Committee/Council: ECOSOC

Issue: Defining governmental intervention in the pharmaceutical industry

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Introduction

The control of the pharmaceutical industry is crucial for a functioning health care system, as the lack of professional knowledge amongst the population is huge, which is, consequently, easily exploited by the industry. Due to the controversy and aggravation concerning this topic it is vital to find measures, which have to protect the citizens without harming the industry. The first step has already been taken many years ago, as almost all countries have now established governmental bodies which control pharmaceuticals concerning their efficiency and safety. The regulations set by those organizations are completely necessary and it is out of question to establish a fully privatized and uncontrolled pharmaceutical industry. Access to health care is a social right and a fully independent pharmaceutical industry would be fatal. The uncontrolled power of health should not be accessible to any company and it is very important that the government plays a major role in the particular industry. The product's safety, efficacy, quality, fair health costs to society and equity in access to pharmaceutical products needs to be controlled and ensured which is the government's responsibility. State involvement in price control could be one way to handle this issue, whereas long-term solutions such as

regulating the amount of drugs allowed on the market for a specific illness are more effective and result in higher quality and lower prices for pharmaceuticals through tougher competition on the market.

The pharmaceutical industry has a big lobby in almost every MEDC, and, therefore, influences the decisions taken by the government which is unfortunately not the only reason why it is difficult to regulate such companies. Doctors are also influenced directly which will be explained in the background information section.

Another issue is price control of pharmaceuticals and how that can be achieved. Although experience of industrialized countries has demonstrated that price control, when properly enforced, can be effective in maintaining low prices, it may not be able to deliver the desired results in terms of equity and efficiency. Price control is a measure which is fastidious in its implementation and economists state that ‘’These mechanisms, in effect, subsidize the cost of drugs for the entire population. In an overall context, the lowest possible price may not be the most desirable. For example low prices may drive excessive consumption, thereby actually increasing pharmaceutical expenditures. Low prices may also not provide sufficient economic incentives for producers of low-cost products sold by generic names to enter the market, and thus will limit price competition. The proper objective should be the attainment of the “right” price which will property balance sometimes conflicting factors in the context of national situations and needs. ‘’

Definition of Key-Terms

The Principle of Public Control

The principle of public control relies on the loose control of prescription-free drugs which are then freely tested on the market, which entails that drugs of that category are easy to obtain and, if problems with their prescribed effect or side effects occur, they are prosecuted by the public. The flaws of that system, for which it is often criticized, are that a harm due to ineffective drugs is not avoided and simply tested on civilians. Besides it is also claimed that financially weak citizens can’t afford lawsuits against huge pharmaceutical companies, and, therefore, most probably won’t receive any damages. In addition to that, although some pharmaceuticals might not pose a threat to the patient, they can also be completely ineffective, which might lead to a worsening of the particular illness due to the fact that patients might rely on the wrong pharmaceuticals. In that case the absence of specialized knowledge on the issue is exploited and the public is endangered, which is one of the major criticisms.

The Principle of Premarket Control

Premarket Control means that all drugs are tested harshly on their effectiveness, and, in most cases, only the most effective ones are then released on

the market. In order to sell a drug on the market the pharmaceuticals require a license given by the licensing authorities. Only then, the company is allowed to sell the product.

Post-marketing surveillance

The Post-marketing Surveillance ensures that after the drug is licensed it is closely monitored. Under special circumstances, the product is limited to a particular patient group, and in other cases the substance is taken from the market completely.

Orphan drugs

"There are special rules for certain rare diseases ("orphan diseases") in several major drug regulatory territories. For example, diseases involving fewer than 200,000 patients in the United States, or larger populations in certain circumstances are subject to the Orphan Drug Act. Because medical research and development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions, fee waivers, and market exclusivity on that drug for a limited time (seven years), regardless of whether the drug is protected by patents." - http://www.chemeurope.com/en/encyclopedia/Pharmaceutical_company.html

Background Information

Licensing Process

In the US, new pharmaceuticals must be approved by the Food and Drug Administration (FDA) as being both safe and effective. This process requires the submission of an Investigational New Drug filing with sufficient pre-clinical data in order to proceed with human trials. The IND approval induces the next process of licensing which consists of three phases, which require progressively larger human clinical. Generally in phase I toxicity is checked on healthy volunteers. In Phase II pharmacokinetics and dosing in patients are monitored and tested. The successful fulfillment of Phase III which consists of a very large study of efficacy in the intended patient group leads to a New Drug Application which is then submitted to the FDA. The results are then reviewed by the FDA and approved, if the clinical studies and the whole study have proven the pharmaceutical to have a positive benefit-risk assessment. As even the largest clinical trials may fail to predict effectively the prevalence of rare side-effects often a fourth phase of approval is required called the post-approval surveillance or post-marketing surveillance mentioned in the Key-Terms section.

