

## **Panel #1 Global Disease Burden; Access and Research Gap**

The disease burden is very asymmetrically distributed through the world. The life expectancy of people in the developing world is significantly less than in the developed world, mostly due to higher prevalence of certain diseases (including but not limited to HIV/AIDS). The top five diseases that are responsible for the highest number of deaths in low income countries include lower respiratory infections, diarrhoeal diseases, HIV/AIDS, TB, neonatal infections and malaria. However, the majority of these diseases are not even prevalent in high income countries (ex: Tuberculosis, Malaria etc). Why is there such an unequal distribution of the life expectancy and disease burden globally? Although one part of it revolves around reasons such as poverty, lack of infrastructure development and education, a huge issue often not talked about revolves around public health- more specifically, basic medical care and access to essential medicines and research.

### *The Access Gap*

The WHO lists 312 essential medicines as basic health care, to which 33% of the world has no access. So, the Access Gap refers to the systematic inability of people to obtain existing, essential medicines. Why is there an access gap? Prices are basically the biggest barrier to accessing essential medicines. Most low and middle income countries can't afford the market prices of essential drugs. The prices of drugs are this high because of patents. Patents essentially allow the organisation or company that has developed a new drug to set the market price of that drug. Patents also give these companies a monopoly on production. They are a way to reward innovation and encourage further research. Drug development costs a lot of money and patents are the way pharmaceutical choose to recoup their costs, and reward innovation. However, pharmaceutical companies make a huge profit (over 25%), and the prices they set for their drugs are often too high to be affordable in developing countries.

### *Research Gap*

Most pharmaceutical companies are based in the developed world, and have two bottom lines- research and profit. Our market dictates what gets researched. So while tons of funding goes into heart disease and cancer, not much research goes into drugs for which there is no demand because of lack of prevalence in the developed world.

## **Panel #2 Intellectual Property Rights, Patents and CAMR**

This backgrounder describes the fundamentals of intellectual property, which is the set of monopoly rights we give to inventors to give them control over their inventions. The three most commonly discussed kinds of intellectual property are:

- \* Patents, which cover inventions
- \* Copyrights, which cover original works of authorship, like books, movies, and songs
- \* And trademarks, which cover brands and other corporate marks

We focus on **patents**, because they are most important for drugs.

The basic idea underlying patent law is to create financial incentives for invention. If you invest lots of time, money etc into an invention that someone else can just copy (and take your profits), there wouldn't be much incentive for you to pursue it. We give inventors of things that are new, useful, and non-obvious the right to exclude others from making, using, selling, offering to sell, or importing those items. Anyone who wants the new invention must come to the inventor and pay her asking price, even if the asking price is substantially higher than the real manufacturing cost of the invention.

There are two major problems with this approach. The first arises because only people with sufficient money to pay the asking price can access the invention. Those individuals without money are denied access. When the invention is a drug, this can mean that many people die unnecessarily. This is called the static inefficiency of IP. The second major problem with the current IP approach is that patents on an existing invention can block future innovations through preventing use of the invention in future research or product development. This is called the dynamic inefficiency of IP. The goal, and challenge, of IP law should be to balance the incentive effects of IP with the inefficiencies it creates.

Recognizing this problem, the member countries of the WTO agreed to the Doha Declaration in 2001, committing themselves to find a solution. In 2003, they agreed to the August 30th Decision. In principle, this allowed countries like Canada to grant licenses to domestic pharmaceutical producers solely for the purpose of exporting needed drugs to countries like Botswana. Some countries (not including the US) have implemented legislation to take advantage of this flexibility.

However, the US government, backed by its extensive pharmaceutical lobby does not have positive reactions towards countries that issue and take advantage of compulsory licenses, and this is often a disincentive to various countries.

Canada has incorporated compulsory licensing into a law called the Canadian Access to Medicines Regime. As of last year, the first shipment of drugs exported under this legislation is en route to Rwanda. However, over 4 years has elapsed

from the creation of the Canadian Access to Medicines Regime to the first shipment of drugs. Furthermore, many pharmaceutical companies have said that they will not follow suit because the bureaucratic red tape involved is too daunting. Currently, many Canadian NGOs are working together to change CAMR policy. The amendments have been made and the bill was introduced in parliament. It is at its second reading. There is lots of support for it from the NDP, Bloc Quebecois and some Liberals but most Conservatives are siding with the pharmaceutical companies.

