People's Health Assembly

Globalisation and Liberalisation of Healthcare Services: WTO and the General Agreement on Trade in Services

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ISSUE PAPER

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Executive Summary

Access to essential drugs and affordable medical services are major consumer concerns. The Health and Pharmaceuticals Programme of Consumers International Regional Office for Asia and the Pacific (CI ROAP) has been campaigning, advocating and lobbying for the formulation and implementation of national drug policies and national health policies. The major components of these national policies include:

- Access to essential drugs and affordable healthcare services

One of the major activities undertaken by the Health and Pharmaceuticals Programme soon after it was set up in November 1986 was to study the impact of pharmaceutical patents on the pharmaceutical supply systems in developing countries. This activity gathered momentum when the Uruguay Round (UR) of Negotiations began in 1987.

In order to alert consumers and to inform policy-makers in developing countries on the impact of pharmaceutical patents and WTO/TRIPs Agreement on access to drugs and healthcare, CI ROAP prepared the six reports and presented them at different forums.

This paper begins with a description of the evolution of the TRIPs Agreement. Initially the developing countries refused to enter the negotiations when the major trading powers attempted to include services, investment and intellectual property, in addition to goods into the Uruguay Round of Negotiations.

A compromise was reached to negotiate services and investment outside the jurisdictional framework of GATT. Negotiations on intellectual property rights (IPRs) would follow the approach in the articles of GATT which ensured that Member States had the freedom to pursue their own regime of protection of intellectual property.

However, soon after the negotiations began in 1987, the US used bilateral threats of trade retaliation and forced developing countries to change their national legislation on patents and go back to the negotiating table. Negotiations continued and the paper describes in some detail the asymmetry of the negotiations. These were dominated by the major powers. The Final Agreement has been described as the most non-transparent, non-accountable, anti-people, pro-TNC agreement in the history of international negotiations and agreements.

The TRIPs Agreement together with Trade Related Investment Measures (TRIMs) have taken away the powers of economic decision making from the national governments and handed them to the dominant actors in the international market place, namely the transnational corporations (TNCs). The international economic order has been radically restructured by the TRIPs Agreement which encompasses virtually the entire economic spectrum.

The GATT/WTO/TRIPs Agreement was ‘negotiated’ as an integral part of the Uruguay Round (UR) of Negotiations. It is one component of a package of commitments. There is the possibility of cross-retaliation in case of non-compliance with any one component. The TRIPs Agreement cannot, therefore, be taken in isolation but has to be examined in the context of the whole GATT/WTO Agreements. WTO Agreements, by liberalising trade in goods and services, promotes the process of globalisation. It is therefore necessary to examine TRIPs not only in the context of other WTO trade agreements but also in the overall context of globalisation.

To understand fully the implications of WTO/TRIPs Agreement on the access of drugs to consumers in the ASEAN region, it will be necessary to examine the pharmaceutical sector in the ASEAN countries and in the world. Empirical data on pharmaceutical production and consumption in five ASEAN countries – Indonesia, Malaysia, Philippines, Singapore and Thailand are given. Relevant data on the worldwide pharmaceutical industry and the multinational drug industry are also given.

Malaysia produces about 50 per cent of the country's requirements of pharmaceuticals. The other four ASEAN countries are almost self-sufficient. However manufacture in all ASEAN countries is limited mainly to formulation of dosage forms from imported raw materials. The pharmaceutical industry in these countries is, therefore, totally dependent on the availability of raw materials in the world market. Before the TRIPs Agreement came into force, the national patent legislation in most developing countries did not provide patent protection for pharmaceutical products. This enabled developing countries like Argentina, China, India, Korea and Mexico to have a strong vertically integrated pharmaceutical industry. They were able to put into the world market raw materials of all essential drugs at competitive prices.

All these countries have now changed their national legislation on patents in accordance with TRIPs Agreement. They will provide patent protection for pharmaceutical products. These countries will not be able to manufacture any drug under patent protection. The period of patent protection is 20 years.

The multinational drug companies will have the monopoly of all patent protected drugs and will not be marketing raw materials at competitive prices. The pharmaceutical industry in developing countries will therefore collapse.

The only way to avoid this and strengthen the pharmaceutical sector in the ASEAN and other developing countries will be through compulsory licensing and parallel imports. These are allowed in the TRIPs Agreement.

National legislation on patents which will allow for compulsory licensing and parallel imports will enable consumers in the ASEAN countries access to affordable pharmaceuticals. This, consumers believe, is a short-term solution.

The paper concludes with a long-term solution.

In order to arrive at a long-term solution, the short and long-term implications of the TRIPs Agreement on access to pharmaceuticals need to be critically examined and analysed. Consumers have expressed the following concerns:

- It is ironical that Geneva, a city renowned for hosting several international meetings to focus world attention towards problems of Third World poverty with a view to developing appropriate remedial measures is also the home of WTO. The way WTO proposes to implement the TRIPs Agreement will lead to the dismantling of the fragile economies of several Third World countries.

- The Uruguay Round of Negotiations and the TRIPs Agreement are attempts to restructure and refashion the rules of the international trading system in accordance with the interests and concerns of the major trading nations and particularly the TNCs.