In the United Kingdom and in the European Union the European Medicines Agency (EMA), located in London, licenses and approves drugs. Although the whole evaluation is done by the EMA in the UK, the Medicines and Healthcare Products Regulatory Agency approves drugs for use. Usually, an approval for pharmaceuticals

in the UK and other European countries is given later than one in the United States. Following the EMA approval it is the National Institute for Health and Care Excellence (NICE), National Health Service (NHS) and the British National Formulary as the core guide for pharmacists and clinicians, for England and Wales, and the respective national agency in every European countries which decide in the end if the product reaches the national market.

In many western countries, except for the US a 'fourth hurdle' of cost effectiveness analysis has been developed before new technologies can be provided. This focuses on the efficiency of the technologies in question rather than their efficacy. The authorities in England and Wales (NICE), Scotland (Scottish Medicines Consortium) and Australia (Pharmaceutical Benefits Advisory Committee) cooperate and those agencies in course of licensing drugs generally follow the same principle of 'value for money' which is one of the most important aspects in protecting the society and controlling the pharmaceutical industry.

Patents and generics

Depending on various factors, a company may apply for a patent for the drug, or the process of producing the drug, granting the "receipt" and, therefore, the production of the particular pharmaceutical exclusively to the company. Those patents, which typically last for about 20 years, are also often sold within the industry. However, authorities grant permissions only after rigorous studies and controls, which in some cases take up to 15 years. This process allows the patent-holder to recover the costs of research and development through high-profit margins for the branded drug. Usually, when the patent for the drug expires, a generic drug is developed and sold by competing companies. As the development and approval of generics is less expensive, they can be sold at a lower price. In most cases, the owner of the branded drug himself will introduce a generic version before the patent expires in order to guarantee the company a head start in the generic market. Resulting out of the mass-patent expiration of products during the industry's "golden era" in the 1990s restructuring has become a routine as the companies fail to promote new blockbuster products.

Controversy about drug marketing and lobbying

There has been increasing controversy surrounding pharmaceutical marketing, and influence, as accusations and findings of influence on doctors and other health professionals through pharmaceutical representatives, including the provision of marketing 'gifts' and biased information to health professionals, have lead to the suspicion of influencing doctors' decisions in a way that profits the pharmaceutical company. This has in some cases resulted in doctors prescribing products, which would not benefit the patient at all or less than other drugs due to the afore mentioned strategies used by the industry to influence doctors in their interest of profit. The negative effect of drug marketing on physicians has often been criticized by advocacy groups such as "No Free Lunch", but the huge lobby the industry has established, makes it difficult for such activist groups to achieve any of

their goals. Lobbying and marketing by the pharmaceutical industry has expanded to highly prevalent advertising in journals and conferences as well as funding independent healthcare organizations and health promotion campaigns and lobbying politicians and physicians more than any other industry in the US. The lobbying agenda of the industry goes even further through sponsorships of medical schools or nurse training as well as continuing educational events in which the companies ensure themselves a significant influence on the curriculum. Also, hiring physicians as paid consultants on medical advisory boards form the entire marketing and lobbying actions of the industry. The extend lobbying has reached in this sector, leads to reasonable fear of how independent doctors nowadays are and this is where the state should interfere in order to provide a fair and more transparent healthcare system, which is truly beneficial for its population. As in this case the population's lack of professional knowledge is deliberately exploited, and it is the governments' obligation to protect its citizens, whereas the industry should of course not be completely disregarded.

The involvement of the industry in the training of doctors and nurses is being fought, as Meta-analyses show that is more likely that a psychiatric study reports positive results if it is sponsored by a pharmaceutical company, the effect is even larger when an employee of the company itself is involved in the study.

