ACCESS TO MEDICINES: Drug Pricing and Patents

WHO estimates that currently one third of the world's population lacks access to essential drugs and that over 50 percent of people in the developing countries in Africa and Asia do not have access to even the most basic essential drugs. Access to essential medicines depends on the following critical elements:

- Affordable prices
- Rational selection and use
- Sustainable financing
- Reliable supply systems

In developing countries 25 to 65 percent of total health expenditure is spent on pharmaceuticals, but the government health budgets are too low to purchase enough medicines and poor people often cannot afford to buy them on their own. Access is a complex matrix, but because money is so limited, developing countries need drugs at the lowest possible price. Drug pricing is often the most important factor restricting access to medicines.

Although, there are many factors influencing and maintaining the higher & unaffordable prices of drugs, most important contributing factors are patents, lack of price control measures and the pricing policies of multinational pharmaceutical companies.

Following are some of the main concerns in the area of access to essential medicines, with special interest to drug pricing and patents:

01. Prices of branded or patented products are often higher than the prices of similar generic products.
02. When generic competition is introduced, prices of the patented products will fall.
03. When a drug company sells the same product, it adopts a policy of price differentiation, setting price levels 'according to what the market can bear'.
04. MNCs practice transfer pricing in the trade of raw materials used in the drugs and this raises the cost of medicines in developing countries.
05. There is a belief that drug companies sell branded products more cheaply in developing countries. This is often not the case. Prices of some branded products are higher in many developing countries. This makes medicines even less affordable as countries with lower per capita incomes have to pay much higher prices for the same medicines as compared to prices in developed countries.

Table 1: The retail prices in USD of 100 tablets of 150mg Zantac (Ranitidine) in 2 developed and 12 developing countries in the Asia- Pacific region. Minimum daily wage and per capita GNP (in US$) are also given.

In US$	Australia	New Zealand	Bangladesh	India	Indonesia	Malaysia	Mongolia	Nepal	Pakistan	Philippines	Sri Lanka	Thailand	Vietnam
Minimum daily wage	46	32	2.1	1.3	0.5	N.a	0.8	1.6	2.2	5.0	1.4	2.9	N.a
GNP per Capita	18,720	14,340	240	340	980	3890	310	200	460	1050	700	2740	240
100 Zantac tablets 150 mg	23	21	9	2	41	55	183	3	22	63	61	37	30

Source: K. Bala, Dr. Oscar Lanza, Shila Rani Kaur, "Retail Drug Prices: The Law of the Jungle "HAI News No.100, April 1998

Globalization, Intellectual property Rights (IPRs) and Patents

National legislation on IPRs is over 500 years old beginning with the Venetian Patent Law in 1474, followed by the French Law in 1791, and the Austrian Law in 1810. The first international agreement, the Paris Convention on IPRs was agreed upon in 1883. Since then, national legislation on IPRs in all countries across the world were in conformity with the Paris Convention (PC). The World Intellectual Property Organization (WIPO) was the UN Agency mandated to implement the Paris Convention.

Throughout the last five centuries, the guiding principle first put in place in the Venetian Law that placed public interests before commercial interests in patent law was strictly adhered to. National legislation on IPRs allowed governments to use any patented invention for the public good. Under the Paris Convention, member States were allowed the freedom to determine the areas of:

- Non-patentability;
- Duration of patents; &
- The set of exclusive rights conferred on patent holders.

Both developed and developing countries used the provisions provided in the Paris Convention to enact their national legislations on IPRs to serve as policy instruments for developing and strengthening their pharmaceutical industries. These provisions included the following:

1. Pharmaceutical products were excluded from patent protection;
2. Patent protection for process was granted for periods of seven to 10 years;
3. The patent holder was obliged to work the patent in the country, which granted the patent. This meant that the product should be manufactured in the country granting patent protection. Imports of finished products do not qualify as working of the patent.
4. Governments could grant compulsory licensing to generic manufacturers.

Using these provisions in the Paris Convention six developed countries refused to grant patent protection for pharmaceutical products until their industries reached a certain degree of development and international competitiveness. The following table lists the six countries and the years they introduced product patents.

Table 2:

Country	Year product patent was introduced
France	1960
Germany	1968
Japan	1968
Switzerland	1977
Italy	1978
Sweden	1978

Source: Sistema Economics Latinoamericano (SELA) "Capitelos Do Sela", Oct/Dec 1988, Caracas Quoted in, "Patenting and the Third World: A Historical Appraisal" by Henk Hotbelink, Coordinator, GRAIN (Genetic Resource Action International) Appartado 23398, E 08080, Barcelona, Spain, 1990 p4.