- The TRIPs Agreement represents an unprecedented transfer of power over economic functioning from the heads of nation states to TNCs.

- There should be a major review of the WTO multilateral trade agreements. Subsequent reforms should incorporate as a central objective the promotion of sustained development in the Third World.

- The special problems of the least developed countries (LDCs) should receive particular attention.

- In 1978, there were according to the United Nations 28 LDCs. In 1998 there were 48. The rapid decline into poverty is due to double dose of liberalisation.

- These countries have to liberalise in accordance with the WTO multilateral trade agreements. In addition they also have to agree to unilateral trade liberalisation measures under the WB/IMF structural adjustment programmes.

- Trade policy should be a powerful instrument for economic development, and this aspect must not be lost sight of by narrowly focussing on liberalisation.

Based on analysis of empirical data on the impact of the TRIPs Agreement on access to drugs and health services in developing countries, the Human Development Report 1999 has listed the following concerns:

- Liberalisation, privatisation and tighter intellectual property rights are shaping the path for the new technologies, determining how they are used. But the privatisation and concentration technology are going too far. Corporations define research agendas and tightly control the findings with patents, racing to lay claim to intellectual property under the rules set out in the agreement on Trade-Related Aspects of Intellectual Property Rights.

- Poor people and poor countries risk being pushed to the margin in this proprietary regime controlling the world's knowledge.

- In defining research agendas, money talks, not need – cosmetic drugs and slow-ripening tomatoes come higher on the priority list than drought-resistant crops or a vaccine against malaria.

- From new drugs to better seeds, the best of the new technologies are priced for those who can pay. For poor people, they remain far out of reach.
- Tighter property rights raise the price of technology transfer, blocking developing countries from the dynamic knowledge sectors. The TRIPs Agreement will enable multinationals to dominate the global market even more easily.

- New patent laws pay scant attention to the knowledge of indigenous people. These laws ignore cultural diversity in the way innovations are created and shared – and diversity in views on what can and should be owned, from plant varieties to human life. The result: a silent theft of centuries of knowledge from some of the poorest communities in developing countries.

- Despite the risks of genetic engineering, the rush and push of commercial interests are putting profits before people.

- There is a need for a comprehensive review of the TRIPs Agreements to redress their perverse effects undermining:
  - food security;
  - indigenous knowledge;
  - biosafety; and
  - access to healthcare.

The paper argues that:

- If WTO continues to refuse to listen to people's representatives' request for a comprehensive review of the TRIPs and GATS Agreements in order to redress their perverse effects.

- If the WTO continues to implement the TRIPs and GATS Agreement the way the TNCs want;

- If the transnational corporations sit on all the important advisory committees, decide detailed policy and set the agenda for WTO;

- If the WTO Trade Agreements continue to be described as a bill of rights for corporate business;

- If the world community ignores the people's call for a more coherent and more democratic architecture for global governance in the 21st century;

  The people will respond in their own way.

People's response has been loud and clear. The tragic event's associated with the people's response to globalisation and multilateral trade agreements have been documented and audio-visually presented. The whole world has followed with deep concern:

- The rioting in Geneva, 1998 during the Ministerial Meeting of WTO
- The battle in Seattle, 1999 during the Ministerial Meeting of WTO
- The chaos in Davos, 2000 during the World Economic Forum
- Shut down in Washington, April 2000 – WB/IMF Meeting

Why have people reacted so violently? People throughout the world were educated and brought up to believe that power was concentrated in political authority – elected governments with presidents, prime ministers, cabinets and oppositions. Democratic elections could make that power accountable to the needs of the people. But today the people see that real power is something else. It is financial and economic and is controlled by powerful market forces operating under faulty global governance supported by rules, institutions and practices that have been formulated by a selected few.

The violent events in Geneva, Seattle and Davos and Washington were passionate and frenzied signals people are transmitting to the world that they be given a participatory role in decision making so that people will be put at the centre of development plans and highest priority be given to goals of enhancing social development and ensuring human well-being for all throughout the world.

People want a restructuring of the present global governance with a new set of rules, institutions and practices that will ensure global responsibility so that the benefits of globalisation will be shared equally by all the people of the world and not exclusively by the 20 per cent of the people living in the richest countries.

The Human Development Report (HDR) 1999, has answered the people's request for restructuring the present global governance.

The Report is the fruit of a collaborative effort by a team of eminent consultants and advisers and the Human Development Report team.

In order to build a more coherent and more democratic architecture for global governance in the 21st century the Report states as follows:

Just as the nineteenth-century mechanisms of national government were inadequate for the challenges of the postwar era, so today's institutions of international governance are inadequate for the challenges of the 21st century. Many of the basic elements of national governance will be needed in a more robust structure of global governance. An essential aspect of global governance, as of national governance, is responsibility to people – to equity, to justice, to enlarging the choices of all. These are, unfortunately, not in the vocabulary of the WTO, WB and IMF.

Some of the key institutions of global governance needed for the 21st century include:

- A stronger and more coherent United Nations to provide a forum for global leadership with equity and human concerns.
- A global central bank and lender of last resort.
- A World Trade Organization that ensures both free and fair international trade, with a mandate extending to global competition policy with antitrust provisions and a code of conduct for multinational corporations.
- A world environment agency.
- A world investment trust with redistributive functions.
- An international criminal court with a broader mandate for human rights.
- A broader UN system, including a two-chamber General Assembly to allow for civil society representation.

