MUNESCO

Forum: Finance (EB2)

Issue: The universal regulation of inequitable prices of pharmaceutical products

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Position: President Chair

Introduction

Pharmaceutical products -as known as medicines or drugs- play an important role in recovering from a fatal disease and maintaining, protecting, ameliorating people's health. So, it is important for the public to have access to medicines with adequate quantity-quality and which don't have excessive prices, but have reasonable and providable prices. Unfortunately, nearly one-third of the world's population (mostly in developing countries) don't have access to pharmaceutical products and the main reason is excessive pricing. Quickly augmenting charges of health care and medicine are concerning every state in the world. Especially the developing countries where 90% of their citizens have to pay all the costs out of pocket. This makes medicine the largest expenditure after food in a family. The international community, national and global health policymakers and World Health Organisation (WHO) drew their attentions to this issue in order to globally regulate the prices and tackle the inaccessibility of pharmaceutical products. However, pharmaceutical industry is not ready to lose all their benefits from this type of pricing and they get away with leaving all the vulnerable people remediless. Pharma companies reason this issue to the fact that pharmaceuticals require expensive research and development (R&D) made by experts. Reports show that, they even increase the prices of top selling pharmaceuticals by doubling or tripling the already existing prices in five years. 30 percent of prescriptions written by doctors are never filled and the reason for that is nearly always the cost. Still, there are many states who don't have a national regulation on drug prices. On the other hand, there are some states where these regulations exist but are either not in progress or are insufficient. In each case, the population can't afford their medications, prescriptions or is obliged to skip one of their prescribed medicines to be able to buy the other "more important" ones. Even though there are many already existing national regulations and frameworks, or some regulations that cover and applied by several countries, a universal regulation has not been constituted yet. All governments must take action and collaborate to decide on a universal regulation on the pricing of pharmaceuticals in order to fulfill their citizens' human rights principles which is already their natural obligation.

Definition of Key Terms

Out of pocket: Paying something from your own money at hand without any financial aid, so you make a financial loss.

Patent: A patent is a right gained after inventing a product which is useful and solving crucial problems. The owner acquires the right to ban every other demander from selling, manufacturing or using it during 20 years after the patent application.

Essential Medicines: Essential medicines are the medicines that are important for the basic health care of people. They are qualified, affordable and numerous (in proportion tothe population).

Clinical Trial: A research&development technique where therapies likely to enter in the market are tried on humans in order to determine their effects and reactions in the human body to ensure safety and the possible effectiveness.

Monopoly: The exclusive, one and only control over some products related with trade or service.

Background Information

Pharmaceutical Companies

Pharmaceutical companies have always claimed that more budget is needed for the research and development (R&D) of pharmaceutical products and if the budget is restricted they would be unable to provide the same innovation. The more they spend money on R&D the more they increase the price of crucial medicines for human well-being. So, it has become a loop. They also mention that the prices they put on these products are worth being paid. On the other hand, many states argue that pharmaceutical companies exaggerate the drug R&D costs and that they gain unnecessarily big profit from these costs when many people die since they can't afford the medicines. Moreover, a new pharmaceutical products' potential market size is determined by the proportion of the population. Major criteria are, the frequency, efficiency, and extensiveness of the disease which the drug is aiming to overcome, the estimated number of people able to afford the medicine and if they think that this price is worth-paying or not. Also, to determine the potential market size is important because it will show them the potential profit they will be gaining. Furthermore, some commissions such as European Commission and The Competition Commission are investigating many reputed pharmaceutical companies such as Roche (Switzerland), known for its breast cancer medicine, Pfizer (USA) , known for its lung cancer medication and Aspen Pharmacare (South Africa), known for its development on cancer medicines. They are all dominant firms in their areas who are accused of excessively increasing the price of their products by hundreds of percents outside of the existing regulatory frameworks.
Below, in the chart, there are some leading pharmaceutical companies based on member states:

Table 1: Top ten global pharmaceutical companies		
Rank	**Company**	**Global prescription drug sales ($bn), 2016**
1.	Novartis (Switzerland)	41.6
2.	Pfizer (USA)	45.9
3.	Roche (Switzerland)	39.6
4.	Sanofi (France)	34.2
5.	Johnson & Johnson (USA)	31.7
6.	Merck & Co. (United States)	35.7
7.	AbbVie (United States)	25.3
8.	GlaxoSmithKline (UK of Great Britain and Northern Ireland)	27.8
9.	AstraZeneca (UK)	21.0
10.	Celgene (United States)	11.1
	Other companies	454.1
	Total industry sales	768

Note from the chair: Please keep in mind that these are only some examples of firms for you to understand the prices. Don't build the whole debate and your resolutions on these firms by giving their names, but refer to them in general.

Millennium Development Goals (MDGs)

Millennium Development Goals were the 8 global goals created in the Millennium Summit of the United Nations in 2000 in order to achieve in a 15-year plan. Each goal has specific target field and specific dates to realize them. In the 8th Goal which is to develop a global partnership, the 8E target is "In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries." The regular reports on the proportion of the affordability and accessibility of essential medicine were written. The data for the sustainable access to affordable essential drugs that the MDG were able to gather was limited but still improvements existed. Generic drugs had the availability of 58 percent in public health facilities. The number is not exact since MDG are lacking the transparent monitoring of essential medicine in all countries.

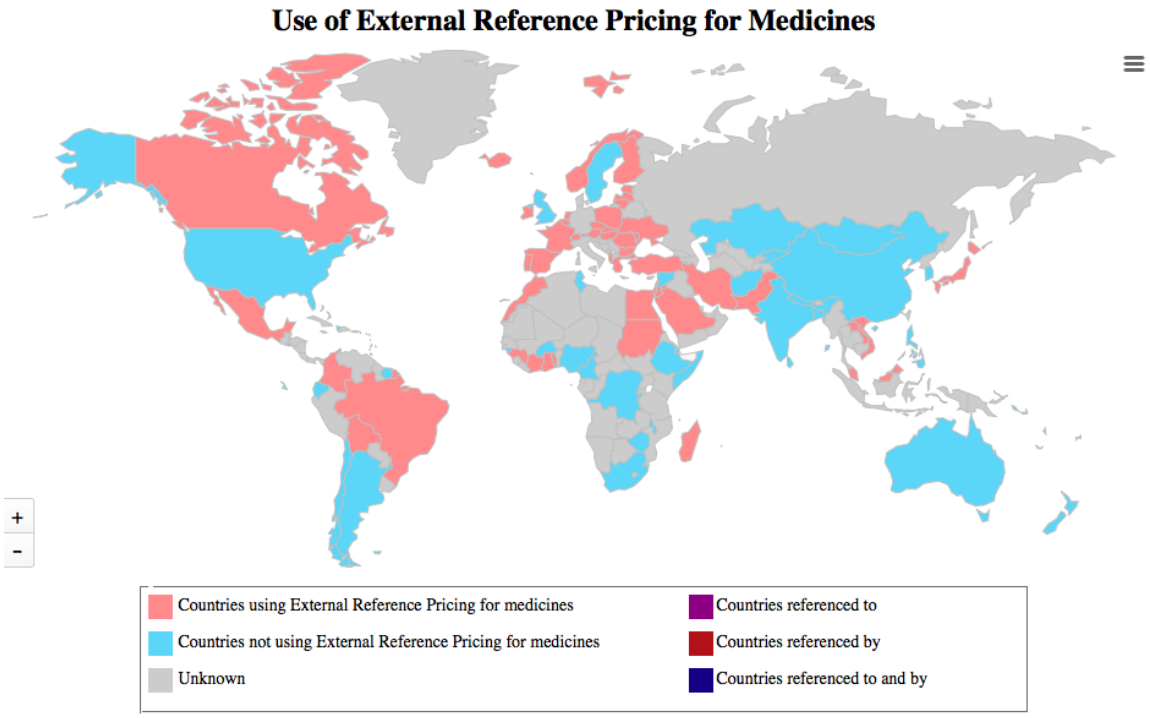
Sustainable Development Goals (SDGs) (2015-2030)

