

Oxfam response to EC working document on Tiered Pricing

1 General Comments

Tiered pricing should refer to a global commitment to reduce the price of medicines for poor countries. The WHO has a unique mandate to lead a tiered pricing scheme. Other relevant United Nations agencies should support the process, contributing their experience and resources.

EU member states should propose WHO leadership at the World Health Assembly, and should support a more active, effective role for WHO in:

- Supporting countries in implementation and monitoring the health impact of TRIPS, including giving advice on the best ways for countries to make full use of the safeguards in the TRIPS agreement.
- providing technical assistance to countries on comprehensive national drugs policies, including price issues and bulk purchasing including setting up a system to provide purchasers with price benchmarks.

EU member states should:

- increase aid to the health sector in poor countries and ensure that funds supplied through the EC Programme of Action, the Global Fund and bilateral aid are used in coherent national programmes based on the essential drugs concept and national drugs policies. These should include all necessary components, such as quality assurance, training and financing for efficient drug management and rational use;
- encourage the international donor community to pay the difference between the lowest price quality medicines, and the price poor countries can afford;
- encourage companies to accept a tiered pricing system and to be transparent about the prices offered and the relation of price to the cost of production;
- guarantee payment for specific quantities of priority drugs, preferably bought in bulk, and always from the lowest-priced source that is able to meet quality and sustainability criteria. These may be brand-name or generic companies;
- encourage industrialised nations including the US to accept the concept of tiered pricing;
- support developing country governments to formulate national health policies and to integrate tiered pricing into properly funded comprehensive health strategies based on national public health requirements;
- Support north/south and south/south technology transfer in the pharmaceutical sector in developing countries where this will encourage price competition, self-sufficiency and access to affordable medicines.

2 Tiered Pricing is not enough

Tiered pricing for medicines is not a sufficient measure to resolve all affordability problems in the developing world, but it is an important part of the solution. The following mechanisms should work together to lower the prices of medicines in developing countries.

- a) Tiered pricing
- b) Generic competition including voluntary licensing, compulsory licensing¹ and patent waivers.
- c) Governments should honour commitments made at Doha and agree to lift TRIPS restrictions on exports of cheaper generic medicines to all developing countries with unmet health needs.²
- d) Flexibility on implementation of TRIPS: transition period for developing countries to be extended and companies to refrain from enforcing patents in poor countries.
- e) Additional resources to be provided through increased aid, debt relief and the Global Fund. The latter should maximise resources by buying the cheapest appropriate medicines, including generics, providing these are of acceptable quality and can be supplied in the long-term in sufficient quantities
- f) Bulk procurement of medicines, including generics, through strengthening pharmaceutical sector financing and capacity for efficient procurement in developing countries

As the EC working document on tiered pricing makes clear, WTO “members remain free to adopt legislative regimes which are flexible enough to allow them to respond to public health concerns, including by authorising parallel imports or by issuing compulsory licences. Tiered pricing, therefore, is additional to, and not instead of, other legitimate means of increasing access to and the affordability of medicines”

However, the EC proposal to the TRIPS Council in June appears to introduce conditionality to compulsory licensing and link it to tiered pricing. This is not acceptable. The Doha declaration affirmed the primacy of public health over intellectual property rights, and the rights of governments to make full use of the public health safeguards in TRIPS. TRIPS does not require that members notify the WTO when they intend to issue compulsory licences. TRIPS does not make the issuance of a compulsory licence dependent on the tiered pricing offers made by a manufacturer. The existing safeguards should not be jeopardized through additional obligations.

¹ Voluntary and compulsory licensing should be used to meet the EC document recommendation to “support to local production of pharmaceuticals in developing countries” P6

² Governments must agree a permanent and effective solution to Paragraph 6 of the Doha declaration which is simple and speedy to implement. The solutions should not be restricted to the poorest countries, particular diseases, or narrow definitions of manufacturing capacity. The current EC proposal on paragraph 6 of TRIPS is too complex and restricted to enable the vast majority of developing countries who import medicines to use compulsory licensing to effectively bring down prices. To this end the EC ought to support a simple Article 30 and longer transition periods for poor countries.

3 Scope of Tiered Pricing

3.1 Geographical scope

- A tiered pricing system should be a global commitment including the USA and Japan. The EU should be working actively to ensure that developing and developed country governments and the pharmaceutical industry recognises the importance of tiered pricing measures.
- The UK government supports tiered pricing and will not use it as a reference point for negotiating reductions in the NHS. Other industrialised countries could make similar commitments.
- Tiered price offers should aim to be regional, and not limited to some countries within a region or sub-groups of the population. This will help reduce incentives for parallel imports between developing countries.

3.2 Eligibility

Oxfam would strongly prefer a tiered pricing system that allows all developing countries access to cheaper medicines.

If, at the introduction of a tiered pricing system, developing countries are not all offered the lowest possible prices for medicines, priority should be given to the most needy developing countries. The most needy developing countries should be offered the lowest possible prices for medicines immediately. Subsequent widening of the tiered pricing offers should be extended to the remaining developing countries as soon as possible.

Assessment of a country's need for cheaper medicines should take account of whether poor and vulnerable women, men and children are able to access the medicines they need to treat the conditions that affect them. Specific indicators that should allow a country to buy medicines at the lowest possible prices might include those countries who rank as low or medium on the Human Development Index³; countries with poverty related diseases affecting over one per cent of the population; countries with GDP per capita of \$2,995 and countries that are within regions where tiered prices apply.