Implications of TRIPs Agreement on Access to Pharmaceuticals: Consumers' Perspectives

A. Introduction

Access to essential drugs and affordable medical services are major consumer concerns. The Health and Pharmaceuticals Programme of Consumers International Regional Office for Asia and the Pacific (CI ROAP) has been campaigning, advocating and lobbying for the formulation and implementation of national drug policies and national health policies. The major components of these national policies include:

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One of the major activities undertaken by the Health and Pharmaceuticals Programme soon after it was set up in November 1986 was to study the impact of pharmaceutical patents on the pharmaceutical supply systems in developing countries. This activity gathered momentum when the Uruguay Round (UR) of Negotiations began in 1987.

In order to alert consumers and to inform policy-makers in developing countries on the impact of pharmaceutical patents and WTO/TRIPs Agreement on access to drugs and healthcare, CI ROAP prepared the following reports and presented them at different forums:

1. Policy Options in Pharmaceutical Patents for Developing Asian Countries. Presented at the International Seminar "Pharmaceutical Patents for Developing Asian Countries", organised by the International Organization of Consumers Unions, Bangkok, 4 April 1987.

2. Third World Sovereignty in Danger. Presented at the National Seminar on GATT, New Delhi, November 1990, organised by National Working Group on Patent Laws.

3. GATT and the Third World. Presented at the International Convention on People's Approach to GATT Negotiations, February 18-20, 1993 organised by National Working Group on Patent Laws, New Delhi, India.

4. Pharmaceutical Patents – And the Consumer. Presented at the PCC '94 Congress "Innovative Pharmaceutical Re-Engineering & Cost Control", July 14-15, 1994, Singapore. Organised by the Institute for International Research (IIR), Singapore.

5. Heads – TNCs Win: Tails – the South Loses or The GATT/WTO/TRIPs Agreement. Presented at the HAI Seminar: World Trade Organization/GATT, Pharmaceutical Policies and Essential Drugs, 4 October 1996, Bielefeld, Germany.

6. Consumers & the WTO/TRIPs Agreement. Presented at the International Convention on the Impact of WTO/TRIPs on Access to Drugs, organised by the Ministry of Health, Pakistan in collaboration with the World Health Organization, Karachi, Pakistan, 26-30 July, 1999.

B. Evolution of the TRIPs Agreement

The GATT/WTO/TRIPs Agreement was 'negotiated' as an integral part of the Uruguay Round (UR) of Negotiations. It is one component of a package of commitments. **There is the possibility of cross-retaliation in case of non-compliance with any one component**. The TRIPs Agreement cannot, therefore, be taken in isolation and has to be examined in the context of the whole GATT/WTO Agreements. WTO Agreements, by liberalising trade in goods and services, promotes the process of globalisation. It is therefore necessary to examine TRIPs not only in the context of other WTO trade agreements but also in the overall context of globalisation.

The Uruguay Round of Negotiations began on September 20, 1986 and ended with the establishment of WTO on January 1, 1995.

There was initial unity of opposition by the developing countries (G77) led by Brazil and India when the major trading powers, at the start of the negotiations in 1986, attempted to enlarge the scope of GATT to include services, intellectual property and investment in addition to goods. A compromise was reached. It was agreed that negotiations relating to services were to be conducted outside the jurisdictional framework of GATT. These negotiations would be guided by the objective of development of developing countries and not just be concerned with liberalisation and dismantling the existing regulatory structures. National regulatory frameworks were to be respected.

It was also agreed that negotiations on IPRs should follow the approach already contained in Article 1 of the GATT Treaty which ensured that every Member State had the freedom to pursue its own regime of protection of intellectual property and which merely required that no Member State may use this freedom arbitrarily and in a discriminatory manner against the products or goods imported from another country. The developing countries were satisfied with the agreement and formal 'negotiations' commenced in January 1987. Little did the G77 know what was to follow; how a master plan would unfold – deception by design – the great betrayal – a broken promise.

In June 1988 the Association of TNCs of the US, Europe and Japan submitted a joint paper to GATT on IPRs. The Association, not a member of GATT, first placed IPRs on the GATT Agenda.

Within two months, in August 1988, the US President Ronald Reagan signed the Omnibus Trade and Competitiveness Act of 1988. This Act created two provisions: Super 301 and Special 301. These provisions strengthened the ability of the United States Trade Representative (USTR) to retaliate against countries for 'unfair trade practices including alleged inadequate protection of IPRs'.

Special 301 requires the USTR to investigate and retaliate against countries which allegedly deny 'adequate and effective protection of IPRs'. Super 301 mandated the USTR to retaliate against foreign practices which are unjustifiable and burden or restrict US commerce.

The stage was now set for arm-twisting, to force countries to change their national legislation on patents and to bring recalcitrant countries to the negotiating table.

Since 1983, a number of international conventions on intellectual property have been adopted. The World Intellectual Property Organization (WIPO) was responsible for administering the main conventions in force.