The industrialized countries, having fully used the provisions in the Paris Convention to enable their pharmaceutical manufacturers to strengthen their innovative capacity, now deny the same privileges to developing countries. This is not morally defensible in a civilized society. The developed countries, particularly the US, are using the TRIPS Agreement to force developing countries to grant strong patent protection for pharmaceutical products & processes for 20 years. Obligation to work the patent is not required. Imports to satisfy the national market would amount to working the patent.

Intellectual property rights and patents have taken a new turn with the introduction of the Agreement on Trade-Related aspects of Intellectual Property rights (TRIPs agreement). The World Trade Organization (WTO) /TRIPs agreement has worsen the situation and will make the current health crisis into a disaster in the near future. Implementation of this agreement entails a very significant extension in the scope and duration of patent protection for products and processes, many of which had not been provided patent protection or provided limited patent protection.

WTO multi lateral agreements play a crucial role in legitimizing globalization, which results in increased poverty, the reason for one third of the world's population have no access to even basic list of few essential drugs. TRIPs is by its coverage the most comprehensive international instrument on Intellectual Property Rights (IPRs) and if implemented, the multinational way, will deny access to essential drugs for more and lead to a situation where over 50 percent of the world population will have no access to essential drugs.

It will throw into the market an abundance of branded drugs designed to meet the needs of the rich. Prices may even stabilize at a higher level. But, the few essential drugs of critical importance to billions of poor consumers in the developing countries will be in short supply and increased in prices. Globalization of the pharmaceuticals will be a feast for the rich and a tragedy for the poor.

Table 3: Comparison of retail prices of the innovators brands of brand forms of nine essential drugs and their generic equivalents in July 2002. The differences in retail prices between the generic and the brand forms expressed as a percentage of the generic prices are given.

Drug	Retail Prices		Difference in prices as a percentage of the retail price of generic forms
	Generic	Innovators brand	
Amoxycillin	1.75	9.90	465
Cotrimoxazole	0.80	9.19	1050
Diazepam	0.07	7.84	1020
Diclofenac	0.58	24.70	4160
Erythromycin	4.00	7.23	80
Furosemide	0.35	1.68	380
Propranolol	0.40	3.75	840
Ranitidine	1.64	13.98	750

Source: K. Bala "Towards affordable and quality medicines to all Sri Lankans" compiled from Sales figures at the Rajaya Osu Sala, Bambalapitiya, Sri Lanka.

DOHA declaration and TRIPs agreement

However, the TRIPS agreement does contain certain provisions that can be used to limit patents and monopolies, highlighted with the 4th Ministerial Conference in DOHA (DOHA declaration). The DOHA declaration affirmed that governments are free to take all necessary measures to protect public health and gives primacy to public health over IPRs.

" The TRIPs agreement does not and should not prevent member nations from taking measures to protect public health" the declaration says, adding that it should be interpreted and implemented in a manner supporting the people who need the public health measures, governments can override patents without the threat of retribution.

The declaration gives an unambiguous road map to all the key flexibilities the TRIPs offers:

- Right of governments to grant compulsory licenses, not only in cases of emergencies
- Leaves countries free to determine what is national emergency or urgency in which case the procedure for issuing a compulsory license becomes easier and faster.
- A clear statement that countries can have parallel import regimes they want through the application of the principle of exhaustion of IPRs.
- A ten-year extension for least developed countries. This means that these countries need to be TRIPs compliant by the year 2016 instead of 2006.
- Exceptions for experimental use and the 'bolar' provision are other measures in the TRIPS agreement

All these measures are perhaps crucial in enabling access to affordable medicines in developing countries that do not yet have the local production capacity in the pharmaceutical sector. But, many of the developing countries have neither provision for these measures in their health legislation and national health policies nor a strong political will to bring about the necessary amendments to their existing legislation. HAIAP is working with its international partners to develop model legal provisions related to patents and medicines.

Parallel Importing

Parallel importing allows a country to look out for the best price of a drug on the global market and import for resale in a country without the permission of the patent holder. The underlying concept for allowing parallel imports is that since the inventors had been rewarded through the first sale or distribution of the product, they have no right to control the use or resale of goods put on to the market with their consent. This is referred to as exhaustion of rights and it applies not only in the exporting country but also in the importing country.

