Poverty, health & intellectual property rights with special reference to India

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This paper examines the nexus between poverty and global health with specific focus on IPR protection and attempts to highlight the current global endeavours to overcome barriers to access to medicines for diseases of the poor. The number of very poor people in the world has increased by 10.4 per cent between 1987 and 2001 to 2735 million. India is now home to the largest number of millionaires in the developing countries. But over 800 million Indians still survive on Rs 20.0 (US$0.5) a day, and rural poverty is on the rise. The link between poverty and health is well established with the underprivileged more vulnerable to major health risks due to poor nutrition, inadequate access to clean drinking water, sanitation, exposure to indoor smoke, etc. all of which contribute to the huge and growing burden of disease in the poor countries. The global disease burden is not just huge but growing: over 10 million children die of preventable conditions including vaccine-preventable diseases, about 14 million are killed by infectious diseases every year, 90-95 per cent in poor countries. An estimated third of global population has limited or no access to essential medicines. While the number of poor and unhealthy is growing, Government expenditure on health is dwindling. Many of the diseases of the poor require new medicines and none are forthcoming as there is little R&D for these infections. There are several barriers to access to existing and the newly discovered drugs. One major reason is the general lack of interest by the pharma industry to discover new medicines for diseases of the poor due to very limited market in developing countries. In addition, global intellectual property rights (IPR) protection regimes like the Trade Related Intellectual Property Rights (TRIPS) are considered a major obstacle for the poor access to medicines. There have been some global initiatives on the need to improve affordability and accessibility of medicines. Some strategies to promote R&D on diseases of the poor such as Prize Fund Model, the Medical R&D Treaty and steps to invoke flexibilities in TRIPS read with Doha Declaration are discussed. Affordable health for the poor is a global problem that requires global solutions with global participation and commitment.

Key words Doha Declaration - Medical R&D Treaty - public health - Trade Related Intellectual Property Rights

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The number of very poor people in the world has increased by 10.4 per cent between 1987 and 2001 to 2735 million - almost half the world’s population\(^1\). This is considered possibly an underestimate of the true breadth and depth of global poverty\(^1\). India is now home to the largest number of millionaires in the developing world with over 1,00,015 people with wealth of at least US$ 1.0 million\(^4\). Only Turkey, Russia, Germany and the USA have more millionaires. And the numbers are expected to rise with the growth rate well over 9.0 per cent. A just released report by the National Commission for Enterprises in the Unorganised Sector (NCEUS)\(^5\) says that 836 million Indians or 77 per cent of India’s population, earn less than Rs 20 (US$0.5) a day or officially designated as ‘poor and vulnerable segment of the Indian population’. This number, equivalent to the combined population of USA, Indonesia, Brazil and Russia, can barely afford the daily minimum calorie intake and other daily needs. According to Arjun K.Sengupta, Chairperson of the NCEUS, while there has been a decline of the extremely poor (wage earning Rs 9 per day) in the last decade from 37.7 (1993-94) to 21.8 per cent (2004-05), the per cent of marginal and vulnerable has actually risen from 51.2 per cent (1993-94) to 55.0 per cent (2004-05). Poverty is therefore surely on the rise in India, with rural poverty rapidly rising in many States, hitting hard the more vulnerable among the poor women and children\(^6\).

It is increasingly being recognized that improving global health is inextricably linked to the challenge of addressing widespread and growing poverty\(^3\) as poverty and health create a vicious cycle\(^7\). The poor are especially vulnerable to major health risks as inadequate and improper nutrition, unsafe water supply, poor sanitation and hygiene, toxic indoor smoke, and extremely limited access to health education and services, all of which contribute to huge disease burden in the poor countries\(^8\). Illness keeps poor wage earners away from work, children away from the school depriving them of education they need.

The global disease burden is growing steadily with both communicable and non-communicable diseases. The total disease load (as % of DALYS lost) shows that the poor countries account for a huge burden of communicable diseases (5.6 vs 53.5) as compared to NCDs (85.7 vs 53.0). Region-wise data show that while in Africa the load of CDs is very high (71.7 vs 19.2), countries in the SEAR region including like India show a trend towards the ‘dual disease’ burden (39.3 vs 47.1) (Table I). Poverty reduction is considered one of the most important factors to improve the health of the people\(^9\). Investing in health and health care therefore are considered central to the promotion of economic and social development and reduction of poverty\(^10\). Economic growth is linked to the health of the people. For example, the estimated GDP lost per year due to malaria alone in Africa is a staggering $1.2 billion\(^11\).

At the United Nations Millennium Summit in September 2000, the eight Millennium Development Goals (MDGs) were agreed\(^12\). Now there are over 190 countries have signed up to them. These Goals were identified with as many as 18 targets as part of a wider attempt to encourage the international community to stop talking about making a difference in the developing world and join forces to start doing something about it.

- Eradicate extreme poverty and hunger
- Achieve universal primary education
- Promote gender equality and empower women
- Reduce child mortality
- Improve maternal health
- Combat HIV and AIDS, malaria and other diseases
- Ensure environmental sustainability
- Develop a global partnership for development

The target to meet these targets is 2015.

### Table I. Proportion of disability adjusted life years (DALYs) lost by disease group 2005 (% of total days lost)

<table>
<thead>
<tr>
<th>Cause</th>
<th>HIC</th>
<th>LIC</th>
<th>Low and middle income countries by WHO Region</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>African</td>
</tr>
<tr>
<td>CD</td>
<td>5.6</td>
<td>53.5</td>
<td>71.7</td>
</tr>
<tr>
<td>NCD</td>
<td>85.7</td>
<td>35.0</td>
<td>19.2</td>
</tr>
<tr>
<td>Injuries</td>
<td>8.7</td>
<td>11.5</td>
<td>9.1</td>
</tr>
</tbody>
</table>

HIC, High income countries; LIC, Low income countries
CD, Communicable diseases; NCD, Non-communicable diseases

Source: CIPIH (2006)\(^35\)
It is significant that health figures in as many as three of the eight Goals. In many cases, it is the accessibility that is the issue to achieve these targets and there is a lot that needs to be done. So, while some significant progress is being made towards meeting the targets in some of the affected countries, in many cases progress is patchy, too slow or non-existent.13

**Disease profile**

**Vaccine preventable diseases**: Each year, a quarter of the children born are not protected through immunization and an estimated 1.4 million children under five years of age still die from vaccine preventable diseases.14 If new vaccines against rotavirus and pneumococcus, deadly forms of diarrhoea and pneumonia, become available over the next few years an additional 1.1 million child deaths could be prevented. While some 103 countries are already protecting 90 per cent of their children against vaccine-preventable diseases another 16 are making slow but steady progress. But we still have a long way to go.13 New vaccine development requires cutting-edge science and heavy investment but not attractive for the pharma industry as the purchases are for the public sector and vaccines are for one-time use unlike drugs. Developing multiple vaccines that would be effective as a single dose, be heat stable, protect from diseases for which currently no vaccine exists, and be affordable to those most in need of them is yet inadequate. The R&D support is still considered sub-critical.