Inspite of the fact there are a number of international conventions on IPRs and the special role of WIPO, for some very strange reason, the TRIPs 'negotiations' were conducted under GATT. **The provisions of the resulting TRIPs Agreement will be enforceable within the framework of WTO – a forum without any tradition of work in the field of IPRs.**

There was hardly any 'negotiations' in the real sense of the word. The negotiators for the developed countries had with them teams comprised of hundreds of experts and specialists who were very knowledgeable in the issues under discussion. Developing countries sent a senior official of the Trade Ministry. There was no technical support. Several small developing countries were represented by the Trade Counsellor of the country's Permanent Mission to the UN in Geneva. It is not unusual to see some of these Trade Counsellors in Geneva being driven from one committee meeting to another. How can a single 'negotiator' deal with teams of specialists and experts? The issues under 'negotiations' were extremely complex in nature. And there was no coordination among developing countries. The result of this asymmetry was that the so-called 'negotiating process' did not involve any give and take.

Developing countries made several concessions, in terms of agreeing to the higher levels of protection of IPRs demanded by industrialised countries but in return got very little by way of tariff reduction in agriculture and textiles.[1]

Adding more confusion to the asymmetry of the 'negotiating process' was the fact that no record of

the TRIPs discussions was made, in line with the general practice within GATT. Proposals have no recognised source and only those who participated, if they can yet remember, will know why certain provisions were adopted. There is no background material that will be vital to interpret the various rules that have been written into the Agreement or at least to find out the premises and intent of the adopted texts.

Further asymmetry. The composition of each working group was determined at the presiding officer's direction and not as a result of a consensus or of a search for a balanced representation of countries at different levels of development.

The entire Uruguay Round of 'negotiations' was withheld from public scrutiny and was kept as a secret preserve for trade officials. Not only the public but even other Ministries or departments in the national governments were not aware of the proceedings. The impact of the Agreement would affect each and every consumer in the world. However, consumers were left out.

In view of how the so-called 'negotiations' took place and the Agreement arrived at, **the Final Act has been described as the most non-transparent, non-accountable, anti-people and pro-TNC Agreement in the history of international negotiations and agreements.** The TRIPs Agreement, in particular, will deny billions of poor men, women and children all over the world access to even a limited number of basic essential drugs for the treatment of common illnesses.

The Final Act was authenticated by Member States in April 1994.

The concluding remarks of the chairman of the Trade Negotiating Committee, the supreme body in charge of the negotiating process, outlined the future of the TRIPs Agreement. This raises serious concerns for developing countries. Among other things, the Chairman of the Negotiating Committee stated at Marrakesh in April 1994:

"Ministers representing a number of participating delegations stressed the importance they attach to their requests for an examination of the relationships between:

- The trading system and internationally recognised labour standards;
- International trade and immigration policies;
- International trade and competition policy including rules on export financing and restrictive business practices;
- International trade and environment;
- Trade policies and policies relating to financing and monetary matters including debt, and commodity matters;
- International trade and company law, the establishment of a mechanism for compensation for the erosion of preferences;
- The link between trade, development, political stability, the alleviation of poverty and unilateral or extraterritorial measures.

There are two major concerns:

- The enormous variety of issues taken into the ambit of WTO (perhaps the only issue yet missing is the relationship between international trade and the colour of the skin!)
- In previous negotiations the various issues were linked to trade by using the by-word 'trade-related'. Now the strategy has progressed to the use of an unconcealed and direct process of simply connecting trade with any and every unconnected area by using the conjunction 'and'.

To understand fully the implications of WTO/TRIPs Agreement on the access of drugs to consumers in the ASEAN region, it will be necessary to examine the pharmaceutical sector in developing countries, in particular in the ASEAN countries and the world pharmaceutical industry.

C. Pharmaceutical Sector in Developing Countries – Pharmaceutical Technology, Production & Trade

Pharmaceutical technology and production can be divided into the following:

i. Research & development
ii. Production of chemical intermediates from basic chemicals
iii. Production of raw materials (or bulk drugs) from:
   - chemical intermediates
   - fermentation
   - plant sources
iv. Formulation of dosage forms (or finished products) from raw materials (or bulk drugs)

In the formulation industry (stage iv) the technology used is relatively simple, capital investment is low and economies of scale are not critical. In the late 1970s, the WHO published a document which described in detail the setting up of a viable formulation plant in countries with a population of three million. The United Nations Industrial Organization provided technical assistance to developing countries in setting up formulation plants. The technology for the production of raw materials from chemical intermediates, plant sources and by fermentation is more sophisticated, capital intensive and economies of scale very critical.

Comprehensive research and development to discover and develop new chemical entities require human, technological and financial resources, which, at present are available in only 10 advanced industrial countries. The United Nations Industrial Development Organization (UNIDO) has classified 190 countries into five groups based on the degree of development of pharmaceutical technology and industrial production. (Table 1)

A critical examination and analysis of the data in tables 1 and 2 will be helpful in understanding the impact of the WTO/TRIPs Agreement on access to essential drugs to consumers in these countries. This analysis is significant in terms of proposing pragmatic options and workable strategies.

The five countries manufacture drugs from imported raw materials and/or chemical intermediates. Malaysia produces only about 50 per cent of its requirements. The other countries are almost self-sufficient producing over 80 per cent of their requirements.

