Editorial

The Medical Student International (MSI) has now grown to be the voice of medical students worldwide. Through the global network of medical students represented by the IFMSA, it has become a means through which medical students demonstrate diverse visions on various global health issues. MSI online and in print, addresses global health issues from fresh perspectives. It highlights intriguing subjects that draw the reader’s attention to global health inequalities, that we, as future physicians, must take an active interest in. MSI will remain a unique resource for medical students.

Get published in MSI and let the world read your thoughts – the IFMSA alone, has an estimated 1 million members in more than 90 countries. And for now, I’d leave you to discover the barriers of “Access to Essential Medicines”.

Ahmed Magdy
Director, Publications Support Division

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The articles featured in this edition of MSI were all written by medical students, young doctors and other health professionals. If you're interested in writing for the upcoming MSI 17 or if you know any other people who would be interested in writing for MSI please contact us at [msi@ifmsa.org](mailto:msi@ifmsa.org).
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“A small step for man, but a big step for mankind”

How Brazil breaks drug patent

“Graca de deus” Thank God - Senora Carolina is not too familiar with common politics but the news of Brazil breaking the patent of the AIDS drug brings a smile to the old lady’s face. Senora Carolina is a resident of one of the poor outskirts of Sao Paolo. She has worked all her life and raised six children. Two of them carry the fatal Human Immunodeficiency Virus, not an uncommon disease considering the UNICEF statistic of 2005 estimates a HIV rate of 0,5% with corresponding numbers of 620,000 infected throughout Brazil. Approximately one third of all HIV infected Latin Americans live in Brazil.

The Brazilian fight against HIV is cited as a model for other developing countries. With an outstanding effort, Brazil lanced their unique programme to battle the incurable disease. This development roots back to the year 1986 when the Brazilian Ministry of Health introduced their national STD/AIDS programme; setting emphasis on prevention and information. The use of condoms is, despite the domination of the Catholic Church, in comparison to many African countries, widely accepted. However, the main target of the government was to provide a 100% free of charge treatment and medication for all Brazilian HIV/AIDS victims. In the year 1997 Brazil achieved the unexpected and granted throughout the population access to the expensive treatment. Today counting on figures of the National STD/AIDS programme there are currently more than 180,000 Brazilians with free access to retroviral medication.

It seems like David versus Goliath. The original imported drug medication produced by big American and European companies like Abbot, Merck and Pfizer is sold to prices which are unaffordable especially to developing countries and countries on the verge of industrialization. Brazil knew that the battle against AIDS could not be won with the help of the pharmaceutical industries.

In the year 1997, in accordance with the WHO, a law was released requiring that foreign products are manufactured within Brazil within three years after receiving a patent. In case that a foreign company does not comply, Brazil can authorize a local company to produce the drug without the consent of the patent owner. This law became known under the term of compulsory licensing. In addition, another law authorizes the import of the lowest priced international generic drug in case of special circumstances. To prevent abuse of these laws they can only be used in the situation of a health emergency or if the pharmaceutical industry abuses pricing. These measures had to be taken to be able to continue with the STD/AIDS programme.

For the pharmaceutical industries these laws are the greatest possible threat as the closure of these markets is the equivalent with the loss of a shear uncountable sum of money. The companies claim that these laws disrespect the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

But can human lives be measured by money or intellectual property?

Under the huge pressure of the pharmaceutical lobby, the US filed a claim against Brazil that it was taking economical advantage of the situation by producing their own Anti Retroviral Drugs. In addition Brazil was set on the “watchlist 301” which involves unilateral economical sanctions.

Brazil should not to be underestimated. Their rising economical power and the growing importance of their market especially to the US, gave the country the possibility to withhold the threats. Additionally, support from many international organisations also helped Brazil to maintain its objectives.

In 2001, the WTO’s 4th Ministerial Conference in Qatar, affirmed in the Doha Declaration the possibility for TRIPS members to provide general access to necessary drugs, “The TRIPS Agreement does not and should not prevent WTO members’ governments from taking measures to protect public health.” The same year the access to AIDS drugs was declared as a human right by the United Nations Commission on Human Rights. Numerous talks with the pharmaceutical industry since then could not lead a way to a general consent.

In the beginning of May 2007, talks with the pharmaceutical giant Merck didn’t convince the company...
to provide Brazil with drugs with the same discount that was granted to Thailand. Therefore the Brazilian government authorised bypassing the patent on the non-nucleoside reverse transcriptase inhibitor (NNRTI) produced by Merck. Brazil saw no other possibility but to import a cheaper, generic Indian-made version of the patented drug. Although the company now claims that Brazil’s decision could discourage pharmaceutical firms from investing in treatments for illnesses prevalent in the developing world, it shows that a free access to drugs can be possible even for countries having less financial power.

The action taken by Brazil was seen as a milestone in the fight against the disease and greatly approved by many HIV/AIDS Organisations.

And of course Senora Carolina is happy that the Brazilian government maintains the free access and gives her children the chance to live their lives.

By:
Melanie Schuster

To Triage or Not to Triage: Knowing Our Limits as Health Care Providers Overseas

While working in the developing world, I found myself in many situations where I either witnessed or fell victim to trauma where proper healthcare was unavailable. I interpreted the overwhelming sense of responsibility I felt, as my calling to medicine. I am now back home in Canada, one year from receiving my Doctor in Medicine. As I learn new skills, I often reflect on the cases I witnessed in the developing world and it is a fulfilling method of study. There is one situation however that I replay over and over, and still cannot decide on how to best respond.

There was an overcrowded bus speeding on a main road, which lost control and flipped over multiple times before landing 500 meters off road. Seatbelts in this country were a luxury so one could imagine the injuries sustained. When my friend and I approached in the taxi, there were over 50 people, many of them covered in blood, lying on the side of the road. Others were running around flagging down cars, as the closest doctor was two hours away and there was no ambulance. We were approached by a very authoritative man who told us about two muzungus (white people) who needed our help. During his instructions, we spotted two topless coloured men piled in the car, holding their blood drenched shirts over the multiple lacerations on their head and neck. Their eyes were scared yet thankful. The man in charge began yelling at our new passengers in an unknown dialect and pulled another couple towards us. Then we spotted one very anxious white woman who had sustained no visible injuries and her husband, whose race was indistinguishable due to a layer of blood which was pouring from his head. The look on the coloured men’s faces as they were told to leave the taxi was a heartbreaking mixture of fear, confusion, defeat and humiliation. Next thing I knew we were driving away from the accident with the “muzungu” couple.

Thinking about that moment and the look in the eyes of those left behind, will haunt me forever. Did I condone a purely race based decision? Or was the triage appropriate? I have spent a lot of time justifying the decision. The couple we took were the only foreigners on the bus and were unable to communicate with the others on the scene; the man was quite sick and the woman was being emotionally disruptive. I often wonder what a good physician would have done in my shoes. Would he or she have obeyed the person in charge? Or taken the reins and done their own triage? The answer must be something in between but it raises an interesting point. No matter how skilled a physician is, it is a challenging history when you don’t speak the language and it is difficult to triage when you are unfamiliar with the region. Moreover passerby physicians without gloves, masks, and other medical equipment are much less helpful, not to mention the risks of liability, licensing, and insurance issues in a foreign country. Medical students and doctors interested in international travel and work should be educated on these issues so they are more prepared if and when problems arise.

By:
Erin Mullan
Access to Essential Medicines

I am tired of not being able to treat patients because the medicines are too expensive. Africans should not be dying because of inability to pay when effective medicines can be available at affordable prices. These medicines are already available in countries such as Thailand, India, and Brazil.

There are more than 1.7 billion people worldwide, most of whom are living in developing states, which lack regular access to essential medicines. This dearth of basic medicines contributes greatly to the unnecessary death of millions of children and adults each year, from a short list of preventable diseases. Underlying the specific constraints to access to medicines and health care are the social and cultural conventions that can disproportionately prevent women, children, ethnic minorities, and other marginalized populations from gaining access to the larger health system.

