TFLMUN'26

WHO STUDY GUIDE

Agenda Item: Combating High Prices in the Medicine Industry and Ensuring Equitable Access to Essential Medicines and Vaccines

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Letter from the Secretary General

Esteemed delegates of TFLMUN'26,
It is a great honour to welcome you to one of the most vivid and inspirational events in our city. As the Secretary General of this valuable conference, it is my pleasure to be a part of the experience.

Our special executives and deliberately selected organization members have set their first priority to seek all of your interests, and we all specifically see our event as a mission to be superior and the most inspirational. Speaking for myself and our team, we worked tirelessly day and night without hesitation for your best interests and to provide you the opportunity to express yourself in every aspect as a delegate of TFLMUN'26. We state that each and every one of our conference's delegates is held in high esteem, and you are welcomed equally. We believe that TFLMUN'26 is going to be one of the only events where everyone is free to be themselves comfortably and enjoy the spirit of Model United Nations.

By attending our conference, you will have the opportunity to engage in meaningful debates, challenge yourself in the aspect of self-confidence, and improve yourself intellectually. You will feel the excitement of new friendships, and most importantly, you will experience the quality of the sensational conference first-hand. We urge you to comprehend that besides being a platform to debate, our conference will be the journey to your personal growth along with unique entertainment.

We look forward to witnessing all of our delegates' efforts and determination. Let TFLMUN'26 be the step for your excellence and self-growth!

Yours faithfully,
Adal Çavuşlu
Secretary General of TFLMUN'26

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1. Letter from the Under-Secretary General of the WHO Committee

Esteemed delegates,

As Under Secretary-General, I am delighted to invite you to the sessions of the World Health Organization Committee and looking forward to meeting you.

This year, we are addressing a topic that is both familiar and of the utmost importance: "Combating High Drug Prices and Ensuring Fair Access to Essential Medicines and Vaccines." Globally, an average of 2 billion people lack access to essential medicines; in low-income countries, a significant portion of deaths among children under five stem from diseases that could be prevented with affordable and accessible medicines. Meanwhile, inadequate health infrastructure, fragile supply chains, and unsustainable pricing mechanisms have transformed this inequality into a structural public health problem. The COVID-19 pandemic has exposed this gap through inequities in vaccine distribution and weaknesses in the supply chain, clearly demonstrating how vulnerable global health systems are. This issue is not only an economic one; it is also a threat to the sustainability of global public health. We have assembled here today to discuss the causes of this problem and find sustainable solutions.

We have done our best to prepare this working guide and have produced a comprehensive document. However, the value of this work will only be realized through your in-depth research and discussions. To play an active role in the committee and help us achieve our goal of drafting a decision document, please strive to provide logical, policy-aligned, and practical solutions to the questions at the end of the working guide. I also strongly recommend that you go beyond this working guide and research your own countries to learn about their policies. If you have any questions regarding procedures or other matters, please do not hesitate to contact me. I wish you success in your work!

I would also like to express my deepest gratitude to the academy and the organizing team, who made this conference possible and have always been by our side.

Best Regards

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2. Introduction to the Committee

a. What is WHO?

The World Health Organization (WHO) is a specialized agency of the United Nations (UN) established in 1948 with the broad mandate to promote the attainment of "the highest possible level of health" for all people and to further international cooperation for improved public health conditions. WHO defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity".

WHO is financed primarily through contributions from member governments and employs experts, staff, and field workers in offices around the world. The WHO is led by a director-general nominated by the Executive Board and appointed by the World Health Assembly. The organization offers governments guidance through its regional staff and expert committees.

WHO was given a broad mandate to promote the attainment of "the highest possible level of health" by all people, defining health as "a state of complete physical, mental, and social well-being and not merely the absence of disease". The organization inherited specific tasks relating to epidemic control, quarantine measures, and drug standardization from the Health Organization of the League of Nations and the International Office of Public Health at Paris.

b. WHO’s Role in Relation to the Agenda Item

Medicines are essential for the prevention and treatment of diseases, and thus also for the protection of public health. They are also responsible for a substantial part of health care costs. In a number of countries in transition in the WHO European Region, ensuring regular access to good-quality, safe and affordable medicines is still a challenge: a one-month treatment of simple hypertension, for example, can cost up to 35 days' wages, most of which is paid out of pocket.
WHO/Europe works with countries to help them ensure that people have equitable access to affordable medicines of assured quality, and that medicines will be prescribed and used appropriately by:

- providing direct technical and policy support to countries (especially countries in transition);
- facilitating networks on policies related to drug regulation, quality, pricing, reimbursement and responsible use;
- building capacity through training and setting up systems for the regulation, provision and use of medicines in countries;
- providing evidence-based tools for implementing pharmaceutical policies;
- supporting monitoring of implementation of policies in countries and networking among countries and professionals;

- working in partnership with the European Centre for Disease Prevention and Control; the European Union; the Global Fund to Fight AIDS, Tuberculosis and Malaria; the United Nations Children's Fund; the World Bank; nongovernmental organizations; and academic and professional institutions and networks; and
- working closely with WHO headquarters, particularly with the essential medicines and health products programme.

3. Introduction to the Agenda Item

a. Understanding the Agenda

Access to medicines, vaccines and other health products is disturbingly uneven in many places and remains deeply unequal across the world.
These disparities have serious consequences for the realization of the right to health, particularly for women and girls, older persons, persons with disabilities, national, ethnic, religious, racial and linguistic minorities, indigenous populations, LGBTI+ persons, migrants particularly undocumented migrants, stateless persons, refugees and displaced persons, persons living in poverty and other persons or population groups at heightened risk of right to health violations. Persons with chronic and non-communicable diseases (NCDs), particularly in low- and middle-income countries, also face significant barriers in accessing medicines, vaccines and other health products due to important out-of-pocket expenditures and limited availability of treatments and diagnostic tools for NCDs.

Equitable and universal access to medicines, vaccines, and other health products is a fundamental component and determinant of the right to health. They must not only be produced and made available; they must also be accessible without discrimination to everyone - everywhere.

The COVID-19 pandemic underscored the critical importance of affordable, timely, equitable, and universal access to vaccines in responding to global health emergencies. While the rapid development of effective COVID-19 vaccines was a major scientific achievement, the failure to ensure universal and equitable distribution had a direct and devastating impact on the enjoyment of the right to health for millions of people — leading to preventable illness, hospitalization, and death.

Access is often most fragile during health crises—such as armed conflicts, natural disasters, and humanitarian emergencies—when medicines, vaccines and other health products are most urgently needed. In such contexts, existing availability and access challenges are compounded by new barriers hindering service delivery, disrupting supply chains, driving up prices, forcing the suspension of vaccination campaigns. Ensuring continuous, non-discriminatory access to medicines, vaccines and other health products in these settings is a human rights obligation.

As digital technologies increasingly shape health systems—from electronic health records and digital supply chains to algorithmic prioritization and AI-assisted diagnostics—their impact on access to medicines, vaccines and other health products is profound and transformative. These tools can support the realization of the right to health, including by expanding reach to remote or underserved communities. Without adequate safeguards, these technologies can also deepen existing inequalities. Ensuring that digital health solutions are governed by human rights principles is essential to realize the right to health for all.

As the world moves toward the 2030 Agenda for Sustainable Development, the promise of Universal Health Coverage (UHC) must be met with concrete, human rights anchored actions. SDG 3 calls for ensuring access to safe, effective, affordable and quality medicines and vaccines for all. Realizing these goals requires legal, political, and financial commitments that place human rights at the centre. Advocating for equitable and universal access to vaccines, medicines and other health products, and ensuring a human rights-based approach is an essential part of this process.

b. Key Terms and Definitions

Health Equity: Equity is the absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality (e.g. sex, gender, ethnicity, disability, or sexual orientation). Health is a fundamental human right. Health equity is achieved when everyone can attain their full potential for health and well-being.Progressively realizing the right to health means systematically identifying and eliminating inequities resulting from differences in health and in overall living conditions.

Access to medicines: Universal health coverage can only be achieved when there is affordable access to safe, effective and quality medicines and health products.

Global health: Global health is a field of study, research and practice that prioritizes improving the health of all people around the world and ensuring equality in health.

Vaccines: Vaccine is biological preparation that provides active acquired immunity to particular infectious or malignant disease.The safety and effectiveness of vaccines has been widely studied and verified.A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, or one of its surface proteins.

Medicines: Medicines can treat diseases and improve your health.

Public health: Public health improves our quality of life, helps children thrive, reduces human suffering and saves money. Every day, the public health field is working often to prevent hazards and keep people healthy.

Universal Health Coverage (UHC): Universal health coverage (UHC) means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care across the life course.

Pandemic Preparedness: Pandemic preparedness is the process of strengthening the national, regional, and global systems so they are able to respond more quickly and effectively to pandemics and other health emergencies. Preparedness is essential to mitigating the morbidity, mortality, and socioeconomic effects of a pandemic.
Resilience refers to the ability to sustain consistent capacities before, during, and after a pandemic. Health systems should be able to recover from a pandemic while maintaining the capacities gained during the emergency situation.

