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ARTICLE

The still incomplete pursuit of universal access to medicines

Paloma Fernández[1], Alicia del Llano[2], Jaume Vidal[3], Jaime Espín[4,5,6] and Juan E. del Llano[2]

[1]Independent Scholar, [2]Gaspar Casal Foundation, Madrid, Spain, [3]Health Action International (HAI), Amsterdam, Netherlands, [4]Andalusian School of Public Health (EASP), Granada, Spain, [5]CIBER of Epidemiology and Public Health (CIBERESP), Madrid, Spain and [6]Instituto de Investigación Biosanitaria IBS, Granada, Spain
Corresponding author: Paloma Fernández; Email: paloma.fercan@outlook.com

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Abstract
A substantial share of the global population continues to face barriers to accessing essential medicines. While the pharmaceutical industry's business model has successfully facilitated the development of innovative medications, efforts to promote universal access to medicines (UAM) remain ineffective. This paper critically assesses the existing barriers to global access to medicines, including the role of unsuitable governance, the protection of intellectual property rights, and other market barriers such as shortages, quality shortcomings, and high prices. Furthermore, we explore a number of promising potential strategies that can help towards achieving the UAM. Specifically, we evaluate the evidence from various initiatives, including alternative models of innovation, manufacturing, procurement, intellectual property management, and structural/organisational operations. We argue that the effective realisation of UAM requires a robust framework to implement these initiatives. This framework must strike a delicate balance between addressing public health needs, incentivising research and development, and ensuring affordability. Achieving such a balance encompasses a careful oversight and collaboration between national and international regulatory bodies.

Keywords: access to medicines; globalisation; pharmaceutical industry; intellectual property; inequality and health; stakeholder effects

1. Introduction

Access to medicines is a vital precondition to activate the so-called right to health (Perehudoff, 2020). Nonetheless, as of March 2020, nearly half of the global population does not have access to a set of medical treatments that are listed as 'essential medicines' by the World Health Organization (WHO, 2020). While globalisation initially contributed to substantial reductions of extreme poverty and disease, it has subsequently exacerbated health inequities (Deaton, 2013). To date, lower-income nations, despite facing a relatively more acute need for such medicines, encounter significant challenges hindering access to them (Peters *et al.*, 2008). The COVID-19 pandemic has underscored the persistent gap in achieving universal access to medicines (UAM).

Only 34 per cent of people in low-income countries (LICs) received the COVID-19 vaccine in June 2023 compared to almost 73 per cent in high-income countries (HICs) (WHO, 2023). Such disparities extend to access to essential medicines like morphine, which is used to alleviate moderate to severe pain and treat severe breathlessness. The daily defined dose of morphine per

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million people is 125.9 in HICs, compared to 24.9, 6.7, and 2.0 in upper-middle-income countries, lower-middle-income countries (LMICs), and LICs, respectively (WHO, 2023) – a difference ranging from 5- to 63-fold. These stark inequalities underscore the persistent disparities in access to basic healthcare service, which are at odds with the realisation of the right to health pursuit insofar as from a human rights perspective, ensuring a country's access to medicines is intertwined with the implementation of principles of equality, non-discrimination, transparency, and participation, which, as we argue in this paper, we are still far from achieving.

These challenges stem from governmental failures of different sorts. Even though national governments in low-income settings have expressed a high-level commitment to enacting laws that ensure the universal health coverage (UHC) and the sustainability of their healthcare systems (OHCHR, 2023), the disjointed and inadequate global response to COVID-19 underscores the pressing necessity for a revamped governance and regulatory framework.

This paper provides a re-examination of the question of global access to medicines. We identify a number of critical barriers that include the role of fragmented governance, the specific business model underpinning the pharmaceutical industry, and the role of regulatory and market barriers. These include the intellectual property-based innovation model and the failure of governments and multilateral organisations to implement effective solutions to counterbalance access barriers. Since the financial rewards of innovation often yield disproportionately high returns on investment, we argue that funding strategies that align risk-taking with equitable rewards are necessary to address these inequalities and promote sustainable innovation (Mazzucato, 2018).

