# THE *Pharmaceutical* INDUSTRY

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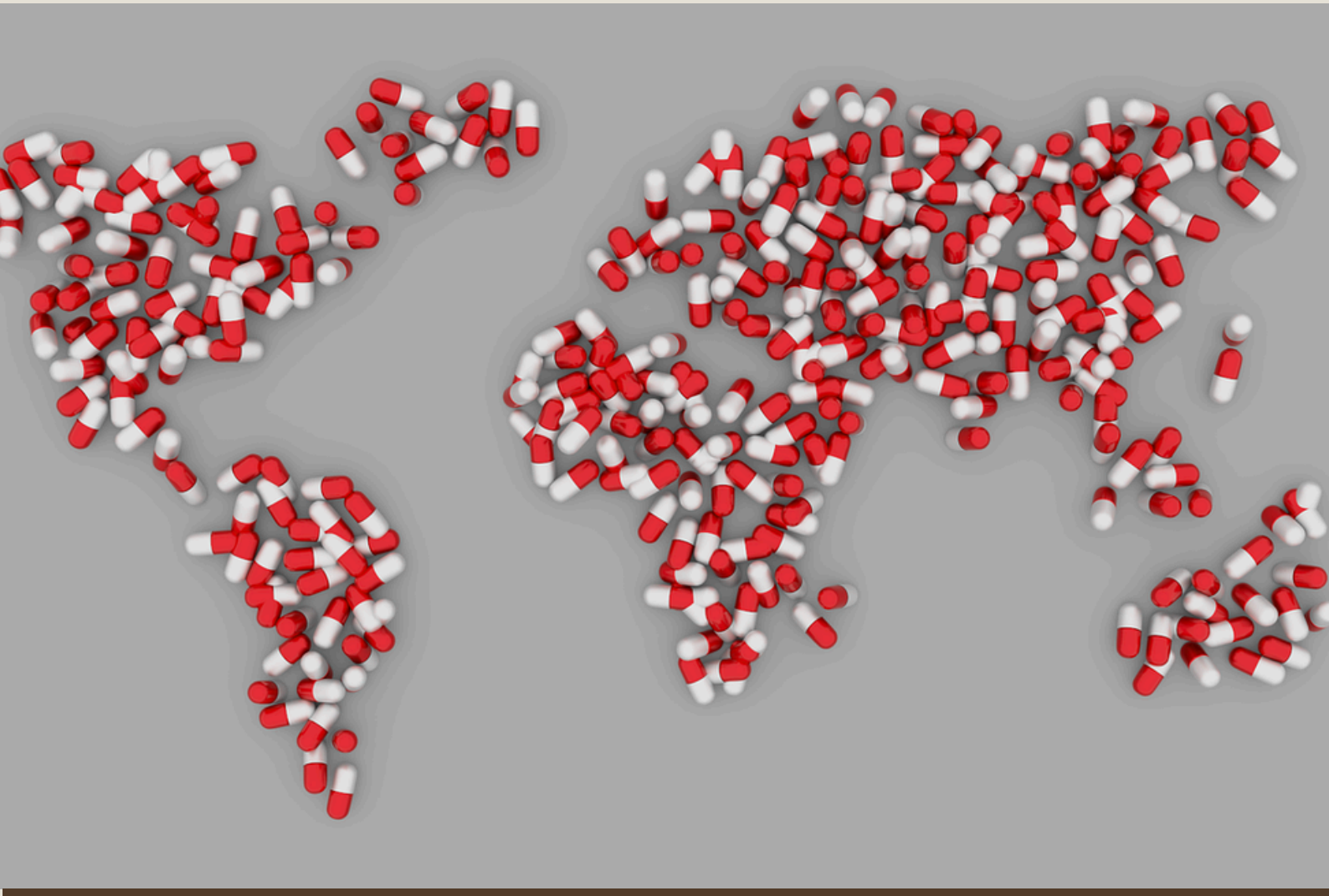

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# LEARNING OUTCOMES

By the end of the lecture and tutorial, students should be able to:

- Define access to essential medicines and analyze the barriers to equitable access to medicines
- Demonstrate an understanding of the effects of global pharmaceutical practices on the availability of antiretroviral medicines in sub-Saharan African countries
- Critically appraise pharmaceutical marketing practices directed at medical students and doctors, including their ethical implications and potential impacts on clinical decision-making

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**This eBook should be reviewed alongside the lecture videos and the *required reading* materials. This PDF is interactive. Please click on the links to navigate through the eBook content.**

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# ACCESS TO ESSENTIAL MEDICINES: BARRIERS, RISKS AND SYSTEMIC CHALLENGES

Despite unequaled medical advances and improvements in overall life expectancy in many parts of the world, the fruits of such global health development have not been distributed equally. Almost two billion people worldwide have no access to essential medicines, causing a crisis of avoidable mortality and morbidity (WHO, 2017). These avoidable differences in access between and within countries reflect deep inequities in how health systems are financed, organized, and regulated.