Equity-Based Approach: A strategy aimed at making health care delivery equitable and accessible to everyone in society, particularly those who belong to socially and economically disadvantaged communities. This is because the strategy seeks to address inequalities through resource allocation according to needs and not socio-economic standing or geographical positioning.

Essential Medicines: Medicines addressing the priority health care requirements of the people. These medicines are chosen according to their importance, safety, efficacy, and economic feasibility, and should always be available in sufficient quantities through functional health care delivery systems. This idea is greatly advocated by the World Health Organization.

Generic Medicines: Drugs which are similar to branded drugs in relation to their quality, safety, and efficacy but available at reduced prices. They are available after expiration of patents on branded drugs, thereby reducing costs and making medication available to a larger number of people.

Compulsory Licensing: It is an instrument within a country's legal system by which the authorities can produce or import drugs based on patents without the permission of the drug manufacturers, mostly in emergencies. This mechanism is acknowledged under various global treaties like the TRIPS agreement and works to enhance accessibility to drugs.

Intellectual Property Rights: These are legal rights that protect intellectual property or inventions by an individual or a corporation, such as inventions in the field of pharmacology. Intellectual property rights give the inventor an advantage of sole manufacturing and selling rights to the new invention for a specified time frame within the healthcare industry.

4. Background Information

a. Historical Context

Inequality access to medicines has been at the center of the global health agenda since the mid-20th century. Efforts to develop an institutional response to this inequality took concrete form with the publication of the WHO's first Model List of Essential Medicines in 1977.

The first WHO Essential Medicines List, published in 1977, was hailed as a peaceful revolution in global public health. The list helped establish the principle that some medicines are more beneficial than others and that essential medicines remain inaccessible to many populations. Since then, the Essential Medicines List (EML) has expanded in scope; the process of defining an essential medicine has shifted from an experience-based approach to an evidence-based one, incorporating criteria such as public health importance, efficacy, safety, and cost-effectiveness. High-cost medicines, such as antiretrovirals, are now included on the list. Differences exist between the WHO Model EML and national EMLs because countries face varying challenges related to costs, drug efficacy, morbidity patterns, and the rationality of prescribing practices. Through the WHO's revised drug strategy, equitable access to essential medicines and their rational use have been promoted. This approach has required the WHO's involvement in issues such as the impact of international trade agreements on access to essential medicines and research and development to ensure the availability of new essential medicines.

b. Defining Essential Medicines and Vaccines

Essential medicines are those that effectively and safely meet the population's priority health needs. These medicines are selected based on evidence regarding their importance, benefits, and risks from a public health perspective, as well as taking into account cost, affordability, and other relevant factors.

Essential medicines must always be available in sufficient quantities within functioning health systems to meet patient needs. Essential medicines should be available in dosage forms appropriate for their intended uses and patients, their quality should be assured, and they should be affordable for both individuals and the health system.

Although essential medicines address a wide range of global health needs, they constitute only a small fraction of the total number of medicines available worldwide. The use of a carefully selected, limited number of medicines can lead to improved supply, better prescribing practices, and reduced costs.

More than 150 countries have adopted national essential medicines lists based on the WHO Model List. Essential medicines lists form the foundation for drug supply and procurement in the public sector, reimbursement and insurance programs, drug donations, and local drug production. When properly implemented, the concept of essential medicines can help improve health outcomes and advance progress toward universal health coverage. This concept has been successfully implemented in various countries and regions. Studies have

shown that essential medicines lists are associated with greater availability of essential medicines compared to non-essential medicines, increased access, better prescribing practices, improved quality of care, and cost savings. The lists are categorized into major groups such as analgesics, treatments for infections, cardiovascular medicines, and vaccines. Vaccines are also included among essential health products they play a critical role in disease prevention and are evaluated alongside essential medicines. The WHO also emphasizes the importance of training for healthcare workers to ensure the safe and effective use of medicines. Despite efforts to improve access, challenges persist in developing countries, particularly regarding issues related to drug quality and drug administration.
The concept of essential medicines can be adapted to different health systems, settings, and income levels. By focusing on a carefully selected, limited number of medicines, countries can improve access to essential medicines while enhancing supply, promoting more rational prescribing practices, and better controlling costs.

5. Parameters for Effective Service Delivery

a. Availability

Availability sufficient amounts of medicines and vaccines must be available within a country's healthcare system so patients can obtain the care they need whenever they need it. In order for healthcare systems to provide quality, effective healthcare services, all healthcare providers must have (and utilize) processes to ensure that they are able to manufacture, store and distribute both new and existing medications and vaccines in a timely manner to hospitals, clinics and pharmacies. Even the most advanced medical technologies will fail if there is not an organized way to distribute the medicines and vaccines that are need by patients throughout our society.

In addition, availability is not simply a question of the number of units of a particular product, but it is also the assurance that there is an ongoing supply of the product to meet patients' needs. For example, patients with chronic diseases, who require medications on a regular basis, require timely delivery of those medications to avoid disruptions in their treatment regimen. Many countries are faced with multiple barriers when it comes to ensuring that they are able to provide a reliable supply of essential medicines. The barriers that many countries face often include lack of capacity to produce enough medicines; inadequately funded research and development projects; and the dependence on importing medicines from other countries.

Countries that become reliant on imported goods are at risk of having acute shortages of medication whenever there are barriers to international trade or political unrest.Most of the countries in sub-Saharan Africa depend entirely on drugs from other countries and hence will not be in a good position to deal with any shortages if they occur at an international level. However, countries which have well developed pharmaceutical industries and capacity for research such as the US, UK, and Israel are in a better position to deal with increased demand

for their products. But even these nations cannot be spared at all during times of shortages of medicines especially when it is a crisis situation worldwide.

During the COVID-19 pandemic, many countries were unable to access the vaccines and resources we needed. Demand surged quickly, whereas production capacity for vaccines remained limited and was only produced in a few countries. Consequently, while countries with access to large amounts of vaccine were able to deliver vaccines quickly to large numbers of people, countries waiting for vaccine supplies took much longer. For example, many high-income countries (i.e., the U.S. and the U.K.) were able to purchase vaccines early due to early purchase agreements. However, many low-income countries were reliant on international relationships to receive vaccines. Israel, on the other hand, was able to administer vaccines fast due to earlier agreements with multiple pharmaceutical firms.

The above clearly indicates that there is inequality in access to healthcare resources globally. According to international bodies such as the WHO, in order to prevent future shortages, it is important to improve pharmaceutical production as well as diversify supply chains. Investing in regional manufacturing facilities, investing in local pharmaceutical corporations and collaborating with other nations are some of the key ways that will contribute towards improving the supply chain. In recent times, there have been many attempts aimed at setting up manufacturing centers in Asia, Africa and Latin America. Such endeavors are geared towards ensuring that the entire process is made balanced by reducing dependence on limited supplier nations.

The benefits of the supply chain are another important factor when it comes to availability. Medicines and vaccines need to be moved safely from the people who make them to the places where they are used. For this process to work, there must be good storage conditions and dependable transportation networks. For instance, vaccines usually need to be kept cold to work. Vaccines can go bad before they get to patients if there isn't enough infrastructure. In many low-income countries, bad transportation networks and not enough refrigeration systems make it hard to get vaccines out to people. Because of this, health policies put a lot of emphasis on improving the infrastructure for cold chain transportation.

b. Accessibility

The term 'accessibility' is defined by the ability of people to get and make use of healthcare services including drugs and vaccines without being hindered by any physical, social, or legal constraints. Although some countries are equipped with adequate supply of medicine, a great number of people may find it difficult to access these drugs because of distance, poor facilities, discrimination, or ignorance. Accessibility also involves availability which means that people need not go through long waits before accessing healthcare services.

Availability of healthcare services varies in different areas globally. Large towns have numerous health centers such as hospitals and clinics. Small towns and villages rarely have these facilities. The patients must travel for miles before reaching the facilities. Patients cannot reach these services easily since the costs of transportation are usually high. Other problems include lack of good transport means and natural barriers like mountains and islands. Patients from poor countries are particularly disadvantaged in this regard. Patients in

rural areas in India and Nigeria have challenges accessing the facilities. On the other hand, the NHS in the UK represents a more centralized healthcare facility that aims to provide equal access to healthcare, although there are variations based on regions. Similarly, access to healthcare services in the US may vary based on location and type of health insurance coverage.

Another barrier is related to discrimination towards individuals of various social strata. Discrimination is one of the major barriers preventing some social classes from having access to health care services. At that, there is an example of a legal restriction preventing particular social groups from having treatment within the health care systems of their countries. It is important for the countries that face the problem of refugees, such as Türkiye, Germany, Jordan, to distribute medications and vaccines among other health care products equally for both refugees and local people without any type of discrimination. According to the report of the World Health Organization, it is vital to have a high level of accessibility of health care services as it contributes to universal health coverage and increases the number of people who can have health insurance. Therefore, accessibility should be guaranteed irrespective of where people live, their socio-economic background, racial or national identity, and other factors. Accessibility is achievable with the improvement of the language competence among patients and increase in health literacy levels. Other measures include expanding the health care networks, educating people about available health care services and encouraging them to use them.

