Equitable Pricing, Affordability and Access to Essential Drugs in Developing Countries: Consumers Perspective

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1. Introduction

In order to examine and analyse drug pricing, affordability and accessibility of essential drugs in developing countries, it will be helpful to examine the economic and demographic profile of these countries. The following information from 110 developing countries have been compiled from UN documents[1]:

- Ten percent or 11 countries have population less than 100,000 each.
- Twenty-four countries have less than one million each; 65 countries have less than 10 million each.
- Twenty countries have an annual GDP of less than $500 million each; 28 less than one billion; 57 less than $5 billion; 75 countries have less than $10 billion each.
- Thirty-five percent or 39 countries have a per capita GNP of less than US$400. The world bank poverty line is per capita GNP of $365.
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are living on a dollar a day (Table 1). Appropriate public policies are the only way by which these people can have access to essential drugs.

Table 1: Per capita GNP in 10 low and middle income countries and the per capita GNP of population sub-groups in each

Population

Consumers welcome initiatives by few drug companies, international agencies and a few developing countries to negotiate discounts on treatments for very visible calamities such as HIV/AIDS, malaria and tuberculosis. **But the problem of lack of access to the two billion people who have no access to essential drugs cannot be solved by negotiating discounts country by country, company by company and drug by drug. And negotiations take place in total darkness since the real costs of production of drugs are not known to the negotiators**. All pricing information is kept in confidence by the manufacturers. These are not therefore fair negotiations.

What consumers want is a long term sustainable solution to improve affordability and accessibility to all essential drugs required to meet the essential needs of the people. The long term solution is promoting competitive generic production of all drugs.

How can generic manufacture be promoted?

To answer this question we need data on worldwide pharmaceutical research and development (R&D), innovation and production. Examination and critical analysis of this data is very important in exploring options to arrive at long-term sustainable solutions to ensure affordability and accessibility of essential drugs in developing countries.

2. Pharmaceutical R&D, innovation and production

United Nations Industrial Organisation (UNIDO) has classified countries in the following categories depending on the stage of development of the pharmaceutical sector (Table 2)

Table 2: A typology of Worlds Pharmaceutical Production

The MNCs in the industrialised countries and the national companies in about 100 developing countries have been able to develop their pharmaceutical industry to present levels because they used the national legislation on patents as policy instrument to develop and strengthen their technological, commercial and economic development. The Paris Convention on intellectual property rights [IPR], adopted in 1883, gave freedom to national governments to define and set standards for pharmaceutical patents.

The therapeutic revolution began in the mid 1940s after the second world war enabled drug companies in the ten industrialised countries to innovate and introduce NCEs which were truly revolutionary**. One of the major contributing factors for this therapeutic revolution was that some countries in Western Europe and Japan refused to grant product patents for pharmaceuticals, until they had reached international competitiveness. These countries provide the most convincing argument that a patent-free environment is essential for the technological development of the pharmaceutical industry. France, Germany, Italy, Japan, Sweden and Switzerland, home of some of the most innovative pharmaceutical companies, persistently resisted providing pharmaceutical product patents until their industries had reached a certain degree of development. France introduced product patents in 1960, Germany 1968, Japan 1976, Switzerland 1977, Italy and Sweden in 1978.**[3]

The development of the pharmaceutical industry in the 100 developing countries in Table 2 was possible because of the flexibility the Paris Convention gave sovereign states to enact appropriate national legislation on patents. None of these countries protected pharmaceutical products. Some of them protected neither products nor processes including Brazil a founder member of the Paris Convention.

The setting up of the United Nations Conference on Trade & Development [UNCTAD] and the formation of G77 [a grouping of developing Member States of the UN] in the 1960s, and the proposals for a New Economic World Order in the early 1970s, set the global scenario for developing countries to explore policy options for the economic technological and commercial development of their countries. One of the sectors identified was the pharmaceutical sector. In the early seventies, it was shownthetaly and th] 2aceutical indus Pcontechnnnovamentarly Jave

3. The TRIPs Agreement, generic manufacture and competition

NGOs, consumer groups, health activists and peoples' organisations have been campaigning for several years to give life and meaning to the two safeguards provided for in the TRIPs Agreement – compulsory licensing and parallel imports.