It is an attractive option for developing countries at this moment as the same brands of medicines are being sold for different prices in different markets. For example, Sri Lanka, which has the retail price of 100 units of Zantac at US$ 61 can parallel import at a much lower price from India, where the retail price of same 100 units Zantac is only US$ 2. (Refer **Table 1**)

However, parallel imports are almost unknown and rarely used by many developing countries. But, many European developed countries benefit from significant parallel trade to reduce the over all cost of medicines. Anyway, with the strict implementation of the TRIPs agreement by 2006, the Multi National Companies (MNCs) will be able to control the prices of the patented products in many countries, leaving parallel trade a less attractive option for developing countries.

Compulsory Licensing

Compulsory Licensing allows the production of generic medicines without the consent of the patent holder. In compliance with the TRIPS Agreement, patent holders would receive adequate compensation. Public authorities for various reasons, including public health or emergency, may issue compulsory licenses. They are neither a form of pirating, a legal loophole nor a way of stealing Intellectual Property (IP), but legal under the TRIPs agreement and are considered a regular feature of any IP legislation.

Both private entities and government can apply for a Compulsory License and the DOHA declaration acknowledges that a country has the freedom and sovereignty in determining the grounds for compulsory licenses. Countries should design fast and simple procedures for granting compulsory licenses to make full use of the safeguards.

Unfortunately, the issue of a Compulsory License alone does not help much in improving the access in the majority of the developing countries without manufacturing capacity. The possibility of issuing a compulsory license to a manufacturing company in another country with the production capacity is still controversial and the TRIPS Council has still not agreed to this procedure. There is a lot of antagonism from the Pharmaceutical giants and their respective countries.

Patents and Research & Development (R&D)

MNCs and supporting sectors claim that patents provide more funds for research and drug development activities. In fact, developing countries make up such a small part of the drug industry revenue, that it is unlikely to hurt the R&D activities. 87% of the $ 364.2 billion worldwide drug market for 2001 was in North America, Europe and Japan. All of Africa accounts for just over 1%. Furthermore, the drug industry is one of the most profitable in the world. In 1998, the top ten companies enjoyed $ 108.1 billion in sales, of which $ 34.7 billion was profit – at 32.1%.

Table 4: 2001 Global Pharmaceutical sales by region

World Audited Market	2001 Sales ($bn)	% Global sales ($)	% Growth (constant $)
North America	$181.8	50%	+17%
Europe	88.0	24	+10
Japan	47.6	13	+4
Asia, Africa and Australia	27.9	8	+9
Latin America	18.9	5	+0.1
TOTAL	**$364.2bn**	**100.0%**	**+12%**

Source: IMS *World Review 2002* and IMS Consulting. Sales cover direct and indirect pharmaceutical channel purchases in US dollars from pharmaceutical wholesalers and manufacturers. The figures above represent 52 weeks of sales data, and include prescription and certain OTC data, exclude US home healthcare sales and represent manufacturer prices.

It is notable that much of the revenue by patents goes into marketing and drug promotional activities rather than R&D. However, companies do not divulge the actual R&D costs per drug and methods for calculating this figure are highly controversial. The drug industry estimates the R&D for each new drug ranges from $ 350 - $ 500 million. These estimates cover many costs including compounds that have failed, overhead and opportunity cost. In contrast,

independent estimates range $ 30 - $ 160 million. In addition, R&D is often funded by the public sector. According to World Bank, half the current worldwide R&D expenditure, estimated at $ 70 - $ 90 billion, is funded by public sector.

Table 5: Relative spending by multinational Pharmaceutical companies in 2001.

COMPANY	% OF REVENUE SPENT ON MARKETING, ADVERTISING & ADMINISTRATION	% OF REVENUE SPENT ON R&D
Merck	13	5
Pfizer	35	15
Bristol-Myers Squibb	27	12
Abbott Laboratories	23	10
Wyeth	37	13
Pharmacia	44	16
Eli Lilly	30	19
Schering-Plough	36	13
Allergan	42	15

Source: Families USA (www.familiesusa.org/new2001data.htm)

We also note negligence in research activities for diseases of the developing countries. Of the 1393 new chemical entities developed from 1975–1999, only 13 were for the treatment of diseases in poor countries, 5 of which were the result of veterinary research.