In this section, we will explore different aspects related to access to medicines with a focus on how these barriers generate and reinforce inequitable access for particular populations.

**Challenges in Low-Resource Contexts**

In low-resource contexts, the availability of essential medicines is often hindered by a combination of stockouts, shortages, and inadequate healthcare infrastructure. Stockouts and shortages of essential medicines in healthcare facilities are common, with studies reporting that up to 50% of public health facilities in some low-income countries experience stockouts of essential medicines (Wagenaar et al., 2014). This lack of availability is exacerbated by poor distribution systems and a shortage of trained healthcare professionals, which can lead to delays in the delivery and administration of essential medicines (Bigdeli et al., 2013). Addressing these challenges requires a comprehensive approach that strengthens healthcare infrastructure, improves supply chain management, and invests in the training and retention of healthcare professionals (Frost & Reich, 2008). Without such reforms, people living in rural areas, informal settlements, and conflict-affected regions are consistently more likely to experience

stockouts than better-resourced urban populations, entrenching inequities in treatment access and outcomes.

**Unaffordability**

Drugs, vaccines, and diagnostics remain unaffordable to almost 90 percent of the people in low-and middle-income countries who purchase medicines through out-of-pocket payments. As middle-income countries become ineligible for aid, the estimated 70% of the world's poor living in these countries continue to face barriers to access to medicines (WHO, 2017). These patterns illustrate how reliance on out-of-pocket payments and fragmented insurance schemes systematically disadvantages people with lower incomes, making access to essential medicines highly unequal both within and between countries.

High pharmaceutical costs in healthcare result from several factors. Patent protections and import expenses inflate prices. The lack of robust local healthcare infrastructure and efficient distribution networks also contribute to higher costs. Constrained national health budgets and limited insurance coverage typically shift financial burdens to consumers. Regulatory frameworks that might not effectively facilitate the expedited approval of generics and biosimilars also sustain high medicine costs (WHO, 2017). These factors mean that people who are uninsured, underinsured, or working in informal economies are most exposed to catastrophic medicine expenditures, while wealthier and better-insured groups are more effectively protected, deepening inequities in access.

**Proliferation of Substandard and Falsified Medical Products**

The proliferation of substandard, dangerous, and falsified medical products presents significant health risks and compounds problems related to access to essential medicines, particularly affecting poorer countries with under-performing drug regulatory authorities. Developed countries advocate for stricter intellectual property regulations to combat this issue; however, international non-profits argue that such measures could further hinder access to safe and effective medications. Instead, these organizations recommend that wealthier nations support the enhancement of drug regulatory frameworks in poorer countries and work to expand access to safe, efficacious, and high-quality essential medicines (Oxfam, 2011). As a result, poorer countries and marginalized populations within them are disproportionately exposed to unsafe products, while people in wealthier jurisdictions benefit from stronger regulatory oversight and safer supply chains.

Moreover, the focus of the majority of pharmaceutical companies on developing new drugs primarily for markets in developed countries leads to shortages in low- and middle-

income countries of older, yet still effective, essential medicines and a reduction in the registration of new products (Access to Medicine Foundation, 2020). Research and development are also predominantly concentrated in a few countries (Access to Medicine Foundation, 2020). Addressing the issue requires improving treatment literacy, including educating about the risks of non-prescription antibiotic use, non-adherence to treatment protocols, self-medication, over-the-counter purchases, and online drug sales (Mendelson et al., 2016). These factors are crucial for controlling the problem of substandard and falsified medical products.

**Antimicrobial Resistance**

Addressing antimicrobial resistance ensures universal access to essential medicines and protects public access to safe and quality drugs. Antimicrobial resistance may develop in resource-constrained situations where people might consume substandard or counterfeit medications either because they cannot afford the completion of the full course of antibiotics or because there is a lack of adequate regulatory control over the distribution of antibiotics. Equally likely is the possibility of overuse and misuse of antibiotics in situations where there might not be a shortage in the supply of antibiotics.

Thus, in the context of access to medicines and antimicrobial resistance, effective regulatory frameworks are critical in preserving the integrity of medical supply chains. This necessitates a coordinated approach involving governments, healthcare authorities, and the agricultural and pharmaceutical sectors. Pharmaceutical companies are instrumental in this fight by developing innovative therapies to replace ineffective drugs, ensuring the continuous availability of high-quality antibiotics, and promoting responsible manufacturing and marketing practices (Access to Medicine Foundation, 2020). Without such coordinated action, AMR tends to first undermine treatment options for people in low-resource settings where inappropriate antibiotic use is more common and alternatives are fewer, thereby widening global inequities in who has access to effective infection treatment.