According to the World Health Organisation (WHO), essential medicines “are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford.” These essential medicines are used against diseases and infections that are outlined by the WHO, and examples include: cardiovascular disease, gastrointestinal disorders, HIV/AIDS, preventable diseases, reproductive health, and vitamin deficiencies to name a few. Also, the Working Group on Access to Essential Medicines of the Task Force on AIDS, Malaria, TB, and Access to Essential Medicines, under the aegis of the UN Millennium Project, has defined ‘access to essential medicines’ as “the proportion of population with access to affordable, essential drugs on a sustainable basis is the percentage of the population that access to a minimum of 20 of the most essential drugs…and having drugs continuously available and affordable at public or private health facilities or drug outlets that are within one hour’s walk of the population.”

In terms of geographic and demographic distribution, together, the people of India and the African continent account for 53% of the world’s population without access to essential medicines. Of that, 38% of those without access to essential medicines live in India. In Latin America, many States offer universal coverage for antiretroviral treatment, however, Brazil remains the only State with a large population to have achieved universal access to AIDS treatment. In Brazil, the most populous State in the region, the national prevalence level is below 1% but it is home to more than 1 in 4 of all those living with HIV. In other areas of the world, Botswana remains the only State in Africa to adopt a policy of making antiretroviral therapies available to all who need them. A handful of companies in southern Africa have announced schemes to provide antiretroviral therapies to workers and some family members. That being said, only a fraction of the millions of Africans in need of antiretroviral treatment are receiving it.

The issues surrounding the lack of essential medicines, as outlined by the UN Millennium Project, are common to many States. The first issue, which is delineated into four sections, is barriers to existing medicines. The first section of that is the inadequacy of States to make commitments in making healthcare a priority from “national to the local levels.” Donor programs can often skew or limit national governments’ abilities to set health policy and debt servicing and loan conditionality from international financial institutions can further limit government responsiveness to basic social service needs of their respective citizens. The second section highlights the inadequacy of human resources. Inadequate pool of allied health professionals and medical professionals threaten to undermine efforts in strengthening health systems and improve the deliverance of health care. The Project also highlights retention plans and compensation schemes for States losing health care workers to satiate health needs from developed States. The third section examines the role of the international community and its role regarding development. The last section that makes up barriers to existing medicines is the lack of coordination of international aid.

The other major barrier is barriers to development of affordable new medicines, which examines the role of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the lack of incentives to promote research and development of medicines and vaccines to address health concerns of developing States. Following the full implementation, as of January 1, 2005, of the World Trade Organisation’s (WTO) TRIPS agreement in India and other developing States not yet granting pharmaceutical patents, access to affordable new drugs is expected to become more difficult. From 2005 onwards, all new drugs are subject to at least 20 years of patent protection practically everywhere except in least developed States. Patent rules may also hamper the development of fixed-dose combinations – the three-in-one pills that have helped simplify patients’ lives – when patents on the different compounds are held by different companies. Although these pills are currently what approximately 70% of all HIV/AIDS patients take as first-line treatment, patent rules in India will make such combinations difficult, if not impossible, to produce in the future. The source of many vital existing medicines for developing States without productive capabilities will be fully subject to TRIPS provisions. Also, there are con-
cerns about the WTO’s decision regarding a waiver for TRIPS Article 31(f), which would allow a compulsory license to be issued by the State in need and by the State that can produce the medicine for export, would be too much of a burden for developing States to exploit. Furthermore, the growing number of bilateral and regional trade agreements with major trading partners, such as the United States of America and the European Union, may often contain provisions that limit developing States’ use of existing flexibilities under TRIPS to protect public health. More recently in July 2005, the Group of Eight committed to universal access to treatment for AIDS by 2010.

Since the issues surrounding barriers to access of essential medicines and health care have many aetiologies, a single solution to improve the current situation is improbable as it needs to be complemented by others. The UN Millennium Project highlights the need for States to examine their national medicines policy and strategies founded on the essential medicines concept, which is outlined by the WHO.

Access to medicines has always been an important concern in health development, policymaking and programming. However, to date, the world remains a long way from attaining equitable access within developing States, let alone across regions. Thirty years ago, medicines policy was a technical discourse mainly among UN agencies, ministries of health and international experts. However, the growing AIDS pandemic has galvanized discussions about access to treatment. The UN, donors, recipient governments, and suppliers are being pressured by a growing global network of public interest non-governmental organisations and civil society groups that need medicines and access to health care but are unable to get them.

Médecins Sans Frontières (MSF) has been campaigning since 1999 to find solutions towards lowering the prices of existing medicines, to bring abandoned drugs back into production, to stimulate research and development for diseases that primarily affect the poor, and to overcome other barriers to access. MSF has been analyzing the drug markets for quite some time and at the most recent 3rd International AIDS Society conference in Rio de Janeiro, Brazil, in July of 2005, and it was a common theme that action was needed to tackle the resurgence of AIDS drug pricing crisis. First, medicines only available from one single producer are still very expensive. For example, the differential price accorded by GlaxoSmithKline for abacavir is over US $800 per patient per year. Second, prices announced by pharmaceutical companies are often not available in reality, because companies have not registered or marketed the drugs in States eligible for differential pricing. Third, some companies do not offer discounts to middle-income States, as this is the case of lopinavir/ritonavir in Thailand and Ukraine, where MSF programs pay US $4,000 to 6,000 per patient per year for this one drug alone. To put these prices in perspective, MSF currently pays less than US $250 per patient per year for WHO-prequalified first-line triple combinations sourced from Indian generic producers.

In 2000, OXFAM also launched a major access to medicines campaign and Third World Network played a key role in developing technical assistance to developing States on how to formulate pro-public health intellectual property legislation as they become TRIPS compliant. It is quite apparent that the emergence of a strong and ongoing global advocacy NGO network on access to essential medicines and health care has been a crucial boost to increase access in developing States. The impact of the network has been felt especially at the international policy levels in new ways. At the State level, NGOs have catalysed and empowered citizens to engage in the political and policy process in new and important ways within the health sector. Furthermore, many well-established NGOs, such as the International Federation of Red Cross and Red Crescent Societies, are involved in advocacy on health and medicine issues and in providing health care in developing States.

The largest health-related public-private partnership is the Global Fund to Fight AIDS, Tuberculosis, and Malaria. It was created as a financing mechanism for State-level efforts to combat AIDS, tuberculosis, and malaria. It is an independent entity, governed by a board of directors that include representatives from donor States, the UN, civil society and NGOs, and the private sector. This Fund provides needed financing for medicines purchases that States otherwise could not afford. Secondly, it has outlined very specific criteria for States to meet concerning procurement, supply and distribution of medicines to help ensure that quality medicines are being bought and that those medicines get to the people who need them. In turn, these requirements are hoped to be prerequisites for governments to improve their current regulatory, procurement, supply and distribution systems, all of which are key to improving access to essential medicines and health care for their respective populations.

Indeed, the need for access for essential medicines and health care is an important one. Access to supplies of medicine and health care for all, especially for those people who have been traditionally marginalized, is indicative of a much more profound, positive, and socially transformative process. No single institution, organisation, industry, or level of government can make this happen alone. Even though the complexities and intricacies are almost overwhelming, the international medical community must be able to deal with this burgeoning issue.

By: Vceek Thankey
Equitable Access to Essential Medicines: 

a Framework for Collective Action

Introduction

Essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used. Still, lack of access to essential medicines remains one of the most serious global public health problems. Although considerable progress in terms of access to essential medicines has been made in the last 30 years since the introduction of the essential medicines concept (Figure 1) not all people have benefited equally from improvements in the provision of health care services, nor from low cost, effective treatments with essential medicines.

Figure 1: The total number of people with access to essential medicines increased from around 2.1 billion in 1977 to an estimated 3.8 billion in 1997

Essential medicines are only one element in the continuum of health care provision but they are a vital element. The major access challenges which can be obstacles for health improvement are:

• **Inequitable access** - about 30% of the world’s population lacks regular access to essential medicines; in the poorest parts of Africa and Asia this figure rises to over 50%.

• **Health reforms** - in many low- and middle-income countries, health sector reforms have led to insufficient public funding for health.

• **Medicine financing** - in many high income countries, over 70% of pharmaceuticals are publicly funded through national health insurance schemes whereas in low- and middle income countries 50% to 90% of medicines are paid for by patients themselves.

• **Treatment costs** - high costs of treatments with new essential medicines for tuberculosis, HIV and AIDS, bacterial infections and malaria will be unaffordable for many low- and middle-income countries.

• **Globalization** - global trade agreements can threaten access to newer essential medicines in low- and middle-income countries.