They have been successful as the following section shows:

i) World Health Assembly Resolution WHA 52.19 of 24 May 1999

The delegates to the World Health Assembly taking note of concerns of many Member States about the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries, requests the Director General to cooperate with Member States, at their request, and with international organisations in monitoring and analysing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximise the positive and mitigate the negative impact of those agreements.

In accordance with this resolution, WHO is using the following four questions to monitor and analyse the effects of globalisation and trade agreements on the pharmaceutical sector:[4]

- **Are newer essential drugs more expensive than they would have been if not under patent?**
- **Is the introduction of generic drugs being slowed?**
- **Are more new drugs for neglected diseases being developed?**
- **Are transfer of technology and direct foreign investment in developing countries increasing or decreasing?**

In the same document the WHO had argued that the current standards on intellectual property – historically derived from those of developed countries – are not necessarily appropriate for countries struggling to meet health and development needs. Developing countries can therefore use the flexibility of TRIPs provisions and its safeguards to protect public health.

[4] Globalization, TRIPs and Access to Pharmaceuticals: WHO Policy Perspectives on Medicines, 3 March 2001, WHO

The WHO recommends that **prompt introduction of generic drugs** can be facilitated by:

- **drafting appropriate legislation and regulations on patentability;**
- **use of exceptions to exclusive rights which permit early testing and approval of generics ("Bolar" provision) including allowing access to pre-registration test data; and**
- **compulsory licensing**

ii) The first two operative paragraphs of the European Parliament resolution on access to drugs for HIV/AIDS victims in the Third World (15/03/2001) B5-0182/2001 are as follows:

- Calls for the development of a system allowing developing countries equitable access to medicines and vaccines at affordable prices, while expressing its solidarity and support for the Governments of South Africa and Kenya in their struggle to use WTO-compliant legislation to gain access to the cheapest possible life-saving medicines
- In this context welcomes the statement by Commissioner Lamy that **the Commission supports the right of developing countries to use the safeguards in the WTO/TRIPs Agreement, including compulsory licensing, and the commitment by the Commission to launch a debate in the WTO on reconciling the TRIPS Agreement with objectives regarding health protection in developing countries**

iii) Human Rights

On August 17, 2000, the UN sub-commission for Protection and Promotion of Human Rights adopted a high profile resolution on "Intellectual Property & Human Rights".

The sub-commission declared that "(…) **implementation of the TRIPs Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights**, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination (…)", "requests all Governments and national, regional and international economic policy forums to take international human rights obligations and principles fully into account in international economic policy formulation." And **"recommends to the World Intellectual Property Organisation, the World Health Organisation, the United Nations Development Programme, the United Nations Conference on Trade and Development, the United Nations Environment Programme and other relevant United Nations agencies that they continue and deepen their analysis of the impacts of the TRIPs Agreement, including a consideration of its human rights implications."**

These are the two safeguards provided for in the TRIPs Agreement.

These conditionalities set by the industry for price discounts are contradictory to the global initiatives to ensure affordability and accessibility to essential drugs. These initiatives support the right of developing countries to use the safeguards in the TRIPs Agreement.

An investigation of the negotiations behind the initiative indicated that the companies were more concerned about protecting their intellectual property rights than in reaching patients. Very little progress had been made. Negotiations are carried country by country, drug by drug and company by company, only. As a result only Rwanda, Senegal and Uganda had

The following information on the relationship between retail prices and MSPs have been taken from the background documents prepared for the workshop by the WTO and WHO secretariats.

a) From the background paper prepared by the WTO secretariat
   - Wholesale and retail margins can be as high as 150 to 200 percent in some developing countries [IFPMA].
   - Retail margins in India are about 25 percent [Jayashree Watal].
   - Distribution margins and taxes can constitute up to 80 percent of the consumer price [WHO]. This will make the consumer pay four times the MSP.

b) From the background paper prepared by the WHO
   - Import duties, taxes and wholesale and retail mark-ups, both formal and informal, can double the price of a drug between manufacturer and consumer.

Which of these internal costs can cause a 58 fold increase[9] in price between the manufacturer and the consumer? None! **Based on the information in the background documents on the relationship between retail prices and MSP and the published data on retail prices, it can be concluded that internal costs within a country cannot cause the very wide variat-12..retailrckgrounm-toegsn2e v**