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Letter From Under Secretary General

Dear delegates,

I welcome you all to the World Health Organization (WHO) and Marinetrain'25. My name is Cihan Mert Sürücü. I'm a first grade medical student at Akdeniz University. Over the course of my MUN journey, I have had the privilege of serving in various roles, both in the organization and the academic side. However, this committee holds a special place for me, as the committee WHO was one of my first and most joyful experiences in the MUN community.

My decision to choose this committee comes from my personal experiences. As a medical student, the agenda items of WHO are pretty interesting for me to work on. Also, I've had the opportunity to attend almost every position within WHO, except for USG, and I wanted to complete my journey here. Even though it's been more than two years, I still remember the excitement and joy I experienced during those first conferences. I hope one day all of you esteemed delegates will remember these days with as much joy as I do.

I've added additional information for all delegates for the purpose of elaborating the discussion. So please take the time to thoroughly read our study guide and work on all of the questions to be addressed listed at the end. This will ensure that our debates run smoothly over the next four days. Remember that your active participation and presence are essential for making this committee successful.

I'm excited to see you all at the committee. In the meantime take care, stay focused and make sure to prepare well enough.

Kind regards,
Cihan Mert Sürücü
Under-Secretary General of WHO

Preparing for the Conference

This section is primarily aimed at delegates with little to no Model United Nations experience, but it also includes helpful advice for delegates with experience.

1. Assess your Allocation

Once you receive your allocation, research your country's policies and its position on the committee's agenda. The study guide includes some of the key countries relevant to the agenda. Even if your country is not included as a key one, each delegate is expected to read the study guide.

2. Read the Study Guide

In addition to researching your allocation, it's important to read all of the study guide. The guide not only includes essential information on your committee and agenda but also provides different viewpoints into the history of the issue, current events and key concerns helping you to understand what you'll be debating about at the committee. Even if you have knowledge about the topic, skipping the study guide will leave you unaware of what the chairboard expects. This can lead you to make a misunderstood speech or prevent you from participating effectively, potentially disturbing the committee's flow.

3. Choose your research sources carefully

While the study guide provides you with the needed information, it's perfectly normal for you to do more research on your country or the agenda item. While doing your research, make sure to use official sources to maintain accuracy and avoid making any incorrect statements during the committee. Be picky with your research sources to prevent misinformation. Try to use official sources such as government websites, United Nations documents, and established international organizations. This will help you avoid misinformation and strengthen your position in the committee and also support productive discussions.

4. Read the Rules of Procedure (ROP)

Standard rules are essential for maintaining a professional environment during the meeting. To ensure that all actions align with proper Model United Nations protocol, the secretariat of each conference presents a document outlining the *Rules of Procedure*. This document allows the chairboard to effectively guide the committee and ensure orderly conduct throughout the session. Before the first official sessions start, the chairboard will inform you about the procedure.

Introduction to WHO

The World Health Organization (WHO) is responsible for directing and coordinating international health within the UN system. Founded in 1948, WHO's ultimate goal is to improve health, keep the world secure and serve the most vulnerable populations across the globe. WHO defines itself as "the directing and coordinating authority on international health within the United Nations system" and is responsible for driving the scientific research agenda, setting norms and standards, articulating evidence-based policy options, monitoring health trends, identifying health research priorities and establishing partnerships across multiple organizational contexts.

In the Model United Nations (MUN) context, the WHO committee provides an interactive space for delegates to discuss pressing global health issues. These issues might include response protocols to infectious disease outbreaks, procedures to mitigate non-communicable diseases, access to mental health support, and questions of health equity in the context of international development. One thing delegates can expect is to look at these issues through a public health policy perspective, as well as engagement of ethical considerations and in terms of international collaboration.

Introduction to Agenda Item

In the last few decades, the pharmaceutical industry has emerged as one of the most powerful and profitable industries in the world. It has become an integral part of medical breakthroughs, drug production and distribution and global health outcomes. The industry's exertion of influence has raised challenges of increased transparency, affordable prices and equitable access to essential medicines. The disproportionate power of the major pharmaceutical corporations often called "Big Pharma" in terms of drug prices and development, research and clinical priorities and control over intellectual property has created a global debate over both corporations and governments' responsibilities in protecting public health.