**Other infectious diseases of the poor**: Diseases like HIV and AIDS, malaria and tuberculosis account for over 90 per cent of the global disease load, while the other more ‘neglected diseases’ like trypanosomiasis, Chagas’ disease, leishmaniasis and dengue also add to the increasing toll of human life.

**Malaria**: Malaria kills an estimated million people each year worldwide – over 80 per cent in Sub-Saharan Africa and mostly children under five years of age.15 Malaria continues to disproportionately affect the poor, who are more exposed to infection with least access to services. Malaria is also holding back economic and social development in poor countries. Annual economic growth between 1965 and 1990 in countries with severe malaria averaged 0.4 per cent of GDP per capita, compared with 2.3 per cent in the rest of the world.16 Most of the drugs for malaria are 40 or more years old and with drug resistant cases being reported and no new drugs, malaria control is seriously hampered. There is not enough R&D for the development of new products that are cheap and simple to use - drugs, a vaccine, diagnostics, long-lasting insecticide treated nets, etc.

**Tuberculosis**: A third of global population is currently infected with the TB bacillus, mostly poor people, who are more vulnerable to infection and suffer more from the consequences. TB infects a new person every second and every 15 seconds someone dies of the disease. Both the diagnosis and treatment of TB still rely on old and imperfect technologies. A new worry has emerged in the recent past - HIV-associated TB and multi-drug resistant TB. Reducing the spread of HIV/AIDS will help reduce TB. Drug- and multi-drug resistant TB is caused by inconsistent or partial treatment (patients discontinue from the 6 month long treatment). Almost nine million people were newly infected with TB in 2004, 741,000 of whom also had HIV17 killing about 1.7 million including 248,000 who were also infected with HIV.17 There is a need to find new technology-based solutions, new drugs that could cut down treatment period, a better vaccine as the current BCG vaccine is of doubtful effectiveness in children and is not cost-effective. However, the search for new drugs and TB vaccines is desultory and under-funded.17

**HIV/AIDS**: Over the last 2 years the number of people living with HIV has increased in every region of the world; 39.5 million people were living with HIV in 2006, two thirds in sub-Saharan Africa. Of the 4.3 million people newly infected, over 2.9 million people have died from AIDS in 2006. Poor countries have the highest patient load: South Africa, 5.5 million; Nigeria, 2.9 million; India, 2.1 million. The number and rates of HIV/AIDS infection are still growing with the number increasing from 36.9 million in 2004 to 39.5 million in 2006. In 2006, there were 4.3 million new infections of which 40 per cent were people aged 15 to 24 yr. Deaths due to AIDS-related causes have also increased to 2.9 million as a huge number still has limited or no access to antiretroviral treatment and improved care. The epidemic remains centred in sub-Saharan Africa which has just over 10 per cent of the global population but home to 63 per cent of HIV-positive people. The most striking increases in HIV prevalence over the past two years have been in East Asia, Central Asia and Eastern Europe. Numbers of people living with HIV in these regions was over one fifth higher in 2006 than in 2004.18

Access to drugs to HIV/AIDS infected continues to be a very serious problem. Some of the toughest legal battles on IPRs have been fought over access to ARTs for the poor with HIV. Providing cheap generics for
first line treatment, finding means of access to the second line treatment, development of new types of ARTs with reduced side-effects, development of AIDS vaccines are some of the critical needs to combat this disease.

Most neglected diseases: There are a few diseases like sleeping sickness, Chagas disease, leishmaniasis and dengue called most neglected as not much attention has been paid to find solutions.

Sleeping sickness: An estimated 50 million people are at risk of contracting sleeping sickness in Africa, with up to 300,000 new cases and 150,000 deaths every year. The production and distribution of the major drug eflornithine was discontinued following market failure. Little or no active research into new drugs for this disease is being currently undertaken by the private sector. For even though the patent has now been assigned to WHO, it has so far been unable to manufacture the drug. Some R&D for new drugs is being undertaken with support from the Gates Foundation and it will take several years before an drug is available. With lack of interest by private companies in drugs for sleeping sickness, it is hardly to be expected that there would be any interest in a search for vaccines for this disease in view of the known market failures of vaccines.

Chagas’ disease: Chagas’ disease occurs in Central and South America, with an estimated incidence of one million cases. The disease causes more than 45,000 deaths per year and there is no effective drug for the treatment. The currently available drugs, Nifurtimox and Benznidazole, have serious side effects and cannot treat the chronic phase. There is a clear need for a safe and effective new drug and none is in the horizon. This has long been recognized but it is not an area where the pharmaceutical companies can expect to make huge profits. So is the wait for a vaccine. More R&D is needed to bring out drugs and vaccine.

Leishmaniasis: The disease occurs in epidemics and is found in one or the other of its forms in Asia, Latin America, Southern Europe and Northern Africa and an estimated 12 million infected and with 350 million at risk. An epidemic in Sudan in 1991-1992 killed between 40,000 and 60,000 people. The first-line drug against the leishmaniasis is pentavalent antimony which is very expensive. However, phase III clinical trials of two drugs miltefosine and paramomycin have just been completed by the ICMR in India and the results have been quite encouraging (Satyanarayana, ., unpublished data). A vaccine development is very essential and desirable for the disease and efforts are on with support from global charities but it will be several years when one becomes available.

Access to medicines

Access to medicines is the most significant tool that society possesses to prevent, alleviate, and cure disease, especially infectious diseases that are either preventable or to some easily treatable with a relatively small number of medicines.