Access to health care and therefore to essential medicines is part of the fulfillment of the fundamental right to health. All countries have to work towards the fulfillment of equitable access to health services and commodities, including essential medicines necessary for the prevention and treatment of prevalent diseases.

WHO Access Framework

Improving access to essential medicines is perhaps the most complex challenge for all actors in the public, private and NGO sectors involved in the field of medicines supply. They must all combine their efforts and expertise, and work jointly towards solutions. Many factors define the level of access, such as financing, prices, distribution systems, appropriate dispensing and use of essential medicines. WHO has formulated a four-part framework to guide and coordinate collective action on access to essential medicines (Figure 2). This framework has also been adopted by WHO’s key partners. The first two components are discussed in more detail below.

Figure 2: Improving access to essential medicines - a framework for collective action

1. Rational selection and use of essential medicines

There are global concepts which can be applied in any country, in both public and private sectors and at different levels of the health care system. Careful selection of essential medicines is the first step in ensuring access. Rational selection and use
can be pursued through various tools, including:

- **National treatment guidelines** are defined by WHO as systematically developed evidence-based statements which assist practitioners and patients to make informed decisions about appropriate health interventions.

- **National lists of essential medicines** should be developed for different levels of care and on the basis of standard treatment guidelines for common diseases and conditions that should be treated at each level.

Rational use of essential medicines requires trained and motivated health staff, and the necessary diagnostic equipment, to ensure safe and effective treatments, minimizing the risks and waste linked to irrational prescribing and use of medicines.

### 2. Affordable prices

With the potential cost of providing a full range of treatments for prevailing common diseases, medicine prices and financing are fundamental factors in access to essential medicines. Affordable prices can be pursued through the following mechanisms:

- **Price information** is essential to obtain the best price.

- **Price competition** through tendering of generic products and therapeutic competition are powerful price-reduction tools, as evidenced by experiences from large producing countries such as Brazil and India. Through generic competition, price reductions of over 75% were achieved over the initial brand prices.

- **Bulk procurement** encompasses that medicine orders are pooled together in order to increase purchasing power. Bulk procurement can be through cooperation of facilities in a country, but positive experience has also been reported from arrangements between countries.

- **Generics policies** are effective instruments when a patent expires. In the United States of America the average wholesale price falls to 60% of the price of the branded medicine when one generic competitor enters the market, and to 29% with 10 competitors.

- **Equitable pricing** is especially important for newer essential medicines that are still protected by patents or other instruments that provide market exclusivity. Equitable pricing is explained as the adaptation of prices which are charged by the manufacturer or seller to countries with different purchasing power.

- **Reduction or elimination of duties and taxes** for both generic and patented essential medicines contribute to price reduction. In developing countries, the final price of a medicine may be two to five times the producer or importer price. This reflects the effects pharmaceutical import taxes and duties, high distribution costs, and dispensing fees.

- **Local production of assured quality** when economically feasible and where it follows good manufacturing practices (GMP) can result in lower medicine prices. Generic companies in Brazil, India and Thailand have offered their help to low- and middle-income countries to produce antiretrovirals locally through technology transfer.

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Please visit the WHO medicines web site: [http://www.who.int/medicines/](http://www.who.int/medicines/)"
The right to health in Ecuador: a lost case?

Even though the World Health Organisation affirms that “essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used”, they also acknowledge that about one-third of the world’s population (the poorest third, of course) are without the access to medicines they need. Unsurprisingly but sadly, the situation in Ecuador does not differ much from that of other developing countries. Ecuador is worldwide-known for its biodiversity and for being one of the most picturesque countries on the face of Earth. However, few are aware of the social inequity in a nation where the top 20% of the population own 64% of the wealth, whereas the poorest 20% own just 2%; where 1.3% of the GDP is used in health issues, as compared to 9% in debt service; where up to 75% of the population do not have health insurance or proper access to health services; and where the monthly expenses for a family of four are estimated to be 455 US Dollars, but the cost of antiretroviral therapy for the same period can be thrice as much. By looking at this information, it would be logical to ask: “Why are Ecuadorians unable to accomplish such an important human right, and provide their people with a proper healthcare system?”

The Political Constitution of the Republic recognizes the role of the State in guaranteeing all the basic rights of its people, and our governments have ratified several treaties that enforce them, so the reason does not lie on legal aspects. Since the war in Iraq began, we face a relative abundance due to the high revenues from our oil exports, so the rationale is not entirely economic either. The analysis is complex but, in my opinion, it can be best explained by the lack of common sense and solidarity which characterize our people.

Having had 11 presidents since 1997 -and up to 6 health ministers per president-, some of the responsibility definitely lies on the common citizen, who has no criterion for electing his/her leaders properly and keeps voting for the same parties who have been looting the country for the past two decades; the common citizen who ignores the responsibilities of his government towards the people, and thinks of healthcare as charity instead of as a right; the common citizen who remains quiet and apathetic about the social crisis that surrounds him as long as the soccer national team qualify to the World Cup. If the inhabitants of a nation show no interest in making their rights prevail, who will enforce them?

Politicians are probably the ones to blame for the inefficiency of our health system. Numerous illogical and unconsiderate decisions on hospital building, equipment purchases, consulting and licitation plans and vaccination campaigns fall inevitably into what is presented as “the right to health” during election times; as a consequence, hospitals are built right across the street from each other, but neither of them has enough equipment nor personnel. Every once in a while, we hear of corruption scandals where tons of non-essential drugs are purchased by hospitals –or even the Ministry of Health-, just to be stored in a basement until they expire. Isn’t this a violation of our human rights?

In the same way, economic interests prevent the State from establishing a more rigorous control on the production, distribution, advertising and commercialization of medicines in the country, and unscrupulous pharmacists are allowed to profit at the expense of people’s health. In Ecuador, if the production or the importation of a certain drug costs $1, it will be sold to the final consumer for $4.50, after adding up the profit margin of the pharmacists, the distributor and the drugstores. Wouldn’t it be logical to lower the cost of medicines and make them more accessible, instead of using those earnings in bribing physicians to make sure they prescribe your product?

Ecuador does not have a national pharmacovigilance system to verify the security and effectiveness of drugs, and despite the fact that a National Table of Essential Medicines was designed in 2000, neither public nor private hospitals purchase their drugs according to it. Little effort has been made by the Ministry of Health in order to solve both of these national priorities. How can such a State guarantee, defend and promote the rights of its people? If democracy is based upon the citizens’ well-being, how can the government secure it, if due to incorrect political management, becomes directly responsible of the inefficiency of those institutions intended to provide people with welfare?

But what can be done to face crisis of the Ecuadorian healthcare system? The answer is quite obvious but extremely hard to perform: by acting with common sense. Now that we are aware of some of our major problems, it becomes imperative to have the citizens actively participate in the country’s decision-making process and supervise the public expenditures; to increase public funding for health and medicines; to enforce the observance of the National Table of Essential Medicines; to allow price competition through tendering of generic products; to introduce and expand the use of generic drugs and reduce their taxes; to control the profit margin on essential medicines; to promote equitable pricing for newer essential medicines that are still protected by patents; and to promote the creation of a national pharmacovigilance system. However, none of these goals will ever be achieved if we do not act honestly and responsibly, understanding our role as active members in our society.

According to Nelson Mandela, “massive poverty and obscene inequality are such terrible scourges of our times -times in which the world boasts breathtaking advances in science, technology, industry and
Access to Essential Drugs in Africa

"Treatment is technically feasible in every part of the world. Even the lack of infrastructure is not an excuse—I don’t know a single place in the world where the real reason AIDS treatment is unavailable is that the health infrastructure has exhausted its capacity to deliver it. It’s not knowledge that’s the barrier. It’s political will.” Peter Piot, Executive Director of UNAIDS

Many countries in Africa barely produce enough food locally to feed their citizenry. Many lack capacity to protect their nationals from the ravages of basic preventable communicable diseases like malaria, tuberculosis, cholera and other childhood infectious diseases. Yet, almost all African countries are being 'induced' to implement vertical programmes like the World Health Organisation’s 3 by 5 Initiative among many others. The goal of the initiative is "universal access to antiretroviral therapy for all living with HIV/AIDS". The target of the initiative is "to have 3 million people living with HIV/AIDS (PLWA) on anti-retroviral treatment by 2005". Over 70% of the world’s population of PLWA is reportedly in Africa (UNAIDS). Access to drugs is increasingly recognised as a key component to comprehensive AIDS strategies. ARVs play a central role in prevention as well as treatment. People are more likely to come forward for testing if there is some hope of receiving treatment and are more likely to adopt lower risk behaviours to avoid infecting others. ARVs also reduce the amount of HIV in the blood, thus reducing the risk of further transmission. Slowing the onset of AIDS allows people to continue leading a relatively normal life, fully contributing to the social and economic life of their country.