All purchasers in eligible countries should be able to buy at a tiered price. Tiered prices should be available to organised public sector, private sector that serves the poor with government authorisation and NGO health systems. This is necessary because so many public health systems have collapsed: private and NGO health facilities are therefore important for access.

3.3 Coverage

Coverage should cover all therapies that have significant public-health relevance in developing countries, and not be confined to the prevention and treatment of HIV/AIDS, TB and malaria. Drugs for non-communicable diseases such as diabetes and asthma are highly

³ The HDI includes a life expectancy index which seeks to measure the extent to which a population has a long and healthy life.

relevant to the poorest people and are significant diseases in the developing world, and so should be available through tiered pricing schemes

If it is decided to commence tiered pricing offers with a pilot for a few diseases, a timeframe for roll out to additional diseases should be established. Diseases covered under an initial pilot should include HIV/AIDS, TB, malaria, acute respiratory infections in childhood and sexually transmitted diseases. It should be noted that there is no need to exclude from the system any category of drugs that a company chooses to offer at a tiered price, providing it appears in a national formulary, national essential drugs list or WHO model list of essential medicines.

4 Components of a Tiered Pricing system

4.1 Supportive policies

A tiered pricing system should be designed to fit with assistance provided to developing countries. Tiered pricing should support pro-poor policies that are in place and should specifically help women and children. Tiered pricing systems should go hand-in-hand with flexible intellectual property rights such as compulsory licensing, the extension period for least developed countries until 2016, the Bolar provision, and no restriction on data exclusivity.

4.2 Voluntary

Oxfam believes that a voluntary system of tiered pricing would be a step in the right direction towards cheaper medicines. In addition to this preliminary work on tiered pricing, the European Commission should consider all longer term means of ensuring that the developing world has access to medicines.

4.3 Long term and Sustainable

- Internationally agreed commitments between companies, the EC, other industrialised and developing countries, and the UN should ensure commitments over long periods.
- Once a price is agreed it should be a maximum price for all countries to whom it is offered for a fixed term. There should be no arbitrary price rises.
- Prices could be reviewed regularly with the possibility of revising downwards to accommodate changes in costs, therapeutic value, patents situation, availability of generics, availability of other medicines of similar or better therapeutic value.
- All tiered price offers should be for a minimum of the remaining length of the drugs patent plus two years. This will allow competition to enter the market and the overall price of the drug to fall.

4.4 Price level

Oxfam agrees with the sentiment in the EC paper that prices should be set as close as possible to the cost of production and that this should be a factor when defining a tiered price. However, production costs are hard to establish accurately: companies are not willing

to disclose real costs. Therefore advice should be sought from a panel of independent technical pharmaceutical experts as to realistic costs of production, and, where possible, comparisons should be made with the price of similar generic versions of the drug concerned.

All price offers submitted as a Tiered Price should, as a pre-requisite for consideration be discounted by a minimum percentage from the OECD average price. The minimum acceptable discount should be based on the discounts currently offered on antiretrovirals.

4.5 Transparency and accountability

Transparency and accountability are essential elements of a tiered pricing system.

4.6 Simple

Any calculation, formula or definition used to define a Tiered Price should be simple and easily understood.

4.7 Governance

The tiered pricing system should be “implemented by an existing or specifically created international body which would publish, monitor and update the offers from the pharmaceutical companies” as proposed in the EC Working Document. Oxfam support the use of existing UN international public health body such as the WHO.

4.8 Predictability

The lead organisation (WHO) could facilitate the estimation of needs and bulk purchasing as measures whereby particular drugs and quantities can be predicted. This would, in turn, help companies to plan production based on accurate estimates. Bulk procurement for regions would provide economies of scale, and would be more helpful to industry than tenders based on national, or sub-national, needs. The end price would be more affordable to clusters of countries with the same disease profiles and therapeutic requirements.

5 Parallel imports of Tiered Price medicines

- The EC Document recognises that, "imports from outside the EC are comprehensively regulated" (page 11) and the volume of parallel imports into the community is "largely theoretical" (point 3.3). Corporate anxieties on parallel imports seem somewhat exaggerated and evidence to support current claims is not available.
- The EC should encourage companies to undertake all possible measures to prevent parallel imports of tiered price medicines into the EU, including the use of differentiated packaging and formulations.
- As tiered pricing is introduced, parallel imports of drugs from outside the European Union should be monitored. European states would then be in a position to consider additional mechanisms to address parallel imports if a significant problem arises.
- Any mechanisms to prevent the re-importation of tiered-priced medicines from poor countries to rich markets should not undermine developing countries' capacity to use

safeguards within the TRIPS agreement and the Doha declaration which allow parallel imports⁴.

6 Tariffs

Any discussions over tariff reduction should be limited to those pharmaceutical products classified as “tiered price” and for the period of time when they are offered at a tiered price. Where a manufacturer is selling a product at a “tiered price”, that single tiered price product should be exempted from tariffs. In all other circumstances, developing country tariffs should be determined by the government and available as a tool to stimulate domestic production.

6.1 Insufficient evidence

Oxfam welcome the EC’s acknowledgement that there is insufficient evidence on the impact of tariffs on prices and support the Commission's decision to gather more data.

6.2 Impact on industry and revenues

Oxfam agrees that additional research is needed to determine the impact of changes in tariff levels on domestic industry and government revenues.

ENDS

⁴ The Doha declaration allows parallel imports as it leaves, “each Member free to establish its own regime for ...exhaustion [of intellectual property rights] without challenge”.