Committee: World Health Organization (WHO)

Issue: Enhancing Transparency in the Pharmaceutical Sector to Ensure Equitable Access to Essential Medicines

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Introduction

Access to essential medicines is a foundational element of the right to health. Yet, inequalities persist: one-third of the world's population lacks reliable access to the medicines they need, and in low-income countries, this figure can reach up to 50%. Medicines are not ordinary consumer goods, they lie as a critical part of disease prevention, management and treatment. Meanwhile, ambiguous pricing mechanisms, limited patent transparency, and monopolistic networks in the pharmaceutical industry have contributed to ever-increasing drug prices, undermining the minimal progress made towards Universal Health Coverage (UHC) and Sustainable Development Goal (SDG) 3.8. (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)

The COVID-19 pandemic has somewhat unraveled these social inequities. Public funding greatly supported wealthy nations through public funding, but the distribution remained highly unequal. Many Low- and Middle-Income Countries (LMICs) were left behind, gridlocked, unable to find a way to acquire treatment options. Including the COVID-19 crisis, these disparities in access were not only a result of limited supply but a comprehensive result of licensing agreements, and clinical trial data.

This agenda aims to explore strategies to enhance transparency in the pharmaceutical sector. Often, discriminatory pricing is a leading cause of global outrage. Monopolies exploit the blind spots of society, where secretive partnerships that use public funds without accountability perseveres. These pervasive ill- mechanisms should be combated by increased transparency in order to reduce inequities, improve access to affordable, safe, and effective medicines globally.

Definition of Key Terms

Essential Medicines

Essential medicines are those that address priority health care needs, and should be available at all

times. It should also be supplied in adequate amounts, in appropriate dosage forms with assured quality. As defined by WHO, "Medicines that satisfy the priority healthcare needs of the population," this list of medicines are used by over 150 countries and updated every two years. However, being on the list does not signify equal accessibility unless transparency and affordability mechanisms exist.

Pharmaceutical Transparency

The public availability of information from production to consumption of medicine, including:

1. R&D Transparency (Research and Development) – The main funder of the innovation
2. Clinical Data Transparency – Trial result disclosure, result bias and non-inclusive results
3. Patent Transparency – Subject, duration, location of patent and accessibility as a single database
4. Licensing Transparency – Voluntary license terms, excluded/included list of countries
5. Pricing Transparency – Procurement price information to consumers, discounts/rebates made public
6. Procurement and Distribution – Competitive and open processes, medicine stock-out reports to the public

TRIPS Agreement

Adopted in 1995, the World Trade Organization (WTO) Agreement on trade related intellectual property rights, which sets minimum standards for Intellectual Property (IP) protection. 20 year patent minimum for pharmaceutical products, trade sanctions imposed for countries violating these rules. TRIPS is designed to reduce flexibility for generic production.

IP protection

Legal methods of IP protection. Patents, trademarks, copyrights to protect brand identity.

TRIPS Flexibilities

Legal options within the TRIPS Agreement. Allow countries to prioritize public health over patent enforcement, bypassing exclusivity in public health crises. Countries may issue compulsory licenses that allow the production of generics without consent. The 2001 Doha Declaration on TRIPS and public health has clarified what constitutes a national emergency-public health crisis.

Patent Evergreening

The practice of making minor modifications to existing drugs to extend patent protection, extending market exclusivity. This may delay generic competition from entering the market.

Voluntary Licensing

Agreements where patent holders permit generic manufacturers to produce patented medicines, often under terms that restrict market access or transparency.

Procurement

Strategic procurement of medicines, medical devices, and related services within the healthcare industry.

Access to Medicines Index (AMI)

A ranking of major pharmaceutical companies based on efforts to improve access to medicines in LMICs. Developed by the Access to Medicine Foundation, 20 largest pharmaceutical companies are evaluated.

History

In 1977, the WHO prioritized cost-effective and life-saving drugs by introducing the Model List of Essential Medicines; many countries further produced national lists based on the original. While the list improved procurement planning, it did not help to alleviate the structural challenges revolving around pricing ambiguity and pharmaceutical grouping.

In 1995, the global outlook shifted dramatically with the establishment of the TRIPS Agreement, which required strong IP protections, including pharmaceutical sector patents. LMICs that previously overlooked the importance of pharmaceutical patents made amendments to constitutions. A widespread concern was triggered, particularly during the HIV/AIDS epidemic, when patented drugs were priced out of reach for millions, and low cost generics also not available.

The 2001 Doha Declaration greatly increased countries' influence over public health related matters, strongly emphasizing TRIPS flexibility when implementing policies. The main point was to prevent TRIPS from asserting dominance (having more control) over countries' rights. However, many

parts of the world continued to face political and commercial pressure when attempting to use TRIPS flexibilities.