Local production and Technology transfer

Investing on developing countries' capacity to research, develop and produce their own medicines will be a key part of a sustainable solution. This will require involving scientists from endemic countries in the R&D process, as well as promoting transfer of technology and knowledge.

But is it really happening? MNCs practice transfer pricing in the trade of raw materials used in the drugs and this raises the cost of medicines.

Table 6: Price comparisons of seven pharmaceutical raw materials in Pakistan.

Drug	Company	Price per Kg (US$)		Percentage Difference
		Transfer Price	International Price	
Xylometazoline	Ciba-Geigy	11,902	320	3360
Piroxicam	Pfizer	8,930	125	7044
Diazepam	Roche	561	27	1978
Pindolol	Sandoz	9,561	1,805	431
Nandrolone decanate	Organon	8,050	940	756
Bromocriptin	Sandoz	65,084	19,737	230
Pizotifen	Sandoz	59,603	22,670	163

Source: Zafar Mirza, HAI News N.78, August 1994.

Only a few developing countries in the South and South-East Asia are engaged in R&D as well as manufacturing activities.

Table 7 – A typology of pharmaceutical industries in South and South – East Asia

Stage of Development	Country
1. Sophisticated vertically integrated pharmaceutical industry with a significant research base	NIL
2. Possessing innovative capabilities. Ability to copy new chemical entities by a process of reverse engineering	India
3. Ability to produce therapeutic ingredients / raw materials from: - Chemical intermediates, - Fermentation and - Plant sources	Bangladesh, Indonesia, Pakistan, Philippines, Thailand
4. Formulating dosage forms from imported raw materials	Malaysia, Myanmar, Nepal, Sri Lanka, Vietnam
5. No pharmaceutical industry	Bhutan, Cambodia, Lao PDR, Maldives

Source: UNIDO The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy by Robert Balance, James Pogauy and Helmet Forsteiner, 1992

Differential / Preferential / Tiered-pricing Vs Equity pricing

Another claim is that a differential/preferential pricing or tiered-pricing system makes drugs affordable. These are merely business terms for pricing practices used by the seller to increase the income and only make limited contribution to address the problem of access to medicines. An example of differential pricing would be sale of a product to poor countries at a lower price than sale of the same product to rich countries. To be effective and equitable, initiatives must be approached on a multi lateral basis, with the participation of patent holders, generic producers and health and drug policy makers of the developing countries, in fair and transparent negotiations.

Reported industry imposed conditions on differential pricing agreements

- Extra processing fees
- Special Training
- Limited geographic distribution
- Disclosure of consumer information to companies
- Unacceptable delivery terms and / or product dating

Source: Joint briefing paper on "Ensuring Accessibility of Essential Medicines" by HAI, MSF, VSO, SCF and Oxfam

Access activists propose the concept of 'EQUITY PRICING' to describe pricing policies that ensure the price of a drug is fair, equitable and affordable, even for the poor population and or a health system that serves them, from the point of view of the community and the individual.

Equity pricing is based on the principle that the poor should pay less and should have access to essential medicines, including the following essential components:

01. *Minimum level* – Prices should tend towards a minimum level for poor countries.
02. *Equity* – Countries at similar low level of development should have access to drugs at the same lower prices – a level playing field between countries.
03. *Sustainability* – Price reductions should be long term and predictable, and the mechanism by which this is achieved should be credible to all.
04. *Range* – Price reductions must not be limited to certain group of drugs.
05. *Quality* – Only manufacturers with acceptable quality standards are included by a global pricing framework
06. *Unconditionality* – Price reductions should not be contingent on any conditions, which may damage other aspects of the access to drugs.
07. *Self-Reliance* – Should strengthen the self-reliance of the developing country in price negotiations and pharmaceutical production.
08. *Accountability* – Governance of equity pricing should be run by a public body or super national level with involvement of developing and developed country stakeholders.
09. *Transparency* – Process of reaching the prices should be transparent to ensure accountability and equity.
10. *Market segmentation* – Prices in developed countries should be maintained.

However, all these measures do not necessarily mean that the lowest prices charged will be affordable. For some countries, even the lowest possible prices will not be affordable; international funding should then be considered to ensure that people have access to the medicines they need.

Drug Donations

Targeted drug donations are not a long-term sustainable solution for the access problem and most drug donation programs have many drawbacks:

- Usually do not cover global need and are limited in time and place
- Often come with burdensome restrictions on recipient health ministries
- Often require extra administrative work, diverting scarce resources from health systems
- Can distort rational drug use

Therefore, drug donations should never be relied upon, portrayed, nor promoted as the best way to improve access to medicines.