We make three key distinct contributions. First, we provide a critical assessment of the critical role of UAM as a core component of pharmaceutical policy, which calls for the strengthening of some effective form of vertical governance in the health and pharmaceutical sector. Second, we argue that access to medicines should be a fundamental criterion in the regulation of both the development and commercialisation of medicines. Regulations should provide incentive structures that strike a finer balance between innovation and the equitable distribution of its benefits. Finally, drawing on the recent experience of the COVID-19 pandemic, we identify several access barriers often overlooked by previous studies and propose alternative regulatory criteria to improve accessibility.

The structure of the paper is as follows: Section 2 analyses global governance as an access barrier to medicines. Section 3 discusses the changing nature of the global pharmaceutical industry and its dependence on intellectual property regulation as an access barrier. Section 4 discusses the role of intellectual property rights as an access barrier to medicines, and Section 5 delves into market-specific access to medicines. Section 6 identifies existing initiatives aimed at addressing these challenges, while also exploring their root causes. A final section concludes.

2. Governance as access to medicines

The attainment of universal access to essential medicines (UAM) is a core component of the right to health, which is legally binding for the 169 national governments that have ratified the International Covenant on Economic, Social, and Cultural Rights. Many countries have integrated this right into their domestic laws (Perehudoff, 2020). Similarly, the United Nations adopted the Sustainable Development Goals in 2015 that target UAM, which specifically include ensuring access to safe, effective, quality, and affordable essential medicines and vaccines for all. They also emphasise supporting research and development of vaccines and medicines for diseases primarily affecting developing countries and utilising the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to protect public health and improve access to medicines. However, the pursuit of UAM as an integral component of the right to health underscores the urgent need for coherent regulation and overcoming governance barriers. The barriers to effective global health governance stem from the fact that regulatory actors are

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essentially national states who are sovereign, have the capacity to exert horizontal governance through agreements, and are influenced by entrenched power dynamics (Gostin, 2005), which limit the enforceability of global regulations. The diffuse distribution of regulatory power in the hands of nations states only strengthens the economic and political influence of some corporations and non-state institutions in lobbying to achieve their desired regulations.

An effective global health governance requires states to transfer some sovereignty to robust institutions like the WHO. Health is a global public good that transcends borders, demanding a coordinated governance framework. However, public health remains a core responsibility of individual nations, often leading to inaction and a lack of transparency in addressing emerging threats like SARS and COVID-19. While vertical governance – where international health agencies establish minimum public health capacities at national and regional levels – offers a structured approach to tackling global health challenges, many governments instead rely on bilateral or regional agreements. These fragmented responses fail to provide harmonised solutions, leaving the world vulnerable to recurring health crises.

This reluctance to transfer sovereignty to multinational authorities stems from entrenched power dynamics, with Europe and North America exerting disproportionate influence over the global health agenda. Overcoming these barriers requires embracing a 'new culture of global health', revising both international and national health legislation, and harnessing the power of comprehensive data governance. A stronger, more centralised WHO is essential – one that respects national sovereignty while effectively coordinating global health efforts. Striking a balance between the interests of larger and smaller nations is critical to fostering sustainable and equitable health governance (Gostin *et al.*, 2020).

In a strengthened WHO setting, global health law can play a central role as a tool to protect public health. Indeed, Gostin and Taylor (2008) describe global health law as a modern paradigm of public health law aimed at creating conditions that enable people worldwide to achieve the highest attainable standard of physical and mental health. While this concept may appear idealistic, such ambition is essential to ensuring global health and well-being. The WHO revised the International Health Regulations in 2005. More recently, the organisation has been mandated to draft a convention, agreement, or other international instrument on prevention, preparedness, and response (PPR) (WHO CA+), drawing on lessons learned from the COVID-19 pandemic and the anticipated threats of future pandemics (WHO, 2023).