Nigeria for example, with an estimated population of 130 million people initiated sometime late in 2001 into early 2002, what was touted in international circles as Africa’s most ambitious ARV treatment plan. The plan targeted placing 10,000 adults and eventually 5,000 children on ARV drugs within the year at fifteen or so designated treatment centres. According to reports, an initial US $3.5 million worth of ARV drugs were imported from India at a cost of US $320 for a full year course per person. The drugs were delivered at a subsidized monthly cost of US $7.0 per person in the targeted population of people living with HIV/AIDS (PLWA). UNAIDS and Nigeria’s Health Ministry figures indicate that around 3.5 million of Nigeria’s 130 million people have the HIV virus as of the end of 2003. With this in mind, it is clear that the near 14,000 people actually enrolled in Nigeria’s pilot ARV programme are just a little drop in the ocean of its PLWA. Notwithstanding, the pilot programme was bedeviled by many logistic problems, including supply chain snafus, lack of awareness by beneficiaries of programme, inadequate provider capacity, inability of beneficiaries to bear the cost of ancillary diagnostic and laboratory services and drug expiration among others. Many beneficiaries had no continuous supply of ARV drugs and consequently suffered treatment stoppages that lasted for over three months in some cases with attendant risks of drug resistance. With new clamour by local activists, another US $3.8 million worth of ARV drugs has recently been ordered and received by the Federal Ministry of Health. In spite of this new order, the jury currently out there, is that Nigeria’s ARV treatment initiative has so far not achieved any desirable public health goal against the background of the estimated people in need and in the context of other competing public health needs. For example, many Nigerian communities still lack access to clean water and basic sanitation. Malaria, cholera and cerebro-spinal meningitis among many other preventable diseases exert deadly and daily tolls on the citizenry and many primary health centres across the country lack adequate personnel and funding. Many regularly have "stock-out" positions on basic essential drugs such as antimalarials, common analgesics like aspirin and common antibiotics like penicillin.

In contrast, in some African countries, ARVs are available for under $140 per person per year (pppy). They are supplied by drug manufacturers in India, South Africa, Brazil, Thailand, and China, who have manufactured generic copies of patented ARV drugs. Fees are not paid to the patent holders and the drugs can consequently be distributed at prices agreeable to the governments and people of developing countries. The reduction in cost has come about from a combination of generic drugs. The DREAM (short for "Drug Resources Enhancement against Aids and Malnutrition", which used to be "Drug Resource Enhancement against AIDS in Mozambique") promoted by the Community of Sant’Egidio has proven to be an efficient means of giving access to free ARV treatment with generic HAART drugs to the poor on a large scale: So far, 5,000 people are receiving ARV treatment, especially in Mozambique, but the program is being built up also in other countries: Malawi, Guinea, Tanzania and others. Despite being free, the program aims at excellence in treatment, providing the best existing range of drugs (HAART) and regular blood testing according to European standards. It is linked with a nutrition program as well as guidance and sanitary education by volunteers (other HIV patients taking part in the program), which encourages new patients to comply and come to the appointments. The compliance rate is very high (94%).

Access to essential drugs in Africa still has a lot of bottlenecks which hinder the effectiveness of distribution to the common man. It is our hope that with time, all these issues will be resolved with better planning by the governments in Africa.

By:

Daniel Etim Bassey
Counterfeit Medicines

From scarcity of basic medicines to unaffordable prices, millions of people have limited or even no access to essential medicines. In such conditions, a new business has developed; it is the business of counterfeit medicines!!!, We usually used to hear about counterfeiting of computer programs but FAKE DRUGS …. That’s a big crisis.

Counterfeit medicines include medicines with lower quality and effectiveness or ineffective at all. In the worst cases, they may include highly toxic substances. In some countries that is rare to happen but in many it is an everyday reality.

Any of us can come across medicines that are packed in the right way and looks good but it does not contain the correct ingredients. Occasionally, there can be a High Quality fake that do contain the appropriate active ingredient. At any case the contents of those fake drugs are unreliable and of unknown source. Any kind of drugs can be counterfeited ranging from expensive anti cancers, antibiotics and drugs for hypertension to inexpensive pain killers. In developing countries the market needs direct the counterfeiting to drugs used in treatment of malaria, TB and AIDS. Advanced printing technology made it difficult to differentiate between fake and real ones by naked eye.

Counterfeit drugs have been firstly reported more than 10 years ago but since 2005 it has witnessed a huge increase and it is expected that the fake drug sales will reach 75 billion dollar by 2010. Although detailed information about the amount of fake drugs in the market is difficult to have but it is estimated to represent 1% of the market value in the developed countries and up to 30% in developing ones. Internet based sales of medicines are counterfeit in 50% of cases. The majority of production of counterfeit drugs takes place in houses and backyards. It makes very high profits due to high demands for medicines and low production costs. Also in some countries, counterfeit drugs are not only sold but may be exported!!!!

Weak drug regulations may also lead to appearance of low quality drugs from official pharmaceutical companies approved by the governments. I do not know if they do not know about those drugs or just accept a lower quality for a cheaper price! In my university, they analyzed 10 tablets from the same pack of a common used drug which is approved and sold in the local market to see the percent of the active ingredient in each…. And what a surprise, the percent varied from a tablet to another and all of them were under the supposed stated level!!!!

In my opinion, counterfeit drugs will be on of the biggest challenges for global health, as we can spot if an area does not have access to essential medicines but it is so difficult to know about the areas having fake access. Solutions MAY include the use of high technology to assure the reliability and the source of the drugs besides having strict drug regulations & effective monitoring systems. Surly, that will lead to more increase in the costs of production to assure quality and in turn the victims will be the developing countries in which people can’t afford even half of the current prices. Beside the fact that in many areas in the developing world, governments are neither dominating nor represented so you can imagine about the possibility to apply any regulations on the drug market (if present).

By: Omar Kamal

Health: Right of all and Duty of the State

Doctor X is in his office analyzing some patients’ handbooks. Suddenly, his secretary, comes to the room bringing some letters. Twelve out of the fifteen he had received corresponded to an avalanche of papers with medicine advertisings from the most diverse types, and those were the remedies he prescribed the most: “These papers only serve as sponsorships for my registrations and trips”.

The pharmaceutical industry nowadays is among the most successful multinationals in comparison to other economical segments as the telecommunications and electronics. This great success happens mainly due to great investments in marketing carried out by these companies. The above-exemplified narrative corresponds to only one of the strategies that the pharmaceutical industry uses to overlap its economical power to health professionals.

A doctors’ position is not considered incorrect from the point of view of the Medical Ethics Code and it is not characterized as a submission position. All professionals should know how to handle their relationships with the different sectors, as the pharmaceutical and health care equipments industries, thus doctors should be coherent with their convictions and positions. It means, prescribing the most efficient medicine for the treatment of the patients, of lowest cost in the case of need, or the most clinically efficient one, but not the most in evidence in the market due to industry advertisements.

Considering technological advances of the different types of companies in this sector, there have been increases of investments in clinical research and also
of the competition among medications due to patent. This stimulates even more investments to the development of new active principles of better effectiveness that may be not so vulnerable to the market. This hunger for new markets is what causes the huge expenses within the advertisement industry.

The currently new developed remedies are made mainly for chronic illnesses, as cardiovascular diseases, cancer, hypertension, amongst others. Why new medicine for acute illnesses as the Malaria, whose treatment time does not exceed six months, are never produced? Because, although the great interest of the pharmaceutical Industry is health, the main objective of the companies is still the profit. If the health problem is solved, but profit is not obtained, the company will not invest on or will not produce the medicine. Pathologies as hypertension or diabetes need to be treated the entire life, therefore the stimulation for new products in this direction is so valued.