For example, states like Brazil have managed to develop community-oriented care facilities where health services are provided right at the doorstep of their people. Digital platforms and telehealth services are also increasingly utilized to ensure increased accessibility of healthcare services to individuals. Such advancements can assist in facilitating connections between those patients who are located at a great distance from the doctors and nurses, and enable them to acquire knowledge related to the administration of treatment alternatives and vaccinations.

For instance, Israel and Estonia have devised advanced healthcare technologies, wherein people can order their medicines and obtain medical advice via the internet. Cooperation among international bodies, governments, and communities is vital in ensuring that appropriate policies are adopted along with substantial financial resources for the development of an infrastructure in the field of healthcare.

Without solving the issue of accessibility, it will not be possible to make any advancements pertaining to the delivery of medicine and vaccines across the world.

c. Affordability

Affordability indicates that people, governments, and healthcare systems can get the medicines and vaccines they need without having to go through a lot of financial trouble. Even when medicines are available and easy to get, high prices can keep a lot of people from getting the care they need. This is why affordability is seen as one of the most important parts

of a good healthcare system. It also has a direct effect on public health outcomes because medicines that are too expensive can lead to untreated illnesses and higher death rates.

In many places around the world, especially lower-income countries, health expenses are typically borne by the individual. This way of paying for health care, or "out of pocket" payments, is often the case in large part because many countries do not have universal health insurance coverage or publicly funded systems of care to assure that people are able to obtain necessary care. As a result of high prices for medications in many countries, those needing medications may have to choose between purchasing them or being able to fulfill other basic needs, such as food, paying rent or obtaining an education. The number of people who delay or avoid receiving health care because they are unable to afford their share of the cost of medications and because they are unable to afford to purchase their medications is significant in some developing areas of the world such as sub-Saharan Africa and Southeast Asia both of which still have few social safety nets and a very limited ability to access either health insurance or health care.

Numerous elements dictate how much you will need to pay for a drug or vaccine, including how much it costs to research and develop a new product, manufacture that product, distribute it, and the intellectual property associated with it, such as pharmaceutical patents. Pharmaceutical patents are intended to help create innovation in the drug and vaccine market; however, they create decreased competition, increasing the prices of drugs and vaccinations, making it challenging for developing countries to afford life-saving medications because they do not have the money to purchase them in large volumes. For example, pharmaceutical companies in the United States, the United Kingdom, and Switzerland are the primary sources of world-wide drug development, but because of their high cost, many developing countries cannot access the medications unless they have some sort of financial assistance program. The affordability of the world's medical resources came into focus due to COVID-19.

Some nations were successful in negotiating advance purchase agreements for their supply of vaccines during the pandemic, while other countries struggled to financially support themselves in order to obtain sufficient doses for their populations. There were global concerns regarding whether the amount of vaccines produced and accessed by nations was equitable and justifiable based on population size when many African countries were either heavily reliant on donations, or on initiatives such as COVAX to obtain vaccinations.

The COVID-19 pandemic prompted international organisations including the World Health Organisation to stress the need for policies that would make medicines affordable for all. Such policies could involve supporting the development of low-cost generic medicines and implementing pricing mechanisms that fairly reflect the costs of producing medicines; providing international financial assistance; and encouraging pharmaceutical companies to enter into voluntary licensing agreements with manufacturers in low- and middle-income countries. Nations such as India are now some of the largest producers of low-cost generic medicines, and have played a critical role in providing affordable treatment for patients worldwide. Another important strategy for improving access to treatments is through

international collaboration. By working together, governments, international organisations and private companies can create global health initiatives and partnerships to help reduce the cost of medicines and ensure vulnerable populations have access to life-saving treatments, as well as provide funding for vaccination programs and the procurement of medicines, programs that have greatly enhanced many global health outcomes. Public-private partnerships have also assisted in reducing the price of vaccines and increasing vaccine production capacity during global health emergencies. To maintain the affordability of medications, pharmaceutical companies must create new drugs. These new drugs will support healthcare systems globally. The goal must be to create a balance between the need for new drug development with the need to keep drug prices affordable and accessible to all people globally. Drug affordability is critical in order to ensure long-term sustainability of global healthcare systems in both developed and developing countries.

d. Acceptability

The concept of acceptability in medicine and vaccination is the degree to which an individual or group considers a particular medicine or vaccine to be acceptable from their cultural, social, and ethical perspective. The individual's or community's decision not to use a medicine or vaccine may also be related to other factors, such as a lack of trust in the healthcare system or differences in culture between the individual and the group receiving the treatment. Ultimately, the acceptability of a medicine or vaccine reflects the human dimension of the healthcare delivery system because the belief, perception, and trust of the individual play an important role in healthcare. The acceptability of a medication or vaccine is also closely tied to the perceived safety and efficacy of a medical intervention, and consequently, an individual will be less likely to use a medical intervention that the individual believes to be unsafe, even when there is significant scientific evidence that the medical intervention is safe and effectivePublic confidence has a vital impact on how successful healthcare initiatives are performed, especially with vaccination efforts. When an individual or community has confidence in their medical system, they will most likely obey the recommendations of the medical system and take part in vaccination programs ^ 3 (Jerry Wilkins-Ng - Frontiers in Public Health). Unfortunately, when public trust levels fall, there is a good chance that misinformation, misunderstanding, and/or fear will spread rapidly and diminish the overall effectiveness of public health programs.

There are many factors that can affect public trust, including government transparency, media communications, and prior experiences with healthcare systems. In countries whose governments provide an open line of communication and consistently provide scientific evidence-based material regarding their health and healthcare system, generally public trust levels remain high and therefore increased participation levels in health programs. Vaccine hesitancy, or delaying acceptance or refusing vaccines even when they are available, is one of the most commonly talked about problems related to acceptability. There are many reasons

why someone may hesitate to receive a vaccine, including social media misinformation, distrust of the government and other institutions, religious beliefs, and fear of side effects from the actual vaccine. During the COVID-19 pandemic, many countries faced difficulties in convincing certain groups of the population to receive vaccines. In some cases, misinformation spread rapidly through online platforms, creating confusion and fear about vaccine safety. This situation demonstrated that ensuring the success of vaccination programs requires not only scientific innovation but also effective communication and community engagement.

Israel benefited from proper health data management systems and effective communication with the public, which contributed to high vaccination rates. In contrast, other countries had adequate vaccine supplies but faced difficulties in convincing individuals to receive vaccinations. Countries employed different approaches when engaging with citizens to get vaccinated, although research indicated that accurate and coherent communication was crucial in promoting vaccination.

Health education plays a pivotal role in fostering trust between the government and its people, according to several organizations, including the World Health Organization. The government must ensure citizens have access to reliable information regarding medications and vaccinations to build and maintain trust among the population. With misinformation rampant on social media platforms, health campaigns play a significant role in educating the population on the significance of vaccination and misinformation.

Furthermore, social media now presents benefits and drawbacks to developing vaccines' public perception. Misinformation can travel rapidly on social media, but governments/health agencies can use social media to communicate with a larger audience while disseminating accurate information.

Creating goodwill is an additional critical aspect of increasing accessibility. Examples of how to accomplish this include including local leaders, health workers, schoolteachers, and local organizations within the delivery of public health programming as ways to create effective partnerships with communities. When communities feel that they have input in decision-making processes, they will be much more likely to support health programs. Partnerships with local religious leaders have been effective in increasing vaccination uptake in countries where religious leaders are respected as their authority dictates.

Additionally, culturally appropriate or culturally sensitive models that are respectful and incorporate local customs and beliefs have produced positive results when delivering health interventions. In addition, ethical consideration is an essential part of access to care. Medical treatment requires adherence to the principles of the autonomy of the patient, a correct understanding of the delivery system and respect for the patient's culture. If a person feels that his/her autonomy is not respected, he/she will likely refuse the treatment even if it medically can assist them.Compliance with ethical principles in the delivery of health care

creates a foundation for long term trust between communities and the health care delivery systems.

In order to better accommodate individuals, it is necessary to appreciate the social and cultural settings of various groups. Healthcare policy should be achieved through a combination of respect for culture and the application of scientific medical procedures. By developing effective channels of communication and trust between government officials and the people they serve, officials can improve acceptance levels of medicine and vaccination, thus enhancing the success of worldwide health programs.It should also be noted that if a certain population does not have trust towards a certain healthcare program, then no benefits will be received from it regardless of the fact that the technology which delivers the healthcare program is advanced and innovative.

It is safe to say that, in the long-term perspective, confidence building and health literacy become crucial elements when it comes to creating an effective healthcare system capable of coping with global health problems in the future.

If people do not enjoy freedom or dignity concerning their treatments, then there is a high probability that even benefits will fail to encourage people to follow their treatment regimes.