Public Private Initiatives (PPIs) & Access

PPIs have direct consequences for Access. Consumers, Governments and donors are being asked to negotiate with pharmaceutical companies on conditions of differential pricing schemes and donations. Furthermore, it is not clear whether or not the desired public health outcomes of large-scale initiatives will improve access, including GAVI (the **G**lobal **A**lliance for **V**accines & **I**mmunizations). The Global Fund and others are at risk because of unaccountable private sector involvement.

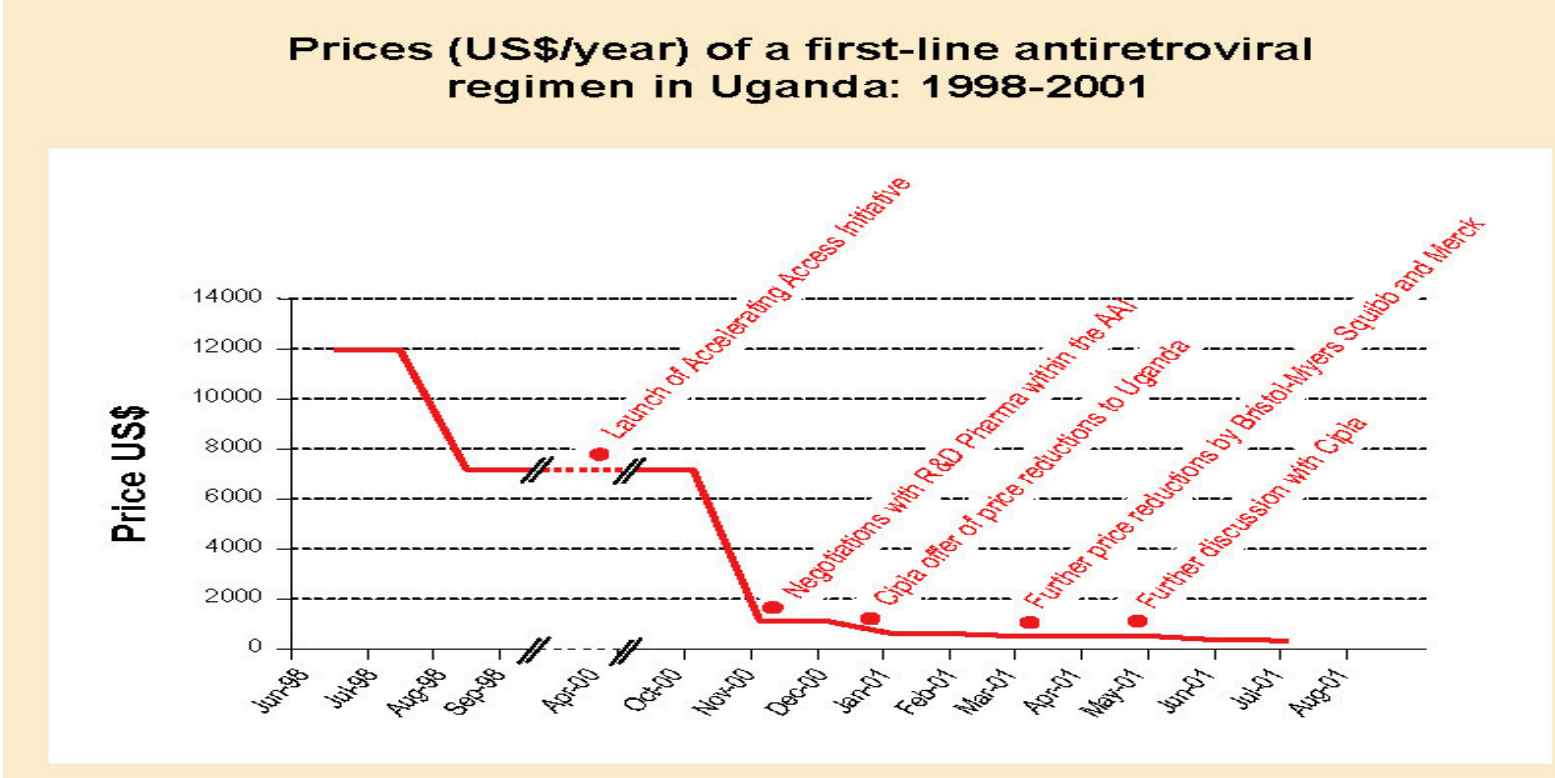
It is unclear on what basis WHO decides that a given PPI is the best way to increase the access. Therefore, measures should be taken up to identify the risks and benefits of the PPIs and to analyze the health and social outcomes and sustainability of these initiatives, in a transparent manner. All public enterprises, including WHO should make sure that no relationship with the industry compromises their technical responsibilities or their credibility towards improving access.