3. The global pharmaceutical industry as an access barrier

Since its inception in the nineteenth century, the pharmaceutical industry has consistently pursued its internationalisation as a strategy to expand its market reach. Initially, this was achieved through foreign investment in segmented and protected national markets. Over time, market liberalisation facilitated a gradual shift toward global integration (Lobo, 2019). However, the process enhanced significantly in the 1990s with the adoption of the TRIPS Agreement by all World Trade Organization (WTO) member states. As we discuss in the next section, by incorporating intellectual property law into the multilateral trading system, the TRIPS Agreement marked a pivotal moment in the global accessibility of medicines. Pharmaceutical companies have maintained control over critical decisions, including where, when, and at what price their medicinal products are marketed.

Nonetheless, over the past few decades, the structure of large transnational pharmaceutical companies has undergone significant transformations. Although historically, these companies operated with a fully integrated value chain[1], over time, they increasingly transitioned into acting as brokers instead, outsourcing and offshoring many of these processes while retaining overall

[1]Encompassing applied science, discovery, preclinical and clinical development, regulatory compliance, manufacturing, and commercialisation.

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strategic control of the supply chain. Indeed, the discovery and early-stage development have become increasingly dependent on publicly funded research institutions and their spin-offs, particularly small biotechnology companies. This shift was triggered by the passage of the Bayh-Dole Act in 1980 in the USA, followed by similar legislation in other Western countries. Such legislation enabled publicly funded entities to patent their inventions, creating a thriving market for product candidates that now serve as the primary source of new pharmaceutical innovations. Global pharmaceutical companies acquire these candidates and gain the exclusive rights to set their prices, often without considering the public investment that facilitated their discovery and development. However, such dynamic raises concerns about both affordability and equitable access, as taxpayers effectively fund early-stage research while the financial benefits remain largely privatised.

Finally, it's worth noting that manufacturing has also undergone consolidation, with production increasingly concentrated in a limited number of facilities to enhance efficiency. Simultaneously, the global pharmaceutical industry has witnessed a wave of mergers and acquisitions, significantly reducing competition and further increasing its market power and lobbying capacity.

4. Intellectual property rights as access barrier to medicines

The market power to influence pricing and, ultimately, access to medicines clings to the enforcement of exclusive Intellectual Property Rights (IPR) over new pharmaceutical products – including patents and other legal instruments such as licences, trademarks, data exclusivity, supplementary protection certificates, and trade secrets (Rovira, 2018). Indeed, the central role of IPR and patents, more specifically in the current biomedical Research and Development (R&D) model, is inextricably linked to the economic globalisation trends of the 1990s, epitomised by the establishment of the WTO (WTO, 1994)[2].

One specific agreement stands out in the context of access to medicines: the TRIPS Agreement, signed in 1994. This agreement established a universal standard for the protection and enforcement of IPR for medicines and other health goods. Effectively, it meant that many developing countries were mandated to grant and enforce patent protection for pharmaceutical products and processes, and such an obligation curtailed governments' abilities to produce or import critical health goods. To address concerns raised by various stakeholders, the agreement included 'flexibilities' or exceptions. However, early attempts by governments to use these measures – particularly during the fight against HIV/AIDS – faced significant challenges. For instance, South Africa faced legal action from 39 pharmaceutical companies, while Brazil endured pressure from these companies and threats of diplomatic retaliation. These incidents revealed an imbalance where health needs were subordinated to market demands.

The Doha Declaration on the TRIPS Agreement and Public Health (WTO, 2001) aimed to reaffirm the legitimacy of these flexibilities, and it provided a detailed framework for their application, guaranteeing member states the right to appeal to them without fear of retaliation through WTO dispute settlement mechanisms (Correa, 2005). Yet, though hailed as a victory for the Global South, the declaration's impact was undermined as trade liberalisation entered a new phase. Bilateral and regional trade agreements began incorporating 'TRIPS+' provisions, limiting countries' abilities to leverage the flexibilities enshrined in the original agreement. Such proliferation of free trade agreements containing TRIPS+ clauses coincided with the crises of the WTO's multilateral approach. Key issues – such as agriculture, fisheries, and the use of compulsory licences by countries lacking pharmaceutical manufacturing capabilities (as outlined

[2]The WTO's significance extends beyond being the first permanent multilateral forum for addressing trade barriers and disputes. Prospective members are required to adhere to binding rules, including those on tariffs, subsidies, and export controls, which have accelerated globalisation to such an extent that it is now often seen as irreversible.