The COVID-19 pandemic further cleared the opacity of voluntary actions performed by companies. Despite public investment exceeding $100 billion in vaccine R&D, pharmaceutical firms continued to reject demands to share findings through WHO's COVID-19 technology access pool. Instead, vaccines were supplied by non-mainstream accesses and secretive deals, resulting in inequities in global immunization.

Key Issues

Non-transparent and Discriminatory Drug Pricing

One of the most critical challenges in the pharmaceutical sector is the lack of transparency and how medicines are priced. Governments often pay incredibly different prices for the same drug, not due to objective factors. Rather, prices are negotiated under surveillance, often protected by confidentiality agreements.. As a result, governments and public buyers are unable to fully fathom what they pay against international standards (Although comparing with international standards does help, it fails to help address the country's unique pricing problem). Moreover, middle countries are frequently excluded from favorable pricing activities, creating a system of global hierarchy where the poorest and the richest sometimes benefit more.

Unclear R&D Costs and Public Investment Accountability

Pharmaceutical companies regularly defend high drug prices by citing the enormous costs associated with research and development (R&D). However, detailed breakdowns of R&D expenditures are rarely disclosed, and there is often a substantial gap between industry claims and independent analyses. Despite being funded by public institutions, the results of research products are often patented and commercialized without any public return in the form of price regulation, equitable licensing, or access guarantees. In many cases, the public ends up "paying twice".

Restricted Access to Patent and Licensing Information

The complexity of the global intellectual property (IP) system makes it difficult for countries to navigate the patent landscape for essential medicines. Companies often file multiple, overlapping patents on the same drug in different jurisdictions, creating legal uncertainty about whether production is possible. Moreover, strategic patenting is used in order to compromise another company's products. For

example, patent thicketing refers to the practice of securing patents of various different aspects of a product, such as specific formulations, newer uses, distribution methods. Abbvie and Humira's patent dispute is a notable real-life example, where Abbvie filed multiple patents to lower Humira's market approval. Also, non-public licences may include restrictive nature on geographic coverage, technology transfer, and supply agreements. This secrecy also hinders regional manufacturing initiatives and discourages smaller generic producers from entering the market due to legal ambiguity. (Multiple interpretations of a single matter)

Regulatory Data Opacity and Limited Trial Transparency

Another layer of the transparency challenge involves the limited availability of clinical trial data and decision-making processes. While many high-income countries require public registration of clinical trials through legislation, further access to trial protocols and efficacy remains inconsistent. Transparency in trial outcomes helps to establish public trust and health, but also ensures development is based on verifiable sources of evidence.

Procurement Fragmentation and Vulnerability to Corruption

The lack of transparency also affects how medicines are procured at the national and regional levels. In many countries, especially those without centralized procurement agencies or digital tracking systems, medicine purchasing is fragmented across public hospitals, insurance systems and local authorities. This fragmentation leads to inefficiencies, inconsistent prices, duplication of supply chains, and increased vulnerability. Weak oversight mechanisms of the pharmaceutical sector make it difficult to detect overpricing, supply manipulation, or quality issues, particularly in emergency contexts when medicines are needed quickly. Corruption in procurement processes not only inflates costs but also erodes public trust in the health system and undermines long-term efforts to ensure equitable access.

Major Parties Involved and Their Views

World Health Organization (WHO)

The WHO has consistently advocated for equitable access to medicines and greater transparency in pharmaceutical markets. It continues to improve and regulate the Model List of Essential Medicines, facilitates practical assistance on procurement and pricing, and has convened important forums such as the Fair Pricing Forum and the Global Strategy on Digital Health. However, WHO's authority is limited to non-binding resolutions and moral persuasion.Its jurisdiction is limited, and policies often rely on the

willingness of member states to implement them. Despite this, the WHO still hold great influence on the global outlook of medicine.

World Trade Organization (WTO)

The WTO plays a pivotal role in the pharmaceutical problem through its enforcement of the TRIPS Agreement. While the organization formally recognizes the right of countries to use TRIPS flexibilities, political dynamics within the WTO frequently constrain such use. Often, unseen or ambiguous financial retaliations are used to influence how countries interact.

Pharmaceutical Industry

Large multinational pharmaceutical companies (such as Pfizer, Novartis, Johnson & Johnson, and Roche) wield significant influence over global medicine access through their control of patents, clinical data, and distribution channels. While some companies agree on the terms of voluntary reporting, they largely oppose mandatory requirements for full R&D cost breakdown, open licensing, or price comparisons. The industry also resists changes to IP norms, claiming that uncertainty would discourage future drug development. In fact, wide disputes revolving around IP jurisdiction remain a large challenge for pharmaceutical companies, often leading to opposing stances amongst them.

