Access to Essential Medicines

Essential medicines are drugs and vaccines that the World Health Organization considers necessary for a basic health care system[1]. The list of essential medicines includes drugs for the treatment of HIV, malaria and tuberculosis, but also non-communicable diseases such as diabetes, cancer and cardiovascular disease.

One third of the world's population lacks access to these medicines[2]. The consequence of this problem is commonly referred to as the **access gap**—where 10 million people die annually from diseases that are currently treatable with current medicines.[3].

The reasons for the lack of access to medicines are diverse: high prices, lack of infrastructure (e.g. refrigerated storage for drugs, transportation to the clinic, clean water), medical staff, and a lack of political will. UAEM (Universities Allied for Essential Medicines) focuses on **eliminating the high price barrier** to accessing needed medicines including, but not limited to, the WHO list.

Why are prices high?

The reasons contributing to the high prices of medicines are complex. Over the past several decades, pharmaceutical and biomedical industries have made tremendous strides in terms of producing an unprecedented variety of effective drugs. However, as the ambitions of researchers grow in their quest to conquer disease, so too has the cost of research grown. From the birth of a new drug in the discovery phase at universities and long-term development at research firms, drugs require stringent testing in order to ensure both safety and efficacy before they are ready for use by the general public. Healthcare economists have recently estimated that for each drug developed, it costs firms approximately $802m USD in order to bring to market; this includes the expenses associated with failed drugs as well.

In order to make it economically feasible for private companies to develop these medicines, countries grant patents on new therapeutics. A **patent** is an exclusive right to manufacture and sell a product in the country the patent was issued in. This exclusivity enables the owner of a patent to recoup the money spent on research and development, by setting the maximum price that they expect the market can absorb—often it is much more than the actual manufacturing cost. Unfortunately, since new medicines are typically sold at such a high price, access is limited to the select, few wealthy countries and the individuals who can afford to pay these prices.

What role does my university have?

Private research firms are not the only engine of biomedical R&D. Many drugs are initially discovered as new chemical entities (NCEs) at public universities.

A researcher at a university who discovers a molecule that may become an effective drug files a patent on that molecule. Since universities do not have the capacity to develop and distribute drugs to market—due to the costs associated with testing and mass production—they **license** the patented technology to a pharmaceutical or biomedical firm, transferring the patent rights to the licensee. Most universities have a special department called a **technology transfer office (TTO)** that negotiates the business and legal agreements between the researcher and the licensee. Transferring the patent rights allows the company to exclusively manufacture and sell the drug to people who can afford it. Some of the profit returns to the university as **royalty revenue**.

However, the typically high prices set by manufacturers frequently put most life-saving drugs out of the reach of the poor. For instance, treatment of HIV-positive patients with a triple-drug cocktail containing the antiretroviral drug *Stavudine (Zerit)*, developed at Yale and then licensed to Bristol-Myers-Squibb, cost $10,439 a year in 2002[5]. For the individuals who live off a few dollars per day, this expense is impossible and the prices set by firms no longer justifiable.

How can my university change?

We at UAEM propose that the university simultaneously license the drug to generic companies, who are able to produce the drug for people living in low- and middle-income countries, at a lower, more affordable price. Under these provisions, brand name pharmaceutical companies can still earn profits selling to high income countries, while generic producers ensure access in low and middle-income countries.

The price of *Stavudine,* decreased more than 100-fold, to $87 per patient per year[4], after activists from the humanitarian organization Médecins Sans Frontières successfully pressured Yale University and Bristol-Myers Squibb (the patent holder and license partner) to allow generic production. UAEM believes that the increased production and availability of generic medicines is one of the keys to solving the current access crisis. For more information about the importance of generic drug manufacturing, please visit <www.avert.org/generic.htm>

A question often asked is, "Won't parallel importation hurt the profits of pharmaceutical companies and of universities?" (Parallel importation is also known as drug diversion, and refers to the selling of generically produced drugs intended for low and middle-income countries, in high-income countries, where pharmaceutical companies still hold patents). Research has shown that this is not a significant concern. For more information, refer to the Journal of the Association of University Technology Managers, Volume XVIII Number 2 - Fall 2006, pp. 29-37.

UAEM members are committed to the idea that preventable deaths due to lack of medication is a problem that can be solved in our generation. UAEM calls on universities to recognize their role as public institutions created to serve the public good, to support those in need by implementing global access provisions, and to use their rights as patent holders and ensure that prices remain within reach of people regardless of where they live or how much money they earn. The University of California at Berkeley and the University of British Columbia have already adopted socially responsible licensing policies and with your help, we can ensure that your university follows suit!

Suggestions for further reading

1. Chokshi DA (2006) Improving access to medicines in poor countries: The role of universities. PLoS Med 3(6): e136. DOI: 10.1371/journal. pmed.0030136

This is one of the first scholarly articles published about UAEM, in the open-access journal Public Library of Science (PLoS). It describes both the access gap and the research gap (referring to a lack of research into treatments for neglected diseases) and is an excellent starting point for new members to familiarize themselves with the issue.

2. Kapczynski A, Crone ET, Merson M (2003) Global health and university patents. Science 301: 1629.

This editorial in the journal Science describes licensing and patenting strategies universities may use to ensure that people living in low and middle-income countries have access to their inventions. It also addresses concerns about possible decreased revenue to universities.

3. Idea #5: Cheap Meds for the World's Poor. The Tyee. <http://thetyee.ca/News/2007/12/21/CheapMeds/>

This article introduces the topic of affordable access to essential medicines and describes the successes of the UAEM chapter at the University of British Columbia, which has recently adopted a set of principles of global access to UBC technologies, which include drugs, biologics and any other health-care related tool.

Works cited

[1]<http://www.who.int/medicines/publications/essentialmedicines/en/>.
[2]Habiyambere V. Progress of WHO Member States in developing national drug policies and in revising essential drugs lists (WHO/DAP/98.7). World Health Organization: Geneva, 1998. <http://www.who.int/medicines/publications/essentialmedicines/en/>.
[3] http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf
[4] DiMasi, Hansen, Grabowski (2003) "The price of innovation: new estimates of drug development costs," *Journal of Health Economics*; Vol 22, pp. 151-185.
[5] Untangling the web of antiretroviral price reductions. Médecins Sans Frontières. <http://www.msfaccess.org/main/hiv-aids/untangling-the-web-of-antiretroviral-price-reductions-11th-edition/>