6. Key Challenges and Barriers

a. Supply Chain and Logistics

One of the biggest challenges for providing the world with affordable drugs and vaccines is the supply chain/logistics systems, as they govern all aspects of medicine and vaccine distribution. The effectiveness of a healthcare system completely relies on medicine and vaccines being produced, transported, stored and delivered effectively to those who need them. At present, the problem that the current global supply chains face lies in their reliance on the manufacture of pharmaceuticals in a small number of countries. Manufacturing of pharmaceutical products is very much concentrated in developed countries like the US, Germany, UK, and India. While it does provide an opportunity for mass manufacturing of medications and vaccines, at the same time, it causes vulnerabilities that may affect communities negatively. Building trust in the community through ethical and safe access to medications and vaccines would facilitate building relationships between the community and the healthcare provider as a system. The problem with relying on a few manufacturing countries in times of a crisis such as a pandemic would manifest itself if some disruption occurs in these regions due to, for example, geopolitical reasons or natural disasters. Such a disruption will have global consequences for the access to medicine and vaccines.

The complexity of transportation and distribution systems presents another challenge, as medicines and vaccines must go through several stages. Manufacturing, packing, international transport, customs clearance and local distribution all add potential delays or inefficiencies in the process. Poor infrastructure in many low-income countries (poor road systems, limited transportation networks or inefficient port systems) complicate the delivery process. The bureaucracies and regulations that exist in various nations make it hard for medicines to be delivered from one country to another, which may delay the delivery process

in case of emergencies, where time is essential. The cold chain logistics make the whole transportation process more difficult since some vaccines must be kept within specific temperature ranges to retain their potency. This means that the vaccines should be kept under cold conditions. It becomes harder to keep these conditions where there is no reliable supply of power or even a reliable refrigeration system. This will mean that the vaccines will lose their efficacy in the process, thereby resulting in wastage and a lower vaccine coverage rate.

The impact of the COVID-19 pandemic demonstrated to us on a worldwide level the extent of those challenges faced by that particular global supply system. Supply Chain systems came under immense pressure as they experienced a sudden spike in demand for both Vaccines and Medical Supplies resulting in longer lead times and massive imbalances in how the goods were delivered globally. Countries defined as "High-Income" had a greater ability to expedite their shipment than "Low-Income" Countries who were faced with various logistical issues that resulted in longer lead-times to receive their products. This shows us that while the Global Supply System is a very technical structure it is also influenced by Political and Economic Power dynamics across the globe.

Moreover, inadequate coordination and transparency within the global supply chain will lead to these issues becoming even worse. In the absence of proper communication from governments and pharmaceutical manufacturers, it would become impossible to predict demand, control inventory, or respond to any shortages. Thus, it is essential that in order to resolve inefficiencies within the supply chain, the process of sharing data should be further improved and that all the involved parties should work together in harmony. The deployment of cutting-edge data systems and tracking technology will make a massive contribution to improving the visibility and responsiveness of the supply chain. To build stronger supply chain and logistics systems will need to invest in infrastructure; simply being able to produce enough medicines and vaccines will not ensure access. Having a more decentralized and flexible global supply chain will reduce the risk involved creating an equitable distribution of medicine and vaccines when there is a health emergency in the future.

b. Healthcare Infrastructure

A necessary part of any successful health system is its ability to deliver quality health services through an efficient healthcare infrastructure, which provides the framework for safely distributing and administering the necessary medications and vaccines. Components of a healthcare infrastructure include hospitals; clinics; labs; pharmacies; medical devices/equipment; and qualified health professionals. If there is no healthcare infrastructure, then distributing and administering medication and vaccines will not happen regardless of their availability.

A strong healthcare infrastructure also assists with preparedness for emergencies; and developing public health over the long run.

Lack of healthcare facilities is a substantial hurdle for many developing nations. Patients who reside in rural or remote regions typically have little or no access to hospitals or clinics,

causing them to have to travel long distances in order to get medical care. Travel delays cause delays in receiving medical care and also discourage people from seeking medical care at all. Some healthcare centres are also understaffed and/or lack basic resources resulting in lower levels of effectiveness. The next large problem is the absence of qualified healthcare personnel, which includes doctors, nurses, pharmacists, and technicians. These individuals provide much of the healthcare service. The problem occurs when professionals leave their country to move to a higher income country in order to have opportunities to advance their career; this is referred to as a brain drain and will create a gap in the capacity to deliver care (the ability of lower income areas' health systems to provide high quality care) within those lower income countries. In order for new healthcare professionals to be trained, both money and time will be needed, making it difficult to fix this in the short term; however, long-term solutions exist.

The United States and the United Kingdom are both developed nations with superior healthcare systems due to the fact that these two countries have developed their healthcare systems into highly sophisticated infrastructures with well-equipped hospitals and trained specialists. However, other issues exist in the United States and the United Kingdom as well; for example, there are large gaps in access to services in urban versus rural areas, and additionally, there are gaps in access to services based on income and the type of health insurance covered by the individual patient. Thus, as this illustrates, the issue of infrastructure challenges occurs throughout the world in both developed and developing nations and also occurs in different forms .

Infrastructure-related problems can also exist, as in many cases medical equipment and technologies required for testing for illness or storing/vaccination are unavailable (in laboratories, it is impossible to diagnose a patient and in healthcare facilities, the equipment to store or vaccinate with is not available). For instance, if there are no proper coolers to store vaccines, there is no way vaccines can be stored, especially since in many cases, there is no stable electricity supply, which means the vaccines cannot be refrigerated. In addition, lack of testing facilities makes it impossible for patients to get treated in a timely fashion and therefore the effectiveness of their interventions is greatly reduced. As stressed by WHO, healthcare infrastructure plays an important role in the provision of universal coverage of healthcare services.

Emergency systems like quick response teams and disease surveillance systems belong to efficient healthcare infrastructure.

Another growing consideration in the global landscape of health policy is digital health infrastructure. Both countries with advanced digital infrastructure, such as Israel and Estonia, can utilize their high-tech systems for things such as tracking patients, recording vaccinations and managing health data. The use of these platforms has better enabled governments to effectively deliver health services and respond to public health emergencies. Telemedicine has gained traction as a mode of delivering medical services to patients as a result of increased reliance on technology during pandemics, particularly when traditional methods of accessing health care are restricted or unavailable. One more key component is the

integration of health services. Many nations' health systems are disorganized; the hospitals do not interact well with each other at all levels. As a result, poor organization and access to health services create problems for the health delivery system. Integrated health systems allow agencies at different levels to work together to provide services in coordination and provide people with ongoing and complete care.

To sum up, in order to overcome the challenges that hinder health infrastructure development, we must develop a plan, staff, and train an effective and consistent workforce to implement our plans. Investing in infrastructure will help us achieve not only easier access to medications and vaccines, but also efficiency of the health care system. To ensure the wellbeing of all individuals, we must lay the groundwork for developing an effective and sustainable health care system.

c. Research and Development Gaps

Gaps in research and development represent two of the greatest barriers to universal availability of affordable medicines and vaccines. Developing new medical therapies requires massive amounts of investment capital, advanced technologies and highly skilled scientists. Because the above resources are significantly lacking across the globe, there is a huge disparity between high-income countries and low-Income countries with respect to their capacity for innovation. Many developing countries are dependent upon other countries to supply them with new medicines and vaccines, which causes delays in treatment, higher treatment costs, and makes it difficult for them to prepare for international health emergencies. Furthermore, discrepancies between the available capacities of R&D represent a long-term disadvantage to developing nations, because it impedes their ability to build sustainable and independent health care systems.

One of the crucial aspects related to this topic is unequal opportunities in terms of the capacity for conducting research globally. USA, UK, Germany, and Switzerland occupy the top positions in regards to innovative ideas in the field of pharmaceuticals as they are well-equipped with proper financing initiatives, high-quality universities, as well as collaboration between government authorities and pharmaceutical companies in this sector. These countries are able to conduct clinical trials and develop innovative drugs. However, for developing countries, attaining these achievements is not an easy task as there are a number of barriers that may come their way. For instance, one such barrier is 'brain drain'.

A crucial issue is the fact that the agenda of international health research is usually dominated by commercial interests instead of true needs. Most international researchers and funding agencies involved in international health research have been drawn from the pharmaceutical companies. Needless to say, such individuals and organizations are interested in making profits through the production of drugs or treatments that might be profitable. In this case, diseases affecting patients residing in rich nations receive more attention than those that are widespread in poor nations. These types of diseases have been termed neglected diseases, which include ailments like malaria, tuberculosis, and other tropical diseases that are now causing suffering to millions of people across the globe. Intellectual property rights and

patenting laws add another layer to the problem. The purpose of a patent is to stimulate innovation by making sure that companies are able to recoup the cost associated with research and development. However, this system may limit access to medicine by discouraging the production of generics. This is especially concerning in times of global pandemics since timely access to medicines and vaccines is critical. In the case of the Coronavirus outbreak, there were significant disputes about the waiver of the patent protection for vaccines. On the one hand, it was believed that such a step would enable mass production and equal distribution of medicines, while on the other hand, the necessity of protecting intellectual property was highlighted.