The WHO estimates that nearly a third of the world’s population lacks access to the most basic essential medicines, while in the poorest parts of Africa and Asia this figure climbs to a half. Although access to essential medicines worldwide increased from roughly 2.4 billion to 4.3 billion between 1975 and 1999, the absolute numbers have still remained at about 1.7 billion. The lack of access to essential medicines is especially severe and concentrated in Africa and India (Fig.). In fact, 39 per cent of the people without access

<table>
<thead>
<tr>
<th>Region</th>
<th>2004</th>
<th>2005</th>
<th>Global share of sales 2005(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>249.0</td>
<td>268.8</td>
<td>44.4</td>
</tr>
<tr>
<td>Europe</td>
<td>169.2</td>
<td>180.4</td>
<td>29.8</td>
</tr>
<tr>
<td>Japan</td>
<td>66.1</td>
<td>69.3</td>
<td>11.4</td>
</tr>
<tr>
<td>Oceania</td>
<td>7.1</td>
<td>7.7</td>
<td>1.3</td>
</tr>
<tr>
<td>CIS</td>
<td>4.2</td>
<td>5.0</td>
<td>0.8</td>
</tr>
<tr>
<td>South-east Asia</td>
<td>25.3</td>
<td>28.8</td>
<td>4.6</td>
</tr>
<tr>
<td>Latin America</td>
<td>24.4</td>
<td>26.6</td>
<td>4.4</td>
</tr>
<tr>
<td>Indian sub-continent</td>
<td>6.6</td>
<td>7.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Africa</td>
<td>6.3</td>
<td>6.7</td>
<td>1.1</td>
</tr>
<tr>
<td>Middle-east</td>
<td>4.7</td>
<td>4.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Total world Market</td>
<td>562.9</td>
<td>605.4</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CIPIH (2006)
to essential medicines live in India, and 15 per cent live in Africa. Together, India and Africa account for 53 per cent of the world’s population without access to essential medicines. The likelihood of an individual having access to essential medicines is still greatly affected by income level. Although the disease burden and mortality from preventable or curable illnesses is highest in Africa, pervasive poverty means that the continent’s share of the global pharmaceutical market is only slightly more than 1 per cent. Global spend on drugs shows that most of the drug sale is only in the developed world with the US leading with almost half of the total sales (Table II). The US, Europe and Japan together account for almost 86 per cent. The global share of developing countries, like India and Africa together was just 2.3 per cent. On the other hand, Americans spend almost US$ 200 billion a year on prescription drugs, and this figure is growing almost 12 per cent per year.

Access to treatment for diseases in developing countries has also become problematic either because many existing drugs are become unaffordable, have become ineffective due to resistance, or are not sufficiently adapted to specific local conditions and constraints. Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has virtually ground to a standstill because the pharma industry is not interested in drugs as they simply cannot recoup the cost of R&D for products to treat diseases that abound in developing countries. Of the 1,223 new drugs approved between 1975 and 1997, approximately 1 per cent (13 drugs) specifically treat tropical diseases.

Overarching barriers to access

The UN Millennium Project identifies six most important barriers to health access, four on existing medicines and two relating to the development of affordable new medicines and vaccines.

1. Inadequate national commitment to making healthcare a priority from the national to the local levels remains one of the greatest barriers to increasing access to existing medicines.

2. Inadequate human resources for health, including pharmacists and pharmacy technicians, is a growing problem that, if unaddressed, threatens to undermine all efforts to strengthen health systems and improve healthcare in much of the developing world.

3. The international community has not provided adequate finance nor consistently fulfilled its existing promises to developing countries either the proposed actions have not been carried out at all and at least not carried out effectively.

4. A persistent lack of co-ordination of international aid that has reduced access to medicines either because the donor funding was sub-critical to achieve universal access to essential medicines and the lack of sector-wise approach.

5. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement that may block access to affordable new medicines and vaccines, especially its impact on countries like India, the source of many vital existing medicines for developing countries without productive capabilities, which after January 2005 have become fully TRIPS-complaint may not be able to do so in future.

6. The current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries the so called neglected diseases.

Health care investments by the State

The government share of health expenditures fell by over half between 1980 and 1998, almost trebling the portion paid by families especially in poor countries. Data show that the worldover, private expenditure is higher than government spend (Table III).

Data from India show the same trend. The total expenditure on health as per cent of GDP is steadily decreasing over the years as also the central government spend on health (Table IV). The out-of-pocket

<table>
<thead>
<tr>
<th>Country</th>
<th>HDI rank</th>
<th>Public (% of GDP)</th>
<th>Private (% of GDP)</th>
<th>Per capita (PPP US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>8</td>
<td>6.8</td>
<td>8.4</td>
<td>5,711</td>
</tr>
<tr>
<td>Korea, Rep. of</td>
<td>26</td>
<td>2.8</td>
<td>2.8</td>
<td>1,074</td>
</tr>
<tr>
<td>Brazil</td>
<td>69</td>
<td>3.4</td>
<td>4.2</td>
<td>597</td>
</tr>
<tr>
<td>Thailand</td>
<td>74</td>
<td>2.0</td>
<td>1.3</td>
<td>260</td>
</tr>
<tr>
<td>China</td>
<td>81</td>
<td>2.0</td>
<td>3.6</td>
<td>278</td>
</tr>
<tr>
<td>India</td>
<td>126</td>
<td>1.2</td>
<td>3.6</td>
<td>82</td>
</tr>
</tbody>
</table>

The result was two-fold. There was a surge in the number of people who fell into poverty by exhausting their income and savings to pay for medical treatment. Government expenditure on health care accounted for just 18 per cent of health care spending, with the rest financed by users - making it one of the world’s most privatized health care systems. In fact, private out-of-pocket expenditure on medicines is the largest household expenditure in many countries - as much 50 to 90 per cent of drugs sales. Predictably, the quality of public health services is low and deteriorating: the infant mortality rate for the poorest fifth of the population is 2.5 times higher than the richest fifth, and poorer children are almost four times as likely to die in childhood.

Cost of purchase of medicines accounts of 60-90 per cent of health expenses for poor houses for which borrowing is common. Also, medicines are the second highest factor in health care spend accounting for between 25 to 65 per cent of total public and private spend on health care. Global cost of final price of medicines in developing countries may be 2 to 5 times the producer or importer’s price, that of course includes taxes also. The private out-of-pocket expenditure on health care in India is 99 per cent which is mostly spent by poor people. It is estimated that Americans now spend US$200 billion a year on prescription drugs which is growing 12 per cent every year.

Low- and lower middle-income countries need to spend at least US$30-40 (2002 prices) each year per person if they are to provide their populations with ‘essential’ health care. This sum is about three times the current average spending on health in the least developed countries and more than current spending in other low-income and lower middle-income countries.