After the Millennium Development Goals, another plan started its process which is Sustainable Development Goals (SDGs), new global goals for sustainable development. SDGs are applying to all nations around the world, trying to overcome many issues in different fields with the aim of tackling the inequality. Regarding this is issue collaborations are being made with UNITAID which's main donors are Norway, France, the Bill & Melinda Gates Foundation, Brazil, the United Kingdom, Spain, Chile, and the Republic of Korea. Its aim is to overcome more quickly, efficiently and with less price, the fatal diseases such as HIV/AIDS and malaria. Moreover, since the majority of the pharmaceutical companies are stated in the Sustainable Development Goals' Healthcare&Sciences field within every 17 goals, they are trying their bests to apply SDGs in their process.

World Health Organisation (WHO) Essential Medicines List (EML)

The WHO Essential Medicines List was first published in 1977 by The WHO Essential Medicines and Health Products Department (EMP) which is in cooperation with the countries to ensure people's access to qualified, effective and safe medicines. Their ideology is based on three words "access, innovation and regulation". EMP provides assistance to healthcare systems of many countries if they are willing to have an assistance and a promoted and determined policy on cost-effectiveness. This system is efficient in low-resourced health systems. It takes their system to an international and equal level so, the manufacture and regulations are at a high standard. The idea of establishing an Essential Medicines List has been an action in order to apply the World Health Assembly (WHA) Resolution WHA28.66. The 20th renewal of the Essential Medicines List was published in June 2017 for the 40th anniversary of the application of WHA resolution. 95 percent of developing countries have published an EML but only 86 percent of them updated it. Since the developing medicines are changing and people's needs are also changing each year, it should be updated regularly in order to have an effective impact on the health system.

Also, there are other regulations that some countries base their health system on. Essential medicines are determined and a price for them is suggested. Here are the countries using external reference pricing:



Patent System and Generic Drugs in Pharmaceutical Industry

In 1994, The World Trade Organization was established after the conclusion of the Uruguay Round of Trade Negotiations. After the succession of the Uruguay Round, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was created. Its main aim was to make the system of international trade more equitable. Pharmaceutical products are a big part of the high technology products which are also included in this agreement. TRIPS Agreement gave least developed countries and developing countries the opportunity to have a patent protection for pharmaceutical products. The more the patent protection increases, the more research-based industries are constituted in developing countries. But still, majority of the pharmaceutical research in these regions are made by the public sector. The pharmaceutical industry complains about the regulations and legal frameworks regarding the costs of pharmaceutical products. Type of patent rights' availabilities especially in Less Economically Developed Countries (LEDCs) is a big controversy between governments and the industry during the last few decades.

A patent is the exclusive rights that someone has when they find a new invention which is a new technical solution to a problem. A patent also excludes other people from manufacturing or selling the said invention for a specified amount of time. In the pharmaceutical industry it is a bit different from others since the patent is the newly found medicine, thanks to an expensive R&D process and clinical testing. When the patent is the newly-founded product itself, it becomes open to replication from other parties excluding the expensive R&D process which is immensely cheaper. So, the pharmaceutical industry always wants to ensure the patent protection in order to defray the money spent on R&D.

Generic Drugs are the copies of normal, brand-named drugs and they also have the same characteristics. Their effects, side effects, amount of medication, route of consuming, they are all the same. There are always concerns about the efficiency, quality and the "reality" of generic drugs since they are cheaper than the original ones. But the only reason they are cheaper is that while firms constitute generic drugs they don't pay for the R&D process and clinical trial. So, they do not have to defray the expenses of marketing a new product as well. As the patent taken by the manufacturer is near the expiration date, other pharmaceutical firms can apply for a permit to produce and sell the generic version of the medicine. Also, when the generic version is allowed, many companies manufacture them. This issue ends up with a competition between firms that lead to price abatement of the medicine.