A critical issue in vaccine and medicine distribution is that there is inadequate technology transfer and information sharing among nations. The transfer of technologies is necessary because this allows developing nations to develop their capabilities in terms of research and manufacturing. However, in many instances, it has been noted that access to new technologies, skills, and knowledge is limited. For instance, rich countries and firms might refrain from sharing this information out of fear of economic rivalry and protectionism. Consequently, developing countries lack local manufacturing capabilities and have to rely on foreign aid and supplies. This becomes especially apparent when there is high global demand for vaccines and medicines.Economic disparities can also lead to inequities in the provision of research and development opportunities. Indeed, high-income nations allocate a higher amount of money towards research and development than low-income nations. Therefore, high-income nations can stay ahead of others in terms of innovation. Meanwhile, insufficient funding, inadequate investments, and limited sources of finance impede developing countries' efforts to establish research organizations. It leads to an uneven development where only nations with adequate funding can benefit from innovations.

The COVID-19 outbreak also brought to light both the positives and negatives of the world’s R&D system. For one, the quick emergence of vaccines proved how capable this scientific enterprise could be in terms of effective collaboration, massive financial backing, and technology development. However, the unequal allocation of such vaccines illustrated how constrained the current R&D system was. The reason for this was the inability of many countries to afford such vaccines due to their lack of money, proper infrastructure, or political clout.

Additionally, lack of regional cooperation among the developing nations further exacerbates research and development disparities. Although there are a number of regional initiatives, most of the developing nations continue to face problems related to research and the lack of common infrastructural facilities. Enhancing regional partnerships can be helpful in allowing countries to work together towards finding effective solutions and using their own innovations for overcoming health challenges.

World Health Organization is one such organization that has taken an active role in overcoming this particular challenge by promoting international cooperation and conducting research. Such international cooperation along with research projects can prove useful in minimizing disparities in terms of research capabilities as well as the transfer of information.

Capacity building activities as well as improving research capabilities of developing nations must also be promoted.

Overall, the gap between research and development activities remains an important barrier in achieving health equity around the world. The unequal distribution of resources, the influence of market-oriented factors on the course of research, difficulties associated with intellectual property issues, inadequate technology transfer, unequal levels of financing, and lack of regional cooperation all play a significant role in this problem. It is necessary to undertake joint measures at the international level to overcome such barriers.

7. Case Studies

a. The COVID-19 Pandemic and COVAX

*COVAX: c*onstitutes the vaccine component of the Access to COVID-19 Tools (ACT) Accelerator program. The ACT Accelerator is a groundbreaking global collaboration aimed at accelerating the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

COVAX is jointly implemented by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and the World Health Organization (WHO), in partnership with UNICEF as a key implementing partner. In the Americas, the PAHO Revolving Fund serves as the designated procurement agent for COVAX. The goal is to accelerate the development and production of COVID-19 vaccines and ensure fair and equitable access for every country in the world.

Managing Partners:

- CEPI (Pandemic Preparedness Innovations Coalition)
- Gavi (The Vaccine Alliance)
- WHO (World Health Organization)
- UNICEF (Lead implementing partner)
- PAHO Revolving Fund (Procurement agent for the continent of America)

The WHO played multiple roles within the COVAX framework: it provided normative guidance on vaccine policy, regulation, safety, research and development, allocation, and country preparedness and distribution.

The WHO Strategic Advisory Group of Experts on Immunization (SAGE) developed evidence-based immunization policy recommendations. The Emergency Use Listing (EUL) / prequalification programs ensured harmonized review and authorization among member states.

WHO has provided global coordination and support to member states on vaccine safety monitoring, developed target product profiles for COVID-19 vaccines, and facilitated technical coordination for research and development.

To explain the role of the WHO in the COVAX framework, we can outline the following points:

- ***Policy and Advice:*** Provide evidence-based policy recommendations through SAGE (Strategic Advisory Group of Experts on Immunization).
- ***Evaluation and Approval:*** Conduct a harmonized review and certification process among member states through the Emergency Use Listing (EUL) and the prequalification programs.
- ***Monitoring Safety:*** Coordinate global vaccine safety tracking.
- ***R&D Coordination:*** Develop target product profiles for vaccines and facilitate technical research.

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020, following the detection of the first cases in Wuhan, China, in December 2019. After being declared a global pandemic, COVID-19 deeply affected numerous countries and strained their healthcare systems. Globally, as of December 19, 2022, there were 649,038,437 confirmed COVID-19 cases, 6,649,812 cumulative deaths, and 64,631 new cases reported in the past 24 hours. Despite various measures taken through global governance mechanisms, the situation becomes even more critical when ATM resources are limited.

This has made COVID-19 the most significant global health crisis since the 1918 flu pandemic. This pandemic has also led to a shortage of working hours, creating shockwaves in the global economy. Many countries have experienced the second, third, or fourth waves of this viral disease. As COVID-19 cases have surged worldwide, efforts to develop a vaccine were required to be completed by the end of 2020.

Out of the 7.8 billion people in the world, 2.3 to 2.6 billion live in low- and middle-income countries. About 333 million people in the upper middle lived in countries with an upper middle income. On the other hand, about 972 million people live in countries with high incomes. But the irony is that the poorest 80% of people only have access to less than 20% of the total wealth, productive capacity. Tedros Adhanom Ghebreyesus (Director General of the WHO) said in his opening remarks, “Vaccine equity is the problem of our time.” “We are also not doing well”.

According to the research findings by various scholars, there were huge differences and inequalities that happened during the COVID-19 pandemic, for example, in testing for infections, hospitalizations, and deaths. A recent study that looked at data up to end of March, 2021 (about 4 months after the first public COVID-19 vaccination, which had happened on December 6, 2020), found that the global Gini coefficient was 0.88 for COVID-19 vaccinations.A subsequent study showed that the distribution of COVID-19 vaccinations did

not get any better, and also differences between vaccinations for COVID-19 have widened by December 7, 2021.

Inequality between continents was slightly less severe, but inequality within continents was very severe. On the other hand, inequality was slightly lower in Europe. Furthermore, although 59.3% of the world's population lives in Asia and 67.8% of the world's vaccines have been administered to Asian countries, not all of them received the same amount of vaccines. Oceania also faced similar issues regarding vaccines. On the other hand, although Africa is home to 17.5% of the world's population, it has used only 3.1% of the world's vaccines. This situation has made vaccine distribution in Africa more equitable than in Asia. However, Europe and South America have received approximately the same number of COVID-19 vaccines relative to their populations, and distribution in these regions has not been as uneven as in Asia, Oceania, or North America.

The unbalanced distribution of COVID-19 vaccines highlights a systemic failure stemming from the TRIPS agreement. The absence of compulsory licensing mechanisms and technology transfer requirements has led high-income countries to monopolize vaccine supplies, rendering COVAX insufficient on its own.

Barriers to Access to Medicines: Given the multifaceted impacts of COVID-19, health equity has become one of the greatest challenges in global health governance. In this context, access to medicines has remained limited due to various barriers, particularly for developing countries.The patents grant one of the critical barriers to the same. It is exclusively given for 20-year territorial rights to a product or process. The patent owner can prevent the product's manufacture, use, sale, import, or distribution.Patent protection gives pharmaceutical companies monopolies on drugs and processes. Patents are one of the most significant barriers to this access. A patent grants exclusive regional rights for a product or process for a period of 20 years. The patent holder can prevent the production, use, sale, import, or distribution of the product.

Price is another barrier to equity in medicines. In some countries, medicines companies have full control over the pricing of their patented products. As a result, the company has full control over the cost of the medicine, which is determined based on a price level it believes best reflects its production capacity and targeted profit margin. The buyers have very little influence over the set price.15 This sudden price increase not only affects buyers but also creates inequalities in the ability of different socioeconomic groups to meet their basic needs.

b. TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement signed by all member countries of the World Trade Organization (WTO). It establishes minimum standards for national governments to regulate the various forms of intellectual property applied to citizens of other WTO member countries. TRIPS was negotiated between 1989 and 1990 at the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and is administered by the WTO.

The TRIPS Agreement was the first to incorporate intellectual property law into the multilateral trading system and remains the most comprehensive multilateral agreement on intellectual property to date. In 2001, developing countries, concerned that developed countries were insisting on an overly narrow interpretation of TRIPS, initiated a series of negotiations that culminated in the Doha Declaration.

The Doha Declaration is a WTO statement that clarifies the scope of TRIPS and specifies that it can and should be interpreted in light of its objective to "promote access to medicines for all."

The developing countries have remained the most affected ones. Many argue that the production of generic brands in developing nations increases competition and is necessary to close the global drug gap.
According to multiple sources, the demand for extra safeguards such as market and data exclusivity impedes low-income countries' ability to manufacture and produce generic pharmaceuticals. However, low-income nations frequently lack the necessary infrastructure to produce generic brands. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the most critical barriers for access to medicines. It is also argued that the TRIPS agreement had a negative effect on the generic drug industries in several countries. On the contrary, it is argued that the agreement is interpretable. In the event of a national emergency, a TRIPS clause allows for compulsory licensing, which allows for the creation of generic versions of patented medications at market-determined pricing.