Taking this into consideration, due to excessive marketing, depreciation of the medical prescriptions because of advertisements, greater interest in the profitability rather than in health promotion, the pharmaceutical industry has been hardly criticized and devaluated by the social segments and differentiated medias lately. The intention of these critics is to discourage the extreme competition in the health market, so that medicine would not have to be produced or studied to supply more profits to the companies, groups or determined countries, but to improve life conditions of the population, looking for new therapeutic formulas for illnesses still not very well known and also increasing the number of available medicines for the most needed population.

Due to these reasons I believe that we, as medical students, all health professionals, among others, must mobilize ourselves against the health industry monopoly. And this may happen either through published articles or by the reputation of the sponsorships made by the pharmaceutical industry in congresses or still having this discussion in the programming of events. According to Brazilian law, health is a right of all and a duty of the State and not a right of the rich ones for a duty of the Industry. Let us be different of Dr. X, let us be coherent with and convict to the principles that guide the medical profession, which struggles for health and life above all.

**By:**

**Paula Consolin – Brazil DENEM**

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**Credit card please??!!**

It's the same question everyday....
How much money can you pay??!
If you pull out a credit card,

Then, we will let you stay!!
Have you ever heard of the old saying "you are worth what you've got; if you own a dime, then you're worth a dime.....it you've got nothing, then you're worth nothing"??

Well, it's amazingly becoming part of our reality. Only I wish it weren't so true among the doctors and health care professionals! It's really disappointing to see such an ideal mission aiming to help people to get easily swept off by the demon of materialism. Materialism has taken over our lives, our jobs, the way we live, behave, and it has even conquered our minds, the way we think, our beliefs, and common sense. This year, I've experienced that, and I've seen some of its worst consequences.

Last summer, after I finished my summer course, I thought about spending the extra time I had left doing something useful, both for me (filling my empty time, and getting more experience) and for the society. So, I thought about volunteering at a near by hospital. Actually, there were two hospitals, a public, and a private one. But I chose the former because the private hospital was practically empty. I spent most of my time in the emergency room. Every day, I saw hundreds of cases. There wasn't even any room for them; some of them were waiting in the halls.

What is astonishing is that some of the emergency cases have gone to the private hospital at the beginning, because they were afraid of not finding room for them at the public hospital because it was always very crowded. But what really got on my nerves is that they were turned back by the private hospital, because they didn't have enough money to pay!! So, they desperately rushed back to the public hospital – which was across the street- praying to find room for them. These cases included a patient with acute appendicitis, and a woman in labor.

The portrait which I drew in my mind about medicine being an ideal career which aims to help people and save their lives was shattered to pieces. How could a doctor see a patient twisting and turning in pain and just stand there, doing nothing because that person didn't have enough money to pay him?? Where are the values?? Where are the morals??

Well, unfortunately, this is reality. I hope that we, as future doctors can change this view towards money and materialism. I hope that each and every one of us can keep this little light inside us, our conscience alive. Because selling your conscience for the money is really not worth it. At least, this is what I think. I hope that you think the same as I do.

**By:**

**Ghada Atallah—Palestine**
One of many disturbing realities

A 50 year old woman, who received a prescription of Volmax, a bronchodilator, was hospitalized after taking Flomax, a drug used for prostate hyperplasia. The case report was handed out to the Food and Drug Administration (FDA) where several other similar cases of errors due to name confusion are reported annually. (1) Since November 2003 to July 2005 in the UK alone, 236 incidents caused by wrong patient identification were reported by the United Kingdom National Patient Safety Agency. (2) Although the health care has tremendously improved during the last centuries, patient safety is surely not a problem of the past times. While health care develops, different problems related to the care delivery keep causing unintended patient harm; and an important part of these faults are caused by human errors.

Aiming to “acknowledge this disturbing truth” the World Health Organisation (WHO) launched in October 2004 the World Alliance for Patient Safety. In May 2007, the Alliance and the WHO Collaborating Centre for Patient Safety Solutions have presented the "Nine patient safety solutions" package, a guide for the redesign of the patient care process towards the efficient prevention of the health care related harm affecting millions of patients worldwide. “Implementing these solutions is a way to improve patient safety” said WHO Director-General Dr. Margaret Chan.

The broad problem…

Although efforts are being made to ensure that new drugs receive names that are significantly different than the already commercialized ones, problems related to drug name confusion are far from being controlled. Even if the issue gained importance in the latter years, similar problems were reported back in 1969 (6) and most probably they occurred even before that date.

The drug naming process can be far more complex than one can imagine. Some details about the drug naming procedures can help a deeper understanding of how this can result in medication errors. Each drug has three types of names: chemical, generic (non-proprietary) and brand (proprietary, trademark) names. While generic names are elaborated as a result of global cooperation, brand names are developed by the product sponsor thus they are difficult to control.

The WHO International Nonproprietary Names (INN) Committee is actively involved in the generic naming process, ensuring the provision of names accepted worldwide and that are not in conflict with any other existing drug names, either brand or generic. (7) But different national agencies work on the same issue, such as the United States Adopted Names (USAN) Council in the US or the British Pharmacopeia Commission in the UK, and several generic names are still different from one country to another. (8) The generic names usually use a specific suffix for each group of medicines, a procedure which proved to help identify the drug class. Although these similarities help remembering, they also contribute to name confusion.

Even more work and research is involved in brand names development process. Several issues should be taken into consideration in this process, from semantic to orthographical; syllabic sequences to create a rhythmic consonance are as important as any relation to what the drug does, the producing company, the drug dosage or its’ generic name. Various different brand names exist for each drug, depending on the producing company or the country where they are commercialized. In order to control this process, brand names shall be approved by designated commissions such as the FDA in the US or the European Agency for the Evaluation of Medicinal Products (EMEA) in the European Union. (3, 8) Yet, with tens of thousands of brand names on the market, similarities are difficult to avoid and thus confusions continue to occur.

Additional causes for drug name confusion are illegible handwriting, the use of verbal (telephone) orders or incorrect selection of a similar name from a com-
puterized product list; similar packing or labelling; re-
ssembling dosages or indications. Furthermore, language
barriers can also contribute to the perpetuation of these
problems, especially for the foreign physicians. Finally,
abbreviations, acronyms or different signs used in
medication prescriptions represent more potential
causes for errors.

Errors can appear at different levels, from prescribing
to dispensing, thus actions for minimizing these risks
should cover all these levels.

**Proposed solutions…**
The WHO proposes a set of solutions to the described
problems, which involve actions taken by health au-
torities to pharmaceutical companies and all settings
where medications are ordered, dispensed or adminis-
tered, including self-medicat ion or care-giver involve-
ment. They promote existing interventions and coordi-
nate international interventions to ensure that the pro-
sposed solutions reach their targets. (3)

**The drug naming**
As the majority of the problems arise from drug nam-
ing, this process should be properly controlled. For
example in the US, the FDA annually revise about 400
new drug names before these are launched on the mar-
ket, and only about two thirds are approved. They fo-
cus on handwriting and voice analysis, labelling and
packing and the name evaluation in general. (1, 8) The
existing or new organisations in charge of drugs brand
name evaluation should follow similar processes of
control and revision of the naming process, for both
new and existing names. (3) Creating a universal drug
naming convention should represent a long-term aim.

Furthermore, efforts should be made so that the or-
ganisations responsible for the procurement of drugs
should consider the dangers of look-alike sound-alike
drugs in the process of new product purchase, and that
they are aware of the fact that one brand name may
correspond to different drugs depending on the provid-
ing country. (3)

**Prescribing and dispensing**
Suggested measures to avoid prescription errors include
the introduction of specific, clinical protocols aiming to
minimize the use of verbal orders, to stress the need to
check the reason for the medication, or to include both
generic and brand name on prescriptions. Moreover,
strategies that avoid confusions due to illegible orders
refer to the printing of the drug names and dosages or
the use of “tall man” letters. Finally, the computerized
prescriber order entry (CPOE) can prove to be a useful
tool if correctly used, yet the current WHO guidelines
include it among the suggested strategies for the future.

According to the WHO and the Collaborating Centre,
With only 28% of HIV/AIDS patients receiving all avenues must be explored to increase access to essential medicines. Starting in 2001 with the clarion call of Yale, d4t, and Bristol Myers Squibb, it has become evident that universities themselves can, and must, serve as part of the solution to the access puzzle by making the fruits of their research accessible to all. Sadly, despite the incredible impact generic production of d4t had on the lives of countless patients who were in dire need of treatment, universities have been slow to implement equitable access licensing policies. However, recent changes in university language provide some hope that the tide is turning, but this language must be followed by serious institutional commitment if we are to see any more success stories like d4t.

