FINANCING AND DIFFERENTIAL PRICING

A developed country government perspective

by

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Introduction

Ladies and Gentlemen,

Since Monday, we have been discussing a whole range of topics related to the differential pricing and financing of essential medicines. I think we have all learnt a lot from this workshop and our efforts to tackle the spiralling health crisis in developing countries cannot but benefit as a result.

Now, as the workshop draws to a close, it is time to put the subject into perspective. I have been asked to do this from the point of view of developed country governments. Of course, it would be presumptuous of me to pretend to speak for all of them. However, as you know, the European Community does have fifteen Member States and the European Commission has been working closely with the Member States and the European Parliament on these issues for almost a year.

During this period, we have been working with all possible stakeholders, representatives of developing countries and international organisations with a view to establishing a comprehensive approach taking account of all interests. At times, of course, we do find ourselves in the middle of the requests of all these parties , and I can assure you it is not always a comfortable position! My intervention will demonstrate this. However, it is important to keep in mind that we are all working

towards a common goal, and that while we may sometimes differ on the means, we are all agreed on the ends. This is what matters.

The European Commission's Programme for Action

The growing scale of the health crisis in Africa, and in developing countries generally, has long been a matter of deep concern to the citizens of Europe. The European Commission, and the Member States of the Union, have responded to this. A number of initiatives have been taken, or are in the process of being taken, by individual countries. And you will all be aware that a few weeks ago, the European Commission adopted a 'Programme for Action' targeted at the three main communicable diseases – HIV/AIDS, malaria and tuberculosis. Copies of this have been made available by the secretariat, but I would like to briefly remind you of what it sets out to do, during the coming five years.

Firstly, it seeks to maximise the impact of what the Community is already doing in the health sectors of developing countries, in particular by speeding up the disbursement of aid to ensure that resources are directed where they are needed, when they are needed. Pharmaceutical policy and practice in these countries will also be strengthened. This means improving financial management, addressing regulatory aspects, promoting information exchange, and developing quality control

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

attack from developing countries, NGOs and the media for their alleged failure to deliver medicines at affordable prices, or for doing so in insufficient quantities. It is the view of the European Commission that a firm, long-term commitment from manufacturers (R&D and generic producers) to supply these products at the lowest possible prices would be a major contribution to the problem of access to affordable medicines. In short, tiered pricing for developing countries should no longer be the exception, but the rule. What is lacking, however, is a clear view of how to proceed in a way which is both *global* and *systemic*.

I should emphasise that I personally do not favour any framework which is too rigid. We need a comprehensive approach which is flexible enough to meet the needs of disparate populations and which can be grafted onto organisational structures of the most varied kinds. However, we all know that even at prices bordering on those for generics, these medicines are still well beyond the reach of the poorest sufferers. In fact, it is clear that the vast majority of those infected in developing countries will never be able to afford either patented or generic medicines unless they are provided almost free of charge.

This probably means indeed that some kind of international funding mechanism needs to be set up. And if public authorities commit themselves to providing substantial funding, pharmaceutical companies must be prepared to sell at sustainable prices which are as close as

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 distributor of the medicines. The cooperation of developing country governments could also be sought to introduce some form of 'ring-fencing', on a national or regional basis, to prevent cheap medicines leaving the recipient country. Another possibility would be for the industry, an international body, or the larger NGOs to supervise the whole chain, from despatch to consumption. The case of vaccines has been encouraging, but it is likely to be more difficult in the case of HIV/AIDS medicines because of the long-term nature of the treatment and the relative weakness of the health infrastructure in most developing countries.

I am not disputing, though, that this is, at least potentially, a serious issue and Commission officials are currently examining what can be done

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, competition aspects need to be taken seriously, but should not be exaggerated and should not be used as an argument to block progress in this debate.

The TRIPs Agreement

A word now on the TRIPs Agreement and its place in the debate on access to medicines. Recently, the Agreement has been criticised for allegedly preventing developing countries from addressing public health concerns, and for enabling the research-based pharmaceutical industry to evade its moral responsibilities towards the developing world.

Now, it is not for me to say what the industry should or should not be doing. What I can say, though, is that the Commission fully supports the TRIPs Agreement and believes the protection it affords ensures that creativity and innovation are properly rewarded. We do not hold with the view that the Agreement only serves the interests of rightholders in developed countries. In fact, developing countries also need an intellectual property system if they want to protect the business interests of their own nationals, or if they want to benefit from, for example, technology transfers, or to promote economic development generally.

Moreover, Commissioner Lamy has said on numerous occasions that the Agreement gives all members, including developing country members, the necessary scope to adapt their intellectual property legislation to widen policy objectives. In this respect, the EC recognises that within the TRIPs Agreement, there exists flexibility to issue

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 stand in the way of, for example, achieving their health objectives, the Commission is willing to promote discussion on this issue in the interests of reaching an international consensus[1]. Indeed, at last week's TRIPs Council, the Commission supported a proposal for a special session of the Council on 'TRIPs and Health' to be held in June. This should do much to clarify the interpretation of the relevant provisions of the Agreement in so far as they have a bearing on public health policy in general, and access to medicines in particular.

The Commission, though, remains of the opinion that the TRIPs Agreement cannot be held responsible for denying developing countries access to medicines. There are many factors which come into play, and one of them is poverty itself. This is why tiered pricing is so important – it addresses, even though it does not solve, the root cause of the problem.

[1] The interpretation of the European Community and the Member States of Articles 31 and 39.3 TRIPs can be found on the following website: http://europa.eu.int/comm/trade/csc/med.htm, particularly in document: http://europa.eu.int/comm/trade/pdf/med_lic.pdf.

Financing

Finally, I shall now turn very briefly to the subject of financing. I say 'briefly' because this has already been discussed in one of Monday's sessions, to which my colleague, Dr. Fransen, contributed.

I said earlier that even at 'rock-bottom' prices - prices which are even at the cost of production - developing countries will be unable to secure for their populations a sufficient quantity of essential medicines to treat the main communicable diseases affecting them. Even if it were possible to treat everyone in sub-Saharan Africa, the cost would run into *billions* of dollars a year. And, since there is no evidence to suggest that the AIDS pandemic has reached its peak, or that malaria and tuberculosis are under control, this figure is almost certain to increase. This means that it is absolutely crucial to put in place effective prevention campaigns and to reinforce health systems in the countries affected. Tiered pricing, therefore, may help in tackling the problem, but it will not solve it.

It is encouraging that some global funding initiatives are now being discussed. There are also a number of major events planned to take place later in the year – the LDC Conference in May, the next World Health Assembly in May and the Special Session of the UN General Assembly on HIV/AIDS in June, for example – which give reason to hope that,

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 amount of time and energy analysing the problems and formulating policy recommendations and recommendations for action. However, as this Workshop has demonstrated, a lot remains to be done. We are prepared to continue to show leadership, but we need your input.

Thank you for your attention.