**Neglected Diseases and Access To Medicines: Ongoing Challenges**

Problems in access to medicines also include the significant gap in drug development for neglected diseases, which primarily affect the world's impoverished populations. The research and development (R&D) for these diseases is often insufficient due to limited commercial incentives. Private companies, driven by the patent system, are hesitant to invest in R&D for these conditions because the

financial returns typically do not justify the substantial costs associated with developing and manufacturing treatments. Additionally, these diseases frequently receive inadequate attention within the public health systems as well. Consequently, populations already experiencing social and economic disadvantage are also those least likely to benefit from new or effective treatments, reinforcing global health inequities.

**War and Conflict**

Finally, war and conflict also create shortages in medicines and often lead to acute shortages of life-saving drugs owing to damage to health infrastructure, weak logistics, and transportation systems, unaccountable and fragmented procurement systems, breakdown of supply chains, and international sanctions that prevent the import of medicines (Debarre, 2018). People living in conflict-affected and occupied settings therefore face some of the most severe and persistent barriers to accessing essential medicines, compared with populations in stable, better-resourced health systems.


- Access to Medicine Foundation. (2020). Antimicrobial Resistance Benchmark 2020 https://accesstomedicinefoundation.org/publications/2020-antimicrobial-resistance-benchmark.
- Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B., & Van Damme, W. (2013). Access to medicines from a health system perspective. Health Policy Plan, 28(7), 692-704. https://doi.org/10.1093/heapol/czs108.
- Debarre, A. (2018). Hard to reach: Providing healthcare in armed conflict. International Peace Institute.
- Frost, L. J., & Reich, M. R. (2008). Access: how do good health technologies get to poor people in poor countries? Harvard Center for Population and Development Studies.
- Mendelson, M., Røttingen, J. A., Gopinathan, U., Hamer, D. H., Wertheim, H., Basnyat, B., Butler, C., Tomson, G., & Balasegaram, M. (2016). Maximising access to achieve appropriate human antimicrobial use in low-income and middle-income countries. Lancet, 387(10014), 188-198. https://doi.org/10.1016/s0140-6736(15)00547-4.
- Oxfam. (2011). Eye on the ball. Medicine regulation not IP enforcement can best deliver quality medicines. 143 Oxfam Briefing Paper Oxfam. https://www.oxfam.org/en/press-releases/crisis-poor-quality-medicines-being-used-excuse-push-prices-poor.
- Wagenaar, B. H., Gimbel, S., Hoek, R., Pfeiffer, J., Michel, C., Manuel, J. L., Cuembelo, F., Quembo, T., Afonso, P., Gloyd, S., & Sherr, K. (2014). Stock-outs of essential health products in Mozambique - longitudinal analyses from 2011 to 2013. Trop Med Int Health, 19(7), 791-801. https://doi.org/10.1111/tmi.12314.
- WHO. (2017). Access to medicines: making market forces serve the poor. https://www.who.int/publications/10-year-review/chapter-medicines.pdf?ua=1.

## NEGLECTED DISEASES

*The WHO identifies neglected tropical diseases as prevalent communicable diseases in the tropical and subtropical regions of 149 countries, affecting around one billion people. These diseases are often worsened by factors such as unsafe water, poor sanitation, inadequate housing, and limited healthcare access. Unlike acute outbreaks with high mortality, neglected diseases typically cause chronic disabilities, severe deformities, and gradual deaths, leading to substantial long-term social and economic burdens and a diminished quality of life for affected populations.*

## FACT CHECK: SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS

- *An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified.*
- *They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals.*
- *Both generic and innovator medicines can be falsified, ranging from very expensive products for cancer to very inexpensive products for treatment of pain.*
- *They affect every region of the world.*

*WHO, 2018*

# GLOBALIZATION, THE PHARMACEUTICAL INDUSTRY AND ACCESS TO MEDICINE

One of the most significant economic challenges arises from the research-based pharmaceutical sector being a substantial commercial enterprise. Multinational pharmaceutical companies based in North America, Europe, and Japan wield significant economic influence, often translating into political clout. A World Health Organization (WHO) report states that a recurrent contentious debate emerges during negotiations at the WHO to enhance access to medicines, highlighting the polarizing tension between economic interests and public health priorities. The report states that this raises the critical question if the economic objectives of the pharmaceutical industry or the health needs of the public should take precedence (WHO, 2017). This tension is especially visible when decisions about drug pricing, patent protection, and global supply are made in ways that privilege profitable markets over populations with the greatest health needs.

