumping? Where some form of financial incentive has been granted by the government in the country of export of differentially priced products, is there a risk that such trade would be considered "unfair" and requests made for the imposition of countervailing duties?²⁶

²⁶ Under the WTO trade rules, a WTO Member is entitled to take measures against dumping (impose anti-dumping duties) in situations where a product is exported from a country at a price which is less than the price at which it is sold for consumption in the country of export. Member governments are also entitled to impose countervailing duties to offset subsidies that have been granted in the country of origin or exportation of a product. In both cases, it must be shown that the imports in question are causing or threatening material injury to an industry in the country of importation or materially retarding the establishment of such an industry.

One particular problem of market segmentation can arise where the prices allowed in one country are determined by reference to the prices practiced in a number of other countries – the issue of international reference pricing. If prices determined in wealthier countries use prices in poorer countries as references, this could constitute a significant disincentive to differential pricing.

A further issue for discussion is how differential pricing can serve the purposes of public/private partnerships which aim to promote the development of new vaccines and drugs to treat conditions prevalent in developing countries. Where there is a significant market for such products in both rich and poor countries, the question is whether differential pricing can help combine, in an optimal way, the incentive effects of the patent system with non-commercial funding aimed at promoting the interests of the people in developing countries in terms both of the generation of new drugs and vaccines and affordable access to them. The question might also be discussed as how the intellectual property regime under such programmes are being or can be formulated to strike this balance.

ANNEX

PHARMACEUTICAL PATENTS AND THE TRIPS AGREEMENT

The purpose of this note is to describe those provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that relate to the standards of patent protection to be accorded to inventions in the area of pharmaceuticals. To set this discussion in context, it is useful to recall three basic features of the TRIPS Agreement:

- that, together with some 25 other legal texts, it is an integral part of the Agreement Establishing the World Trade Organization (and therefore subject to the WTO dispute settlement system);
- that it covers not only patents but all the other main areas of intellectual property rights; and
- that it lays down not only the minimum substantive standards of protection that should be provided for in each of these areas of intellectual property, but also the procedures and remedies that should be available so that rights holders can enforce their rights effectively.

The basic balance in the TRIPS Agreement

Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is not always easy. Doing so at the international level is even more difficult than at the national level. Perhaps nowhere do these issues excite stronger feelings than in regard to pharmaceutical patents, where tension between the need to provide incentives for research and development into new drugs and the need to make existing drugs as available as possible can be acute.

The TRIPS Agreement attempts to find an appropriate balance. Its Article 7 entitled "Objectives" recognizes that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of users and producers of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. It is not an Agreement about simply maximizing the level of protection for intellectual property; rather, it emerged from a genuine negotiating process where the need for balance was very much to the fore.

What pharmaceutical inventions must be patentable under the TRIPS Agreement?

The main rule relating to patentability is that patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability – namely, novelty, inventive step and industrial applicability. In addition, Members are required to make grant of a patent dependent on adequate **disclosure** of the invention and may require information on the best mode for carrying it out. Disclosure is a key part of the social contract that the grant of a patent constitutes since it makes publicly available important technical information which may be of use to others in advancing technology in the area, even during the patent term, and ensures that, after the expiry of the patent term, the invention truly falls into the public domain because others have the necessary information to carry it out.

Three types of exception to the above rule on patentable subject-matter are allowed. These may be of interest from a public health perspective:

- inventions the prevention of whose commercial exploitation is necessary to protect *ordre public* or morality, including to protect animal or plant life or health;
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.

What are the rights conferred by a patent under the TRIPS Agreement?

The minimum rights that must be conferred by a patent under the TRIPS Agreement follow closely those that were to be found in most patents laws, namely the right of the patent owner to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product or a product obtained directly by the patented process.

Term of protection

Under the TRIPS Agreement, the available term of protection must expire no earlier than 20 years from the date of filing the patent application. It should be noted that, although the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the Uruguay Round negotiations, the TRIPS Agreement does not contain an obligation to introduce such a system.¹

Limitations/exceptions to these rights

Under the TRIPS Agreement, patent rights are not absolute but can be subject to limitations or exceptions. These can be put into three categories:

- the Agreement allows **limited exceptions** to be made by Members provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Thus, for example, many countries allow third parties to use a patented invention for research purposes where the aim is to understand more fully the invention as a basis for advancing science and technology. The WTO Panel in *Canada – Patent Protection for Pharmaceutical Products* decided that this provision, allowing limited exceptions, covered a provision of Canadian law which permits the use by generic producers of patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires. (This provision is sometimes referred to as the "regulatory exception" or as a "Bolar" provision.) The Panel Report was adopted by the WTO Dispute Settlement Body on 7 April 2000;

¹ The effective period of patent protection for inventions of new chemical entities is much less than the full 20 years, because a large part of that period will have expired before marketing approval is obtained from the public health regulatory bodies. For this reason, most of the major developed countries have introduced systems whereby a prolonged period of protection can be obtained to compensate, at least in part, for this loss of the effective period of protection.