### Table IV. Expenditure on health in India (1997-2003)

<table>
<thead>
<tr>
<th>Selected National Health Accounts Indicators</th>
<th>1997</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total expenditure on health as % GDP</td>
<td>5.3</td>
<td>5.0</td>
<td>5.1</td>
<td>5.0</td>
<td>5.0</td>
<td>4.9</td>
<td>4.8</td>
</tr>
<tr>
<td>General Government expenditure on health as % of total expenditure on health</td>
<td>15.7</td>
<td>18.4</td>
<td>24.6</td>
<td>24.6</td>
<td>24.2</td>
<td>23.7</td>
<td>24.8</td>
</tr>
<tr>
<td>Private expenditure on health as % of total expenditure on health</td>
<td>84.3</td>
<td>81.6</td>
<td>75.4</td>
<td>75.4</td>
<td>75.8</td>
<td>76.3</td>
<td>75.2</td>
</tr>
<tr>
<td>General Govt. expenditure on health as % of total government expenditure</td>
<td>3.2</td>
<td>3.5</td>
<td>4.5</td>
<td>4.3</td>
<td>4.2</td>
<td>3.9</td>
<td>3.9</td>
</tr>
<tr>
<td>External resources on health as % of total expenditure on health</td>
<td>2.3</td>
<td>2.4</td>
<td>1.2</td>
<td>2.2</td>
<td>2.0</td>
<td>1.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Social security expenditure on health as % of general government expenditure on health</td>
<td>NA</td>
<td>NA</td>
<td>4.4</td>
<td>4.4</td>
<td>4.4</td>
<td>4.4</td>
<td>4.2</td>
</tr>
<tr>
<td>Out of pocket expenditure as % of private expenditure on health</td>
<td>100.0</td>
<td>100.0</td>
<td>96.6</td>
<td>96.4</td>
<td>96.3</td>
<td>96.2</td>
<td>97.0</td>
</tr>
<tr>
<td>Private prepaid Plans as % of private expenditure on health</td>
<td>NA</td>
<td>NA</td>
<td>0.6</td>
<td>0.7</td>
<td>0.8</td>
<td>0.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Note: NA: Not available

Source: World Health Report (2006)\textsuperscript{26}; National Health Profile (2006)\textsuperscript{27}

### Table V. Trends in health expenditure in India (1950-51 to 2003-04)

<table>
<thead>
<tr>
<th>Year</th>
<th>Health expenditure as % of GDP</th>
<th>Per capita public exp. on health (Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950-51</td>
<td>0.22 NA 0.22</td>
<td>0.61</td>
</tr>
<tr>
<td>1955-56</td>
<td>0.49 NA 0.49</td>
<td>1.36</td>
</tr>
<tr>
<td>1960-61</td>
<td>0.63 NA 0.63</td>
<td>2.48</td>
</tr>
<tr>
<td>1965-66</td>
<td>0.61 NA 0.61</td>
<td>3.47</td>
</tr>
<tr>
<td>1970-71</td>
<td>0.74 NA 0.74</td>
<td>6.22</td>
</tr>
<tr>
<td>1975-76</td>
<td>0.73 0.08 0.81</td>
<td>11.15</td>
</tr>
<tr>
<td>1980-81</td>
<td>0.83 0.09 0.91</td>
<td>19.37</td>
</tr>
<tr>
<td>1985-86</td>
<td>0.96 0.09 1.05</td>
<td>38.63</td>
</tr>
<tr>
<td>1990-91</td>
<td>0.89 0.06 0.96</td>
<td>64.83</td>
</tr>
<tr>
<td>1995-96</td>
<td>0.82 0.06 0.88</td>
<td>112.21</td>
</tr>
<tr>
<td>2000-01</td>
<td>0.86 0.04 0.90</td>
<td>184.56</td>
</tr>
<tr>
<td>2001-02</td>
<td>0.79 0.04 0.83</td>
<td>183.56</td>
</tr>
<tr>
<td>2002-03</td>
<td>0.82 0.04 0.86</td>
<td>202.22</td>
</tr>
<tr>
<td>2003-04</td>
<td>0.86 0.06 0.91</td>
<td>214.62</td>
</tr>
</tbody>
</table>

Source: National Health Profile (2006)\textsuperscript{27}
Annual expenditure on medicines in 2000 varied from US$ 396 per head in high-income countries to only US$ 4 in low-income countries. At the same time, medicines accounted for a higher percentage of total health expenditure in low-income (19%) and middle-income countries (25%) than high-income countries (14%). There is a clear trend of the rise in non-communicable diseases and lifestyle diseases alongside communicable diseases (Table VI). But interestingly, both the R&D spend as also the spend as DALYS is disproportionately large for the lifestyle diseases. For example, against an average DALY spend on diabetes is $102.07 and just $6.2 for malaria. But diseases like dengue seem to be receiving much needed attention. But investing in health care saves lives. The mortality rate in the United States has declined by over 75 per cent over three years through the use of ARV drug cocktails.

**Why poor access: 10/90 gap**

The Commission on Health Research for Development estimated that less than 10 per cent of the US$ 30 billion global health research resources were spent to address the health problems of developing countries, which accounted for over 90 per cent of the world’s health problems. This imbalance subsequently became known as the ‘10/90 gap’. Subsequently, the WHO Ad Hoc Committee on Health Research Relating to Future Intervention Options estimated that although the global health R&D spend in 1992 rose to US$55.8 billion, the ‘10/90 gap’ still persisted. An estimated global R&D expenditure on health in 2001 was US$105.9 billion - 44 per cent by the public sector, 48 per cent by the private for-profit sector and 8 per cent by the private not-for-profit sector. The high income countries together account for over 96 per cent of the total expenditure on R&D with the lower middle income countries accounting for just 4 per cent with public and private sector contributing equally (Table VII).

### Table VI. Disease burden and funding comparison (2001-2002)

| Condition | Global disease burden (million DALYs) | % Total global disease burden | Deaths (million) | % Total global disease deaths | R&D funding (US$ million) | R&D funding per DALY
<table>
<thead>
<tr>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>148.190</td>
<td>9.9</td>
<td>16.733</td>
<td>29.3</td>
<td>9,402</td>
<td>63.45</td>
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<tr>
<td>HIV/AIDS</td>
<td>84.458</td>
<td>5.7</td>
<td>2.777</td>
<td>4.9</td>
<td>2,049</td>
<td>24.26</td>
</tr>
<tr>
<td>Malaria</td>
<td>46.486</td>
<td>3.1</td>
<td>1.272</td>
<td>2.2</td>
<td>288</td>
<td>6.20</td>
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<tr>
<td>Tuberculosis</td>
<td>34.736</td>
<td>2.3</td>
<td>1.566</td>
<td>2.7</td>
<td>378</td>
<td>10.88</td>
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<tr>
<td>Diabetes</td>
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<td>1.1</td>
<td>0.988</td>
<td>1.7</td>
<td>1,653</td>
<td>102.07</td>
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<td>0.0</td>
<td>0.019</td>
<td>0.0</td>
<td>58</td>
<td>94.16</td>
</tr>
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### Table VII. Estimated global health R&D funding, 2001 (in current US$ billion)