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in Paragraph 6 of the Doha Declaration) – proved difficult to resolve. It took nearly two decades for WTO members to amend the TRIPS Agreement, a process widely criticised as overly complex and impractical. Although the handling of IP-related matters with direct implications for access to medicines within a trade forum rather than the global health institution of sovereign governments faced considerable resistance, attempts to bring these issues under the purview of the WHO were thwarted by countries advocating for a maximalist IP agenda within the WTO.

Following the Doha Declaration, a period of trilateral cooperation between the WHO, the World Intellectual Property Organization (WIPO), and the WTO was established to address IP and health. Over two decades, the WHO ceded its leadership on IP and health issues to WIPO and the WTO – organisations with better funding and mandates more aligned with corporate interests. This shift constrained the WHO's efforts to evaluate the impact of trade agreements on access to medicines, promote the use of flexibilities for public procurement, and address the role of monopolies in influencing medicine availability and pricing. However, underfunded and overburdened, the WHO embodied the dilemma of global health governance: widely recognised as a priority, yet lacking the necessary resources and political influence to deliver.

Given the substantial role of IP enforcement in shaping access to medicines, several tools have been developed to assess its impact and have been widely implemented by a number of countries. This includes the IPRIA Model, which evaluates the implications of IP changes on medicine access (Rovira and Cortés-Gamba, 2021) in various Latin American contexts. Additionally, Health Action International has introduced the TRIPS Flexibilities Navigator (HAI, 2022), which assists stakeholders in leveraging these provisions to improve access to safe, effective, and affordable medicines. However, the unbalance in the resources available to the national government and the WHO and those of the global pharmaceutical industry is a core barrier limiting global access to medicines across the world.

5. Market barriers to medicines access

In 2016, the UN Secretary-General's High-Level Panel on Access to Medicines published its report, *Promoting Innovation and Access to Health Technologies* (UNSG, 2016). The panel was tasked with assessing proposals and recommending solutions to address policy incoherence between the legitimate rights of inventors, international human rights law, trade regulations, and public health. It identified several barriers to accessing health technologies, including exclusive marketing rights, high costs, poor quality, inappropriate use, procurement challenges, supply chain inefficiencies, and regulatory obstacles. At the same time, the Lancet Commission on Essential Medicines Policies (Wirtz *et al.*, 2017) highlighted additional barriers, such as shortcomings in sustainable financing and inadequate R&D investment for essential medicines. These challenges reflect broader weaknesses in public health systems, particularly in resource-constrained countries, where limited infrastructure and governance gaps leave them vulnerable to capture by private interests. We specifically identify three different market barriers, including the proliferation of low-quality products, the emergence of shortages, and finally, the role of high prices as a central market barrier.

5.1 Quality barriers to access

Poor-quality medicines, including substandard and falsified products, are significant barriers to access. Their impact can range from having no treatment effect to causing human disasters. A systematic review in 25 LMICs showed a median prevalence of substandard medicines of 28.5 per cent (11–48 per cent) (Almuzaini *et al.*, 2013). Also, the presence of poor-quality medicines has increased in HICs recently, mainly driven by online trade. This is of specific concern as in such a setting individuals tend to trust branded products distributed by global pharmaceutical corporations (Costa-Font, 2016).

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Approval of medicines by the national regulatory agencies is mandatory as the only way to ensure that marketed medicines meet the required standards (safety, efficacy, quality). This requirement extends to clinical trials, manufacturing premises and processes, and marketing conditions authorisation. Hence, a fundamental initiative lies in harmonisation and mutual recognition of these public health requirements, an endeavour pursued at the global level by the International Conference of Drug Regulatory Authorities (WHO, 2023)[3]. The harmonisation of regulatory requirements was pioneered by the European Commission in the 1980s, as Europe moved towards developing a single market for pharmaceuticals. Since then, its regulatory arm, the European Medicines Agency (EMA), has become a benchmark worldwide with an impact on the access to medicines beyond Europe. Thirteen out of 20 regulators of Latin American countries directly recognise or abbreviate the marketing authorisation process in case of earlier approval by the EMA. This is also applicable to the US Food and Drug Administration (FDA) and Health Canada (Duran *et al.*, 2021).

