Committee: Economic and Financial

Topic: The question of protection from pharmaceutical medicines globally

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Summary

The modern pharmaceutical supply chain is an intricate international endeavour, with one of the biggest issues facing the pharmaceutical industry is its necessity. Pharmaceutical products are made from ingredients sourced from many different countries. Final formulations are then exported, packaged, repackaged with the view for the sale of these items to not only be within the country of manufacture, but across the globe. The multi-faceted involvement of not only manufacturers, but consumers, leaves more and more opportunity for substandard and in some cases lethal products to infiltrate the market.

The pharmaceutical industry is structured in a manner that ensures that companies can communicate with each other on a frequent basis, directly and in person, which often allows for collusion.

Whilst pharmaceutical companies have historically been seen to work alongside governments, as it is regarded in many countries' agenda as a part of their welfare commitments, have now come under great scrutiny. The rising power and capability of pharmaceutical companies to function as a business rather than solely as a catalyst for social and health social good has led to a shift in the balance of power and priority of those organisations.

This generates it a problem for member states. Will this mean that more regulation should be put in place to manage these 'businesses? How do we safeguard citizens? Is it the role of the state to safeguard citizens in hope of not being an autocratic, totalitarian, paternalistic state?

Definition of Key Terms

Negative externalities – A negative externality is a cost that is suffered by a third party as a result of an economic transaction.

Regulation – Is a rule or directive made and maintained by an authority.

Pharmaceutical – Is relating to medicinal drugs, or their preparation, use, or sale.

Pharmaceutical company - The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered to patients, with the aim to cure them, vaccinate them, or alleviate the symptoms.

Totalitarian – Is relating to a system of government that is centralised and dictatorial and requires complete subservience to the state.

Paternalistic – Is relating to or characterised by the restriction of the freedom and responsibilities of subordinates or dependents in their supposed interest.

Autocratic – Is relating to a ruler who has absolute power, taking no account of other people's wishes or opinions; domineering.

Background Information

Changes to the way that pharmaceutical products are manufactured and distributed could not only improve pharmaceutical product quality around the world, but the monopoly of trade that some manufacturers have within the industry. A key problem with the pharmaceutical industry is that as many member states are unable to produce the products themselves, they rely upon suppliers, which gives them the leverage to be able to be able to charge at their own will. This has risen to prominence within the United Kingdom with the Competition and Markets Authority (CMA) stated that the cost of prochlorperazine (a product used to treat nausea most commonly but also schizophrenia, migraines and anxiety) rose from £6.49 per pack to £51.68 after suppliers came to the agreement to not compete with each other. With the annual cost for the National Health Service (NHS) for prochlorperazine increasing from £2.7 million in 2013 to £7.5 million in 2018, despite less packs being dispensed in 2018.

Major Countries and Organisations Involved

United States of America

7 top pharmaceutical executives have testified before the Senate Finance Committee, they were from AbbVie Inc., AstraZeneca, Bristol-Myers Squibb, Johnson & Johnson, Merck & Co., Pfizer and Sanofi.

In the United States of America approximately three-quarters of all pharmaceuticals are bought in retail pharmacies, half of which are national chains or food stores with an internal pharmacy.

There has been an increase in critical opinions expressed towards pharmaceutical companies and the pharmaceutical products that are administered. There has also been an increase in the pricing of these products as a result from what can be considered as a rise in the power of multinational corporations (MNCs), leading to a decrease in state power.

Last year, several companies agreed to hold off on planned price increases, but only for six months, and seemingly only after President Trump chastised them on Twitter. Those same companies have aggressively resisted both state and federal efforts to enact formal changes to medicine pricing rules and attempts of regulation.

President Trump has not kept his campaign promise to “negotiate like crazy” with pharmaceutical companies to lower the cost of their products, and his statement last May that the industry would soon announce “voluntary, massive” price cuts came to naught. However, his bluster on the issue, along with his blueprint for resolving it, has at least helped to keep a prominent spotlight on the pharmaceutical industry and its questionable practices.