The United States remains a major hub for drug innovation, production, and sale. Conversely, Asia, especially India and China, has become a crucial hub for manufacturing, especially generic drugs. The shift to Asia has been influenced by global supply chains, the search for low-cost production, and the proliferation of sophisticated manufacturing capacity in India and China, steadily increasing their global market share in finished drugs and raw materials. The expansion of global supply chains has triggered and reinforced the globalization of the pharmaceutical industry (Tannoury & Attieh, 2017). Consequently, outsourcing specific drug development, production, and sales activities, including R&D, has been dispersed across countries. This global division of labour has important consequences for which countries host high-value innovation activities and which primarily supply low-cost generics, with downstream effects on medicine prices, availability, and health security in different regions.

This globalization and dispersion of activities underscore the complex interplay between neoliberal economic policies and the strategic operations of the pharmaceutical industry. As detailed below, the underpinnings of this relationship reveal significant implications for global health,

especially concerning access to medicines.

**Defining Key Terms: Capitalism, Globalization, and Neoliberalism**

**Capitalism** is an economic system characterized by private ownership of the means of production and the creation of goods or services for profit. Central features include capital accumulation, competitive markets, and a price system (Scott, 2019).

**Globalization** refers to the process by which businesses or other organizations develop international influence or start operating internationally, marked by free trade, the free flow of capital, and the tapping of cheaper foreign labor markets (Bhagwati, 2004).

**Neoliberalism** is a policy model that embodies free market trade, deregulation of financial markets, individualization, and the shift away from state welfare provision. It seeks to transfer part of the control of the economy from the public to the private sector, under the belief that it will produce a more efficient government and improve the economic health of the nation (Harvey, 2005).

While capitalism is a broad economic system, neoliberalism is a more specific ideology that arose in the late 20th century, advocating for expanding market relationships, deregulation, and privatization within that system. Capitalism as an economic system does not inherently prescribe a minimal state intervention policy. In contrast, neoliberalism explicitly promotes reducing state influence in economic affairs and enhancing the role of the private sector in society (Harvey, 2005).

**Neoliberal globalization** refers to a set of economic and social policies advocating privatization (transfer of public sector assets to the private sector), liberalization (removing trade barriers and restrictions in economic and social policy), and deregulation (removing government controls or regulations in particular industries) to promote market-driven transnational integration of economies. In the context of healthcare, the influence of neoliberal policies often shifts the perception of health services from public goods that should be universally accessible to private commodities, which are managed through market mechanisms. This shift can lead to increased privatization of healthcare services, making access dependent on individual ability to pay rather than being based on need. This transition aligns with a broader neoliberal agenda of promoting efficiency, competition, and consumer choice, often at the expense of equity and public welfare. Thus, this paradigm shift has redefined health and healthcare from being considered public goods towards being viewed increasingly as private goods, reflecting a focus on market-based solutions for healthcare access and delivery (Labonté & Schrecker, 2007; Harvey, 2005). These changes have

profound implications for public health policies and access to healthcare, as they may prioritize economic efficiency over universal healthcare coverage, potentially increasing disparities in access to medical services and treatments. In the pharmaceutical sector, these same dynamics influence which drugs are developed, how they are priced, and which health systems can afford to procure them, thereby contributing directly to inequities in access to essential and life-saving medicines.

**Neoliberal Globalization and the Pharmaceutical Industry**

Within the above process, transnational corporations, international agencies, and neoliberal regimes and institutions such as the World Bank, the International Monetary Fund, and the World Trade Organization played a significant role in dismantling domestic protections. Specifically, the World Trade Organization enforces the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, setting conditions for intellectual property protection and drug registration that limit access to essential medicines in low- and middle-income countries. These rules have often reduced the policy space available to governments seeking to prioritise public health over commercial interests.

Neoliberal globalization has significantly benefited the pharmaceutical industry, particularly large multinational corporations, or "Big Pharma." The liberalization of trade and investment has facilitated global expansion and increased market penetration for these companies, allowing them to maximize profits and reduce costs through economies of scale and access to cheaper labor markets (Drahos & Braithwaite, 2002; Koivusalo & Mackintosh, 2011). At the same time, these arrangements can deepen power asymmetries between multinational firms and states with limited negotiating capacity, making it harder for the latter to secure equitable access to affordable medicines for their populations.

Moreover, intellectual property rights have been strongly protected under neoliberal policies, exemplified by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This agreement has reinforced the patent rights of pharmaceutical companies, enabling them to maintain monopolies on new drugs and secure higher returns on their investments (Correa, 2000). In tandem with free trade agreements, these restrictions go beyond intellectual property protections to impact national pharmaceutical policies and practices. These agreements affect the affordability of medicines, compromise rational drug use, and impact local production and health security (Gleeson et al., 2019). For people living in low- and middle-income countries,

this can translate into delayed introduction of new treatments, persistent dependence on imported products, and unequal access to life-saving medicines such as antiretrovirals.

