FINANCING AND DIFFERENTIAL PRICING

A developed country government pernfsDctive Tj 21095 -9 civU TD UtD /F2 12 r

networks. It means ensuring that essential drug policies are more closely focussed on developing countries so that medicines are available in sufficient quantities to cope with emergency situations. In the longer-term, it also means assisting these countries to set up their own production facilities, in partnership with European, or non-European, generic and research-based industries.

Secondly, and this is the area of most immediate interest to us here, the Programme for Action calls for key pharmaceuticals to be made more affordable. The health crisis is not going to go away unless there is widespread access to essential medicines at prices people in developing countries can afford. We consider that a global differential, or *tiered*, pricing system currently represents the best chance of pushing back the menace now hanging over these countries. The European Commission is committed to working with the international community, governments, the public and private sectors, and NGOs in order to achieve this. Of course, there are many potential problems and I will be returning to those, but this workshop is an important step on the road.

Thirdly, the Programme for Action contains a commitment to strengthen and increase investment in research and development, particularly on new products targeted at the major communicable diseases.

A lot of hopes are riding on this Programme for Action, and on others developed elsewhere. Its existence is proof of the commitment that developed countries are making. However, good intentions are not enough and, if we are to see real progress, we have to face up to some hard questions. And some of the hardest questions are those we have been trying to answer in this workshop ….

Tiered pricing

I return now to the main theme of this workshop – tiered pricing. This is widely agreed to be an essential tool in increasing the affordability of essential medicines, both patented and generic, so that sufficient volumes reach the populations most in need of them. The concept itself is nothing new and has been applied to vaccines for very many years. However, and despite a number of widely-publicised initiatives to bring down the cost of, for example, antiretrovirals in developing countries, tiered pricing has still not yet been extensively applied to medicines. It remains a fact that even such promising schemes as the Accelerating Access Initiative – a genuine public/private partnership of the kind we are all so anxious to promote - have so far been limited in their impact.

In recent months, developed country governments, and their research-based pharmaceutical industries, have come under increasingly fierce

possible to the cost of manufacturing. This also requires accountability, if we want to make sure that the taxpayer agrees to substantial funding. More detailed work on the scope and modalities of tiered pricing is needed, urgently.

Industry should come forward with proposals for a global and systemic approach. The ball is in their court.

The problem of parallel imports

The chief problem with supplying medicines on the vast scale required, as perceived by the research-based industry at least, is that they might find their way back onto developed country markets, exerting downward pressure on prices and therefore reducing the margins which enable the industry to make the necessary investment in developing the next generation of medicines.

This assertion is, so far as I am aware, unproven. And even if it were true, it would be no easy task to quantify. Would the rate of parallel imports increase in line with the volume of cheap medicines supplied to developing countries? And how large is the potential market for such imports? The medicines we are talking about are, in principle, sold only on prescription in Europe and are tightly controlled – and normal competition rules do not apply to the largely public health sector.

Moreover, since most European citizens are covered by reimbursement schemes and some diseases hardly appear in Europe, one may wonder whether there will a great demand for lower prices. Of course, in countries with less developed social security systems, it may be a different story.

Fortunately, there are already many ways of preventing such product diversion. The Commission's Programme for Action refers to a number of technical measures, such as differential labelling, packaging and trademarks to identify preferentially priced products. There is also plenty of scope for contractual arrangements between the exporter, importer and couenty

ld is alay soughtrks tcou proeand sope miys ion1rkag-nty

saptmedicineury.

coue. Anowhethpommibilcuriw (ld bcope fwheand) Tj T* -0.8365 Tc 722863 Tindusoutelop

s

countrory.

I amo otome putkag, though, thgrethre iuregrelea mopotferentiaregialriousber

8

to ensure that effective safeguards are available should they be needed. It may well be that special enforcement procedures will have to be implemented in the importing and/or the exporting country, although care will have to be taken that any measures which are adopted do not affect the free movement of goods *within* the Community.

I was encouraged during our discussion to note that, in this group, there appears to be consensus that nothing in the TRIPs Agreement prevents WTO Members from adopting legislation preventing the re-importation of medicines exported at tiered prices.

As things stand at present, if goods protected by a patent in the Community enter a Member State from a third country without the consent of the patent holder, the latter can take legal action in a national court to have the goods confiscated, to seek an injunction to prevent further imports, or to obtain damages. This is because the Community applies *regional* exhaustion – it would not be possible in the few countries which apply *international* exhaustion. So, effective remedies are available, although the fact that they are purely *national* can be considered a weakness in terms of their timeliness and cost. We all look forward to the day when a Community patent regulation finally enters into force …

Trademark law provides similar rights. Like patents, enforcement is on a national basis, although the existence of a Community trademark system makes life a good deal easier, and cheaper, for the right holders.

We believe these remedies could well be sufficient. However, we are conscious of the importance of the issue and we are aware, too, that not everybody is of the same opinion. That is why, as I mentioned earlier, the Commission services are currently looking at the whole range of possible ways of combating parallel imports. For example, one way might be to withhold marketing approval; another might be to amend the rules on the wholesale distribution of medicinal products to exclude any that are imported from certain developing countries; yet another might be to amend existing, or introduce new legislation so as to be able to block imports at the Community border. I am not saying that these are feasible, or indeed necessary at this stage – just that they are avenues which may be worth exploring. However, it risks being difficult to draft rules, which are applicable specifically to re-imports of medicines exported at tiered prices. In addition, we need to establish how we can avoid that tiered pricing be used to undermine prices on the export markets. Also,

compulsory licences, in certain circumstances, in order to address urgent public health issues. The Agreement also allows developing and least developed country members long transition periods for implementing the Agreement.

However, if developing countries can show that they are having problems implementing the Agreement, technical assistance is available to help them. In addition, if these countries feel that the Agreement does

Financing

come the 4th WTO Ministerial in November, the international community will be well on the way to defining a concerted approach to this truly global challenge.

Invitation

For all these reasons, you are all invited to work with the European Commission on all these issues. We have already spent an enormous