The expansion of the criteria of the Diagnostic and Statistical Manual of Mental Disorders has been claimed to represent an increasing medicalization of human nature, also known as "disease mongering", driven by drug companies which again shows the influence the industry has on the physicians. The influence this has on the treatment through the abovementioned medicalization is that psychological sessions, which aim at a drug-free patient recovery, are replaced by a pharmaceutical treatment which benefits the industry. The problem is that pure psychological treatment via sessions with professionals in combination with the lowest use of pharmaceuticals is often more beneficial for the patient than a treatment with psychiatric drugs. This is due to the fact that psychiatric drugs have a huge amount of strong side-effects, such as but not limited to weight loss or gain, as well as the precision rate of such drugs is low, which in some cases can lead to a worsening of the patient. The suspicion for direct conflict of interests has been raised lately, as about half the authors who composed he DSM-IV psychiatric disorders (one of the most important list of mental disorders) , have, or have had financial relationships with the pharmaceutical industry.

Since 2013, accompanied by the Physician Financial Transparency Reports (part of the Sunshine Act), the Centers for Medicare & Medicaid Services obligatory collects information from group purchasing organizations and applicable manufacturers in order to report their financial relationships with hospitals and physicians. Data is then publicly accessible in the Centres for Medicare & Medicaid Services website, providing full transparency.

Major Countries and Organizations Involved

FDA

"The **Food and Drug Administration** (**FDA** or **USFDA**) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products." – Wikipedia

EMA

"The European Medicines Agency is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. It began operating in 1995." – EMA

Relevant UN Treaties, Resolutions and Events

"Finding Evidence – Recognising Hype"

There also have been related accusations of disease mongering (over-medicalizing) to expand the market for medications. A conference on that subject took place in

Australia in 2006 leading to the establishment of the government-funded National Prescribing Service, and, launching the "Finding Evidence – Recognising Hype" program. Its goals were the education of General practitioners on methods for independent drug analysis.

Previous Attempts to solve the Issue

Previous attempts to solve the issue can be found in almost all countries, whereas many of the measures mentioned in the *Possible Solutions* section have been domestically enforced. A resolution by the UN on the issue has not been passed yet, and, therefore the International community should make even stronger efforts. An example for government intervention is the "Finding Evidence – Recognizing Hype" program in Australia (mentioned above). Other similar programs have been established in several countries, whereas a combination of those may result in a final solution for the topic.

Although measures have been imposed, the industry has used the power it has in politics through lobbying and most measures include loopholes. Thus, it is easy for companies to use those. In Europe the situation is not as critical as it is in the US where the industry is practically unassailable. In the end, the legislation missing is regulations that prevent exploitation at such a degree, and, especially in that industry, which the whole population relies upon and is therefore easily exploited.

Possible Solutions

The intervention of the government into a particular industry is always a difficult and controversial topic, since measures need to be implemented that regulate the industry without harming it, and, protect the population simultaneously.

Considering this topic, the problem is the versatility of the lobbying and the marketing the pharmaceutical industry is processing. One of the strategies is the direct influence on physicians which needs to be tackled immediately. Effective legislation to prevent and monitor such should be proposed, whereas the transparency provided in some countries is the first step towards a fair healthcare system aiming at the best possible treatment for the patient and not maximum profit. Although those measures make it harder for companies, this is just a small step towards a controllable industry. In order to provide the best service for patients, a doctor needs to be free of any possible profit he might have, and, in order to achieve this, pharmaceutical industries must be prevented from being able to somehow influence doctors, which could be achieved through the imposition of financial punishments.

Besides, the worldwide regulation of drugs allowed on the market for a particular illness should be established. This will provoke competition, as only the most effective and cheapest drugs will be licensed, thus, the industry will "regulate itself" through competition.

When governments intervene in pricing, the goal is to determine prices that will ensure affordability and equitable access, and to limit unnecessary consumption and rapid price growth, in order to avoid excessive costs resulting in societal burdens. Whereas LEDCs and developing countries have to emphasize on improving access, while MEDCs focus on cost-containment. Many mid-income countries deal with both challenges.

Alternatives exist which can achieve the same goals as price control. Access to healthcare can be improved through shifts in financing methods such as but not limited to the expansion of insurance coverage. Price competition can also be enhanced in markets in order to contain lower prices without direct intervention by promoting the use of compulsory licensing for products with limited competition.

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