Last March, eleven of America’s top research institutions and the Association of American Medical Colleges issued a white paper entitled “In the Public Interest: Nine Points to Consider in Licensing University Technology”, publicly recognizing for the first time the responsibility universities have to implement equitable access licensing guidelines. The statement addresses the changing role of the university in an age where research is an enterprise requiring mass action and collaboration and the demand for its results is both urgent and global.

If implemented, the guidelines would have drastic and widespread results. With many of the most important AIDS drugs, including zidovudine, stavudine, zalcitabine, abacavir, and a number of protease inhibitors resulting at least in part from public research institutes, the white paper delineates principles upon which universities may license innovations to the private sector while ensuring that intellectual property rights and licensing agreements do not prohibit access to the innovation in low- and middle-income countries. The white paper is in essence a signal of recognition: recognition that current intellectual property procedures are failing the most vulnerable among us; recognition of the voices of student activists calling for change; and recognition that universities must not stand by idly, doing nothing. For this, the white paper is exhilarating, insightful, and optimistic and yet, it is only a beginning.

For all the promise held in the white paper, it is for now only eloquent words on a blank page. Though endorsed by eleven research institutions, the white paper lacks any sense of commitment from its signatories. Without commitment, there will certainly be no implementation. Without implementation, there will be no change. The university community can, and must, do much better. At best it is a statement of principles which the universities will try and uphold whenever possible; at worst, it is a token gesture.

The cynical student activist might see it as the latter and become discouraged by what seems like an empty statement. This characterization quite plainly is not entirely off-base. Right now the white paper is a gesture. It lacks teeth. More action is clearly required—namely, the revision of university policy and protocol to include the recommendations of the white paper—if we are to see results. But cynicism can blind, and to adopt this view of the white paper would be to miss what the white paper represents in the movement to improve access to university technologies.

It is an invitation.

An invitation hinting that the door is open if only people would come knocking. The default nature of student activism is to point out what university administrations aren’t doing. This activism has historically taken place outside the conference room, on the quads and in the student unions with demonstrations, petitions, and powerful speeches. It has rarely, if ever, meant having a seat at the administrators’ table. The white paper is the invitation to this table, a recognition that administrators are willing to talk, a chance for students to recognize what university administrators are doing. We as students, the initiators of this conversation, must now seize the opportunity to engage our administrations in a professional dialogue. If we fail to do so, the white paper will quickly become obsolete, and we will have neglected our duty to make our voices heard.

Now, more than ever, students must find their voice in order to exert pressure on their universities to ensure that the policies delineated by the white paper are incorporated into university licensing practices. Universities are communities in which students serve as the primary voice for change. The white paper is a signal that administrators are waiting for their cue, waiting for pressure from students so that they can bring something to the table. Figuratively, the administrators are standing by the bleachers at a school dance, waiting for someone to take them up on the extended offer.

Medical students in particular must take the lead in this effort. There are many noble causes in need of medical student attention, but few are so central to what the goals of medical education are and should be. Our patients need these drugs. Our labs’ research leads to these drugs. We must have these drugs in our arsenal if we are to keep people from dying. We must take the time to walk over, to engage others in this
important conversation, to build consensus, and to affect change despite our hectic schedules and rigorous academic load. Medical students must help build a movement on our medical school campuses, in our clinics, and in our hospitals—a movement for equitable access. Organisations such as Universities Allied for Essential Medicines (UAEM) and the American Medical Student Association (AMSA) are already involved in this movement and we must join them in increasing numbers, adding our voices to theirs.

The white paper has ushered in a new day of student activism—a day where we as medical students can sit down with faculty and administrators and dialogue civilly and professionally. Let us applaud the steps university administrators are now taking to address access to essential medicines, while at the same time continue to pressure them to make the recommendations of the white paper a concrete reality. Only by doing so will access to essential medicines become more of a concrete reality for the most vulnerable among us.

By:
Nathan Trayner
Jennifer Hasvold

Access to Proper Health Care and Essential Medicines: Perspectives from Nepal

Scenario 1: A remote village somewhere in the hills of Nepal
A nine year old boy has been having a fever and cough for the last 5 days. His parents think it is just a simple cough and cold and do nothing about it. The child starts to deteriorate. That’s when the parents start getting concerned. The nearest health center is 2 days away on foot. By the time they get there, the child’s state is really critical. There are no intravenous antibiotics available. The child is referred to a district hospital which is still 2 more days away. The child dies on the way. The parents mourn for a few days and life moves on.

Scenario 2: The capital city- Kathmandu
A 55 year old man gets sudden chest pain on the left side which radiates to the jaw. Immediately an ambulance is called for and he is taken to the nearest hospital. Quick investigations are done and the ECG reveals a myocardial infection. Necessary interventions are carried out and his life is out of danger.

The two scenarios presented above try to put into perspective the vast differences in health accessibility among different parts of the country itself. Almost all of the modern and proper health care system has been centralized to the major towns while the people in the remote villages are living in extreme poverty and lack of basic health care. The access to proper health care and essential medicines comes into the picture here.

The provision of essential drugs was put as one of the eight elements of Primary Health Care by the Alma Ata conference. The eight elements including the provision of essential drugs were mainly targeted towards the betterment of the health situation in developing countries like Nepal. But has the goal been achieved? As we reflect upon the mortality and morbidity indicators, still infectious and simple curable diseases like tuberculosis, pneumonia, and diarrhea and malnutrition problems pose a significant problem.

What add to the gravity of the problem is the lack of skilled health professionals and the provision of the basic essential medicines to the people in need.

Impact of corruption:
Millions of dollars are being poured in. But is enough being done? The data tell a different story. And the recent civil war that gripped the country for more than a decade didn’t help matters. Even the few doctors who were willing to go the remote places to work were unable to do so because of security reasons and the instability of the governments made it impossible to implement long term health related plans. On top of that, the widespread corruption rampant in the country has engulfed the health sector too. This has led to the funds being deviated away from the real needy people. The money that should have been utilized for the implementation of newer health projects and the procurements of essential drugs is being pocketed by the politicians and other top government officials.

What can be done?
So this brings us to the bigger question, what can be done? It would be unfair to be absolutely pessimistic and state that nothing is being done. There is always light at the end of the tunnel and there are ways of improvement even in the direst circumstances. Here are a few suggestions that can be pondered upon:

1. Proper Planning:
Even though lots of short term and long term projects have been put in place, lots of them haven’t been able to deliver the goods. One of the major reasons behind this has been the lack of proper research and planning. Either we have overlooked the places and the people who are in real need or we have failed to identify the areas of priority. It is highly recommended that the government hires experienced health professionals who have worked in the remotest parts of the country and take necessary suggestions from them. Also forming small task forces to gather health related data from all over the country and careful analysis before implementing projects is a must.

2. Collaboration and partnership with National and International Organisations:
Access to Essential Medicines

By: Bikki Gautam

Access to essential medicines in Peru

According to the WHO Policy Perspectives on Medicines released in March 2004, “Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford”.

Obviously, essential medicines save lives and improve health when they are available, affordable and of assured quality. Still, lack of access to essential medicines remains one of the most serious global public health issues. In fact, one-third of the world’s population lacks access to essential medicines and in the poorest parts of Africa and Asia this figure rises to one-half. But what is the situation in Peru?

Peru is one of the richest countries in the world in terms of natural resources and biodiversity. With an area of 1,285,215 square km, Peru is the third-largest country in South America after Brazil and Argentina, ranking it amongst the world’s 20 largest nations. However, Peru is also one of the poorest countries of South America, economically speaking, with an estimated 27 million population (according to the last population study in 2005) and a gross domestic product (GDP) of USD 2180 per capita. Although the health situation has improved greatly over the last years with government’s new policies and health models, Peru still has a high infant and maternal mortality rate, one of the highest incidence rate of tuberculosis in Latin America and an HIV prevalence among adults ranging between 0.35% and 0.5%, which means that about 76,000 persons are living with HIV/AIDS.