In May 2019, 44 states filed 500 page lawsuit against 20 generic pharmaceutical companies (in that they produce a variety of products), alleging product inflation of as much 1,000%, including TEVA USA, a subsidiary of the Israeli company Teva Pharmaceutical Industries Ltd. The products that the companies cited produce include antidepressants, anti-inflammatory medicine, contraceptives, products to treat cancer, high blood pressure treatment, HIV treatment and oral antibiotics. The lawsuit seeks damages, civil penalties and actions by the court in a bid to restore competition to the pharmaceutical industry.

People’s Republic of China

China is fast encroaching upon the United States of America’s global status, it is on the rise not only in a corporate sense but also in that of a political one.

In pharmaceuticals specifically, China is comfortably the second-largest national market in the world, with healthcare analytics firm Iqvia putting its value at $122.6 billion in 2017 and projecting growth to as much as $175 billion by 2022.

Multinational pharma firms are starting to make China a major priority for pharmaceutical product sales, as the potential for profit is now widely seen as a decisive counterbalance against the risks of operating under the Chinese regime.

The government's Healthy China 2030 policy places public health at the heart of its decision-making, and the acknowledgement that foreign innovators have a large role to play in meeting the country's health objectives is another signal that there has never been a better time for the pharma industry to invest in China.

United Kingdom

An influx of new research has led to the rise in families choosing to not vaccinate their children in 2019 in other member states, which echoes the events of 1974 in the United Kingdom where a report lay 36 neurological reactions firmly at the feet of a pertussis (also known as whooping cough) vaccination, which caused a decrease in the vaccination uptake from 81% in 1974 to 31% in 1980. As a result of the decrease in vaccinations there was a pertussis outbreak, which placed the National Health Service under great strain.

Commission on Narcotic Drugs (CND)

In the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem, adopted by the Commission on Narcotic Drugs in 2009, Member States established 2019 as a target date for the goals set out in the Political Declaration.In light of the 2019 target date, the Commission decided to convene a ministerial segment (CND Resolution 60/1) at its 62nd regular session from 14-15 March 2019, taking stock of the implementation of the commitments made to jointly address and counter the world drug problem.The Commission adopted a detailed work plan to prepare for the ministerial segment and held three rounds of inter-sessional meetings in September, October and November 2018. More information on the CND preparatory process for 2019. In addition, the Commission held a special segment on the preparations for 2019 at its reconvened session in December 2018.

International Narcotics Control Board (INCB)

The International Narcotics Control Board (INCB) is an independent, quasi-judicial expert body established by the Single Convention on Narcotic Drugs of 1961 by merging two bodies: the Permanent Central Narcotics Board, created by the 1925 International Opium Convention; and the Drug Supervisory Body, created by the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs. INCB has 13 members, each elected by the Economic and Social Council for a period of five years. INCB members may be re-elected. Ten of the members are elected from a list of persons nominated by Governments. The remaining three members are elected from a list of persons nominated by the World Health Organisation (WHO) for their medical, pharmacological or pharmaceutical experience. Members of the Board shall be persons who, by their expertise, competence, impartiality and disinterestedness, will command general confidence. Once they have been elected, INCB members serve impartially in their personal capacity, independently of Governments.

World Health Organisation (WHO)

WHO works worldwide to promote health, keep the world safe, and serve the vulnerable. Their goal is to ensure that a billion more people have universal health coverage, to protect a billion more people from health emergencies, and provide a further billion people with better health and well-being.

Timeline of Events

Date	Description
1839 – 1842	The first Opium War - due to military defeats China was made to sign treaties which allowed many ports to be open for trade. Certain restrictions under the Carton system were abolished and Opium, despite imperial prohibitions, now became a regular item of trade. This opium flooded the Chinese market, its price dropped, local consumption increased rapidly, and the drug penetrated all levels of society. Imports began to increase rapidly in the 1830s, however, as “free trade” agitation gained strength in Britain and the East India Company’s monopoly over the China trade approached its termination date (in 1834). The Company became more dependent than ever on opium revenue, while private merchants hastened to increase their stake in the lucrative trade. On the eve of the first Opium War, the British were shipping some 40,000 chests to China annually.