Novartis - Gleevec Case: The case of Novartis v. The Union of India and Others is a decision by a two-judge bench of the Supreme Court of India regarding whether Novartis had the right to patent Gleevec in India, and it marks the conclusion of a seven-year legal battle. The Supreme Court upheld the Indian Patent Office's decision to reject the patent application.

As part of this agreement, India made changes to its patent law; the most significant of these was that, whereas product patents were not permitted prior to these changes, they were subsequently allowed—albeit with restrictions. India also made certain amendments to its patent law in 2005, just before the laws came into effect, and these amendments played a significant role in the rejection of the patent application.

In 1993, during a period when India did not allow patents on products, Novartis had patented imatinib in many countries but had not been able to patent it in India.There were differences between the two patent applications, such as details and features.

The EMR was approved in November 2003. Novartis filed a lawsuit against certain generic drug manufacturers who had already launched Gleevec in India, using the EMR as a basis. Novartis set the price of Gleevec at $2,666 per patient per month; generic companies were selling their versions for between $177 and $266 per patient per month… Novartis also launched a program, concurrent with the product launch, to assist patients who could not afford its version of the drug.

When the examination of Novartis's patent application began in 2005, it was immediately challenged by objections filed by generic drug companies and advocacy groups already selling Gleevec in India. The application was rejected by the patent office and an appeals board. The primary basis for the rejection was a section of India's patent law, established by an amendment in 2005, which clarified the patentability of new uses for known drugs and modifications of known drugs. Section 3(d) of the amended law stipulated that such inventions were patentable only if they "differed significantly in their efficacy." At one point, Novartis filed a lawsuit to invalidate Section 3(d), arguing that the provision was unconstitutionally vague and violated the TRIPS Agreement. Novartis lost that case. Novartis then appealed the Patent Office's rejection to the Supreme Court of India.

The Supreme Court case hinged on the interpretation of Section 3(d). The Supreme Court ruled that Novartis had failed to provide evidence of a difference between the final form of Gleevec and the raw form of imatinib, and therefore the patent application had been correctly rejected by the Patent Office and the lower courts.

Although the court's decision was narrow in scope and specifically noted that the application in question was filed during a transitional period in Indian patent law, the ruling sparked widespread global attention. Had Novartis won the case and obtained the patent, it could not have prevented generic drug companies in India from continuing to sell generic Gleevec, but it could have required them to pay a reasonable royalty under a transitional provision in India's patent law.

c. Generic Drug Production in India

India is known as the "pharmacy of the world" for good reason. The country supplies about 20% of all generic drugs – cheaper versions of brand-name medicines, widely prescribed around the world.

As such, India's pharma industry is never far from the headlines. But it presents both significant successes and persistent challenges while some stories tout the sector's meteoric growth, others tell of quality issues with effects beyond national limits.

The industry is also growing: one estimate suggests that the country's pharma export market will increase at least tenfold by 2047, bringing its value to $350bn. So the pressure is on to ensure that the medicines coming out of India are not only safe but effective – and to reassure the world of the same.

Beyond quality concerns, the sector also faces emerging geopolitical pressures that threaten its global reach. The industry was shielded from a serious setback when United States exempted pharmaceutical products from the tariffs. However, he later said that tariffs targeting the sector were on the way.

While Indian drug companies are hopeful they can remain competitive, higher tariffs could make some drugs financially unsustainable and could lead to shortages in the US and beyond.

Improving quality and strengthening oversight mechanisms in generic drug production requires a combined approach that encompasses both access and safety.

When did it all begin? As early as the 18th century, locally made drugs rooted in traditional remedies were widely used across India. But over time, the domestic industry began to face stiff competition from imported drugs. These tended to be preferred by the Bengali middle classes and were further supported by central government, both before and after independence in 1947.

A milestone moment came in 1970, when the Patents Act changed the exclusive rights that could be granted to the inventor of a drug, limiting them to manufacturing processes only (and not final products). This meant that Indian companies could now reverse-engineer branded drugs and develop affordable alternatives, known as generics.

India's then-prime minister Indira Gandhi, who said western pharma companies had been exploiting patent laws to keep drug prices high, was a big advocate for this reform. She saw the Patents Act as a tool to break foreign monopolies, boost local production and secure patients' access to affordable medicines.

She was right. Production and exports skyrocketed, and Indian pharma companies soon thrived. Even when patent laws were tightened in 2005, the country managed to stay competitive by focusing on making and exporting drugs whose patents had expired. Key to this success were India's cost-effective labour and manufacturing processes.

What is India's generics industry known for? Primarily, its global exports. In the US, for instance, where nine out of ten prescriptions dispensed are for generics, India provides around 40% of those generic drugs. In the UK, it supplies around 33% of generics, which account for four out of five NHS prescriptions. India is also a key source of pharma products for sub-Saharan Africa, where people often depend more heavily on affordable medicines Historically, India's generics industry first gained global attention in the early 2000s, when the Mumbai-based producer Cipla revolutionised access to HIV medications. Cipla's chairman said he was driven by concern about the HIV/Aids epidemic in Africa to reduce the cost of vital drugs known as antiretrovirals.

With no patent protection in place in India at the time, Cipla managed to create a drug combination that could be priced far lower than the patented versions sold by pharma companies.The move helped to reduce the annual cost per patient of HIV/Aids treatment in Africa from about $15,000 in the 1990s to approximately $200 in 2005.

Are Indian-made drugs safe? There are longstanding concerns about the quality and safety of generics made in India, partly because the country's regulation standards are not necessarily in line with those of other nations. In 2014, India's chief drug regulator said that adhering to US standards would mean shutting down most drug manufacturing facilities in the country.

Companies are also not required to follow international inspection standards – India has so far not joined a global scheme designed to harmonise pharma inspections. And even when inspections do happen, some companies have been caught destroying manufacturing records.

India's state-run labs, which are responsible for testing a drug's quality before any medicine reaches patients, are often underfunded, short-staffed and lacking the right equipment. The country is also low on local inspectors for drug testing and factory visits. The national drug regulator has only 2,000 officials to oversee more than 10,000 factories and a million pharmacies.

Lax oversight can allow unscrupulous companies to cut corners, especially under the pressure of government-imposed price caps on essential drugs. This can lead to lower-quality drugs, including those with the wrong amount of active ingredient or those containing contaminants.

What can be done to improve the quality of Indian drugs? Since 2023, India's government has been rolling out stricter quality regulations for pharmaceutical manufacturers, requiring them to upgrade their facilities to meet higher standards. The industry has been slow to respond, despite compliance deadlines getting pushed back.

The government also is investing in projects to centralise data on manufacturers and supply chains; the aim is to make monitoring more efficient and streamline licensing and export approvals.

Stronger collaboration with global regulators could also help India meet international standards. A first step could be its participation in bodies that work to standardise drug regulation and inspections, something that has been encouraged by the US's Food and Drug Administration.

8. International Frameworks and Conventions

a. Sustainable Development Goal 3 (SDG 3)

The goals of Sustainable Development Goal 3 are to ensure healthy lives and promote well-being for everyone of all ages.

Significant progress has been made against many of the leading causes of death and disease. Life expectancy has increased considerably; infant and maternal mortality rates have fallen; significant progress has been made in the fight against HIV; and malaria-related deaths have been halved. Good health is essential to sustainable development, and the 2030 Agenda reflects the complexity and interdependence of the two. It takes into account widening economic and social inequalities, rapid urbanization, threats to the climate and environment, the continuing burden of HIV and other infectious diseases, and emerging challenges such as non-communicable diseases. Universal health insurance will be an integral part of achieving Sustainable Development Goal 3, which aims to end poverty and reduce inequalities. Emerging global health priorities not explicitly addressed in the Sustainable Development Goals, including antimicrobial resistance, also require action.

However, the world is off track in achieving the health-related Sustainable Development Goals. Progress is uneven, both between and within countries. There is a 31-year gap between the countries with the shortest and longest life expectancy. While some countries have made impressive gains, national averages mask the fact that many are lagging behind. Multi-sectoral, rights-based, and gender-sensitive approaches are essential to address inequalities and build a healthy health system for all.

- *REDUCE MATERNAL MORTALITY*

By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births.

Maternal mortality ratio declined by 40 percent between 2000 and 2023, there were approximately 260,000 maternal deaths worldwide in 2023, most from preventable causes. In 2015, maternal health conditions were also the leading cause of death among girls aged 15–19. Key strategies for meeting SDG 3 will be to reduce adolescent pregnancy (which is strongly linked to gender equality), provide better data for all women and girls, and achieve universal coverage of skilled birth attendants.

- *END ALL PREVENTABLE DEATHS UNDER 5 YEARS OF AGE*

By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under‑5 mortality to at least as low as 25 per 1,000 live births.

- *FIGHT COMMUNICABLE DISEASES*

By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases.

- *REDUCE MORTALITY FROM NON-COMMUNICABLE DISEASES AND PROMOTE MENTAL HEALTH*

By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.

- *PREVENT AND TREAT SUBSTANCE ABUSE*

Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

- *REDUCE ROAD INJURIES AND DEATHS*

By 2020, halve the number of global deaths and injuries from road traffic accidents.