Regular availability of raw materials in the international markets at competitive prices will be critical for the pharmaceutical industries in these countries. The industry will collapse if raw materials at competitive prices are not available in the world market. In this context table 3 is relevant.

Analysis of the data in table 3 is helpful in discussing options open to developing countries to ensure regular access to essential drugs at affordable prices and also conform to the WTO/TRIPs Agreement.

The table provides the following information:

- The international non-proprietary, or the generic or the chemical name of the seven selected drugs. Five of them are the five top selling drugs in the world market. The other two are commonly used in the management of HIV/AIDS.
- The international patent status of each drug.
- The package size, strength and dosage forms of each of the seven drugs and the brand names under which they are marketed in India, which provides patent protection for processes but not products, and Italy, which provides patent protection for products & processes
- Retail prices of these drugs in India and Italy.
- Market prices of active substances quoted by manufacturers in selected countries.

Table 3 shows that the prices of the seven drugs are very much lower in India than in Italy. A major argument put forward by multinational drug companies for strong patent protection is to have exclusive rights for a period of time so that they can earn adequate profits to cover their costs of R & D and to

continue further R & D. This seems to be a justifiable argument. We need to know how much profits MNCs make, how much it costs to develop a new chemical entity and the amounts MNCs spend on R & D.

The data in table 3 can be used to estimate the profits companies make on these prescription drugs. The prices of raw materials or bulk drugs are given in the last column. The prices are quoted by manufacturers in China and India and one from Canada. MNCs with very large economies of scale available to them can certainly manufacture raw materials at lower costs.

Let us estimate the cost of production of zantac/zinetac tablets. It is assumed that Glaxo India can manufacture its raw material at the same cost as Indian manufacturers if not lower.

i. 10x300 mg tablets will contain 3000 mg or 3 g of the active substance.
ii. One kg of ranitidine in India costs $30. One gram will therefore cost 0.3 cents.
iii. 3 g of ranitidine (10 x 300 mg tabs) will therefore cost 3 x 0.3 = 0.9 cents.
iv. Conversion costs – this includes converting the active substance to tablets, packing them in aluminum foils, leaflet, etc will cost another 9 cents (For economy packing in bottles, the conversion costs will be less).
v. 10 x 300 mg tablets or ranitidine will therefore cost 18 cts. Glaxo sells it at 41 cents in India and makes a profit of 127 per cent.

It would appear that Glaxo prices its product in India because of the competition it faces. Several generic manufacturers produce ranitidine. However, it sells at much higher prices and earns more profits in other countries in the region as shown in table 4.

Parallel imports are encouraged by the European Commission. It is unheard of in Asia. If parallel imports are allowed, many countries in Asia can provide Zantac to their consumers at much lower prices.

The data in table 3 shows India is able to produce the drugs yet under patent because its national legislation on patents does not provide product patents. India has now joined the WTO. Very soon its national legislation on IPR will have to be reformulated to give protection to products. It will then not be able to manufacture drugs protected by patents. However, if compulsory licensing is allowed, Indian manufacturers will be able to continue manufacture drugs protected by patents, paying a royalty to patent holders. Compulsory licensing will help India, China and the Republic of Korea but not the other countries in Asia. Parallel imports will be one option for these countries to import their raw materials and finished products from countries like India, China and the Republic of Korea.

D. The Multinational Drug Industry

Pharmaceuticals have clearly begun to assume an international character but the industry is not a global one in the same sense, for example, as textiles, food processing, clothing or even steel. The contrast between the international character of pharmaceuticals and the concentration of the drug industry in 10 countries are equally great when concentration turns from countries to firms. A small number of about 50 multinational drugs companies (MNCs) account for more than two thirds of the world's production and exports each year. The latest estimate of the annual worldwide sales of pharmaceuticals is about $320 billion. The worldwide sales of the top 50 MNCs in 1995 were US$273 billion well over two-thirds. The total worldwide sales of the top 10 companies were $130 billion or 40 per cent of the global production. These firms are exceptionally large; annual sales of individual companies are in the region of several billions.[2]

How do MNCs set their prices? HAI has argued that MNCs practice price discrimination. Prices are set according to what the markets can bear. HAI based its conclusions on the surveys on retail prices of drugs.[3] [4] [5]

In January 1999 issue of SCRIP Magazine carried an article, "Quotable Quotes", where the author highlights selected important quotes of 1998, related to pharmaceuticals. One of them was attributed to HAI. The quote was, "Retail Drug Prices Resemble the Law of the Jungle where Right is Might", stemming from a critical analysis of empirical data on retail prices of selected drugs in several countries. Table 5 provides an example of price discrimination. Retail prices for 100 tablets of 150 mg of zantac, manufactured and marketed by the same manufacturer varied from two dollars to $196. The prices in two least developed countries, Mongolia and Tanzania are very much higher than in advanced countries like Australia, Canada and New Zealand.

MNCs are able to practise price discrimination because of the manner in which they operate:

(i) Patents are secured for inventions at global levels;
(ii) All medicinal substances and chemicals are distributed through subsidiaries and licensees;
(iii) Licensees and joint venture partners have to purchase intermediates and raw materials from approved sources and not from the world market; and
(iv) They practice transfer pricing. Table 6 gives example of transfer pricing.