<table>
<thead>
<tr>
<th></th>
<th>US$ billion</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>105.9</td>
<td>100</td>
</tr>
<tr>
<td>Total Public Sector</td>
<td>46.6</td>
<td>44</td>
</tr>
<tr>
<td>Total Private Sector</td>
<td>59.3</td>
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<tr>
<td>Total private for-profit</td>
<td>51.2</td>
<td>48</td>
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<tr>
<td>Total private not-for-profit</td>
<td>8.1</td>
<td>8</td>
</tr>
<tr>
<td><strong>High income countries</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public sector</td>
<td>44.1</td>
<td>42</td>
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<tr>
<td>Private for-profit</td>
<td>49.9</td>
<td>47</td>
</tr>
<tr>
<td>Private not-for-profit</td>
<td>7.7</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total high income countries</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public sectors</td>
<td>2.5</td>
<td>2</td>
</tr>
<tr>
<td>Private for-profit sectors</td>
<td>1.8</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total lower middle income countries</strong></td>
<td>4.3</td>
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</tbody>
</table>

The TRIPS which introduced intellectual property law into the international trading system for the first time remains the most comprehensive international agreement on intellectual property to date. The impact of implementation of TRIPS agreement in developing countries, especially in respect of access to medicines in poor countries has been controversial. In fact, ever since the TRIPS Agreement has come into force in 1995, WTO Member States from the developing world as also independent observers foresaw significant gaps in the Agreement in respect of overall trade gains to the rich countries hitting the poor hard through patent protection and limiting access to life-saving medicines, for poor countries especially those with little capability of innovation. Slow progress over the years to address this problem has contributed to the growing frustration among poor countries in finding a meeting ground between the developed and developing countries. In fact, there are no documented studies of positive impact of TRIPS on innovation in the medical field although developing countries also bear the cost of implementation of the Agreement.

Some concerns related to TRIPS and access to medicines to the poor include:

- Increased patent protection leads to higher drug prices. The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices. As a result, the access gap between developed and developing countries will widen.

- Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend.

- It is unlikely that TRIPS will encourage adequate R&D (one of the key arguments put forth at time of TRIPS negotiations) in developing countries for diseases such as malaria and tuberculosis, as there is just not sufficient market for the pharma companies to invest in R&D to bring out medicines for the diseases of the poor.

Some provisions of TRIPS that have a bearing on public health include:

- Transition periods (Articles 65.2, 27 and 33, 65.4, 70.8 and 70.9, 7.8, 66)
- Compulsory licensing (Article 31)
- Public, non-commercial use of patents (Article 31b)
- Parallel Importation (Article 6)
- Exception to patent rights (Article 30)
- Exemptions from patentability (Article 27.1, 27.3)
- Limits on data protection (Article 39.3).

In view of the constraint of space, only most critical issues that impact access to medicines to the poor will be discussed.

While the TRIPS took effect on 1 January 1995, WTO Members considered as developed countries were given one year to comply. Developing countries and transition economies were given until 1 January 2000 although for developing countries required to extend product patent protection to new areas such as pharmaceuticals, a further five years was provided before such protection had to be introduced. Least Developed Countries (LDCs) were expected to become TRIPS-compliant by 2006; the Doha Declaration allowed them a further 10 years in respect of pharmaceutical products.

Compulsory license (CL) or “Other use without authorization of the right holder” is a license to exploit a patented invention granted by the State upon request by a third party. Such licenses are granted through government authorization and remuneration is paid to the patent holder. CL is considered an essential element of health-sensitive legislation especially if such countries that do not have strong anti-trust legislation. CL is also an important and strong public policy tool to promote competition to bring down the prices of drugs. CL also compensates the patent holder for the use of invention. Competition is considered the most powerful instrument for the reduction of price of public goods including drugs after the life of the patent. It has been proved beyond doubt that the average drug prices drop to 60 per cent or less when there are more competitors.

Parallel imports or exhaustion of rights at regional and/or international level involve import and resell in a country without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner. The Parallel imports flexibility of the TRIPS agreement is an important pro-competition tool to promote access to cheap medicines which aims to take advantage of current differential pricing practices used in several countries. It is not considered of violation of TRIPS as the patent holder’s right was already
exhausted in the country where the product was originally commercialized at a lower price\textsuperscript{44}.

Exception to patent rights (Bolar exception or early working exception) allows a company to complete all the procedures and tests necessary to obtain market approval for a generic producer before the original patent expires\textsuperscript{46}.

Exemptions from patentability permit member countries to grant patents only as per the requirements of the TRIPS agreements \textit{i.e.}, grant of patents to products and processes which are new, involve an inventive step and are industrially applicable. The Agreement does not require patents to be granted to new use of known products including drugs, and permits member countries to define novelty, inventive step and industrial applicability, as TRIPS allows countries to define and interpret these terms. It is in the interest of the developing countries to incorporate in their national laws definitions to exclude frivolous inventions, prevent ‘ever greening’ that extend patent life and exclude granting of patents for new uses of a known product and diagnostic, therapeutic and surgical methods from patentability\textsuperscript{37,42}.

\textbf{Data protection}

As a condition for registering pharmaceutical products, countries normally require applicants to submit (disclose) data relating to quality, safety and efficacy (so called “test data”), as well as all other relevant information on the physical, chemical characteristics and composition of the product for marketing approval\textsuperscript{37,47}.

Data protection is not a property right or does it prevent other generic companies to rely on such data for marketing approval of the same drug except when the data are used for unfair commercial purposes. The TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity. So, if the patent period has expired, or there is no patent on the product, this type of data exclusivity may delay the entry of generics into the market as drug regulatory authority cannot use the data in the period of protection to approve a product, even if bioequivalence of the product is proven. The only option for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective\textsuperscript{47}. Countries like India which have a strong generic industry are yet to take a policy stand.

Developing countries where generics form the backbone of their public health system should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or invoke the use of flexibilities built into TRIPS\textsuperscript{37,46,47}. It has been widely recognized that the single most important factor forcing down prices of medicines is generic competition\textsuperscript{45-50}.

In addition, there is also a growing concern\textsuperscript{51} as some developing countries often incorporate some clauses in bilateral or regional trade agreements that limit developing countries’ use of existing flexibilities under TRIPS to protect public health such as restrictive compulsory licensing conditions and parallel importation provisions, extended data protection, and requiring medicines regulatory agencies to take on national patent office oversight duties\textsuperscript{10}. What is more, through bilateral and regional trade agreements, the IP protection systems are being made stringent (TRIPS-plus)\textsuperscript{53}.