The need for improvements in safer infrastructure and government regulation continues. In countries with great success, such as Sweden that boasts a 66 percent reduction in injury and deaths from 1990 to 2015, tough government regulation has been key.

A Decade of Action for Road Safety 2011-2020 was declared in March 2010 by the United Nations General Assembly. In February 2020, the Stockholm Declaration that set a global target of reducing road traffic deaths and injuries by 50 percent by 2030. In August 2020, the United Nations ratified the Stockholm Declaration declaring 2021–2030 the Second Decade of action for Road Safety.

- *UNIVERSAL ACCESS TO SEXUAL AND REPRODUCTIVE CARE, FAMILY PLANNING AND EDUCATION*

By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes.

- *ACHIEVE UNIVERSAL HEALTH COVERAGE*

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

- *REDUCE ILLNESSES AND DEATH FROM HAZARDOUS CHEMICALS AND POLLUTION*

By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.

- *IMPLEMENT THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL*

The WHO Framework Convention on Tobacco Control has been ratified by the great majority of countries (180 countries). The WHO Tobacco Free Initiative, Secretariat of the WHO Framework Convention on Tobacco Control and the Protocol to Eliminate Illicit Trade in Tobacco Products is the main custodian. WHO member states and party states to the Framework Convention on Tobacco Control provide data.

- *SUPPORT RESEARCH, DEVELOPMENT AND UNIVERSAL ACCESS TO AFFORDABLE VACCINES AND MEDICINES*

Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the

TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

- *INCREASE HEALTH FINANCING AND SUPPORT HEALTH WORKFORCE IN DEVELOPING COUNTRIES*

Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States.

- *IMPROVE EARLY WARNING SYSTEMS FOR GLOBAL HEALTH RISKS*

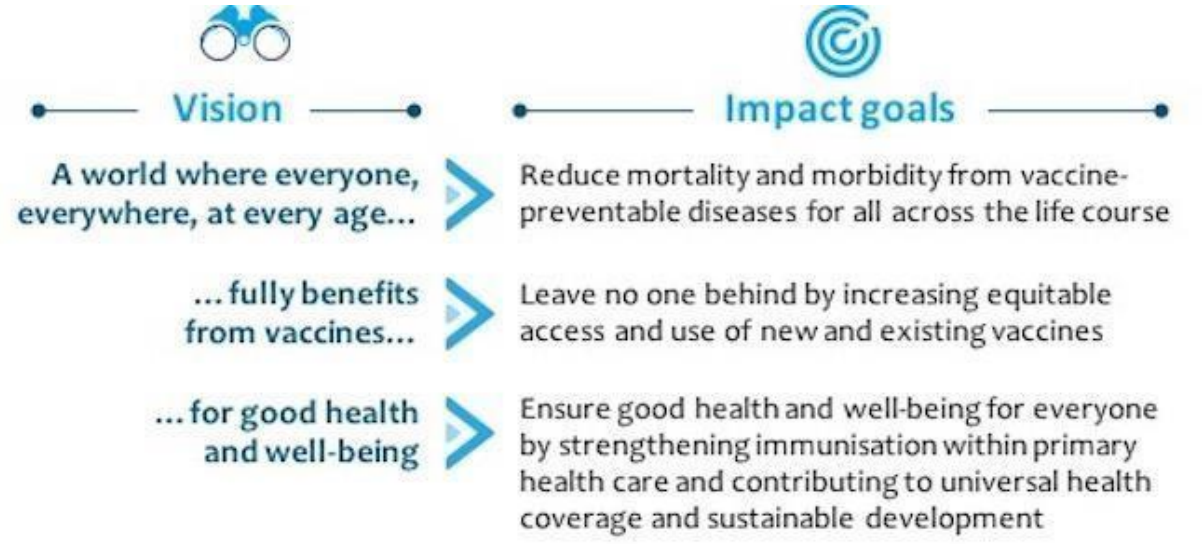
Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.

b. Immunization Agenda 2030 (IA2030)

Immunization is a global health and development success story, saving millions of lives every year. We now have vaccines to prevent more than 20 life-threatening diseases, helping people of all ages live longer, healthier lives.

Immunization is the foundation of the primary health care system and an indisputable human right. It's also one of the best health investments money can buy. Yet despite tremendous progress, far too many people around the world – including nearly 20 million infants each year – have insufficient access to vaccines. In some countries, progress has stalled or even reversed, and there is a real risk that complacency will undermine past achievements. To address these challenges over the next decade, a new global vision and strategy, co-created by countries and development partners has been endorsed by the World Health Assembly.
The COVID-19 pandemic has reminded the world of the power of vaccines to fight disease, save lives, and create a healthier, safer, and more prosperous future. Now we must rapidly and equitably deliver COVID-19 vaccines to the world. Moving forward, strong immunization systems will be needed to ensure that people everywhere are protected against COVID-19 and other diseases. Ensuring everyone receives the vaccines they need will provide exceptional return on investment and help keep the world safe from future pandemics.

IA2030 envisions a world where everyone, everywhere, at every age, fully benefits from vaccines to improve health and well-being. It aims to maintain hard-won gains in immunization, recover from the disruptions caused by COVID-19, and achieve even more – by leaving no one behind, in any situation or at any stage of life.



Strategic priorities: IA2030 has been developed through a "bottom-up" co-creation process, with close engagement of countries to ensure that the vision, strategic priorities and goals are aligned with country needs. As an adaptive and flexible strategy, the IA2030 framework is designed to be tailored by countries to their local context, and to be revised throughout the decade as new needs and challenges emerge.

The Monitoring and Evaluation (M&E) Framework includes tailored indicators to enable the use of data for action to continuously improve immunization programs at all levels.

Underneath IA2030's three Impact Goals are seven Impact Goal Indicators to monitor progress across country, regional and global levels. The M&E framework provides strategic priority objectives and indicator options for regions and countries to inform the development of their own M&E Frameworks.
IA2030 goals are designed to inspire action for implementation and support efforts to improve health security, universal health coverage, access and equity for immunization and innovation.

For countries, this could mean setting country-specific targets and milestones for the decade toward those goals. For regions, this could mean contextualising global goals and setting specific targets and milestones in Regional Vaccination Action Plans. For partner organisations, this could mean aligning organizational strategies and indicators to support the attainment of IA2030 goals.

Core principles: The IA 2030 strategy—to extend the benefits of vaccines to everyone, everywhere—is underpinned by four core principles: it puts people in the centre, is led by countries, implemented through broad partnerships, and driven by data. The IA2030 strategy systematically applies the core principles across each of the strategic priorities.

Strategic Priority Goals: Each strategic priority has strategic priority goals as the basis for evaluating progress. These goals complement existing disease-specific goals, broader health goals, and the Sustainable Development Goals (SDGs). The strategic priority goals mirror the ambition of these existing commitments and aim to galvanize efforts to achieve important gains in immunization over the coming decade.

Immunization is playing a critical role in achieving the Sustainable Development Goals (SDGs). Immunization reaches more people than any other health and social service, making it the foundation of primary health care systems and a key driver toward universal health coverage. This makes immunization critical to SDG3 – to ensure healthy lives and promote well-being for all at all ages. Because health is so fundamental to development, IA2030 will also contribute—either directly or indirectly—to 13 of the other SDGs.
Immunization is an investment for the future, creating a healthier, safer and more prosperous world for all.

c. Existing Mechanisms and Tools

Several international mechanisms exist to bridge the gap between innovation and equal access in the pharmaceutical industry.

Medicines Patent Pool (MPP): A UN supported organization. It aims to enable generic drug manufacturers in low- and middle-income countries to produce medicines at lower costs and, to this end, enters into voluntary licensing agreements with patent holders. This initiative is limited to the voluntary participation of pharmaceutical companies.

Tiered/Differentiated Pricing: A practice of setting different prices for medicines based on a country's income level. This practice includes HPV vaccines. It depends on the manufacturer's willingness, and measures must be taken to prevent parallel trade.

Advance Market Commitments (AMC): Donor governments encourage developing companies and low-income countries to produce for low-income markets by committing to guarantee purchases of medicines or vaccines. This approach was also used under COVAX; however, the COVID-19 pandemic revealed the system's failure during crises, particularly as high-income countries failed to meet expectations due to bilateral agreements.

Push and Pull Financing: This approach is vital for researching neglected diseases where market incentives alone are insufficient. Push mechanisms provide upfront public funding for R&D and reduce financial risk in production. On the other hand, pull mechanisms reward successful developments through means such as incentive funds.

Centralized Procurement: Countries collectively negotiate drug purchases to enhance their bargaining power. Examples of this approach include the PAHO Revolving Fund and the African Union's African Medical Supplies Platform.