Six TNCs transfer raw materials to their subsidiaries in Pakistan at prices very much higher than the prices of the same raw materials in the world market. Consumers in Pakistan are forced to pay high prices for these drugs.

Having the monopoly for exclusive marketing rights, MNCs allocate considerable sums of money in the Third World on promotion to secure brand loyalty of the prescribers or Deception by Design as HAI has described industry promotion.[6]

The MNCs, particularly the American industry supported by the United States Trade Representative have been advocating that developing countries need to provide strong protection for pharmaceuticals for 20 years in their national legislation. During this period, the patent holder will have exclusive monopoly for the manufacture, distribution and sales of the patented drugs. Generic manufacturers can copy them only after the patents expire. If developing countries have to wait for 20 years to manufacture the new life-saving drugs they will be waiting in vain. Modern drugs have short lifespan. The top sellers of today will be almost extinct in about 10-15 years. Table 7 gives the US ten top prescription drugs in 1983 and traces their ranking during the following 14 years.

Of the top ten US prescription drugs in 1983, only three Tagamet, Feldene and Naprosyn were able to retain their ranking within the top ten after five years in 1988. Four drugs – Motrin, Aldomet, Keflex and Diabenese were pushed far down. These four disappeared from the world market in 1997. They were not in the list of the 500 top selling drugs that year. Three of the top ten drugs in 1983 which were able to maintain their position within the top ten in 1988 were pushed to the mid one hundred in 1997 (146, 153 & 154). The other three were pushed further down – 296, 321 and 365.

The consumer organisations, therefore, reject the position taken up by MNCs and their supporters including the United States Trade Representative, that the TRIPs Agreement should be implemented in ways which would prevent compulsory licensing and parallel imports, among other things. Consumers reject this position because no drug at the end of 20 years will be worth manufacturing. The prices fixed indiscriminately by the MNCs, as in table 6, will prevent access of the life-saving drugs to over two billion people.

E. Options Open to Developing Countries to Improve Access to Essential Drugs

Short term options:

- The Uruguay Round of Negotiations and the TRIPs Agreement are attempts to restructure and refashion the rules of the international trading system in accordance with the interests and concerns of the major trading nations and particularly the TNCs.

- The TRIPs Agreement represents an unprecedented transfer of power over economic functioning from the heads of nation states to TNCs.

- There should be a major review of the WTO multilateral trade agreements. Subsequent reforms should incorporate as a central objective the promotion of sustained development in the Third World.

- The special problems of the least developed countries (LDCs) should receive particular attention.

- In 1978, there were according to the United Nations 28 LDCs. In 1998 there were 48. The rapid decline into poverty is due to double dose of liberalisation.

- These countries have to liberalise in accordance with the WTO multilateral trade agreements. In addition they also have to agree to unilateral trade liberalisation measures under the WB/IMF structural adjustment programmes.

- Trade policy should be a powerful instrument for economic development, and this aspect must not be lost sight of by narrowly focussing on liberalisation.

The Human Development Report 1999 states the following on the impact of TRIPs Agreement on access to drugs and healthcare:

- Liberalisation, privatisation and tighter intellectual property rights are shaping the path for the new technologies, determining how they are used. But the privatisation and concentration technology are going too far. Corporations define research agendas and tightly control the findings with patents, racing to lay claim to intellectual property under the rules set out in the agreement on Trade-Related Aspects of Intellectual Property Rights.

- Poor people and poor countries risk being pushed to the margin in this proprietary regime controlling the world's knowledge.

- In defining research agendas, money talks, not need – cosmetic drugs and slow-ripening tomatoes come higher on the priority list than drought-resistant crops or a vaccine against malaria.

- From new drugs to better seeds, the best of the new technologies are priced for those who can pay. For poor people, they remain far out of reach.

- Tighter property rights raise the price of technology transfer, blocking developing countries from the dynamic knowledge sectors. The TRIPs agreement will enable multinationals to dominate the global market even more easily.

- New patent laws pay scant attention to the knowledge of indigenous people. These laws ignore cultural diversity in the way innovations are created and shared – and diversity in views on what can and should be owned, from plant varieties to human life. The result: a silent theft of centuries of knowledge from some of the poorest communities in developing countries.

- Despite the risks of genetic engineering, the rush and push of commercial interests are putting profits before people.

- A need for a comprehensive review of the TRIPs Agreements to redress their perverse effects undermining:
  - food security;
  - indigenous knowledge;
  - biosafety; and
  - access to healthcare.

The long-term solution:

- If WTO continues to refuse to listen to people's representatives' request for a comprehensive review of the TRIPs and GATS Agreements in order to redress their perverse effects.

- If the WTO continues to implement the TRIPs and GATS Agreement the way the TNCs want.

- If the transnational corporations sit on all the important advisory committees, decide detailed policy and set the agenda for WTO as stated in *The Lancet*.[7]

- If the WTO Trade Agreements continue to be described as a bill of rights for corporate business.[8],[9]

- If the world community ignores the people's call for a more coherent and more democratic architecture for global governance in the 21st century;

  The people will respond in their own way.