While the August 30th Decision reached under the Doha Declaration is a theoretical solution to the access problem, it has not so far proved a practical one. The current situation as it now stands is that many, many people in developing countries lack affordable access to essential existing medical treatments. This is in large part due to regulatory control of intellectual property.

### **Panel #3- Possible and Innovative Solutions**

#### **Role of universities**

Many commercial drugs to day have been discovered in universities. Universities have increased the number of patents significantly, increasing the public profile and it's profits. However, the first role of universities is to serve the public interest with innovations. Thus inventions should get used for public good and get distributed equally.

What's the process of discovery to product? Universities invent and licence to someone that can produce it (commonly a pharmaceutical company). They pay royalties to the university. Is it possible to include global access provisions, so that drugs are sold at a subsidised price to Developing Countries? We can through Global Access Licensing

What does Global Access Licensing mean?

- i) Sell the high-income country (HIC) rights on an exclusive basis (to drive development of the technology)
- ii). Reserve the low-middle income country (LMIC) rights for later non-exclusive licensing to generic companies, who will compete on price and therefore sell the drugs at cost.

#### **Public Private Partnerships (PPPs)**

Despite major advances in drug development in recent decades, essential medicines to treat many diseases that affect the world's poor are either too expensive, no longer produced, highly toxic, or ineffective. Recognising these issues from its field experience, Médecins Sans Frontières committed its 1999 Nobel Peace Prize funds to develop an alternative model for the research and development (R&D) of new drugs for neglected diseases.

As a result, in 2003, seven organisations from around the world joined forces to establish DNDi: five public sector institutions – the Oswaldo Cruz Foundation from Brazil, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Ministry of Health of Malaysia and France's Pasteur Institute; one humanitarian organisation, Médecins sans Frontières (MSF); and one international research organisation, the UNDP/World Bank/WHO's Special Programme for Research and Training in Tropical Diseases (TDR), which acts as a permanent observer to the initiative.

Drugs for Neglected Diseases initiative (DNDi) is a collaborative, patients' needs-driven, non-profit drug research and development (R&D) organization that is developing new treatments for malaria, visceral leishmaniasis (VL), sleeping sickness (human African trypanosomiasis, HAT), and Chagas disease.

Working in partnership with industry, academia and NGOs, DNDi has built the largest ever R&D portfolio for the kinetoplastid diseases and currently has seven clinical/post-registration and four preclinical projects underway. DNDi successfully delivered two antimalarial products in 2007 and 2008 respectively. Acting in the public interest, DNDi bridges the existing R&D gaps in essential drugs for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners

#### *Altruistic Research Funding*

The Bill and Melinda Gates Foundation has contributed millions to fund research in neglected diseases, thus trying to solve the problem of lack of market interest in neglected diseases.

We will also discuss the role of NGOs and the new and innovative solutions developed by them (with a focus on the Patent Pool campaign by MSF)

#### **Panel #4 Global Governance, Human Security and Contextualisation**

In this panel we hope to contextualise the issue of Access to Essential Medicines in the broader context of human security. We will talk about why public health is a human security issue, and how it lies outside the realm of traditional security studies and why it still fits into the framework for International Relations.

The World Health Organization (WHO) recently estimated that more than 40% of the world's deaths each year are avoidable, given existing global knowledge, technologies and resources. Although some of these deaths are due to infectious diseases and access to medicines, they are also complemented by other underlying factors, such as- nutritional deprivation, maternity-related risks of unsafe childbearing and violence—can be prevented only by reaching people trapped in poverty or conflict.

Hence, although dealing with the issue of access to essential medicines is an important step in the right direction, it cannot be a solution by itself, unless it is compounded by other broader measures to deal with the underlying issues of diseases.

In this panel, we will talk about other measures that need to be addressed once a solution is found to the problem of affordable essential medicines. Issues such as neglected approaches for neglected diseases, scaling up of health interventions and global governance problems will be discussed.