**TRIPS and Access to Medicine**

The TRIPS agreement has been contentious in terms of its impact on access to medicines. The enforcement of strict intellectual property rights under TRIPS often limits the availability of affordable generic medications, particularly in low- and middle-income countries. This restriction can result in higher healthcare costs and limited access to essential medicines, as pharmaceutical companies can effectively set higher prices without facing competition from generics (t' Hoen, 2009). These constraints disproportionately affect countries with a high burden of infectious diseases and constrained health budgets, thereby exacerbating global inequities in who can obtain timely treatment.

The case of HIV/AIDS medication in Africa illustrates these dynamics. In the late 1990s and early 2000s, patented antiretroviral drugs were sold at prices that were completely unaffordable for most people living with HIV in sub-Saharan Africa, even as the region faced some of the highest HIV prevalence in the world (t' Hoen, 2009). Networks of people living with HIV, health activists, and civil society organisations in countries such as South Africa, Brazil, and India organised campaigns, legal challenges, and international advocacy to contest high prices and restrictive patent rules (Bermudez & t' Hoen, 2010; t' Hoen, 2009). In some cases, such as the court challenges brought by activists against pharmaceutical companies and governments in South Africa, public pressure contributed to policy shifts and opened space for the use of TRIPS flexibilities and the procurement of lower-cost generics (t' Hoen, 2009).

Using these flexibilities, several African governments issued or threatened compulsory licences and imported or procured generic antiretrovirals, especially from manufacturers in India, leading to dramatic price reductions and enabling large-scale treatment programmes to expand access for millions of people who would otherwise have gone without therapy (Bermudez & t' Hoen, 2010). At the same time, the need for sustained activism, litigation, and international mobilisation to achieve these changes highlighted how strict patent protection under TRIPS had initially constrained access, and why public-health-oriented interpretations of trade rules, and the active participation of affected communities,

remain essential for achieving more equitable access to HIV treatment in sub-Saharan Africa (t' Hoen, 2009).


- Bhagwati, J. (2004). In Defense of Globalization. Oxford University Press.
- Bermudez, J., & 't Hoen, E. (2010). The impact of the TRIPS agreement on generic drug supply in developing countries. Clinical Pharmacology & Therapeutics, 88(3), 348-352.
- Correa, C. M. (2000). Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options. Zed Books.
- Drahos, P., & Braithwaite, J. (2002). Information Feudalism: Who Owns the Knowledge Economy? Earthscan Publications.
- Gleeson, D., Lexchin, J., Labonté, R., Townsend, B., Gagnon, M.-A., Kohler, J., Forman, L., & Shadlen, K. C. (2019). Analyzing the impact of trade and investment agreements on pharmaceutical policy: provisions, pathways and potential impacts. Globalization and Health, 15(1), 78.
- Harvey, D. (2005). A Brief History of Neoliberalism. Oxford University Press.
- Koivusalo, M., & Mackintosh, M. (2011). Commercial influence and global nongovernmental public action in health and pharmaceutical policies. International Journal of Health Services, 41(3), 539-563.
- Scott, R. (2019). Capitalism: Its Origins and Evolution as a System of Governance. Springer Publishing.
- t'Hoen, E. (2009). The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation, and the Application of the WTO Doha Declaration on TRIPS and Public Health. AMB Publishers.
- Tannoury, M., & Attieh, Z. (2017). The influence of emerging markets on the pharmaceutical industry. Curr Ther Res Clin Exp, 86, 19-22. https://doi.org/10.1016/j.curtheres.2017.04.005
- WHO. (2017). Access to medicines: making market forces serve the poor. https://www.who.int/publications/10-year-review/chapter-medicines.pdf?ua=1.



# GLOBAL HEALTH AND PHARMACEUTICALS: ETHICS, ACCESS, AND INDUSTRY PRACTICES

As we have seen so far from the lecture and this e-book, access to medicines spans economic, ethical, and healthcare domains, impacting populations globally but with particular urgency in low- and middle-income countries. This section delves into the complexities surrounding the availability and rational use of essential medicines, and explores how market dynamics, regulatory frameworks, and global health policies intersect to shape access.

**Barriers to Rational Prescribing**

Good prescribing serves the aims of maximizing effectiveness, minimizing risks and costs, and respecting patient choices. It tests the prescribers' knowledge and application of therapeutic principles, communication

skills, and appreciation and approximation of the involved risks and uncertainties.

Irrational prescribing fails to meet good standards of treatment and may take the form of under-prescribing, over-prescribing, incorrect prescribing, extravagant prescribing, and multiple prescribing (Ofori-Asenso and Agyeman, 2016).

Prevailing evidence indicates that irrational prescribing is influenced by patients (e.g. evidence on patients' influence on the prescription of antibiotics), prescribers, workplace (health system resources), industry influences, the robustness of regulation, and availability of drug information or misinformation among others (Ofori-Asenso and Agyeman, 2016).