Peru, like other countries of the Andean Community (CAN), is a member of the World Trade Organization (WTO) and therefore, bound by the obligations of the Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS). On the other hand, due to previous legislation that did not allow pharmaceutical patents, most of essential medicines currently on the market in Peru are not protected by one. The few Peruvian patents that exist are patent laws available known as “safeguards” to counterbalance the negative effect of patent protection of pharmaceuticals.

To further regulate the patents, now there are compulsory licenses which are an authorization given by the State for the use of a patented invention and any interested person can request a license to the “Office of Inventions and New Technologies” of INDECOPI, the patent office in Peru.

Another option for a greater access to essential medicines in Peru, are the parallel imports in which medicines could be imported without the authorization of the patent owner. However, the importer needs to get an authorization from the Ministry of Health to ensure the safety, efficacy and quality of the product to import it in Peru. This is a very important issue as people will buy what is cheaper for them as drug expenditures in the Peruvian Health System are out of pocket and only 23.5% of the population benefit from national or private social security (although this is changing...
nowadays with the government introducing new insurances for the babies, kids, teenagers, pregnant women and old people).

Still a number of generic manufacturers are present on the Peruvian market and they also compete with other manufacturers of original brand-name products. An example of the market competition is antiretrovirals. Competition has forced the price of first-line AIDS medicines down to as little as $408 per person per year, compared to $4,300 per person per year for brand-name drugs. However, despite competition, prices of some essential medicines in Peru remain very high compared to prices in the international market and with regard to the buying power of the population.

This is an issue that concerns us all, not just us, as future physicians but healthcare providers in general, governments, and organizations such as the WHO, UNAIDS, UNICEF, etc. We, have the responsibility to demand the best possible level of care for our patients.

By: Eduardo Rodríuez Zárate
Jessica Valeria Tang Herrera

Patent protection and the access to essential medicines

Diseases like HIV/AIDS, Malaria or Tuberculosis have reached apocalyptic levels in many developing countries, especially in the sub-Saharan region and millions of infected people in these countries have no access to adequate treatment. This lack of access to essential medicines can be seen as one of the most important factors which contribute to this disastrous situation.

However, assessing the dimension and the horrible effects of the pandemic threats seems easy compared to finding coherent explanations for this development. Many western NGOs and governments of developing countries claim to have identified a simple reason for this disastrous situation: the international system of patent protection comprised by the WTO and its “Treaty on Trade-Related Aspects of Intellectual Property Rights” (TRIPS).

Patent protection is a way to assure that an invention (in this context mostly a newly developed active agent which can be used for the production of drugs) is not commercially used by third parties without permission of the inventor. The protection of intellectual property rights has its roots in the early beginnings of the industrial age when the financial aspects of inventions became more and more important. It is widely recognized that this basic principle of modern law helped to boost innovation, both for companies and private inventors, and is still the main incentive to risk high expenditures for the development of new products. The protection is geographically limited to the state which grants the patent and has a time restriction of 20 years.

Concerning active agents for medicines, the inventing company is not directly allowed to market its invention due to time and money-consuming approval testing. These necessary admission procedures lead to an additional financial burden and reduce the prevailing protection time to 8-12 years. Thus, patents limit the free access to inventions temporally and geographically for third parties. These principles form the basis of mentioned TRIPS-system which has 150 member states today.

This system is relatively unsensational as long as it is about “normal” inventions – and not about medicines which decide upon life and death. As mentioned above, many protagonists blame the TRIPS to also limit the access to essential medicines for the affected poor in developing countries. This assumption brings a special ethical dimension into the discussion because it implies that the existing legal system of patent protection hinders the production, introduction and distribution of cheap drugs in developing countries and thereby is directly responsible for evitable millionfold deaths.

The lack of access to essential medicines is unquestionably an intolerable shame which needs to be eradicated quickly and permanently. Thus, one has to look for the underlying factors of the current situation. Blaming the international treaty system for the suffering of millions of poor people is of course an easy and convenient way to mobilise public protest. But can it really explain the reason for this grievance?

Maybe a short look on some remarkable (but often omitted) facts would help to get a clearer picture:

95% of the medicines which the World Health Organisation (WHO) considers indispensable (“WHO essential drug list”) have never been or are no longer protected by patent rights. In many developing countries, patent protection on a lot of medicines against HIV, Malaria or Tuberculosis does not exist at all: Only 15% of the anti-retroviral drugs used in the fight against HIV/AIDS are patent protected in the African states.

In the case of other severe diseases with high prevalence in developing countries, these rates are even lower: 12 of the 13 most effective anti-Malaria drugs are not protected in any African state – with the one resting drug being protected in only 5% of these states. And not even 1% of the medicines used in the therapy of Tuberculosis falls under patent laws in developing countries; for medicines against the sleeping sickness this rate is even under 0,5%.

These figures show that the rate of patent protected medicines for HIV/AIDS, Malaria, Tuberculosis and other malicious diseases with pandemic prevalence in developing countries is indeed very low. Furthermore,
health’ in 2001 and the Amendment of December 2005, developing states obtain a bunch of possibilities to ensure that the access to essential medicines is not restrained by international patent laws.

The declaration made clear that the TRIPS-system shall not hinder the member states to protect their public health and that its legal interpretation should not weaken the rights of the states to ensure the access of the population to medicines. The least developed member countries already benefit from long transition periods until 2016. This time-frame can be extended which means that these countries will not have to abide by the patent protection of the TRIPS in the predictable future.

All member states can issue compulsory licences if the owner of a patent refused to offer the medicine on the national market to reasonable prizes. In the case of national emergency compulsory licences can even be granted without prior contact of the owner of the patent. The affected states can define themselves what they consider as an emergency or other matter of exceeding urgency; e.g. the AIDS pandemic which has reached alerting dimensions in certain African countries. These licences not only allow these countries to produce formerly patent protected medicines cheaply for its own market, but also to import them in case the member state does not have its own generics industry.

The figures mentioned above make clear that patent protection cannot be the main reason for the poor access to essential drugs in developing countries. The then listed instruments of the treaty and the Doha-declaration show that the existing system possesses the necessary flexibility to meet the needs of the developing countries.

The failing supply of the population (better: of certain groups within the population) in a country which is affected by a health crisis is the outcome of a highly complex combination of social, political and economic factors and cannot be reduced to one single "external evil" as many NGOs and also government assert. They come along with the absence of a functioning national health care system, poor infrastructure, war and/or unstable political situations, missing education and prevention, lack of human resources, high custom duties (import taxes make up to 35% of the price of antiretroviral medicines in developing countries!) and of course the general consequences of economic poverty and un development.

The impact of TRIPS on the failing access to essential medicines in developing countries is by far overvalued. On the contrary, patents play a central role in the development of new drugs as it gives security and incentives to invest huge resources in precarious research projects. Without patent protection only a fraction of the existing research activities would take place. On an international level, the TRIPS finds an adequate balance of interests between the need for legal protection and the needs of the developing countries, apart from the fact that the large majority of the relevant medicines do not even fall under its regulation.

Thus, a reduction of the problem to the international legal system undermines an open discussion and consequently constructive solutions to this pressing issue. For this purpose, concerted and long-lasting activities have to be pressed ahead by the international community. In this process patent protection should be considered part of the solution, not part of the problem.

By: Florian Vogt

Men and Women for Others: The Case for University Adoption of Socially Responsible Licensing Practices

We've all heard the statistics: 6,000 people in Africa die of AIDS every day, while 49 die in North America. According to the World Health Organisation, one-third of the world’s population lack access to medicines essential for life. Despite international efforts, treatable and preventable diseases remain the leading causes of death in poor countries.

The massive inequities in access to essential medicines are painfully clear. Less apparent, however, is the role that research-based universities can and should play in bridging this gap. As key stakeholders in the development of the world's most important medicines and vaccines, these institutions have the leverage and motivation to ensure that their discoveries benefit the world's poor. Universities can best achieve this end through socially responsible licensing policies.

Breakthroughs in university research often open new doors to the development of life-saving drugs. The rights to these discoveries are then licensed to pharmaceutical and biotech companies for drug development, clinical testing, and submission for FDA approval. As universities continue procuring intellectual property rights, they are becoming increasingly important actors in the creation of life-saving medicines. Between 1993 and 2003, for example, the number of patents and license agreements executed by universities have almost doubled.

International Federation of Medical Students’ Associations
The unique character of universities, however, attaches an obligation to their increasing leverage in patent negotiations. Though they often work together, the goals of university research are very different from those of pharmaceutical companies. Instead of looking for blockbuster drugs to maximize revenues, university research is aimed at promoting public goods.