Timeline of Major Events

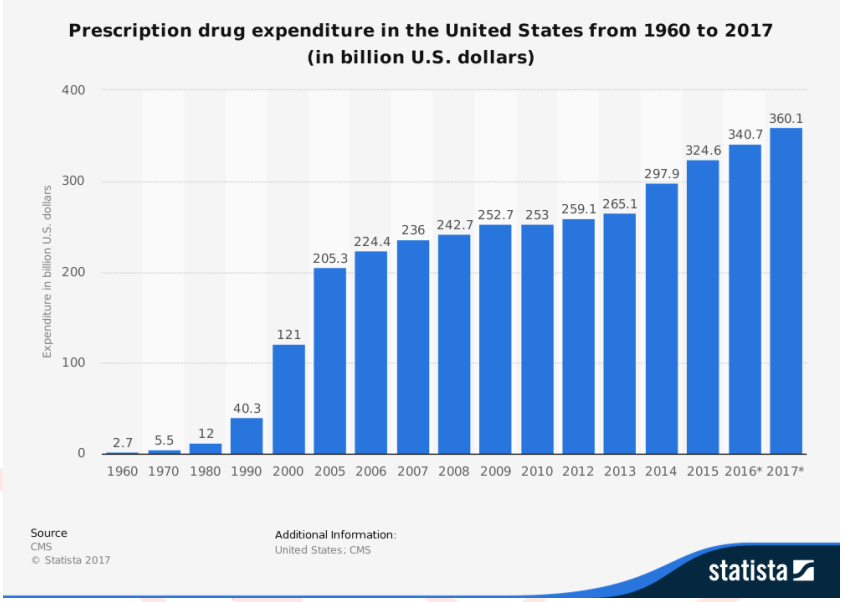
Date of Event	Description of Event
May 29th 1975	World Health Assembly's first resolution on the necessity of developing drug policies (WHA28.66)
1977	The establishment of the first World Health Organization Essential Medicines List
September 20th 1986	The Uruguay Round of Trade Negotiations
January 1st 1995	The establishment of the World Trade Organization (WTO)
September 2000	The United Nations Millennium Declaration (The United Nations Millennium Development Goals)
September 25th 2015	The United Nations Sustainable Development Goals

November 19th 2015	The establishment of United Nations Secretary-General's High-Level Panel on Access to Medicines
July 18th 2016	United Nations Human Rights Council adopts a resolution on "Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (A/HRC/RES/32/15)

Major Countries and Organizations Involved

United States of America

The US food and drug administration does very little to regulate drug prices. Over the last decade and a half, the US drug companies have spent nearly 3 billion dollars lobbying congress to prevent federal government from increasing such regulations. Perhaps for this reason the US drug prices are some of the highest in the world. 72% of the Americans think that drug prices are unreasonable. The inequitable prices of drugs had also become a political issue during the presidential elections.



Also, it is a very current topic in the United States of America. President Donald Trump stated that his administration will be dealing with the excessive and inequitable drug prices and he also said that pharmaceutical companies are “getting away with murder”. Americans are currently paying two to six times more than the other country’s people for the same treatment. United States of America is actually determining the “monopoly” itself by giving the rights to keep a patent for 20 years or even more at the same one manufacturer.

Canada

Canada is paying one of countries who pay the highest prescription drug prices in developed countries. Sometimes it causes limited access to healthcare and it is a big financial burden for Canadians. In May 17th 2017 Canada decided to amend its drug price regulations after a long time. Also in April 1, 2018 a new regulation will be in progress about generic drugs. Canadian drug industry will take most commonly prescribed generic drug prices from 25 per cent to 40 per cent. So generic drugs will be 90 per cent cheaper than their brand-name equivalents. This will be a five-year agreement and the pharmaceutical industry will know the prices before putting them in the market. It will also, reduce the medicine prices in total because of such competition.