Regarding industry influence, there is evidence that pharmaceutical sales representatives exaggerate the efficacy of drugs, and their visits to doctors have been associated with the prescription of the promoted drug and a decrease in the market share of alternative drugs. Evidence from systematic reviews also reveals that the physician's exposure to information from drug companies sometimes resulted in lower prescribing quality (Ofori-Asenso and Agyeman, 2016).

Examples of irrational prescribing include inappropriate use of antimicrobials, polypharmacy, inappropriate use of injections vs oral formulations, and prescription of drugs that do not align with clinical guidelines (WHO, 2012).

**Some Irregular Marketing Practices of Pharmaceutical Companies**

Pharmaceutical companies, while central to drug development and distribution, often engage in practices that can compromise health outcomes. These include (Rahman et al., 2021; WHO, 2002; WHO, 2012):

- Promotion of irrational products and irrational prescribing (promotion of drugs with questionable therapeutic value)
- Dumping of banned drugs (refer to the case of Bangladesh and Dr. Zafrullah's Choudhury's campaign on Essential Medicines)
- Incentivizing doctors and hospitals to promote/prescribe their medication
- Fraud in clinical trials
- Medicalization and disease mongering.

These practices can undermine rational prescribing, increase costs for patients and health systems, and raise important ethical concerns about conflicts of interest and patient safety.

**Patents and Data Exclusivity**

Intellectual property rights, including patents and data exclusivity, play a crucial role in access to drugs.

Patents grant exclusive rights for an invention, which is a product or a

process that provides, in general, a new way of doing something or offers a new technical solution to a problem (WIPO, n.d.).

“Data exclusivity protection allows for a period of time following marketing approval during which competing firms may not use the innovative firm’s safety and efficacy data, from proprietary preclinical and clinical trial results, to obtain marketing authorization for a generic version of the drug” (Lybecker, 2014).

While patents safeguard inventions allowing the holder to exclude others from making or selling the patented invention, data exclusivity protects the data submitted to regulatory authorities, regardless of the patent status of the drug, thereby preventing others from relying on this data to register equivalent or bio-similar products. It can therefore delay the entry of generic drugs into the market, thus keeping prices high and limiting access to essential medications (Hemphill & Sampat, 2012).

**Evergreening of Patents**

In the pharmaceutical industry, evergreening is when brand-name companies patent “new inventions” that are only minor or insignificant modifications of old drugs, lacking any significant therapeutic advantage (Collier, 2013). The idea is to prolong profits from high-revenue drugs by extending the patent’s term.

A notable legal instance occurred when the Indian Supreme Court denied Novartis a patent for an updated form of its cancer medication, Gleevec (imatinib mesylate), on the basis that Indian patent law rejects the concept of evergreening. For a detailed analysis of this case, see the article by **Gabble and Kohler (2013)**.


- Collier, R. (2013). Drug patents: the evergreening problem. CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne, 185(9), E385-E386. https://doi.org/10.1503/cmaj.109-4466
- Gabble, R., & Kohler, J. C. (2014). “To patent or not to patent? the case of Novartis’ cancer drug Glivec in India”. Globalization and Health, 10, 3-3. https://doi.org/10.1186/1744-8603-10-3
- Hemphill, C. S., & Sampat, B. N. (2012). Evergreening, patent challenges, and effective market life in pharmaceuticals. J Health Econ, 31(2), 327-339. https://doi.org/10.1016/j.jhealeco.2012.01.004
- Lybecker, K. M. L. A. (2014). When patents aren’t enough: the case for data exclusivity for biologic medicines. IP Watchdog. Retrieved 22 Feb 2024 from https://ipwatchdog.com/2014/07/09/patents-arent-enough-data-exclusivity-for-biologic-medicines/id=50318/
- Ofori-Asenso, R., & Agyeman, A. (2016). Irrational use of medicines—A summary of key concepts. Pharmacy, 4(4), 35. http://www.mdpi.com/2226-4787/4/4/35.
- Rahman, M. S., Matanjun, D., D’souza, U. J. A., Wan Saudi, W. S., Kadir, F., Tan, T. S., & Mohd. San, M. H. (2021). Rational use of drugs. Borneo Journal of Medical Sciences 15(1), 5-9.
- World Health Organization (WHO). (2012). The pursuit of responsible use of medicines: Sharing and learning from country experiences. Technical Report prepared for the Ministers Summit, p. 78. https://www.who.int/iris/bitstream/10665/75828/1/WHO_EMP_MAR_2012.3_eng.pdf?ua=1
- WHO. (2002). Promoting rational use of medicines: core components. World Health Organization. https://iris.who.int/bitstream/handle/10665/67438/WHO_EDM_2002.3.pdf
- WIPO. (n.d.). Patents. World Intellectual Property Organization. Retrieved 22 Feb 2024 from https://www.wipo.int/patents/en/

# ENHANCING ACCESS TO ESSENTIAL MEDICINES: STRATEGIES AND PRACTICES

Access to essential medicines is a cornerstone of effective healthcare systems and is fundamental to global health equity. The World Health Organization (WHO) has developed strategic approaches to ensure that essential medicines meet the priority healthcare needs of populations, emphasizing safety, efficacy, and cost-effectiveness, particularly in resource-limited settings. These strategies include promoting the use of generic drugs, ensuring rational prescribing practices, and supporting both compulsory and voluntary licensing frameworks.