HIV & AIDS and Access to Essential Medicines

There are 42 million individuals living with HIV worldwide in year 2002, of which 3.2 million are children below the age of fifteen years. Five million new infections occurred during 2002, and three million individuals would die of HIV related causes. In Asia and the pacific, now, 7.2 million people are living with HIV.

The HIV/AIDS epidemic is progressing rapidly and the window of opportunity to curb the epidemic for many countries is narrowing with time. The drugs play a crucial role in this effort and the fluctuations in the market prices of HIV/AIDS drug are a clear example of how the MNCs have their own pricing policies targeted only at profits and how Generic competition paves way for falling drug prices.

Table 8: The drastic fall in the prices of a first line antiretroviral regimen in Uganda over the last 3 years



Source: WHO/UNAIDS, 2002

Free Trade Agreements(FTAs) and Access to Medicines

FTAs are another tool used by multi national drug exporting countries to achieve extremely restrictive TRIPs PLUS intellectual property provisions. These could put an end to competition from generic manufacturers and to country's ability to make use of existing safeguard against patent abuse. These agreements will severely restrict peoples' access to medicines.

Recommendations

At National Level:

01. Adopt and implement National Drug Policies (NDP) based on the concept of essential drugs that are formulated with substantive involvement of citizens and NGOs.
02. Produce National Drug Formulary and Therapeutic Guidelines based on the essential drugs concept and containing drug-pricing information.
03. Promote and encourage generic competition
04. Eliminate barriers to access to medicines and raw materials, including overly rigid and / or expensive regulatory requirements, unnecessary margins on prices.
05. Develop systematic and transparent solutions to ensure equity pricing and cautious about accepting deals with unreasonable conditions.
06. Incorporate into the national legislations, the mechanisms to enable for compulsory licensing, parallel importing and early working (bolar) provisions as provided by the DOHA declaration on TRIPs agreement.
07. Educate consumers, health providers, health activists and administrators on the concept of essential drugs, generic names and rational & economic use of drugs and create awareness on the drug pricing issues.
08. Implement strict price control measures with upper ceiling prices for both branded and generic drugs.
09. Oversee Public Private Initiatives (PPI), especially concerning the essential medicines, to ensure that the relationship and negotiations protect the citizens, are without undue conditions imposed by industry and lead to systematic solutions to increase access to medicines.

At International / Regional level:

01. Countries should be able to exercise their rights in determining their public health priorities and be allowed to take necessary measures independently.
02. Bilateral pressure from multi-national drug exporting countries placed on developing countries must be stopped.
03. Patents on pharmaceuticals should be kept away from any bilateral agreements and not to be allowed as a trade off for economic incentives.
04. Countries those do not have local manufacturing capacities in producing medicines should have measures to issue compulsory licenses to firms in countries that can meet their production needs and have the production shipped to them.
05. Educate health activists and key policy makers of developing countries on the safeguards provided by the Doha Declaration on TRIPs, that will enable the developing countries to manufacture or import cheaper drugs.
06. Developing countries should develop a comprehensive international legal framework to ensure the optimal utilization of the Doha declaration safeguards and priority to public health interests.
07. Promote more funding and investment in research on the diseases of the poor.
08. Pharmaceutical companies should follow an international transparent system of equity pricing to cut down the prices of key medicines to developing countries.
09. International funding should be increased to subsidize drug purchases and delivery systems in the poor developing countries and the purchases should be the cheapest available quality drugs.
10. Developing countries in a region should actively promote regional production and / or centralized pool purchasing & supply of medicines among themselves.
11. Databases on essential drug prices are to be continuously developed and updated, linking with information from the pre-qualification process and the WIPO for patent status information.
12. WHO and representatives of civil society should continue to play an active role as official observer at the WTO and WIPO.
13. WHO and civil society organizations should assist countries to develop and formulate pro-health laws and regulations, including providing models for the safeguards of TRIPs that will help overcome current barriers to accessing essential medicines.

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