The COVID-19 pandemic has served to illustrate what has been exposed to be a pharmaceutical ecosystem that reveals structural weaknesses all the way down to vaccine nationalism and inequitable access to treatments that save lives. It has created difficult choices for many governments trying to balance their own support for pharmaceutical innovation with the need for the protection of their populations. As an example, issues such as regulatory capture, patent monopolies, price transparency and equitable access to clinical trial data continue to loom large.

This agenda item encourages delegates to consider the appropriate role of governments in regulating pharmaceutical companies. Conversations may revolve around approaches to ensuring equitable access and fair pricing of essential medicines, enforcing ethical research practices, promoting generic drug production and rethinking the patent system as it exists.

Delegates will also think about international cooperation, public-private partnerships, and WHO guidelines in building a more equitable and accountable pharmaceutical sector.

IFPMA

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a global, non-profit, non-governmental organization representing research-based pharmaceutical companies and associations. Founded in 1968 and headquartered in Geneva, Switzerland, IFPMA serves as the voice of the innovative pharmaceutical industry at the international level, particularly with United Nations agencies, including the World Health Organization.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is crucial to the international pharmaceutical environment. As the collective voice of the research-based pharmaceutical industry, IFPMA has worked to advocate for patent protections, free-market pricing and government non-interference in the treatment of pharmaceutical innovation. While it works within multilateral frameworks such as the WHO, when it represents industry in negotiations with policymakers, its agenda reflects that of large pharmaceutical companies, which does raise concerns for public health advocates (including governments). Arguably, one of the most contentious issues in governance for global health is the extent to which governments can regulate the price of medicines and the patenting system. IFPMA strongly supports patent systems, arguing that they create incentives for one of the largest working capital investments required for pharmaceutical R&D activities. However, it is contested by critics who argue that interfering with patent monopolies drives high drug prices and accessibility to vital medicines in low and middle income countries.

Pricing in the Pharmaceutical Sector

Pricing in the pharmaceutical sector remains one of the most complex issues in global health policy. The process by which drug prices are determined is influenced by a variety of factors, including research and development (R&D) costs, patent protections, production and distribution expenses, market exclusivity and national regulatory policies. However, a significant lack of transparency around these factors has created widespread concern regarding fairness, accessibility and public accountability.

- **Market Freedom and Price Regulation**

At the core of the international pharmaceutical issue is the duality between market freedom and government price control. How medicines are priced, how quickly they are delivered to patients and whether they are available at all, given economic and geographic barriers, depends on the tension between market freedom and regulation.
Pharmaceutical companies and industry organizations such as the IFPMA claim that market freedom is key to innovation and continues to produce innovative medicines that benefit society. They posit that classification as free pricing provides companies with mechanisms to set prices in some way that captures underlying value and risk inherent in the research and development process. However, many governments and health advocates claim that to let

market forces alone determine price and access to essential medicines is to guarantee gross inequalities, especially in low- and middle-income nations. Profit-driven market prices can incentivize companies to monopolize patented treatments for extended periods of time and charge prices that exceed the costs of producing the product. Regulation, in this view, is not about stifling innovation. It's about ensuring fairness, accountability and access. Tools such as price caps, public price negotiations and compulsory licensing are seen as mechanisms to protect public health over corporate profit.

- **Price Caps**

Price caps are a form of government intervention used to limit the maximum price that pharmaceutical companies can charge for specific drugs, especially essential medicines. The primary goal of such caps is to ensure that critical treatments remain affordable and accessible to the general population.

There are many implementation models of price caps such as,

- **International reference pricing (IRP):** Setting domestic drug prices based on average prices in other countries.
- **Cost-plus pricing:** Allowing a price only slightly above the production and R&D cost.
- **Value-based pricing:** Pricing a drug based on its clinical benefit compared to alternatives.

Governments have implemented a variety of price-limiting policies, often with mixed results. While they can reduce costs for consumers and governments, pharmaceutical companies sometimes respond by suspending products, limiting innovation or delaying market entry in restricted areas.
The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and most of its member companies oppose mandatory price caps.