People's response has been loud and clear. The tragic event's associated with the people's response to globalisation and multilateral trade agreements have been documented and audio-visually presented. The whole world has followed with deep concern:

- The rioting in Geneva, 1998 during the Ministerial Meeting of WTO
- The battle in Seattle, 1999 during the Ministerial Meeting of WTO
- The chaos in Davos, 2000 during the World Economic Forum
- Shut down in Washington, April 2000 – WB/IMF Meeting

Why have people reacted so violently? People throughout the world were educated and brought up to believe that power was concentrated in political authority – elected governments with presidents, prime ministers, cabinets and oppositions. Democratic elections could make that power accountable to the needs of the people. But today the people see that real power is something else. It is financial and economic and is controlled by powerful market forces operating under faulty global governance supported by rules; institutions and practices that have been formulated by a selected few.

People have, therefore, decided to take control of the uncontrolled, unregulated market power that has deprived them of active participation in global governance. They want to reassert the need for a political process that will be truly representative and among others, provide an enabling environment for social development.

The violent events in Geneva, Seattle and Davos and Washington were passionate and frenzied signals people are transmitting to the world that they be given a participatory role in decision making so that people will be put at the centre of development plans and highest priority be given to goals of enhancing social development and ensuring human well-being for all throughout the world.

People want a restructuring of the present global governance with a new set of rules, institutions and practices that will ensure global responsibility so that the benefits of globalisation will be shared equally by all the people of the world and not exclusively by the 20 per cent of the people living in the richest countries.

The Human Development Report (HDR) 1999, has answered the people's request for restructuring the present global governance.

The Report is the fruit of a collaborative effort by a team of eminent consultant and advisers and the Human Development Report team.

In order to build a more coherant and more democratic architecture for global governance in the 21st century the Report states as follows:

Just as the nineteenth-century mechanisms of national government were inadequate for the challenges of the postwar era, so today's institutions of international governance are inadequate for the challenges of the 21st century. Many of the basic elements of national governance will be needed in a more robust structure of global governance. An essential aspect of global governance, as of national governance, is responsibility to people – to equity, to justice, to enlarging the choices of all. These are not in the vocabulary of the WTO, WB and IMF.

Some of the key institutions of global governance needed for the 21st century include:

- A stronger and more coherent United Nations to provide a forum for global leadership with equity and human concerns.
- A global central bank and lender of last resort.
- A World Trade Organization that ensures both free and fair international trade, with a mandate extending to global competition policy with antitrust provisions and a code of conduct for multinational corporations.
- A world environment agency.
- A world investment trusts with redistributive functions.
- An international criminal court with a broader mandate for human rights.
- A broader UN system, including a two-chamber General Assembly to allow for civil society representation.

Even before these long-term changes are initiated or achieved, many actions could be taken in the next one to three years:

- Developing countries could take collective – especially regional – initiatives to strengthen their positions in global negotiations in trade, intellectual property rights and other areas.
- Individual countries could set up a high-level group to coordinate policy on globalisation and manage their integration for a more positive impact on human development.
- Donor countries could accelerate action on debt relief and redirect aid in favour of poorer countries and human development.
- An independent legal aid facility and ombudsman could be created to support the poor and weak countries in the WTO.
- All countries could cooperate more to fight global crime, relaxing restrictive bank secrecy laws.
- New sources of financing for the global technology revolution could be investigated, to ensure that it is truly global and that its potential for poverty eradication is mobilised. Two proposals: a bit tax to generate resources, and a public programme for development technology similar to CGIAR's programme for food.
- A representative task force could be set up to review global economic governance, including in some 20 or so countries – large and small, rich and poor – but also the private sector and the civil society. It could report jointly to ECOSOC, the IMF Interim Committee and the World Bank Development Committee.

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[3] K. Balasubramaniam, "Pharmacoeconomics", HAI News No. 68, December 1992.

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[8] Balanya B, Doherty A, Hoedeman O, Ma’amit A, Wesselius E. “WTO millennium bud: TNC control over global trade politics”. Corp Eur observer 1999; 4: 3
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Tables

Table 1 – A typology of world's pharmaceutical industries

Stage of development	Number of countries		
	Total	**Industrial**	**Developing**
Sophisticated pharmaceutical industry with significant research base	10	Belgium, France, Germany, Italy, Japan, Netherlands, Sweden, Switzerland, UK & US	Nil
Innovative capabilities [1]	17	12	5. i.e. Argentina, China, India, Mexico, Republic of Korea
Countries with reproductive capabilities: (a) Those producing both therapeutic ingredients & finished products. (b) Those producing finished products only.	14 89	6 2. Albania, Greece	8. i.e. Bahamas [2], Bolivia, Brazil, Cuba, Egypt, Indonesia [3], Macau [4], Puerto Rico 87
Countries/states without a pharmaceutical industry.	60	1. Luxemberg	59

(1) Each country in this group discovered and marketed at least one new chemical entity between 1961-1996.

(2) Bahamas – Firms produce therapeutic ingredients for export.

(3) Indonesia – Every foreign-owned factory is required to produce at least one therapeutic ingredient within five years of start-up.

(4) Haviones (Portugal) subsidiary produces antibiotics and cortico-steroids for export.

Source: UNIDO – The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy by Robert Balance, Janos Pogany & Helmet Forsteiner, UNIDO, 1992.