- the Agreement also allows Members to authorize use by third parties (**compulsory licences**) or for public non-commercial purposes (**government use**) without the authorization of the patent owner. Unlike what was sought by some countries in the negotiations, the grounds on which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner. There is not space to discuss all of these here, but two of the main such conditions are that, as a general rule, an effort must first have been made to obtain a voluntary licence on reasonable commercial terms and conditions and that the remuneration paid to the right holder shall be adequate in the circumstances of each case, taking into account the economic value of the licence;
- the Agreement recognizes the right of Members to take measures, consistent with its provisions, against **anti-competitive practices** and provides more flexible conditions for the grant of compulsory licences where a practice has been determined after due process of law to be anti-competitive. For example, each of the conditions specifically referred to above for the grant of compulsory licences may be relaxed in these circumstances. The Agreement also provides for consultation and cooperation between Members in taking action against anti-competitive practices;
- the TRIPS Agreement makes it clear that the practices of WTO Members in regard to the **exhaustion** of intellectual property rights (e.g. a Member's decision to have a national exhaustion regime, under which right holders can take action against parallel imports, or an international exhaustion regime, under which they cannot) cannot be challenged under the WTO dispute settlement system, provided that they do not discriminate on the grounds of the nationality of right holders.

Other policy instruments

It should be remembered that governments have a range of public policy measures before them outside the field of intellectual property to address issues of access to and prices of drugs. For example, many countries use price or reimbursement controls. Article 8 of the TRIPS Agreement makes it clear that WTO Members may, in formulating or amending their rules and regulations, adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the Agreement.

Transition provisions

The TRIPS Agreement lays down some rather complicated transition provisions which give countries periods of time in order to adapt their legislation and practices to their TRIPS obligations, which periods differ according to the type of obligation in question and the stage of development of the country concerned. Here we will limit the discussion to those transition provisions which relate to the application of the obligations on substantive standards for the protection of pharmaceutical inventions. For these purposes, the obligations should be divided into two categories:

- (i) the obligations relating to the introduction of product patent protection for pharmaceutical products in those developing and least developed countries which do not yet grant it. Since most developing and least developed country Members of the WTO already provide for product patent protection for pharmaceuticals, a relatively small number of countries are concerned;
- (ii) obligations regarding process patents for this group of countries and all patent protection obligations for other developing and least developed countries.

With respect to the second category above, the basic rule is that developing country Members had until 1 January 2000 and least developed country Members have until 1 January 2006 to meet the obligations in question. At that time, the rules of the TRIPS Agreement will apply not only to new patent applications but also to patents still under protection in their territories.

With respect to the first category of situations referred to above, the developing countries in question have until 1 January 2005 to apply product patent protection to pharmaceutical products and the least developed countries until 1 January 2006. Notwithstanding proposals to the contrary, the TRIPS Agreement does not require the bringing under protection of pharmaceutical inventions that were in the "pipeline" in these countries at the time of entry into force of the WTO.² However, with effect from the entry into force of the WTO (1 January 1995), these countries have been under an obligation to provide a system whereby applications for patents for pharmaceutical product inventions can be filed (often referred to as a "mailbox" system). These applications do not have to be examined until after 1 January 2005 (or 1 January 2006 in the case of least developed countries). If found to be patentable by reference to their filing (or priority) date, a patent would have to be granted for the remainder of the patent term counted from the date of filing. In the event that a pharmaceutical product that is the subject of a "mailbox" application obtains marketing approval prior to the decision on the grant of a patent, an exclusive marketing right of up to five years will have to be granted provided that certain conditions are met.

Concluding remarks

It will be noted that most developing and least developed countries already grant patent protection for pharmaceutical products. In these countries, the TRIPS Agreement will therefore not lead to fundamental changes in this regard, although a certain amount of adjustment in legislation, for example in respect of patent term and compulsory licencing, may be necessary. With respect to the fairly limited number of countries that did not provide patent protection for pharmaceutical products at the time of entry into force of the WTO Agreement, some, including Brazil and Argentina, have decided to bring such protection into effect more quickly than is required under the TRIPS Agreement.

It will also be noted that the TRIPS Agreement pays considerable attention to the need to find an appropriate balance between the interests of rights holders and users and that this was an important theme in the negotiations. This is not only reflected in the basic underlying balance related to disclosure and providing an incentive for R&D, but also in the limitations and exceptions to rights that are permitted and in the transition provisions.

It should also be appreciated that the protection of pharmaceutical inventions is one aspect of a much wider agreement, covering not only the protection of intellectual property in general in a coherent and non-discriminatory way but also further liberalization and strengthening of the multilateral trading system as a whole. While it is true that some countries put particular emphasis on TRIPS matters in the Uruguay Round negotiations, it is also true that other countries attached great importance to other areas, for example textiles and agriculture. It is a belief shared by all WTO Members that a strong and vibrant multilateral trading system is essential for creating conditions for economic growth and development worldwide. This in turn provides for the generation of the resources required to tackle health problems.

² The "pipeline" refers to the backlog of inventions of new pharmaceutical products that were no longer patentable on that date, because disclosed, but not yet on the market because pending marketing approval.

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