\textbf{The Doha Declaration on Public Health}

Since the implementation of the TRIPS agreement in 2005, many developing countries and NGOs grew frustrated waiting for WTO Members to improve the situation of access to medicines as poor countries were fast losing the battle against diseases as tuberculosis, malaria, and HIV/AIDS therefore actively campaigned for both structural and operational changes within the WTO\textsuperscript{39}. While some attempts were made at the Third Ministerial Conference, held in Seattle in 1999, the process of resolving several key health issues did not materialize until the next Ministerial at Doha in 2001. In the interim period, a number of other factors shaped the debate on TRIPS and access to medicines, especially the continued and huge death toll due to HIV/AIDS in sub-Saharan Africa and the unaffordable cost of patented drugs for ART. The others included dispute of South Africa with the research-based pharma over patent protection on HIV/AIDS drugs and the threat of granting a compulsory licensing by the US over the anthrax issue post 9/11\textsuperscript{41}. The Fourth Doha Ministerial Conference (Doha Round) adapted in 2001 the Declaration on TRIPS and Public Health (Doha Declaration)\textsuperscript{52}, restating and affirming that public health overrides the IP rights and that Member States can take all necessary measures to that end.

The Declaration also clarified several ambiguities contained in TRIPS which eventually helped developing countries and LDCs in resolving their public health
crises. Also, it was at the Doha Round that international health and development was discussed at every level of WTO. The Declaration is thus viewed as the first significant victory for developing countries in the short history of TRIPS. It is also for the first time that the highly visible voluntary agencies which have been tirelessly campaigning against poor access to medicines in developing countries tasted success. The Doha Declaration also recognized for the first time that public health issues can take precedence over the rights of private intellectual property holders.

The Declaration also points out for the first time that the provisions of the TRIPS Agreement provide “flexibility” in implementation to enable WTO member countries to exercise their right to protect public health and promote access to medicines for all.

While the Doha Declaration clarified several contentious aspects of TRIPS, it did not completely resolve the debate over patent protection in the developing world. Instead, it left one important and highly contentious issue unresolved: the availability of compulsory licensing exceptions to patent protection for those countries suffering through a public health crisis with insufficient or no manufacturing capabilities. The importance of this issue cannot be understated, as TRIPs Article 31(f) conditions the issuance of compulsory licenses on them being “predominantly for the supply of the domestic market of the Member authorizing such use”; meaning a nation could override valid patent laws only so long as that nation ordered the generic drugs from domestic producers.

Global initiatives to study the impact of IPRs and health in poor countries

In the post-Doha period, in view of the continued global concern on the impact of the TRIPS agreement on the poor people in the areas of health, agriculture and other livelihood issues of the poor at least two major global studies were commissioned (i) the Commission on Intellectual Property Rights (CIPR) was set up by the Department for International Development (DFID), UK with John Barton as chair; and (ii) the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) established by the Director-General, WHO in 2003. These studies bring out very important issues on the impact of global IPR regimes on public health in poor countries.

Commission on Intellectual Property Rights (CIPR):

The CIPR looked at the development objectives that need to be integrated into the making of policy on intellectual property rights, both nationally and internationally with the following specific objectives:

- how national IPR regimes could best be designed to benefit developing countries within the context of international agreements, including TRIPS;
- how the international framework of rules and agreements might be improved and developed – for instance in the area of traditional knowledge – and the relationship between IPR rules and regimes covering access to genetic resources;
- the broader policy framework needed to complement intellectual property regimes including for instance controlling anti-competitive practices through competition policy and law.


The Commission observed that poverty reduction in developing countries will be hindered if intellectual property (IP) rights are expanded without taking into account the individual circumstances of poor nations. The Commission warned that by serving the interests of companies based primarily in the developed world, the IP system increases the cost of access to many products and technologies that developing countries need in areas such as health, agriculture, education and information technologies. The Report also criticised the WTO, WIPO - principal institutions responsible for formulating international IP policy - for failing to fully take into account the complex links between IP protection and development. The Commission recognizing that stringent IPRs are hindering access to medicines for poor countries recommended greater use of compulsory licensing. The Commission suggested that rather than adopt a standard international form of intellectual property protection, developing countries need to shape their IP laws to promote development generally, and keep in mind some of the negative aspects of overly generous IP protection. The Commission urged the developed countries to pay more attention to reconciling their commercial self-interest with the need to reduce poverty in developing countries. For instance, while patenting of technologies generally promotes innovation and incentives for research, it can also inhibit research that is needed to make use of those protected technologies, especially for health products for poor countries that do not have commercial potential.
**Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)**

In response to resolution WHA56.27 in May 2003, the Director-General, WHO established the WHO Commission on Intellectual Property Rights, Innovation and Public Health in February 2004, to “collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries ...” 54. The Commission had 10 members, drawn equally from developing and developed countries, and was chaired by Ms Ruth Dreifuss, former President of Switzerland. A first report of its kind mandated by the WHO, the Commission analyzed the relationships between intellectual property rights, innovation and public health, mobilizing the available evidence and analysis and the perspectives of different stakeholders. The Commission held wide global consultations, and an open forum at WHO in Geneva besides an electronic discussion forum to stimulate constructive debate and dialogue. Besides commissioning 22 studies on existing state of knowledge on the subject and to generate some new evidence, the CIPIH also received nearly 50 submissions from individuals and organizations. The report was submitted to the DG, WHO in April 2006.

The Commission has made several far-reaching recommendations which aim to promote innovation (i.e., new diagnostics, vaccines and medicines) relevant to the needs of sick people in developing countries and how accessibility of health-care products could be improved. The Report exhorts developing countries to ensure that they fully explore their options under international patent agreements to secure access to essential drugs at affordable prices by using their right to compulsory drug licensing. It also urges the WHO to produce a global action plan that will “secure enhanced and sustainable funding” to develop products for neglected diseases, and to make these products affordable to those who need them. The Commission, however, did not recommend any significant changes to the overall international patent system, emphasizing instead the need and potential for action at a country level.

The WHO has since constituted the Inter-Governmental Working Group (IGWG) “…to draw up a global strategy and plan of action in order to provide a medium-term frame-work based on the recommendation of the commission” 55.