This is particularly true at Georgetown University. As a Jesuit institution committed to social justice, Georgetown has developed a culture of orienting its ideals toward practical but socially beneficial outcomes. In the words of its Office of Technology Licensing, "Georgetown is committed to the policy that ideas or creative works produced at Georgetown should be used for the greatest possible public benefit, and believes that every reasonable incentive should be provided for the prompt introduction of such ideas into public use, all in a manner consistent with the public interest."

Additionally, President John J. DeGioia has expressed his desire for Georgetown to become an institution deeply involved in global affairs. In a Faculty Town Hall meeting on January 19, 2007, President DeGioia referred to the present as a "defining moment for Georgetown; a moment that demands that we respond to issues and opportunities that are truly global in nature". President DeGioia’s vision is particularly pertinent to global health issues, as evidenced by his stated commitment to the fight against HIV/AIDS.

As a major contributor to the development of the breakthrough HPV vaccine, Georgetown is in a position to lead the fight against global health inequities by putting these stated commitments into practice. Dr. Richard Schlegel, chair of the Department of Pathology at the Lombardi Cancer Center, played an integral part in the research leading up to the current vaccine’s creation. Though rights to the first generation vaccine have already been licensed, a second generation vaccine is already being developed. Many in the Georgetown community believe Georgetown has an opportunity, and a responsibility, to act now.

There is a serious demand for the HPV vaccine in the developing world, where 85% of new cervical cancer cases and deaths occur each year. The 200,000 women who die of the disease in poor countries often lack access to pap smears and preventative screenings, making the need for this vaccine even greater. The cost of the current HPV vaccine, however, is prohibitively expensive. Currently priced at $360 for a course of three shots in the United States, widespread HPV vaccination at any similar price point is out of the question for low-income countries that spend roughly $8 per person on all health service provision annually.

Specifically, what can Georgetown do to ensure that the next generation HPV vaccine, and subsequent drugs developed from the University’s research, are made available to the world’s poor? By instituting a socially responsible licensing policy, Georgetown can ensure that the poor have access to the fruits of its discoveries. One such policy proposed by Universities Allied for Essential Medicines utilizes an Equal Access License, which allows life-saving technologies developed with university research to be produced by generic manufacturers for distribution at affordable prices in poor countries only. Under an EAL-based policy, these generic manufacturers would be required to pay royalties to the pharmaceutical company and the university that developed the technology, guaranteeing revenue for all parties involved.

A University commitment to serving marginalized populations through research is not without precedent. Schools including Yale University, the University of Washington, the University of California-Berkeley, and the University of Nebraska have all taken concrete steps to use socially responsible licensing for technologies produced by university research. None of these universities, however, has incorporated broad-based poverty-oriented provisions directly into its licensing policies. This has the unfortunate consequence of medicines being made available on a case-by-case basis. As such, Georgetown has the unique opportunity to play a leading role in addressing gaps in access to medicines by instituting a general socially responsible licensing policy that will solidify its status as a truly global university.

The Georgetown movement for socially responsible licensing has already received widespread support from the Georgetown community. In a world where market inadequacies continue to marginalize impoverished and sick populations around the world, socially responsible licensing programs present an opportunity that is both ethical and economically feasible. Georgetown University, a school committed to “women and men for others,” is in a unique position to lead in this area by making socially responsible licensing an integral part of its practice. We sincerely hope that other universities will do the same.

For more information about the Socially Responsible Licensing Movement at Georgetown or elsewhere, please contact Teddy Svoronos at ts263@georgetown.edu.

By: Teddy Svoronos

Access to essential medicines: Antiretroviral therapy in Malawi

In December ’06-February ’07, during the Australian summer, I worked in a volunteer capacity in Ghana, Kenya and Malawi. Following my time in Ghana and Kenya where I spent the majority of my time in blindness prevention projects, I travelled to Malawi and was based in Nkhoma. Nkhoma features a mission hospital founded by the Dutch Reformed Church. It is situated 50km to the east of the capital Lilongwe. Serving a population of over 33000 in the surrounding 10 Kilometres, it also has a referral population of over 60,000. In addition to providing general medical,
surgical, obstetrics/gynaecology and paediatric services, the hospital also offers comprehensive, but not exhaustive, HIV/AIDS services.

In many of the regions which I visited, the principle of diagnosis and treatment was ‘to do your best in spite of inadequate conditions and equipment/medicines.’ Heartbreaking stories were commonplace, most of which could have been prevented with adequate stocks of pharmaceuticals. Witnessing patients dying of pulmonary emboli because stocks of heparin were depleted or suffering from severe post—operative wound infections and systemic sepsis because the only antibiotic available at the time was PR metronidazole was difficult to comprehend in its entirety. Undoubtedly, these episodes should have been prevented. Yet, simple medicines which are easily taken for granted in developed countries, are in widespread need throughout the developed world.

**HIV in Malawi**

During my stay in Malawi, I spent time within the HIV/AIDS unit undertaking clinical and research roles. The current population of Malawi is approximately 12 million. In 2003 the HIV prevalence in adults (15-49 years) of population that is infected with HIV was estimated to be 14.4%, with 58% being women. There are also 70,000 children infected. The annual deaths due to HIV/AIDS are estimated at 80,000. Thus, these disturbing rates of HIV infection need urgent figures intervention. Many organisations, government and non-government (NGO), are currently working to achieve better treatment for those affected and improved preventative strategies for those at risk. However, more funding is needed to ensure the grow, development and maintenance of such initiatives.

**Antiretroviral therapy (ART) services at Nkhoma**

During my time in Nkhoma I managed to assist with an audit of the hospital VCT (voluntary counselling and testing for HIV/AIDS) services. Of the 1703 patients tested at Nkhoma in 2005, 451 returned a positive serological diagnosis.

Reasons for commencing ART in Malawi are the following; having a World Health Organisation (WHO) stage III (symptomatic HIV infection) or WHO IV (AIDS) disease status or having a CD4 count < 200. Unfortunately the latter test is out of the reach of most budgets, because testing costs roughly $10 US, and most earn far less than that per day. Furthermore, patients must travel to Lilongwe to undertake the test. Of those eligible for ART, 281 patients (67.22%) were stage III, 127 patients (30.38%) were stage IV and 10 (2.39%) had a CD4 count < 200.

Starting in late 2004, 418 patients had commenced ART at Nkhoma as of December 31st 2006. 36% of patients were male, 64% female and 5% were under the age of 5. The majority of patients on ART were farmers (71%). Coexistent Tuberculosis infection, pulmonary or extra-pulmonary, and being pregnant whilst HIV+ve are further indications for commencing ART in Malawi.

HIV positive patients in Malawi receive their ART at a time in which they are already very ill with disease. If ART is commenced at stage I or II infection, improved outcomes can result, including increased life expectancy, increased CD4 counts and decreased viral loads. They also have been shown to decrease passage of the virus to (newly born) children of infected mothers. Yet, due to financial constraints and insufficient foreign aid, patients receive their ART often at a time when it is too late to make a difference to patients’ health and well being. 337 of the 418 who commenced ART are still taking ART to the Malawi Ministry of Health (MOH) recommended schedule, 36 have died, and only 8 have reported significant side effects of therapy.

HIV +VE individuals require more medicines than merely ART. Treatment of opportunistic infections is a veritable challenge, especially considering the often inadequate diagnostic facilities present in developing regions. Improved access to antibiotics (as well as antivirals, anti-TB, antifungals etc) will ensure that affected patients can have decreased morbidity associated with treatable infections. Although the HIV virus is not amenable to curative therapy at present, patients deserve the best treatment available.

During my stay at Nkhoma hospital, I gained a valuable insight into tragedy of HIV in Sub-Saharan Africa and the uphill battle that the region faces in order to effectively combat the crippling situation. Generations will be wiped out unless urgent assistance is taken immediately. Thus, foreign aid, with the assistance of drug company financial support should assist in the prevention and treatment of this cruel and devastating disease. More funding and improved access to vital medicines is required to ensure the ongoing running of the VCT and ART programs at Nkhoma and other regions of Malawi and Sub-Saharan Africa. This would help to ensure that patients receive ART at a time which would turn HIV into a ‘chronic disease’ as opposed to a death sentence.

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