France

Generic drugs are widespread in France. Normally, the government was taking a little part of the family budget and income and kept in in a bank account. It is similar to the taxpayer-funded system. When people bought medicines, firstly they payed, but after that they got the money back from the government with the insurance system's help. But, this system isn't effective anymore. The government is in a big debt because of the prices of medicines and they asked the public if they would accept if they pay only the cheap medicines out of pocket and the rest would be belonging to the government. Since French people were used to the other process, they didn't want to pay the cheap medicines as well. So, the government is in a controversial status right now and it is trying to arrange and decide on the budget allocation.

Brazil

10 years before now, many maladies were widespread in Brazil. Health Ministry saw the increasing prices of pharmaceutical products and claimed them as a treat to the well-being of their people and revolted against these prices. After that, Brazil decided to violate the international patent system and develop unauthorised generic drugs. With the commencement of the produce of generic drugs, pharmaceutical prices decreased 80% which lead to demands of 40 pharmaceutical company to an investigation against the Brazilian Government. There are developments in Brazil for the treatment of local diseases. They are using patents from pharmaceutical industries in order to sell them at reasonable prices where the local disease exists so that countries that can not afford normal medicines will be able to afford these ones.

United Kingdom

United Kingdom's drug prices are in the cross-country comparison between developed countries in order to see the ceiling prices. The pharmaceutical products' prices are used as a reference in many countries such as, Portugal, Luxembourg, Italy, Ireland and Greece. United Kingdom has one of the lowest medicine prices and it is estimated that it will be decreasing in the upcoming years. U.K. uses taxpayer-funded National Health Service which ensures people the chance to have free healthcare.

Previous Attempts to Solve the Issue

For decades, this issue is trying to be solved. However, the dispute between governments and pharmaceutical industry doesn't end. Drug companies argue that, if the money spent on medicines decrease, then they won't have enough budget to realize effective R&D and clinical trial process, which will lead to less-tested and risky medicines in the market. On the other hand, people are dying, since they can't afford the inequitable prices of pharmaceutical products. Many in-state or in-continent regulations

have been made. But nothing was applicable as a universal regulation. There have been resolutions of UN Human Rights Council and World Health Assembly who were adopted (note: I put their links in the next part) but they didn't work. The United Nations Secretary-General itself established a panel with a special emphasis on this issue but it wasn't enough and it didn't cover global actions. European Union members are doing physical arbitrage across country borders and it has a chance to reduce the prices in the market. The prices started being uniform with this technique but it is only legal in E.U. It is illegal between most countries. Generic drugs are produced but still some people don't trust to them and not every type of medicine's generic is existing because of the patent system and its long duration.

Possible Solutions

Even though, there are some price regulations between countries, a universal one hasn't been established yet. It is really hard to convince each State to agree on the same rules and procedure by pricing medicines in their market. Briefly, this regulation should cover up the negotiations between the payer and the manufacturer. Each country's GDPs can be used as a measure to determine the prices of pharmaceutical products in their market. The patent system could be changed and a patent's duration could be decreased in order to produce more generic drugs for different types of diseases. Since, R&D is one of the major causes of the augmentation of the medicine prices, R&D costs should be de-linked from the price of the product. Governments need to negotiate as much as possible in order to take action against high R&D costs.

Useful Links For Further Research

*https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf (Highly suggested to read. It gives further detail on the aforementioned points)
*https://epha.org/wp-content/uploads/2017/10/EPHA-Reflection-Paper-Beneluxa-A2M.pdf (Also highly suggested to read for the negotiation of several countries commenced by Belgium and The Netherlands)

*http://ap.ohchr.org/documents/alldocs.aspx?doc_id=26940 (click to A/HRC/RES/32/15)
*https://home.kpmg.com/content/dam/kpmg/xx/pdf/2017/05/sdg-healthcare-life-science.pdf
*http://www.un.org/millenniumgoals/2015_MDG_Report/pdf/MDG%202015%20rev%20(July%201).pdf
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