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 W3(the .5(ck)12.3(g)12.712.)-11.1(c-0.00cut)7.3(sing914132.4(10.9(t2.3(e)-0.(to

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

Frequently, commentators write as if developing countries in general did not provide product

2.2 Assessment of resources required to purchase essential drugs

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?

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.

3.3 Why is differential pricing not more common?

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

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?

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

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

A second way in which intellectual property rights can prevent the diversion of preferentially

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

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

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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.

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

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

- the Agreement also allows Members to authorize use by third parties ( ) or for public non-commercial purposes ( ) 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

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

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