	By this date, it was estimated that there were probably around ten million opium smokers in China, two million of them addicts.
December 1853	United Kingdom Vaccination Act 1853 made it compulsory for all children born after 1 August 1853 to be vaccinated against smallpox within the first three months of their life
1992	Prescription drug user fee act was created by Congress in 1992 and authorises FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.
2007	FDA amendments Act
2009	The Biologics Price Competition and Innovation Act of 2009 was enacted as part of the Affordable Care Act. This statute created an abbreviated pathway to approve biosimilar products. A biosimilar is almost identical to the biologic parent compound. Therefore, a biosimilar product is not a generic. For a product to be approved as a biosimilar, it must have the same mechanism of action, dosage form, strength, and indication as the biologic or reference product. In addition, to get a biosimilar approved, this legislation “requires that there are no clinically meaningful differences in safety, purity, and potency between a biosimilar and the originator product. A demonstration of

biosimilarity requires analytical data, animal testing, and clinical studies, unless a requirement is determined by the Secretary [of the Department of Health and Human Services] to be unnecessary." Finally, manufacturers must show that their facilities meet FDA standards when producing these biosimilar products. Because of the complex biologic structure and numerous testing guidelines and standards needed to obtain approval of a biosimilar, not many of these products are on the market.

March 23 2010

President Obama signed Into law The Patient Protection and Affordable Care ActThe Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the PHS Act and other statutes to create an abbreviated approval pathway for biological products shown to be highly similar (biosimilar) to, or interchangeable with, an FDA-licensed reference biological product. of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act amends section 735 of the Federal Food, Drug, and Cosmetic Act to include 351 applications for biosimilar or interchangeable biological products in the definition of "human drug application" for the purposes of the prescription drug user fee provisions.The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a user fee program for biosimilar and biological product applications for FYs 2013 through 2017.

2013	The Venezuelan crisis can be pressured to kickstart here - with the death of Hugo Chávez.Maduro, who Chávez groomed to replace him, was elected into office less than a month later, gaining 50.6 percent of the vote.Chávez was a charismatic and admired leader in Venezuela, largely thanks to his social welfare programs. After he assumed the presidency in 1999, he continued nationalising the oil industry and used the profit to fund food subsidies, education and health care programs. Under his administration, unemployment and poverty halved, and income per capita more than doubled.
December 30 2014	Venezuela's Central Bank confirmed on December 30 that the country had entered a recession due to plummeting oil prices. The inflation rate that year surpassed 63 percent, the highest in the Americas. The government was forced to make cuts in public spending, making it difficult for poor Venezuelans to access food and medicine.
November 8 2018	The United Nations Refugee Agency announced that over 3 million people had fled Venezuela due to massive shortages of food and medicine.
May 2019	44 states file a lawsuit against 22 generic pharmaceutical companies in the United States of America

Relevant UN Treaties and Events

Single Convention on Narcotic Drugs of 1961 1961

The 1961 Single Convention is an international treaty with the role to expand existing control measures to cover the cultivation of plants from which narcotics are derived. These provisions placed an especially heavy burden on the traditional producer countries in Asia, Latin America and Africa where the cultivation and widespread traditional use of opium poppy, coca leaf and cannabis were concentrated at the time. The Single Convention set the target of abolishing traditional uses of opium within 15 years, and traditional uses of coca and cannabis within 25 years. Given that the Convention entered into force in December 1964, the 15-year period for gradually eliminating opium use came to an end in 1979, while the 25-year deadline for coca and cannabis expired in 1989. Traditional practices including religious use and the widespread "quasi medical" use of the three plants had to be abolished.

Convention Psychotropic Substances of 1971

The Convention establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other.

The three resolutions that were adopted in this convention:

Resolution I

PROVISIONAL APPLICATION OF THE CONVENTION ON PSYCHOTROPIC SUBSTANCES PENDING ITS ENTRY INTO FORCE

The Conference,

1. Invites States, to the extent that they are able to do so, to apply provisionally the measures of control provided in the Convention on Psychotropic Substances pending its entry into force for each of them;

2. Requests the Secretary-General to transmit this resolution to the Economic and Social Council, the General Assembly and the World Health Organisation, with a view to their reaffirming the invitation contained herein.