Table 2 gives the pharmaceutical production and consumption in five ASEAN countries.

Table 2 – Pharmaceutical production and consumption in five ASEAN countries

Country	Consumption per capita US$ (1990)	Percentage ratio of production to consumption	
		1975	1989
Indonesia	3.9	94.6	98.8
Malaysia	7.8	27.5	49.5
Philippines	7.7	98.5	89.7
Singapore	20.1	58.2	83.5
Thailand	6.6	71.7	87.6

Source: UNIDO, op. cit.

Table 3 - Retail prices of the five top-selling drugs in the world and two drugs used for the management of HIV/AIDS in 1997 in India and Italy. The market prices of the corresponding active substances quoted by manufacturers from selected countries and the patent status of the seven drugs are also given.

Active substance/chemical name (Pharmacological action)	Patent Status	Package size, strength, dosage form	India		Italy	
			Brand name	Price US$	Brand name	Price US$
Simvastatin (cholesterol reducing)	SUP	20 x 10 mg, tabs 10 x 20 mg, tabs 10 x 40 mg, tabs.	Simvotin Simvotin	3.80 3.33	Liponorm Modiolanum Zocor	29.6 15.1 29.8
Omeprazole (anti ulcer)	PCO	14 x 20 mg, cap.	Acichek (Boehringer Mannheim) Zopep (Pharma Upjohn)	1.00 0.97	Losec Antra	31.4
Fluoxetine (antidepressant)	PE	12 x 20 mg, caps	Dawnox Prodac (Searle)	0,34 0.66	Prozac Fluoxerene	19.5 19.5
Enalapril (antihypertensive)	PCO	14 x 20 mg, tabs 28 x 5 mg, tabs	Envas Ena (Menarini)	1.20 0.80	Converten Enopren	12.3 10.3
Ranitidine (antiulcer)	POSC	20 x 150 mg, tabs 10 x 300 mg, tabs	Zinetac (Glaxo) Zinetac (Glaxo)	0.45 0.41	Ranidel Zantac (Glaxo)	17.2 16.9
Fluconazole (antifungal)	POSC	10 x 100 mg, tabs 2 x 150 mg, tabs	Syscon Bisflu	5.10 0.95	B-zolene Elazor Diflucan	65.7 23.5
Zidovudine (anti HIV/AIDS)	POSC	60 x 300 mg, tabs 100 x 100 mg, tabs	Retrovir (Glaxo) Zidovir	127.40 44.10	Retrovir(Glaxo) Retrovir (Glaxo)	305.0 183.0

Patent Status:

PE Patents expired
PCO Patents coming out in certain countries
POSC Patents came off in some countries
SUP Still under patent

Source: Personal communication, Vico Hemsi, Milan, Italy.

Table 5 – The retail prices in US dollars of 100 tablets of 150 mg of zantac (zinetac in India) in 12 selected countries in January 1995. The minimum daily wage and per capita GNP in US dollars are also given.

	Developed Countries			Developing Countries						
	Australia	Canada	New Zealand	Bangladesh	Chile	El Salvador	India	Mongolia	Nepal	So Af
Minimum daily wage in USD	46.0	33.0	32.0	2.1	9.8	5.5	1.3	0.80	1.6	
Per capita GNP in USD	18720.0	19380.0	14340	240	4160	1610	340	310	200	
Zantac 100 tabs. .iIn US$	23	77	21	9	196	132	2	183	3	

Table 4 – Retail prices in USD of 100 tablets of Zantac in 11 Asian countries

Countries	Zantac (100 x 150 mg) in US$
Bangladesh	9
India	2
Indonesia	41
Malaysia	55
Mongolia	183
Nepal	3
Pakistan	22
Philippines	63
Sri Lanka	61
Thailand	37
Vietnam	30

Source: Retail Drug Prices: The Law of the Jungle, HAI News No. 100, April 1998.

Table 6 – Price comparisons of seven pharmaceutical raw materials in Pakistan, 1994

Drug	Company	Price per kg (USD)		Percentage difference
		Transfer price	International price	
Xylometazoline	Ciba-Geigy	11,092	320	3,360
Piroxicam	Pfizer	8,930	125	7,044
Diazepam	Roche	561	27	1,978
Pindolol	Sandoz	9,591	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 no. 78, August 1994.

Table 7 – The top ten US prescription drugs in 1983, their ranking in US in 1988 and in the world in 1997

Product	1983 sales 1983 rank	1988 sales 1988 rank	500 prescription drugs by worldwide sales, 1997 - rank
Tagamet (SK&F)	1	2	154
Inderal (Ayerst)	2	13	321
Dyazide (SK&F)	3	12	365
Motrin (Upjohn)	4	39	-
Aldomet (MS&D)	5	72	-
Valium (Roche)	6	25	296
Feldene (Pfizer)	7	10	153
Naprosyn (Syntex)	8	4	146
Keflex (Dista)	9	44	-
Diabinese (Pfizer)	10	98	-

Source: (1) 1983 & 1988 US ranking, SCRIP No. 1381, Jan 27, 1989, p. 17.
(2) 1997 Ranking: Annual Report 500 Drugs: 500 Prescription Drugs by worldwide sales, Pharma Business, July/ August 1998.