**Essential Medicines**

The World Health Organization (WHO) defines essential medicines as satisfying the population's priority healthcare needs, ensuring efficacy, safety, and cost-effectiveness (WHO, 2019). The concept of an essential medicines list is to standardize and optimize treatment, especially in resource-limited settings.

The WHO maintains two model lists of essential medicines aimed at addressing various global health challenges, including HIV, hepatitis C, tuberculosis, and cancer.

- WHO Model List of Essential Medicines, 21st List, 2019
- WHO Model List of Essential Medicines for Children, 6th List (March 2017, amended August 2017).

To promote equitable access to these medicines, the WHO emphasizes four key areas:

- Rational selection of medicines based on community health needs.
- Ensuring affordable prices through negotiations and partnerships.
- Sustainable financing by governments and international bodies.
- Building reliable health and supply systems to manage and deliver medicines effectively.

**Promoting Generic Drugs**

To increase access to medicines, the WHO also supports the use of generic drugs by advocating for fewer barriers to their entry into the market and by encouraging countries to adopt policies that favor generic drug production and procurement. What are generic drugs?

Let’s review some concepts before we

focus on generic drugs.

An innovator drug is the first drug created containing its specific active ingredient to receive approval for use. It is usually the product for which efficacy, safety, and quality have been fully established (MOH, n.d.).

An active ingredient is the chemical contained inside a drug that makes it work.

A **generic drug** is made of the same active ingredient as its innovator drug. In other words, the pharmacological effect of a generic drug is exactly the same as its innovator counterpart. Other companies can manufacture generic drugs when the patent expires. Generic drugs are less expensive to produce because there are no advertising and costly research costs. Generic drugs are crucial for increasing access to medicines due to their affordability (MOH, n.d.).

**Promoting Rational Prescribing of Drugs**

Rational prescribing ensures that patients receive medications appropriate to their needs, in doses that meet their own requirements, for an adequate period, and at the lowest cost to them and their community. Rational prescribing is vital for maximizing the effectiveness of treatment while minimizing risks and costs. The WHO provides resources and guidelines to healthcare providers worldwide to ensure that prescribing practices are based on the latest evidence, optimizing patient outcomes and resource utilization (WHO, 2002).

**Compulsory and Voluntary Licensing**

The integrated strategies of compulsory licensing and voluntary licensing form a robust framework for improving access to essential medicines, ensuring sustainable health outcomes, and supporting global health equity.

**Compulsory licensing** is a legal framework endorsed by the WTO's TRIPS Agreement that allows governments to manufacture or import patented drugs without the patent holder's consent under specific conditions, such as serious public health needs or where public interest dictates such a need (WTO, 2001).

**Voluntary licensing** involves a patent holder granting a license to another party, allowing them to produce a patented product under agreed terms. This approach is often used to increase the supply of essential medicines in low-income markets at more affordable prices, thereby improving access for people who could not otherwise afford treatment (IFPMA, 2010).

In conclusion, the strategies discussed in this section, together, form a comprehensive approach to improving access to essential medicines, addressing market dynamics and regulatory frameworks to help ensure that people in different settings have

more equitable access to the medications they need to achieve good health.

**Robust Regulation of Drugs**

Effective national regulatory authorities are vital for promoting access to essential medicines by ensuring that pharmaceutical products are high-quality, safe, and effective, which in turn helps make them more accessible and affordable to the public.

In Australia, the regulation of drugs is overseen by the Therapeutic Goods Administration (TGA), which is responsible for ensuring the safety, quality, and efficacy of therapeutic goods, including pharmaceuticals. The TGA operates under the Therapeutic Goods Act 1989 and regulates the registration, evaluation, and monitoring of medicines to ensure they meet stringent standards before being made available to the public. The TGA also plays a crucial role in post-market surveillance to monitor the safety and effectiveness of drugs once they are on the market.

On the other hand, in Malaysia, the National Pharmaceutical Regulatory Agency (NPRA) is the key regulatory authority responsible for the registration, licensing, and surveillance of pharmaceutical products in the country. The NPRA operates under the Poisons Act 1952, the Dangerous Drugs Act 1952, and the Control of Drugs and Cosmetics Regulations 1984 to ensure that pharmaceutical products, including medicines, vitamins, and health supplements, comply with regulatory requirements and are safe for public consumption. The NPRA's role includes evaluating new drugs, monitoring the quality of pharmaceutical products, and enforcing regulations to safeguard public health.