- **Research and Development (R&D) Cost**

One of the most frequently cited justifications for high drug prices is the enormous cost and risk associated with research and development (R&D) in the pharmaceutical sector. Developing a new medicine is a long, complex, and expensive process that typically spans 10 to 15 years and involves preclinical research, multiple phases of clinical trials, and extensive regulatory approval procedures.
Estimates of the average R&D cost for bringing a new drug to market vary significantly but often range between $1 billion and $3 billion. These figures usually include laboratory research, clinical trial management, regulatory compliance, the cost of the failed projects and the theoretical returns companies could have made by investing elsewhere. Critics assert that these estimates are often inflated or obscure because many studies have industry funding or influence beyond the control of either regulatory body. Some independent analyses suggest that the actual costs may be significantly lower, especially if the development costs from public funding, university research or tax incentives are included in the estimate of "costs" for early development stages.
By comparison, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) conveys the message that R&D costs are justified as a fair reason for

drug price and patent protection considerations. The implications of price regulation may dissuade the condition of future breakthroughs especially for high-risk or low-demand type treatments.

Patenting in Pharmaceutical Sector

- **Purpose of Patents**

Patents play a central role in the pharmaceutical industry by granting companies the exclusive right to manufacture and sell a new drug for a limited period of time (usually 20 years from the date of application). This monopoly is intended to allow companies to recover their R&D investments and to profit from their research. However, in the context of essential medicines and global health equity, the patent system is increasingly under analysis.

Pharmaceutical patents seek to incentivize innovation through a temporary guarantee of market exclusivity, provide a rationale in countries with weak patents and where investment in high-risk, high-cost research could otherwise be discouraged, and provide the returns necessary to fund future research and development. However, critics point out that the effective market exclusivity is often much shorter due to the time needed for clinical trials and regulatory approvals and some companies engage in **“evergreening”** filing minor changes to extend patent protection without substantial innovation.

- **Evergreening**

Evergreening refers to the practice by which pharmaceutical companies extend the life of a drug patent by making minor or incremental modifications to the original formulation, often without significant therapeutic improvements. These changes can include altering the dosage form, changing the delivery mechanism, creating new combinations of existing drugs and filing patents for new uses of a known drug.
By obtaining new patents for these variations, companies can delay the entry of generic competitors, effectively prolonging their market exclusivity and maintaining high prices sometimes for years after the original patent expires.

- **Compulsory Licensing**

Compulsory licensing is a legal mechanism that allows a government to authorize the use of a patented invention without the consent of the patent holder usually in exchange for reasonable compensation. The purpose of compulsory licensing is to ensure public access to essential products during global emergencies or when a patented product is unaffordable or inaccessible. Recognized under the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) of the World Trade Organization. Countries can use compulsory licenses under specific conditions. While patent-holder companies indicate that compulsory licensing undermines research and the purpose of patenting, public health advocates argue it prioritizes human lives over profit. Companies get paid during the event of compulsory licensing but not with the market price. **"Reasonable Compensation"** The TRIPS Agreement (Article 31) requires that the patent holder receive adequate remuneration

considering the economic value of the license. The government or court of the country issuing the compulsory license typically sets the royalty rate. Rates vary but they often range from **1% to 6%** of the generic product's sales which is pretty low considering the market price and sales among the globe. The government does not use international funds or subsidies to pay the company. The payment usually comes from the generic manufacturer producing the drug under the license. Basically when a compulsory license is issued, the government doesn't directly pay the patent-holding company. Instead, the generic drug company that gets permission to produce the medicine pays a royalty to the original patent holder. So, the government enables the license but does not pay the patent holder itself. Nor does it use foreign aid or public funds to compensate the original company.

Government and Private Sector influences on the market

- **Price Control**

Price control refers to government-imposed limits on how high or low a price can be charged for a product or service in a market. It's used to protect consumers or stabilize an economy but it can also lead to deficiencies or excesses if not carefully managed. There are two ways of price controlling which are price ceiling and price floor.

Price ceiling is a government putting a legal maximum price that can be charged for a product or service. The risk of price ceilings is they can cause shortages (more demand less product). Price floor is the opposite of price ceiling meaning it is the legal minimum price for a good or service. The risk of price floor is it can cause surpluses (more supply than demand). Patent holder companies state that price control discourages investment and innovation.

- **Trade Policy**

Trade policy refers to a government's laws, regulations, and agreements that influence international trade, especially the import and export of goods and services. In the context of the WHO or global health agendas, trade policy directly impacts access to medicines, medical equipment and health services.