Perehudoff *et al.* (2021) have studied the mechanisms through which EU action affects medicines access in LMICs and document that the EU's external, treaty-based actions (TRIPS+) establish explicit agreements with LMICs that can affect their pharmaceutical trade, sales, and use. Similarly, the EU's internal market regulation, standards, and methods are used as bases, models, or sources of inspiration for pharmaceutical governance in LMICs. That is, 'soft' forms of EU influence manifest through the EU's technical assistance, its mobilisation of R&D funding, and its 'capacity building' activities towards LMIC actors in the field of pharmaceuticals. The impacts of EU action ranged from the development of new medicines primarily for LMICs to changes in the availability of generics and on medicines spending and the potential for a more efficient yet less autonomous local market approval process. These forms of influence also affect the foreign action of the major world powers, mainly the USA, via TRIPs + and other mechanisms, although this is insufficiently studied.

Nevertheless, harmonisation of marketing authorisation falls short to guarantee access to all medicines, as illustrated by the fact that even in the EU, 12 per cent of all the products approved by EMA are not accessible in Germany, while this figure can be as high as 74 per cent in Latvia (Zozaya *et al.*, 2022). Hence, one ought to look at other reasons, including the decision by pharmaceutical companies on where to market their products.

5.2 Physical barriers: availability, supply chains, and shortages

An important challenge in ensuring medicines access is their physical availability. Beyond the well-documented scarcity of medicines in many LMICs, shortages have appeared during the last decade in all markets. The globalisation of the manufacturing chains has reduced costs for companies but has exponentially increased supply risks. Approximately 80 per cent of the active pharmaceutical ingredients (APIs) used globally are produced in India and China. India leads in drug production, contributing over 20 per cent of global generics and 62 per cent of vaccines and providing 80 per cent of HIV treatments used in Africa (India NHP, 2023). In December 2019, China temporarily halted its factories. In March 2020, India banned exports of certain medicines. In December 2022, China announced a suspension of ibuprofen exports to supply its own 1.4 billion population (Londeix and Martin, 2023).

The pandemic exacerbated an already strained system. A study in the US FDA, (2019) identified three primary root causes: a lack of incentives to produce low-profit drugs, inadequate rewards for maintaining high-quality manufacturing systems for mature brands, and logistical and regulatory challenges following disruptions. A subsequent study by the European Commission (EC, 2021) found similar issues in the EU, citing poor manufacturing quality of

[3]A forum where drug regulatory authorities of WHO Member States discuss ways to strengthen collaboration and determine priorities for action in national and international regulation of medicines and vaccines.

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APIs and finished products (51 per cent of shortages), commercial factors (25 per cent), unexpected surges in demand, and other contributing factors.

Medicine shortages impact a wide range of treatments but are particularly severe for pain relievers, antihypertensives, antibacterials, antacids, and chemotherapy drugs. Alarmingly, 97 per cent of shortages involve off-patent products, with generics accounting for 52–79 per cent. However, the strongest link to shortages is seen in single-source products. Reports from the European Alliance for Responsible R&D (2022) and the European Pharmaceutical Strategy propose solutions, including increased transparency in the global supply chain and stronger industry obligations to prevent and mitigate shortages.

A key recommendation is the reindustrialisation of Western countries' pharmaceutical manufacturing capabilities, aiming to reverse the effects of globalisation to some extent. This proposal extends to strengthening the manufacturing capacity of the Global South to supply their population and prevent future episodes like the hoarding of COVID-19 vaccines by HIC during the pandemic. A paradigmatic example is the mRNA vaccine technology transfer hub (WHO, 2021) established in South Africa by public and private partners under WHO's auspices and the Medicines Patent Pool to build capacity in LMICs to produce mRNA vaccines through a network of technology recipients (spokes). Announced in June 2021, it has already signed contracts with companies in 10 countries, including Brazil, Argentina, Kenya, Nigeria, and Egypt, and produced the first batches of vaccines. This initiative is complemented by a new global training hub in biomanufacturing in South Korea, established by this country and the WHO (WHO, 2023).