Lower and Middle Income Countries (LMICs)

Many LMICs face significant barriers in accessing affordable medicines due to weak negotiating positions, limited domestic production, and lack of regulatory infrastructure. Countries like India, Brazil, Thailand, and South Africa have historically led calls for expanded TRIPS flexibilities and stronger public-sector involvement in pharmaceutical production in response to public health demands. India's role as a major generic manufacturer gives it an interest in challenging restrictive patent regimes and promoting open licensing.

Civil Society and Non-Governmental Organizations (NGOs)

Organizations such as Médecins Sans Frontières (MSF), Health Action International (HAI), Oxfam, the Access to Medicines Foundation, and the Transparency International Health Initiative have been at the forefront of efforts to expose secrecy and advocate for reforms. While civil society influence

varies by context, these actors have been instrumental in shaping public discourse and mobilizing support for policies like open licensing, patent pooling, and data sharing.

Evaluation of Previous Attempts to Resolve the Issue

Over the past two decades, numerous initiatives have sought to address transparency and access challenges in the pharmaceutical sector. While some have achieved localized success or raised global awareness, most efforts have failed to create a fundamental structural change. The pattern of failed policies has a common problem. The voluntary mechanisms without enforcement have limited impact, especially in the face of concentrated industry power and weak international legal measures.

WHO's Fair Pricing Forum, held in 2017 and 2019, provided an important platform for countries and stakeholders to share experiences and explore policy options for fairer pricing. However, the recommendations issued were non-binding and rarely followed up with concrete implementation. They were merely "options" that could be easily dismissed by those with greater influence. Although severely symbolic, the resolution lacked mechanisms to ensure responsible action, leading to inconsistent uptake across regions.

With failed policy implementation, the COVID-19 pandemic tested the global community's accountability to equitable access and transparency. WHO's launch of the COVID-19 Technology Access Pool (C-TAP) aimed to create a platform for sharing patents and trial data. However, participation was minimal, with no major company contributing core technologies due to its voluntary nature.

In another instance, the TRIPS waiver proposal, submitted by India and South Africa in 2020, sought to suspend IP protections for COVID-19 technologies. It drew support from over 100 countries and civil society groups, but was delayed and watered down by resistance from high-income nations and industry allies.

The establishment of the Medicines Patent Pool (MPP) in 2010 has facilitated access to generics for diseases like HIV, hepatitis C, and COVID-19. Yet MPP remains restricted by its reliance on voluntary licensing.

Possible Solutions

Establish a Binding Global Framework for Pharmaceutical Transparency

WHO, in partnership with relevant UN agencies and regional bodies, should lead the development

of a multi-party agreement or convention requiring a standard for the disclosure of R&D processes (expenditures), clinical trial data, patent status, and procurement prices. This framework could follow the precedent of the Framework Convention on Tobacco Control (FCTC), providing both moral authority and legal obligation for member states. A central transparency registry, managed by WHO, would host accessible data for use by policymakers, civil society, and international procurement agencies.

Mandate Transparency for Publicly Funded Research

Governments and philanthropic donors should make transparency a mandatory condition of public or subsidized R&D grants. This would include obligations to publish clinical trial protocols, report final costs, and ensure equitable licensing through mechanisms such as open-access patent pools. Such measures would assure that public investment would lead to direct public benefit and reduce the ability of companies to privatize returns from taxpayer-funded innovation.

Promote Regional Pooled Procurement and Price Benchmarking

Countries can strengthen their negotiating power by forming regional procurement alliances and agreeing to share price data transparently. Entities like the Pan American Health Organization (PAHO), the African Medicines Agency, and ASEAN could serve as platforms for joint purchasing agreements. Regional benchmark databases would help reduce price variation and smaller countries to negotiate on equal footing.

Ensure Civil Society and Public Participation in Policy-making

Transparency must extend beyond institutions to include the communities most affected by medicine access barriers. Countries should institutionalize participatory decision-making processes that involve patients, healthcare workers, and advocacy groups in the development of pricing policies, medicine selection, and regulatory oversight. This democratic approach would increase accountability and ensure that reforms reflect the real-world needs of patients.

Establish a Global Fund for De-linked R&D

To encourage innovation without monopolies, governments could pool resources into a global R&D fund that rewards scientific progress through milestone payments, innovation prizes, and open-licensing conditions. This de-linked model has already shown success in some tuberculosis and neglected disease programs and could be scaled for antibiotics, cancer drugs, and rare diseases. For example, the Global Health Innovative Technology (GHIT) fund is a public-private partnership established by the Japanese government in order to concentrate R&D support for neglected diseases. It

provides funding in multiple stages of R&D, mandates to prioritize affordable access and restricts patent power in LMICs.

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