

WHO – Topic 1 – MEASURES TO IMPROVE THE GLOBAL PHARMACEUTICAL INDUSTRY



World Health Organization

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INTRODUCTION TO THE COMMITTEE

The World Health Organization (WHO) is a specialized agency of the United Nations responsible for international public health. The WHO is headquartered in Geneva, Switzerland and was established on April 7, 1948. It consists of 194 member states and two associate members. The organization is governed by the World Health Assembly, which meets annually and is attended by delegations from all member states.

Its primary objective is to ensure that people around the world enjoy the highest possible level of health. The organization is responsible for a wide range of activities, including disease control and prevention, health promotion, and emergency response. The WHO is also responsible for coordinating the global response to pandemics and

other health emergencies, and for providing technical assistance and support to countries in need.

INTRODUCTION TO THE TOPIC

The global pharmaceutical industry is a complex and highly regulated sector that is responsible for developing, manufacturing, and distributing drugs and other medical products around the world. The industry is made up of a wide range of companies, from large multinational corporations to small startups, and it employs millions of people across the globe. The industry is also subject to a range of regulations and standards, which are designed to ensure that drugs are safe, effective, and of high quality.

Despite the challenges facing the industry, it continues to be a critical part of the healthcare system, and it plays a vital role in improving health outcomes for people around the world. It is facing several challenges that have led some experts to call for reform. Some of the most pressing issues include high drug prices, limited access to affordable medicines, and concerns about the safety and efficacy of some drugs. Additionally, there are concerns that the industry is not doing enough to promote innovation, particularly in areas where there is a high unmet medical need. By reforming the industry, it may be possible to address some of these issues and ensure that people around the world have access to the medicines they need to stay healthy.

HISTORY

The pharmaceutical industry is one of the largest markets in the world. But whereas some earn billions of dollars annually, others are suffering from the consequences of globalization. In almost all developing countries, a basic supply of medicines fails due to the systematic neglect of the development of medicines for the diseases that are widespread there and due to high price policies.

Compared to the many diseases, there is a very poor health care system and, above all, a very poor pharmaceutical industry. More than 85% of people worldwide have no or insufficient access to medicines, 90% of which are consumed by the richest 15% of the world. In addition, the global healthcare system is more than exhausted. Global pandemics like COVID-19, which can hit us all at any time, have shown that even economically strong countries lack sufficient health care.

CURRENT ISSUES

The global pharmaceutical industry faces several challenges and issues. Some of the current issues include:

1. High drug prices: The cost of drugs has been a long-standing issue in the pharmaceutical industry, with some drugs being priced out of reach for many patients. This issue has led to debates about the affordability and accessibility of essential drugs. There have been numerous reports and studies conducted on high drug prices in the pharmaceutical industry. Here are a few examples:
 - a) The Kaiser Family Foundation conducted a study in 2019 that found that nearly 1 in 4 Americans reported difficulty affording their prescription medications. The study also found that prescription drug prices are the top healthcare priority for Americans.
 - b) A report by the RAND Corporation found that the prices of prescription drugs in the U.S. are significantly higher than in other countries and that this difference cannot be explained by differences in research and development costs or manufacturing costs.
 - c) A study published in the Journal of the American Medical Association (JAMA) in 2019 found that the cost of prescription drugs for multiple sclerosis, cancer, and rheumatoid arthritis had increased significantly over the previous decade, with some drugs costing tens of thousands of dollars per year.

2. Intellectual property rights (IPR): The pharmaceutical industry is heavily reliant on intellectual property rights to protect its investments in research and development. However, critics argue that these protections can stifle innovation and limit access to essential medicines, particularly in low-income countries. Here are some reports and studies related to IPRs in the pharmaceutical industry:
 - a) A report by the World Health Organization (WHO) found that IPRs can limit access to essential medicines, particularly in low-income countries. The report called for greater collaboration between industry, governments, and public health stakeholders to ensure that essential medicines are available to all who need them.
 - b) A study published in the Journal of Medical Ethics found that patents can sometimes create a monopoly for drug manufacturers, leading to higher drug prices and reduced access to medicines. The study called for greater consideration of the ethical implications of IPRs in the pharmaceutical industry.