**IPRs and Innovation**

As pointed out by the CIPIH 35, the TRIPS by imposing minimum standards of global IP protection, is theoretically one form of incentive for innovation in both developed and developing countries. At the time of GATT negotiations, it was argued that strong global IPR systems stimulate economic growth which, in turn, contributes to poverty reduction in poor countries. Encouraging inventions and new technologies, it was argued, will increase agricultural or industrial production, promote domestic and foreign investment, facilitate technology transfer and improve the availability of medicines necessary to combat diseases in poor countries.

To be sure, the technological disparity between developed and developing countries is huge. Low and middle-income developing countries account for about 21 per cent of world GDP, but for less than 10 per cent of worldwide research and development (R&D) expenditure. Over 60 per cent of the world’s poor live in countries that have some scientific and technological capabilities and the great majority of them live in China and India. China and India, along with a few other smaller developing countries, have higher skills in world class capacity in some scientific and technological areas like space, nuclear energy, computing, biotechnology, pharmaceuticals, software development and aviation. Yet, almost without exception, developing countries are net importers of technology 41. Overall, the innovative capacity of these countries to create new health products is currently extremely limited as countries like India are yet to introduce a new drug molecule. Some countries like India have started supporting innovative R&D in drugs and pharma with Government support 56. Despite the hype, developing countries like India, Brazil or China still have a long way to bring out new drugs into the market. Many developing and virtually all least developed countries do not have the technological capability even to produce generics.

**The Way ahead**

The major causes of concern continue to be the steady rise in the disease burden in poor countries, poor access to the existing medicines to those who need them and the near empty pipeline for new drugs for diseases of the poor. Four inter-related components identified
(for drugs) by the CIPIH\textsuperscript{37} include: (i) available in sufficient quantities; (ii) acceptable both in terms of their usability and their appropriateness, given cultural and other factors; (iii) effective and of good quality; and (iv) the lowest possible cost to facilitate access\textsuperscript{35}. An estimated four million lives could be saved with prompt diagnosis and appropriate treatment\textsuperscript{37}.

In all the above, innovation and IP have a critical role to play. For example, availability envisages existence of a product which could be produced through an innovation. There are no products for most neglected diseases like trypanosomiasis, Chagas or dengue or ineffective drugs for drug resistant TB or malaria, or more suitable drugs that could cut down the impractical six months treatment for TB, just to name a few. New products are required. Acceptability envisages the right kind of products to suit technical and social needs like having interventions that are long acting and easy to use, which can be stored, transported and administered in adverse climatic conditions of poor countries. These products also need high technological skills to develop. Effective and good quality health products can be put into medical practice only through rigorous clinical trials and manufacture all of which require acceptable global quality standards, and funds. Finally, access for products required by poor countries envisages large scale manufacture of the available medicines.

Promoting R&D for diseases of the poor

More R&D spend by countries: In the current system patents do not provide sufficient research incentives where the market for the product is insufficient and therefore there is no R&D by the industry\textsuperscript{36}. This needs to be addressed from several angles. Firstly the innovative R&D on drugs should be strongly encouraged in countries like India, Brazil and South Africa which have the infrastructure, technological capability and pharma industry that could take up the challenge. In fact, India has already initiated several steps in that direction\textsuperscript{36}. The developing countries should also enhance their R&D allocation for diseases of the poor. The CIPIH report\textsuperscript{37} notes that the US National Institutes of Health spends just 4 per cent on diseases that primarily affect developing countries. This major global funding agency with fiscal year 2003 budget of $29.87 billion, invested $2.7 billion in domestic and international HIV/AIDS research, with an estimated spend for ‘global health’ component of $683 million. The total NIH spend on R&D for TB, vector-borne diseases, such as malaria was a mere $122 million\textsuperscript{39}.

It is now well recognized that commercial R&D for essential medicines for diseases for the poor is almost non-existent\textsuperscript{37,38}. To attract private sector R&D on drugs for disease of the poor, both “push” and “pull” mechanisms could be used\textsuperscript{30}. Generally, “Push” mechanisms reduce costs and risks of R&D and can include tax credits, R&D grants, and support for clinical trials, etc. “Pull” measures, on the other hand, help create a market for drugs or increase their profitability. Some examples include, the creation of purchase funds and “patent exchange,” whereby a company would invest in developing a drug for a neglected disease and then, once the drug was approved, would have the right to extend the patent on one of its other, more profitable drugs. Both “push” and “pull” mechanisms are essentially market-based measures that aim to increase the investment return for a drug to a level that will attract private sector investment.

Medical Innovation Prize models: There could be different models for prizes\textsuperscript{60-62} which basically aim to de-couple incentive from the price of product and reward only successful outcomes. The advantages is that the prizes pay only for performance thus ensuring that anyone with a good idea, not just the experts, can take a crack at a tough problem. Prizes could well substitute for IPR, compatible with IPR, or a new system of IPR with IPR voluntary licensed in return for a prize. Prizes could be given without such licenses or countries could decide that prizes would replace exclusive marketing rights. Rewards for priority R&D on types II and III diseases can improve health outcomes with prizes proportional to therapeutic benefit. Prizes would be paid out over 10 years to allow for proven effectiveness among patient populations with the fund is supported by proportionate contributions by all countries. At the point of marketing approval, exclusive rights to product are eliminated, and generic competition is permitted.

Medical Innovation Prize Fund - US Congress: The Medical Innovation Prize Fund Act (H.R. 417)\textsuperscript{63} was introduced by Rep. Sanders in 2005. This bill would separate the market for medical innovation from the market for medicines by creating a fund to reward innovators who develop new pharmaceuticals. Rewards would be paid out over ten years, and the size of the reward payments would be based upon evidence of: (i) the number of patients who benefit from a drug, biological product, or manufacturing process including (in cases of global neglected diseases, global infectious diseases, and other global public health priorities) the
number of non-United States patients; (ii) the incremental therapeutic benefit of a drug, biological product, or manufacturing process, compared to existing drugs, biological products, and manufacturing processes available to treat the same disease or condition; (iii) the degree to which the drug, biological product, or manufacturing process addresses priority health care needs, including neglected diseases that primarily afflict the poor in developing countries; and (iv) improved efficiency of manufacturing processes for drugs or biological processes. Under this bill, once a drug receives FDA marketing approval, generic firms could obtain licenses to produce and sell them. Competition in the market would lower prices.

Industry R&D Facilitation Fund (IRFF): The IRFF has been proposed with a view to easy implementation by public policy-makers. Implementing the IRFF would allow G8 countries to rapidly fulfill their July 2005 pledge of ‘increasing direct investment … through such mechanisms as Public Private Partnerships … to encourage the development of … drugs for AIDS, malaria, tuberculosis and other neglected diseases’.