Resolution II

RESEARCH ON THE AMPHETAMINE DRUGS

The Conference,

Considering that the amphetamines are particularly liable to abuse and are objects of illicit traffic,

Considering that the therapeutic value of these drugs, though acknowledged, is limited,

1. Requests the World Health Assembly to encourage research on less dangerous substances capable of replacing the amphetamine drugs, and to sponsor such research within the limits of the available resources;
2. Recommends that governments with the necessary facilities should take similar action.
Countries are encouraged to to carry out research and expand their knowledge on alternatives to amphetamine drugs and hopes for a heavy handed global effort to be made from those able.
Resolution III
TRIBUTE TO THE FEDERAL GOVERNMENT OF THE REPUBLIC OF AUSTRIA
The Conference,
Being convened by resolution 1474 (XLVIII) of the Economic and Social Council of 24 March 1970,
Having met in Vienna from 11 January to 21 February 1971, at the invitation of the Government of the Republic of Austria,

United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988

This Convention provides comprehensive measures against drug trafficking, including provisions against money laundering and the diversion of precursor chemicals. It provides for international cooperation through, for example, extradition of drug traffickers, controlled deliveries and transfer of proceedings.
None of the controlled drugs were declared in the aforementioned treaties as 'illegal'. The drugs were only brought under different levels of control, depending on which Schedule they were classified in. The substances in themselves were not prohibited, but their production and trade were subject to strict controls in order to limit their use to medical and scientific purposes. The oft-mentioned terms 'illegal drug' or ‘illicit drug’ do not actually appear in the United Nations conventions.

1925 International Opium Convention

This was due to the high rise of usage of the substance in China. Twelve countries met in Shanghai and set up the International Opium Commission to discuss the possibilities for imposing international controls on the opium trade for the first time. The delegates resolved – though without committing themselves – to put an end to the practice of smoking opium,

restricting its use to medical purposes, and control its harmful by-products. No attempt was made at the time to apply criminal law in this regard.

Previous Attempts to solve the Issue

Building upon existing efforts of the United Nations, MI4A is a database with the purpose to identify and attempt to address the issue of affordability and shortage for self-funding, self-procuring and emerging member states that find themselves to be excluded (either intentionally or unintentionally). This database acts as a tangible response to World Health Assembly (WHA) Resolutions and World Health Organisation Strategic Advisory Group of Experts (SAGE) requests for action.

Furthermore, the International Federation of Pharmaceutical Manufacturers and Associations (FPMA) has committed to continuing their work advocating for policies to be implemented that support further access to medicines. The International Federation for Pharmaceuticals Manufacture and Associations put great emphasis upon the idea the pharmaceutical industry is a global concept, with the organisation having member companies implement more than 200 programmes, worth an estimated $9.2 billion.

Possible Solutions

To what extent do pharmaceutical companies have human rights responsibilities to uphold a person's right to healthcare?

More regulation - Usually to curb a MNCs free reign in the market, regulators and regulation is used by the government. Could this be done for pharmaceuticals? Delegates must consider whether they want to disrupt their free market and perceive whether they value the pharmaceuticals to administer public goods rather than go without or raise the price of that good/service.

Pharma industry has an influx of power as they are an oligopolistic/monopolistic market - right now the the industry contains; research, trails conducted, administration, producing and selling of drugs. A parallel can be seen between the present-day pharma industry and the past American oil company belonging to John Davison Rockefeller. Delegates can look at the past consequences and actions taken to break the monopoly.

Information provision/freedom from biased research - In increasing the amount of research conducted this would help rule out the bias in the production of these industries. Using the vaccine as an example where research should be conducted and also free from restriction.

The possible addition of new firms, to the market however the loss of efficiency or the guarantee of efficiency. Depending on the country and its own economy this may make a substantial difference for each country if it were inaction. It also is important to understand how a country would have to either increase or decrease this, will it be government led in regulation or will it be a softer approach where governments aim to encourage or use methods of soft power as opposed to hard?

Does this industry run as a business or as a public service? (countries may perceive this differently and act accordingly). This is a heavy topic of discussion and countries may view this hard to answer. When looking at your country take into account it's welfare services, for example The Uk had the NHS which acts as a public service rather than a business. This is different in some countries, perhaps the US.

Should there be an international organisation to which administers health care to those most vulnerable (So that conditions in countries such as Venezuela and Ukraine never become so severe) - would the UN are states finance it?

Should terms be redefined, as this is what held back a lot of the previous resolutions passed? Redefined terms will make it hard for a country to accept a resolution and not ratify it, as this is what happened in the past. It will make them accountable for what they sign and agree to, this may have a negative effect as it could make countries less willing to agree or sign resolutions.

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