9. Critical Countries Views

China: At this point, we must emphasize that China has played a vital role in ensuring the global accessibility of essential medicines and vaccines. Given China's significant economic power and its status as a leading pharmaceutical manufacturer, the country is recognized as a key actor in the field of global health governance. In this context, China has essentially transitioned from a planned economy to a more market-oriented one; as a result, the country has undergone a rapid industrialization process, including in the pharmaceutical sector. Today, it can be said that China is one of the leading producers of active pharmaceutical ingredients (APIs) required for various medications worldwide. According to current statistics, approximately 40% of global API production is accounted for by China. Despite the potential advantages and disadvantages of China's dominance in the supply chain, its ability to produce on a large scale and at lower costs helps reduce global pharmaceutical costs, making medications more accessible. China's role in pharmaceutical production and exports has grown during the coronavirus pandemic. In the early days of the pandemic, the healthcare sector and manufacturing were among the sectors facing challenges in China. However, after overcoming the difficulties brought by the first wave of the pandemic, China emerged as a leading producer of face masks, personal protective equipment, and vaccines. China has produced various types of vaccines, including Sinovac and Sinopharm, which have been distributed worldwide. According to reports, by the end of 2022, China had provided billions of vaccine doses to over 100 countries for donation or sale.

India: The recognition of India as the "Pharmacy of the World" is rooted in a unique combination of affordable prices and guaranteed quality, which has led to the widespread preference for Indian medicines in global markets. Cost-effective production, supported by a strong scientific workforce and large-scale manufacturing, has enabled the consistent supply of essential medicines without compromising on standards.
In international forums, India has consistently advocated for the use of TRIPS flexibilities—including compulsory licensing—to safeguard access to affordable medicines for developing countries. It has been a leading voice in promoting technology transfer and opposing measures that would extend patent protections beyond TRIPS minimum standards. However, India faces significant internal challenges. Regulatory oversight remains inconsistent, and concerns persist regarding quality control and production standards in the pharmaceutical sector. Internal disparities in access to healthcare between urban and rural populations also highlight the gap between India's global role as a pharmaceutical supplier and the unresolved health inequities within its own borders.

South Africa: South Africa is taking on a regional leadership role in the areas of pharmaceutical production and regulatory harmonization with the aim of lowering drug prices and improving access to vaccines. By hosting major facilities such as Aspen Pharmacare and promoting local production, the country is reducing its dependence on expensive imports. South Africa uses structured tendering systems and works within the framework of African Union initiatives to ensure that essential medicines are more affordable and accessible across the continent.

Despite such efforts, challenges such as reliance on imported active pharmaceutical ingredients and capacity constraints in large-scale production persist.
South Africa emphasizes the importance of combining local production with regional cooperation to improve access to medicines.

Brazil: Brazil has one of the largest pharmaceutical markets in Latin America and plays a significant role in regional health policy, particularly through its commitment to universal health coverage under the Sistema Único de Saúde (SUS).

Brazil faces challenges in ensuring equal access to prescription medications for its population. Socioeconomic inequalities contribute to health disparities that affect access to healthcare services, including medications. Brazil's Unified Health System aims to provide universal health coverage, yet only 30.5% of the population can obtain all their prescription medications free of charge through public channels.

Brazil's pharmaceutical market is large but highly concentrated, characterized by low investment in original research and development (R&D) and excessive reliance on imported active pharmaceutical ingredients. Challenges include vulnerability to economic and external factors. Additionally, high drug prices, the prioritization of producing expensive new drugs over medications for common diseases, and drug shortages contribute to inequities in access. Regulatory issues, inadequate funding of healthcare services, and legal inconsistencies exacerbate these challenges but also present opportunities for reform. There is a reliance on imported active pharmaceutical ingredients, and organizations such as Fiocruz are helping to develop vaccines and reduce this external dependency.

Switzerland: Switzerland is a country with good access to medicines. In various international studies, Switzerland ranks among the top countries in Europe. According to a study by EFPIA, Switzerland ranks fourth in Europe for access to new medications and second for access to oncology medications. However, compared to other European countries, Switzerland has the highest prices for medications and the highest per-capita costs. Healthcare costs are one of the biggest concerns for the Swiss population. Rising premiums are placing an increasingly heavy burden on households. Medications account for more than 20% of costs within the mandatory (basic) health insurance system. Consequently, increases in drug prices contribute to rising basic health insurance premiums.In Switzerland, medication expenditures for outpatient care reached 9.2 billion Swiss francs in 2024. This amounts to approximately one-fifth of total basic health insurance costs.Over the past decade, there has been a disproportionate increase in the costs of new medications listed in the Medicines List. On average, these costs have risen by more than 50% compared to a decade ago. Since premiums follow costs, a sharp increase directly impacts the level of health insurance premiums. Relatively high prices mean that innovation is already heavily rewarded in Switzerland today. The FOPH, together with other federal agencies, aims to promote fair framework conditions for the pharmaceutical industry. Regulatory authorities such as the Federal Office of Public Health (FOPH) aim to strike a balance between fair pricing and

maintaining favorable conditions for the pharmaceutical industry, and to promote fair framework conditions for the pharmaceutical industry.
Switzerland demonstrates a balancing act between rapid access to innovative medicines and the financial sustainability of healthcare systems, highlighting the need for policies that strike a better balance between affordability and innovation.

Germany: Germany is one of Europe's leading actors in addressing high drug prices and ensuring equitable access to essential medicines and vaccines. As a high-income country with a strong pharmaceutical industry and an advanced public health system, Germany plays an influential role both nationally and internationally.
At the national level, Germany has implemented significant reforms in drug pricing over the past decade. Historically, Germany was one of the few countries where pharmaceutical companies could freely set the prices of their products. This situation changed with the enactment of the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, which established a new pricing framework. Under this system, companies have the freedom to set a drug's price for the first twelve months following its market launch; however, they must demonstrate that the drug provides additional clinical benefit compared to existing treatments. If they fail to do so, the drug is subject to the reference pricing system. These reforms are projected to yield significant savings within Germany's statutory health insurance system. Price reductions and price-freeze measures are currently estimated to yield annual savings of approximately 1.2 billion euros. In particular, given Germany's role as a key reference market, pricing decisions exert downward pressure on drug prices in approximately 18 other countries that use Germany as a pricing benchmark.

Russia: Russia holds a vital position in guaranteeing availability of cheap medicine and vaccines across the world. As a major political force endowed with a rich scientific tradition and an already developed pharmaceutical industry Russia impacts global health by way of production and cooperation. Nevertheless, the role Russia plays in global health cannot be described in isolation from the economic and political situation in the country.

Before, the centralized healthcare delivery system that Russia adopted was based on the legacy of the previous Soviet state. With the dissolution of the USSR in 1991, many changes have occurred in the Russian healthcare system, including cuts in the health budget, poor-quality infrastructure, and inadequate provision of medicines. Although there have been multiple reforms in the Russian healthcare system, there are some obstacles to improving the current situation in this sphere. Among the main strengths of the Russian healthcare system is the country's capacity to manufacture drugs locally. Some steps have been taken by Russia in an attempt to enhance its capacity to manufacture drugs locally so that dependence on foreign-made pharmaceuticals would be minimized. In light of the geopolitics of the region where Russia operates, it has become important for the country to ensure that it can manufacture drugs independently. Additionally, sanctions and the economic situation impact the healthcare sector in terms of a limited access to innovation technologies and import medicines. Despite the efforts made by the government to regulate costs and ensure the affordability of medical products, this balance is hard to achieve.

In conclusion, Russia is a considerable but problematic actor on the international health scene. There are certain strengths that belong to Russia as an actor, namely scientific research, manufacturing and participation in international projects. At the same time, problems associated with regional differences, financial matters, and politics exist.

10. Questions a Resolution Should Address

1. How can the international community ensure affordable access to essential medicines in low- and middle-income countries while protecting medicines innovation and R&D costs?

2. How can TRIPS flexibilities and compulsory licensing be optimized to allow developing nations to produce or procure affordable generic medicines during health emergencies?

3. What reforms or supplementary frameworks are needed within the TRIPS Agreement to better align intellectual property rights with the fundamental human right to health?

4. How can the global pharmaceutical supply chain be made more sustainable and resilient by spreading production across different regions and reducing reliance on specific countries?

5. What strategies should be implemented to address gaps in the cold chain infrastructure and ensure vaccine availability to populations that are not able to access these services properly?

6. What are the alternative financing models that will ensure access to new medicines developed for neglected diseases?

7. How can international cooperation support the development of local pharmaceutical production capacities in low-income countries?

8. What concrete mechanisms can ensure medicine access for refugees and stateless persons in host countries?

    8.1. What concrete legal and financial measures should be taken to eliminate the barriers faced by refugees and those living in poverty?

    8.2. How can international cooperation ensure sustainable access to medicines in regions affected by armed conflicts and natural disasters?

    8.3. How can digital health services be used to reach areas with limited access to health care?

9. How should the WHO's role in coordinating global medicine pricing, supply, and distribution be strengthened, particularly during crises such as pandemics?

10. What reporting and reporting mechanisms should be established to track the progress made by member states regarding access to essential medicines under SDG 3 and the 2030 Vaccination Agenda?

11. What financial mechanisms and international cooperation can be established to promote local production and prevent brain drain in developing countries?

12. In major generic drug-producing countries such as India, what global cooperation mechanisms can be established to develop drug quality control systems that comply with international standards?

13. How can public health communication strategies be strengthened to counter rising vaccine hesitancy and distrust in medicines caused by misinformation on digital platforms?

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