

## **EXPERT REPORT JR**

### **PROMOTING AFFORDABILITY OF ANTIRETROVIRAL THERAPY (ART) IN SOUTH AFRICA**

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#### *Introduction*

There are undoubtedly many factors that determine access to medicines, including the availability of health care infrastructure, information, social norms, and the affordability of medicines. I will address the issue of affordability, with a particular emphasis on problems facing the poor.

The affordability of medicines for HIV-AIDS is directly related to income and wealth, either of the household or of the country. The expenses involved in the treatment of chronic conditions such as HIV/AIDS cannot be addressed by voluntary insurance schemes, because there is no uncertainty involved, hence, no risks to pool. Social or mandatory insurance schemes, based on a principle of solidarity, are required in order to cover predictable health expenses and cross-subsidize those with incomes so low that cannot afford to pay a fair premium. When no social insurance is available, as may often

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be the case in developing countries, it is household income that determines how much health care can be 'consumed' by the poor.

### *Expenditure & Minimum needs*

In OECD countries, a typical share of national income spent on healthcare is 8.4 percent<sup>2</sup>. In developing countries in Africa and Asia, the share of national expenditures on healthcare typically ranges from 4%-5%.

Public sector budgets for medicine purchases are often limited, and medicines financed by the public sector are often rationed in a number of ways. To the degree that public sector expenditures on medicines are resource constrained, as is always the case in poor countries, lower prices will increase access to medicines by allowing the government to extend their outlays without necessarily increasing expenditure.

Prices are also important in the private sector. Empirical evidence shows a limited willingness and capacity to spend on health care at low-income levels. Empirical evidence from South Africa, particularly from household income and expenditure data gathered over the years<sup>3</sup> suggests that the poor typically spend a *lower* percentage of their income on health care than do higher income households. Among the main reasons for this trend there might be the availability of subsidized public-sector health services for the poor, and possibly, the need to spend a large portion of income on subsistence, especially food.

Surveys of household expenditures in South Africa suggest that the lowest income groups allocate as little as 1% of total household expenditures on health care, while high income groups spend more than 5% on health care. Also, the poor spend larger percentages of their income on necessities like food (as much as 50%-60% of the budget) as compared to the rich.

A reasonable economic approach to modelling household affordability of medicines might rely on the assumption that there is a minimum fixed consumption of goods— such as food, shelter, clothing – over time. Such goods may be considered a necessity for subsistence, and it is reasonable to assume that only after these needs are covered can the remaining income be allocated to other unpredictable or occasional needs. The affordability of goods such as medical treatment and drugs can be measured in terms of the amount of household income *beyond* the minimum subsistence level (sometimes defined as the poverty line).

There are a number of ways to estimate a minimum subsistence level, using income, consumption or social indices. Any definition will have a certain degree of analytical discretion. International development organizations, including the World Bank and the United Nations Development Program, have defined a range of ‘minimums.’ For instance, at a global level, the income-poor are defined as those earning under \$2/ day<sup>4</sup>.

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<sup>2</sup> OECD data (<http://www.oecd.org/dataoecd/10/20/2789777.pdf>)

<sup>3</sup> 1993 IHS, 1993 KIDS, 1998 KIDS, 2000 IES (Statistics South Africa, [www.statssa.org.za](http://www.statssa.org.za))

<sup>4</sup> For more information, see Millennium Development Goals ([www.developmentgoals.org/Poverty.htm](http://www.developmentgoals.org/Poverty.htm)) or the World Bank, Measuring Poverty ([www.worldbank.org/poverty/mission/up2.htm](http://www.worldbank.org/poverty/mission/up2.htm))

Individual developing countries may have constructed their own national poverty lines, which provide more precise measures of deprivation.

### *Estimating Affordability*

To evaluate access to medicines under economic assumptions of household expenditure allocation, we might follow these reasonable steps:

- (1) Estimate non-subsistence income/ expenditure (that is: total minus ‘minimum’)
- (2) Allocate a reasonable percentage of this remaining amount to health care (given the number of household needs other than health care, and the relatively small proportion left over after minimum expenses are met, this allocation should be a small figure).
- (3) Define unaffordability of health care as a situation arising when treatment costs (including medicine costs) exceed the amount arrived at in (2).
- (4) Further define unaffordability as a situation where the cost of treatment to be procured (including medicine costs) exceeds the government’s budget for health care.

Applying this conceptual framework to affected households in South Africa under a broad range of acceptable assumptions<sup>5</sup>, it is increasingly clear that ART cannot be considered an affordable good for a large proportion of the South African population.