“The Essential research obligation”: The Drugs for Neglected Disease Working Group has suggested that a new treaty be agreed embodying an “essential research obligation” whereby pharmaceutical companies reinvest a percentage of their sales in R&D for neglected diseases as a global public good.

Patent buy-outs: These are similar to prizes but require considerable information about the value of invention. These could be implemented as voluntary or non-voluntary transactions and have recently proposed for developing country rights to HPV vaccine patents.

The Medical R&D Treaty (MRDT): The Treaty would finance all projects that support Qualified Medical Research & Development (QMRD), including Priority Medical Research and Development (PMRD) selected by Member States through public sector support for QMRD, tax expenditures, investments, philanthropic expenditures on QMRD etc. The MRDT directly addresses the need to ensure adequate and sustainable global investment in medical R&D forcing inappropriate patent and pricing requirements. Encourages funding for neglected diseases other priorities. Enables each country to meet commitments as appropriate domestically. The MRDT has been supported by 162 NGOs, academics, elected officials, parliamentarians, health ministers, etc. SEARO, EMRO Regions and others at the IGWG. In fact, the situation would improve if countries merely fulfill their earlier commitment to providing an amount equal to 0.7 per cent of gross national income (GNI) on official development assistance (ODA).

Advanced Purchasing or Advanced Marketing Commitments: These are largely used for late stage vaccine development, or for vaccine development. These enjoy strong industry and community support as there could be subsidized products and link incentives to delivery systems. But the APC/AMC do not address issues like IPR or pricing issues beyond initial outlays, link price and incentive and also concerns of developing countries of their share.

Political direction and political will: A key factor in the formulation and implementation of national public health policy in the light of the TRIPS Agreement is political direction and political will. An example is the enhancement of biodefense spending by the US due to anthrax scare - the funding to the National Institutes of Health rose from US$ 53 millions (2001) to 1.6 billion
(2004)\textsuperscript{63}. Similar strong policy-driven measures are required to address the issue of access to medicines.

**Global funding mechanisms:** Developed countries do currently contribute to the fight against diseases in a number of ways, including partially financing medical programmes such as the Global Fund to fight AIDS, Tuberculosis and Malaria. Increased levels of properly targeted, long-term aid would go a long way towards alleviating the public health crises\textsuperscript{67}.

**Utilize the capability of developing countries to source cheap drugs:** Enhancing local manufacturing capability of developing countries to manufacture generics of global quality and standard exclusively for other developing countries would increase access to essential medicines\textsuperscript{68}.

**Use TRIPS flexibilities effectively:** All developing countries should use the flexibilities as reiterated in the Doha Declaration effectively. The patent laws should be amended incorporating the most essential TRIPS requirements. They should not hesitate to invoke flexibilities under the TRIPS Agreement like compulsory licensing and parallel imports to ensure affordable medicines to their people.

**Public-Private Partnerships (PPPs):** PPPs provide a viable solution to improving the public health crises without the need to tackle the reform of intellectual property systems. PPPs address both the underlying problems of affordability and development by providing an alternative to dependence on donations from governments and other organisations or access to essential medicines from pharmaceutical companies. Under the PPP model, private companies provide technology as well as development and distribution expertise, while the public sector partners fund development costs and help ensure the medicines reach those who are most in need\textsuperscript{69}. Some major successful PPPs include (i) The Drugs for Neglected Diseases initiative (DNDi); (ii) Institute for One World Health; (iii) International AIDS Vaccine Initiative (IAVI); (iv) Aeras Foundation; (v) Medicines for Malaria Venture (MMV); (vi) International Partnerships for Microbicides; and (vii) Global Alliance for TB Drug Development.

According to Moran\textsuperscript{64}, if neglected disease R&D is to be supported by public funds, then policy-makers should choose the cheapest and most effective approach that is best achieved by combining industry drug development skills with public neglected disease skills through PPPs, including partnerships with interested or potentially interested multinational companies and with small firms who could derive commercial benefit from neglected disease R&D\textsuperscript{64}. Small company market-driven neglected disease activity is recommended to take care of the uncertainties of long term funding commitments and as the commercial scale of these firms is more compatible with neglected disease markets than that of multinational pharmaceutical firms\textsuperscript{64}. Significantly, PPPs provide a solution to tackle the issue of access to medicines without a need to reform the global IPR systems.

**Alternative intellectual property strategies:** In addition, alternative intellectual property strategies, such as placing medical innovations in the public domain, sharing bundles on IPRs, patent pools, patent clearinghouses, public databases and non-rival access to knowledge must be further studied and implemented\textsuperscript{66}. A public sector funded collaborative ‘public goods model’ used for the Human Genome Project is suggested as an option for R&D for emerging infections\textsuperscript{31}. The Millennium Project\textsuperscript{60} also recommends that the WHO in co-ordination with WTO and other trade bodies, should monitor the impact of TRIPS compliance on access to medicines.

**Amend the TRIPS agreement:** There is no consensus that stringent global patent protection through TRIPS is not the cause of worsening the public health crisis in the developing world. There are still gaps in the regulation of IPRs at the global level that need to be addressed\textsuperscript{67}. Steps could be taken to relook at TRIPS agreement\textsuperscript{67} and the discourse should shift from trade to health\textsuperscript{65}. However, it is well known that consensus decision making in the WTO significantly impedes progress or amendments of any kind. For instance, Members negotiated for over two years to reach a consensus to a solution on the Paragraph 6 issue of the Doha Declaration and it seems unlikely that any revision of TRIPS will be any easier\textsuperscript{67}. In addition, poor countries should strengthen expertise to understand international agreements like TRIPS and their impact on access to medicines to especially ensure that regional and bilateral agreements do not compromise their ability to invoke TRIPS flexibilities.

**A final word**

It is still not possible to fully explain why one-third of the world’s poor lack access to essential medicines. Expanding access to essential medicines requires attention through overall integrated health system policies to a diverse set of policy challenges and cannot
be addressed in isolation of the overall health system of a country. In the current globalized world, any public health crisis in any part of the world, developing or developed, any potential solution should also be global with participation by all countries. More importantly, the developed countries should take a lead role not just out of the responsibility towards other human beings but because they have the financial, technical resources needed to address this problem.

Today health for the poor is truly at the top of global health agenda. What is required is a renewed commitment with different inputs and commitments from various participants like the governments and public sector R&D agencies of both the developed and developing countries, pharma industry (especially from developed countries), voluntary agencies and international (UN) agencies like the WHO, WTO, etc. The disease burden is too large, the avoidable deaths and too tragic, the task massive and the responsibility too onerous for any single player to address effectively.

Acknowledgment

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