3. Clinical trials and drug safety: The safety and efficacy of drugs are typically tested in clinical trials, but there have been concerns about the transparency and rigor of some trials. There have also been instances of drugs being approved and later found to have serious safety issues, leading to calls for greater oversight and regulation of the industry. There have been numerous

studies done on this such as:

- a) A report by the Institute of Medicine found that the clinical trial system in the U.S. needs significant reform, with many trials being conducted too slowly and at too high a cost. The report called for greater collaboration between industry, government, and academia to improve the clinical trial system and ensure that drugs are brought to market more quickly and efficiently.
 - b) A study published in the Journal of the American Medical Association (JAMA) found that many clinical trials do not provide adequate information about adverse events, making it difficult for patients and clinicians to make informed decisions about the risks and benefits of drugs.
 - c) A report by the Government Accountability Office (GAO) found that the U.S. Food and Drug Administration (FDA) could do more to improve drug safety monitoring after drugs are approved for sale. The report called for greater use of electronic health records and other data sources to monitor drug safety more effectively.
4. Counterfeit drugs: The sale of counterfeit drugs is a significant problem in the pharmaceutical industry, particularly in low-income countries where regulation and oversight may be weaker. These drugs can be dangerous and ineffective, and they can undermine public trust in the industry. Such dangers caused by this can be shown through reports such as the ones bellow:
- a) A report by the World Health Organization (WHO) found that counterfeit drugs are a significant and growing problem, particularly in low- and middle-income countries. The report estimated that up to 30% of drugs in some developing countries are counterfeit or substandard.
 - b) A study published in the American Journal of Tropical Medicine and Hygiene found that counterfeit drugs for malaria and other diseases are widespread in many parts of the world, including sub-Saharan Africa and Southeast Asia.
5. Pandemic preparedness: The COVID-19 pandemic has highlighted the need for greater investment in pandemic preparedness and vaccine development. The pharmaceutical industry has played a critical role in the development and distribution of COVID-19 vaccines, but there have been concerns about equity and access to these vaccines, particularly in low-income countries.

Overall, the pharmaceutical industry faces significant challenges related to drug pricing, intellectual property, safety, and access. Addressing these issues will require collaboration between industry, regulators, and public health stakeholders to ensure that patients have access to safe, effective, and affordable medicines.

PAST ACTIONS

1. The WHO has established various initiatives and programs to promote access to medicines, including the Global Drug Facility, which provides affordable drugs for the treatment of tuberculosis, and the Medicines Patent Pool, which facilitates the licensing of patented medicines for low- and middle-income countries.
2. The United Nations Conference on Trade and Development (UNCTAD) has worked to promote access to medicines by advocating for policies that enable generic drug production, as well as measures to address intellectual property rights and pricing issues.
3. The World Intellectual Property Organization (WIPO) has developed international agreements and standards related to intellectual property rights in the pharmaceutical industry, including the Patent Cooperation Treaty and the Madrid Protocol.
4. The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are among the regulatory bodies that oversee drug approvals and monitor drug safety in their respective regions. These agencies work to ensure that drugs are safe, effective, and affordable for patients.
5. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a global organization that brings together regulatory authorities and the pharmaceutical industry to develop guidelines and standards for drug development and approval. The ICH aims to streamline drug development and approval processes while ensuring the safety, efficacy, and quality of pharmaceutical products.

CONSIDERATIONS FOR THE FUTURE

The pharmaceutical industry is one of the largest markets in the world. But where some earn billions of dollars annually, others have to suffer the consequences of

globalization. In almost all developing countries, a basic supply of medicines fails due to the systematic neglect of the development of medicines for the diseases that are widespread there and due to high price policies. Compared to the many diseases, there is a very poor health care system and, above all, a very poor pharmaceutical industry. More than 85% of people worldwide have no or insufficient access to medicines, 90% of which are consumed by the richest 15% of the world. In addition, the global healthcare system is more than exhausted. Global pandemics like COVID-19, which can hit us all at any time, have shown that even economically strong countries lack sufficient health care.

CONCLUSION

Overall, the global pharmaceutical industry faces a range of challenges, including high drug prices, limited access to affordable medicines, and concerns about the safety and efficacy of some drugs. Additionally, there are concerns that the industry is not doing enough to promote innovation, particularly in areas where there is a high unmet medical need. These issues have led to call for reform of the industry, with proposals including increasing transparency around drug pricing, improving access to affordable medicines, and promoting innovation through patent reform.

USEFUL LINKS

<https://www.cambridge.org/core/journals/american-journal-of-law-and-medicine/article/abs/aids-drugs-the-pharmaceutical-industry-a-need-for-reform/C354E49F6F7B5EA6B6029AEAA6BBDFFE>

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

<https://digitallibrary.un.org/record/714323>

https://en.m.wikipedia.org/wiki/Health_care_reform