### *Exclusion of South African households to ARV medicines<sup>6</sup>*

Prices of ARV medicines, per person per year, in Rand (@US\$1~R7.5)	At 5% of disposable income going to ARV medicines, exclusion is <i>at least</i>	At 15% of disposable income going to ARV medicines, exclusion is <i>at least</i>	At 25% of disposable income going to ARV medicines, exclusion is <i>at least</i>
12600 (US \$1680)	>>> 78.1 %	>>> 78.1 %	>>> 78.1 %
5250 (US \$700)	>>> 78.1 %	78.1 %	55.4 %
1500 (US \$200)	~ 55.4 %	55.4 %	55.4 %

<sup>5</sup> The assumptions used are varying medicine prices, and varying proportions of disposable income applied to the purchase of antiretroviral medicines. At the household consumption level, it is assumed that only one member is HIV+. For lack of substantive data, it is assumed that HIV incidence is equal across all income levels.

<sup>6</sup> Sources: Household income data from IES 2000 (Statistics SA), Minimum Subsistence Levels (MLL) from the Bureau for Market Research, University of South Africa, Pretoria.

### *Increasing Affordability*

In order to increase affordability, the government could increase public financing of ART: but such an approach is constrained by the ability of the government to raise taxes from higher income groups, or to reduce other categories of public expenditure. These options might well be politically unfeasible or have unbearable social costs.

Another strategy is to lower the prices of drugs, whenever this is feasible. With off-patent medicines, reducing the prices to competitive levels can be achieved by strategies such as implementing a policy for generic medicines and instituting appropriate regulation and financing mechanisms. But in the case of on-patent medicines, (as with many of the medicines for HIV-AIDS), the ability to apply price reducing policies is constrained by the monopoly situation derived from patent-related market exclusivity rights.

### *Intellectual Property Rights (IPR)*

If some of the unaffordable medicines are patented products, a government may try to negotiate with the patent-holder for discounts or voluntary licenses at reasonable royalty rates. But country governments are also in a position to issue compulsory licenses on patents, in line with the guidelines laid out in the agreement on TRIPS and trade rules of the WTO. A compulsory license issued with the view of promoting the generic supply of a medicine is likely to result in a lowering of prices. Lower prices would in turn result in medicines becoming more affordable.

The Doha Declaration on TRIPS and Public Health requires WTO member countries to implement intellectual property laws in a manner that promotes access to medicine for all. Faced with a problem of affordability that causes high levels of premature mortality and suffering, solutions such as access to antiretroviral therapy should lead a country to carefully consider the cost and benefits of a given IPR regime.

A patent can be considered a social contract between society and the innovator: society receives the benefits of access to the knowledge developed by the innovators and the innovator, in exchange, receives the privilege of a temporary monopoly. Under this interpretation of IPR it is obvious that the innovator is not expected to abuse its privilege, and that society has the right to cancel or modify the IPR for the sake of general welfare. IPRs should not be considered as ends in themselves, but as a means – like the competitive market – to reach social goals.

Moreover, there is no evidence that the existence or non-existence of patent protection of drugs in *developing* countries is likely to significantly decrease R&D activity in *developed* countries, particularly for diseases mainly prevalent in developing countries (since the key markets for innovator companies are rich countries, especially, USA, EU and Japan). Neither is there any evidence that patent protection is likely to significantly affect R&D activity in *developing* countries.

## *Conclusion*

Compulsory licensing is a legitimate mechanism for country authorities, explicitly considered in the TRIPS agreement.

In analyzing whether medicines are unaffordable, it is important to understand – in the context of an epidemic like HIV-AIDS – that there are two ways by which the poor can acquire medicines: either by buying them directly, or by having a third party (the government or an employer) buy medicines on their behalf. In all cases, procurement price is crucial.

Once a standard quality can be ensured, for instance, by means of national quality assurance scheme and a generic medicines policy, or, by taking advantage of WHO's pre-qualification project, cost becomes the key factor in the procurement of medicines, whether for the individual or the state. Particularly in the case of antiretroviral medicines in South Africa, but so also for patented medicines in developing countries in general, awarding fair royalty compensation to the patent holder (rather than granting exclusive patent rights) seems to be an appropriate policy to ensure access to drugs from the point of view of efficiency and equity<sup>7</sup>.

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<sup>7</sup> As prices of standard quality generics are currently, in general, lower than even the discounted prices offered by originators.