- IFPMA. (2010). Voluntary licenses and non-assert declarations. International Federation of Pharmaceutical Manufacturers and Traders Retrieved 22 March 2024 from https://www.ifpma.org/news/voluntary-licenses-and-non-assert-declarations/
- MOH. (n.d.). Generic vs innovator drugs. Myhealth Ministry of Health Malaysia. Retrieved 22 Feb 2024 from http://www.myhealth.gov.my/en/generic-vs-innovator-drugs/
- National Pharmaceutical Regulatory Agency (n.d.). Retrieved from https://npra.gov.my/index.php/en/
- Therapeutic Goods Administration. (n.d.). About the TGA. Retrieved from https://www.tga.gov.au/about-tga
- t Hoen, E. (2002). TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha. Chic J Int Law, 3(1), 27-46.
- World Health Organization. (2019). World Health Organization Model List of Essential Medicines, 21st List, 2019. https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06
- WHO. (2002). Promoting rational use of medicines: core components. World Health Organization. https://iris.who.int/bitstream/handle/10665/67438/WHO_EDM_2002.3.pdf.
- WTO. (n.d.). Compulsory licensing of pharmaceuticals and TRIPS. World Trade Organization. https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm


From the Classroom to Prescriptions: Pharma's Early Influence on Medical Careers

# MARKETING PRACTICES EMPLOYED BY PHARMACEUTICAL COMPANIES WITH MEDICAL GRADUATES AND STUDENTS

Pharmaceutical companies employ various marketing strategies to influence the prescribing behaviors of medical professionals, including medical students and graduates. These practices often begin early in a medical professional's career, with companies establishing relationships with medical students through sponsorships, gifts, and educational seminars (Sierles et al., 2005). Such interactions can significantly affect future doctors' prescribing habits and their attitudes toward particular medications.

The marketing techniques include providing free samples, funding for educational and social events, and offering gifts, which can range from meals to more substantial financial

incentives (Austad et al., 2011). These strategies are designed to foster a positive relationship between the pharmaceutical industry and medical students, with the long-term goal of influencing their future prescribing decisions. Pharmaceutical companies may also subsidize the printing costs of lecture notes or other educational materials for medical students, which can create a sense of obligation among the students to repay these favors (Barfett et al., 2020). This raises important questions about how commercial interests may shape clinical decision-making and professional judgment.

Research shows that these interactions can lead to increased requests for sponsored medications by students once they begin practicing, suggesting a bias introduced during their training (Grande et al., 2013). Furthermore, the prevalence of such marketing practices varies significantly across different regions and medical schools, indicating a lack of uniform policy or enforcement of existing guidelines regarding interactions between medical students and the pharmaceutical industry (Korenstein et al., 2013).

Austad, K. E., Avorn, J., & Kesselheim, A. S. (2011). Medical students' exposure to and attitudes about the pharmaceutical industry: A systematic review. PLOS Medicine, 8(5), e1001037. https://doi.org/10.1371/journal.pmed.1001037.

Barfett, J., Lanting, B., Lee, J., Lee, M., Ng, V., & Simkhovitch, P. (2020). Pharmaceutical marketing to medical students: The student perspective. McGill Journal of Medicine, 8(1). https://doi.org/10.26443/mjm.v8i1.376

Grande, D., Frosch, D. L., Perkins, A. W., & Kahn, B. E. (2009). Effect of exposure to small pharmaceutical promotional items on treatment preferences. Arch Intern Med, 169(9), 887-893. https://doi.org/10.1001/archinternmed.2009.64

Korenstein, D., Keyhani, S., & Ross, J. S. (2010). Physician attitudes toward industry: a view across the specialties. Arch Surg, 145(6), 570-577. https://doi.org/10.1001/archsurg.2010.75.

Sierles, F. S., Brodkey, A. C., Cleary, L. M., McCurdy, F. A., Mintz, M., Frank, J., Lynn, D. J., Chao, J., Morgenstern, B. Z., Shore, W., & Woodard, J. L. (2005). Medical students' exposure to and attitudes about drug company interactions. A national survey. JAMA, 294(9), 1034-1042. https://doi.org/10.1001/jama.294.9.10

# MUST KNOW

- What are essential medicines?
- What are the challenges with regard to access to essential medicines?
- The marketing strategies of pharmaceutical companies.
- The role of neoliberalism in globalization and access to medicines.
- TRIPS.
- How pharmaceutical companies influence doctors and medical students into undertaking irrational prescribing.
- The effects of global pharmaceutical practices on the availability of antiretroviral medications in sub-Saharan Africa.

THEME II:POPULATION, SOCIETY HEALTH AND ILLNESS
Med1100/1200 Semester 1

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