WHO – WTO Workshop : Differential pricing and financing of essential drugs.

A developing country perspective

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Introduction

In keeping with the invitation to this meeting, it is worth emphasising at the onset that the views reflected in this paper are those of the author and do not necessarily reflect the position of the South African Government.

Given the wide remit that I and others have apparently been given in terms of our contribution to the meeting, I intend to firstly respond to the more general issues that have been raised in each of the background documents and to then attempt to engage the proposed discussion points in a more direct fashion.

General comments

The authors of both background documents must firstly be complimented on a job well done under what may have been novel and perhaps even difficult circumstances. The WHO document in particular, bears the tell tale signs of a difficult gestational process. The literary flow and by extension the flow of ideas, is at times noticeably interrupted by the addition of a qualifying statement or remark. Balance is of course a desirable quality that ought to be pursued to the furthest extent possible but not to the point of appearing neutral. WHO's core business is health and its advocacy role should, in my opinion, never be subsumed within the desire to appear balanced.

The issue of therapeutic competition i.e. competition within the same therapeutic class, is raised in the executive summary of the WHO document and in section 1.3 of the WTO document, as a possible means of reducing prices but is not really discussed in either document. I consider it important to dispel this notion and will attempt to do so by recounting our experience in this regard. In the South African context, newer and therefore patent protected products of the same therapeutic class, have always tended to be clustered in the same price range and this relationship was maintained even as prices increased. So if anything, our experience is directly opposite to that which the authors suggest.

The issue of the eligibility of countries is a central consideration in this discourse, so it would be just as well to express some thoughts on this matter at this early stage. This is particularly relevant in the South African situation where the overall economic data project a comforting impression of a middle income

country, a view no doubt reinforced in the mind of the visitor during the short drive in from the airport. Yet the reality is very different. Even though some real improvements have taken place in the seven years since democracy, South Africa continues to reflect two societies; one is wealthy and largely white and the other is poor and almost exclusively black. Which of these should be looked at when the decision is to be taken as to whether we should be eligible or not ? Who is better qualified than the national government to make this decision, WHO or WTO, the development assistance agency or the trade ministry of bilateral donors, the pharmaceutical industry, all of the above or none of the above ? We need to clarify terms like richer and low income, so that we can apply them more appropriately but in truth, I think that this alone is not likely to resolve the issue.

This situation becomes even more complex when one considers the regional situation. South Africa's destiny is inextricably intertwined with that of our neighbours, economically, politically and socially. Like the European project, economic integration is driving integration in other areas within the Southern African Development Community (SADC), as people and ideas begin to circulate almost as freely as goods. More than half of the members of SADC are classified as least developed countries (LDC's) and on this basis, would appear to meet the eligibility criteria. Would anyone seriously attempt to exclude South Africa and the other non LDC's from such a scheme ?. Would the same apply to Brazil or Argentina, or India and Indonesia, in terms of schemes that may apply in Latin America and Asia ?

Paradoxically, quite the opposite may apply to the countries of Central and Eastern Europe whose actual health situation may warrant inclusion, but whose geographical location may work against them.

The next general issue that would appear to warrant a response is the rather optimistic portrayal of the Accelerating Access Initiative when in my opinion, this is quite clearly not (yet ?) the case. If the intention of this meeting is to generate trust amongst the participants and in this way build bridges, then we must be prepared to be frank and honest.

To begin with, there are many who are of the view that this was just a public relations exercise designed to deflect the criticism that was expected to be directed at the pharmaceutical industry during the World Health Assembly and the International Aids Conference.[1] The manner in which this announcement was made left much to be desired and did indeed generate very high expectations that sadly remain unfulfilled. Through our close engagement in this process as the representative of the SADC region, we have attempted to move away from the tortuous country by country, company by company and product by product discussions that have marked this process thus far, but with little success. In my view, this is the reason why only three countries, Senegal, Uganda and Rwanda have concluded agreements under this Initiative and not

[1] Barton Gellman. "The turning point that left millions behind." Washington Post, 28 December 2000.

because countries lack national HIV care strategies and action plans as is implied in the document.

The programmes in question remain small; Senegal had 102 patients enrolled as at December 2000 and proposes to expand to around 900 by 2003. Uganda has around 5000 people enrolled in various ARV programmes, a significant increase from the 900 or so who were on the UNAIDS Drug Access Initiative. A first hand account from the manager of one of these programmes, ascribes this increase largely to the importation of cheap yet effective generic anti-retrovirals[2]. It may be that the Initiative started the cascade of price reductions that has brought us to this point. The challenge now is for us to learn from this in order to take the process forward.