High prices or IP restrictions can make medicines too expensive for developing nations.

- **Public Sector Services**

Governments often use public healthcare systems as both regulators and providers, which gives them powerful tools to influence pharmaceutical companies and promote equitable access to medicines.

- **Healthcare**

The functioning of health systems affects pharmaceutical markets depending on many different variables. Some of these factors include the access to medicines, licensing, pricing and reimbursement policies.

The overall objective of publicly funded health systems is to control pharmaceutical prices and reduce costs. While this provides patients with access to medicines at more reasonable prices, it can negatively affect the profitability of pharmaceutical companies.
In private health systems, competition is at the forefront. firms often direct the majority of their investments to marketing and innovation. This increases the cost of medicines and makes it more challenging for patients to access medicines.

Health systems also affect the process of market introduction and approval of medicines. In developed countries, this can be a long and strict process, whereas in other countries it can be faster and more flexible. This can affect the time it takes for new medicines to reach patients and hinder the effective development of the pharmaceutical industry.

In essence, health systems and the structure of these systems affect the economic and social structures of pharmaceutical markets. an effective and balanced health system is one of the most important steps in protecting public health and one of the most important factors for a sustainable pharmaceutical industry.

Transparency and Ethics of the Pharmaceutical Market

The pharmaceutical sector, which is one of the basic components of a reliable health care system, should be subject to very strict supervision. The main reason for this is the possibility of corruption at every stage. The pharmaceutical sector, which is one of the basic building blocks of a reliable health care system, should carry out each stage with serious honesty and transparency so that other potential issues do not arise at later stages of the process. High transparency and reliability are needed not only for the health of the sector, but also for public trust and the fulfillment of ethical rules, from the beginning of the production process of pharmaceuticals to the end of the pricing process.

Drug Pricing Transparency

Transparency in pharmaceutical pricing is important for the sustainability and proper functioning of patients and the health system. The inconsistency and high cost of pharmaceuticals today is a well-known fact. Many pharmaceuticals are beyond the purchasing power of patients, leading to inequalities in the health sector. prices are usually calculated by taking into account the costs of r&d, production and marketing. However, in many cases, these elements are not disclosed separately, resulting in a lack of transparency. Making the costs of these processes publicly available in detail can prevent monopolization in the pharmaceutical sector. not only that, but it also allows patients to evaluate prices by knowing the production processes of the medicines they purchase. This is an important step towards a transparent pharmaceutical sector. as a result, transparency in the pricing of medicines not only allows many patients to access medicines, but also allows for more efficient use of resources

R&D Cost Transparency

R&D is often cited as the reason responsible for high drug prices. According to dndi, the cost of R&D ranges from 4 to 60 million USD. Although the range and amount is high, these costs are generally unknown. The transparency of these costs is vital for trust in the pharmaceutical industry and a transparent marketplace. In particular, the transparency of publicly funded research is important for the credibility of government agencies and the public's belief in them. Transparency of research data enables the development of policies in the public interest and clarifies the ethics and social responsibilities of pharmaceutical companies.

Ethics in Drug Development

The process of drug development goes through long and complicated stages, from laboratory testing to human experimentation. The application of ethical rules in this process is vital. especially in the final stages, i.e. human experimentation, voluntariness and scientific integrity must be guaranteed. In addition to voluntariness, transparency of the process, probabilities of benefit and harm, informed consent and confidentiality rules are also important in the process.

informed consent in clinical trials is one of the most important elements to ensure ethical competence. participants must be informed in detail about the purpose, risks, side effects and expected data of the trial. After that, it must be ensured that participation is of their free will. This vital process is not carried out with sufficient transparency and detail, as seen in recent studies, i.e. participants are not sufficiently informed.

Another ethical issue is publication bias and data manipulation. Some pharmaceutical companies hide negative or ineffective results by publishing only the positive results of trials. This leads to biased knowledge in the medical literature and a loss of trust in the pharmaceutical industry. It also puts patients' health at risk**.**

QUESTIONS TO BE ADDRESSED

- How can governments increase the oversight of pricing, R&D expenses and patent processes by major pharmaceutical companies?
- Should governments require pharmaceutical companies to publicly disclose research funding and trial data?
- How can evergreening be prevented or minimized?
- How can the amount to be paid for coverage during the compulsory licensing process be calculated in more detail?