In concluding these general remarks on the WHO paper, I wish to offer full endorsement of the *indications of success,* as listed on page 15.

Responding to the WTO paper has been rather more difficult because the substance of the text is often not in dispute or where there are indeed divergent views, the available evidence tends to be insufficient to swing the debate one way or the other.

a) I would agree that the mark ups tend to excessive but based on my experience, I would regard the figures quoted in section 1.2 as being on the high side. In South Africa, the wholesaler mark up has traditionally been 17.5 % while the retail mark up has been a further 50 %. We have attempted to introduce transparency into the supply system by introducing legislation which would provide for a single price for any particular product ex manufacturer and by substituting a professional dispensing fee for the mark up at the retail end.

b) I found Section 3.2 difficult to read, possibly because I am not an economist, but largely because I was confused by the way the term uniform pricing has been used especially in the first two sentences of the third paragraph on page 12.

c) In my view, getting Ramsey pricing to work would firstly require the validation of the R & D costs for a particular product, bearing in mind that there are currently figures in circulation which range from $ 250 million to $ 1 billion. Secondly there would have to be agreement on what would constitute “normal” profit. These issues sit at the very core of this longstanding and polarized debate and while I look forward to the debate, I do so without much optimism.

[2] Personal communication 6 April 2001

1. Which health problems and products should be priorities for differential pricing ?

I think that most would agree with the proposals reflected on page 18 of the WHO text. The two processes described in paragraph two are not mutually exclusive and in reality, they reflect what we do in international health i.e. think globally but act locally.

2. **Which countries should benefit ?**

I have already indicated possible concerns that could arise in this regard. There would clearly be a need for a process that would attempt to establish the criteria for eligibility. I would also agree that we would need to be pragmatic; complex multi-tiered structures are not likely to work. Given the obvious health needs, I would question the need to have a long pre qualification process. We all agree that there must be clear intent backed up by a workable plan so as to ensure that the necessary resources are correctly applied and in my opinion, this should suffice.

3. **How can differential pricing be achieved in the context of international agreements ?**

Firstly, it is my impression that given sufficient good will and trust, any one of these options will work. In my opinion, where it is feasible to do so, the opportunity to undertake local manufacture under the necessary licensing conditions, appears to offer a viable option to lower costs and to ensure sustainability. At the usual licensing fee around 5% of projected sales, we thought that this was something worth pursuing. We have raised this issue with the patent holders and the initial responses have not been encouraging. It is common knowledge that the South Africa is also pursuing options with other manufacturers and indeed with other likeminded governments. I do not believe that any state should have to waive its rights and would strongly support the call for transparency.

4. **What factors will contribute to lower prices ?**

As indicated in the text, the framework presented is well established in international and national health policy and does not warrant any additional comment.

5. **Should a target price be set for individual products ?**

The analysis is indeed one that I would agree with. Were this route to be pursued, I think that we would favour option 3.

6. **How would differentially priced products be financed ?**

I agree with the position presented in the framework.

7. **Who should purchase and distribute differentially priced drugs ?**

At the international level, it would appear from recent announcements that a number of possible contenders are beginning to emerge and this is a area that we will watch with some interest. I anticipate that there could be some variation at the national level. It would indeed depend on what channels exist and whether or not they are efficient. The latter aspect of course includes a consideration of whether or not these channels are secure because it can be in no one's interest for the drugs to go astray.

8. **How can diversion away from intended countries and populations be prevented ?**

Each of the options that are presented in the analysis are potentially workable. The limitations of resource poor settings should be appreciated and unrealistic demands should not divert scarce national resources. Changing the physical appearance of the medication would appear to be the most reasonable place to begin.

9. **How can developed countries be persuaded not to demand the same low prices ?**

This is once again a difficult question because in a sense it repeats the question of eligibility but from a different angle. Ultimately, this will require agreement between and within developed countries. Developing countries can, by virtue of being part of the international community, assist in creating an environment that may facilitate these discussions. We should however, never forget the crucial role that civil society in the North has played in bringing us collectively to this point. Whether or not such solidarity requires reciprocity, is a question best left to those qualified to speak on behalf of this constituency. It will suffice to say as a South African, that we never forget our friends.

10. What mechanisms are needed to ensure sustained and dependable differential pricing ?

My first instinct was to suggest that the inner satisfaction that comes from having done the right thing, should be enough, but I can appreciate that the meeting would probably seek a more tangible response. I would personally welcome any agreement that not only entrenches the principle of equitable and affordable access to essential drugs, but which also points to a clear yet simple process by which this principle may be operationalized. I would therefore favour option 3 of the framework.