5.3 High prices: barrier to accessibility and affordability

Finally, the most common market barrier is the high price of medicines, limiting their affordability. This is explained by the market power of pharmaceutical manufacturers, which hinders patients' access and threatens health care budgets, limiting funding for other needed areas (Rovira, 2015). Pharmaceutical expenditure accounts for 20–60 per cent of total health care expenditure in LMICs, compared with around 18 per cent in OECD countries, according to WHO (Rovira, 2015). In countries without UHC, high prices can result in unaffordable out-of-pocket costs for individual patients, as in developing countries, up to 90 per cent of the population pays out-of-pocket for medications. In the USA, a quarter of the population can't afford optimal therapy. President Biden highlighted this issue in his 2023 State of the Union address, citing the high price of insulin of about $400–500 per month per patient, and proposed a cap of $35 for the 200,000 young people with type 1 diabetes in this country.

The escalating prices of new therapies, almost exclusively biological products, are also a cause of concern. In 2018, global spending on cancer treatments was approximately 150 billion and has increased by more than 10 per cent in each of the past 5 years (Rajkumar, 2020). In Spain, expenditure on oncologic and rare disease medicines has risen by 94 per cent and 66 per cent, respectively, in the last 5 years.

Cell-based therapies, such as CAR-T (chimeric antigen receptor T-cell) therapy and gene therapy products (collectively known as advanced therapy medicinal products) aimed to alter part of the patient's genome, are a fast-growing area of innovation and hold a promise for clinical care, being curative in some cases. But they have exceptionally high costs: the last gene therapy product approved by the FDA (etranacogene dezaparvocec, hemgenix) for adult patients with haemophilia B costs $3.5 million per patient. Similarly, the revolutionary technology CRISPR is expected to launch its first drug in 2023 at a similar price. These prices impede access for all potential beneficiaries and threaten the sustainability of health systems.

To help national policymakers manage pharmaceutical expenditures driven by high prices, the WHO has developed guidelines on pharmaceutical pricing policies, offering evidence-based recommendations (WHO, 2020). These recommendations vary significantly depending on the challenges of implementation in different contexts, and countries should adopt a combination of

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approaches to address both supply and demand issues. Despite this variation, one policy is consistently recommended: promoting the use of quality-assured generic and biosimilar medicines. This goal is achieved by facilitating their early market entry through legislative and administrative measures that ensure quality, safety, and efficacy while maximising their uptake. Generic medicines have been among the most effective tools for improving access to essential medicines globally (Kanavos *et al.*, 2008). However, the production of biosimilars remains limited due to higher manufacturing complexity and costs, reducing competition and leading to higher prices and restricted access.

Certain patenting practices, such as patent thickets, further exacerbate the issue by extending market exclusivity for biological products and blocking generic competition (I-MAK, 2022). Additionally, the concept of value-based pricing has sparked debate, as defining value – whether for patients, healthcare systems, or shareholders – remains complex. Critics argue that pharmaceutical companies often appropriate the full value without fair distribution of risks and rewards across the value creation chain, calling for a more equitable pricing framework (Mazzucato and Roy, 2019).

Following the World Health Assembly resolution 72.8 (WHA, 2019), the WHO guideline recommends improving transparency in medicine prices by sharing the net transaction prices of pharmaceutical products with relevant stakeholders, disclosing prices along the supply and distribution chain, publicly reporting R&D contributions from all sources, and communicating pricing and reimbursement decisions to the public. Other initiatives include the Oslo Medicines Initiative (OMI), kick-started in 2020 by WHO Europe and the Norwegian government together with other European countries to define roles and responsibilities of the public and private sectors with respect to research, development, and affordable access to effective, novel, high-cost medicines, through multi-stakeholder dialogue with the pharmaceutical industry and civil society. The proposal includes the creation of a Novel Medicines Platform. One of its technical reports portrays pharmaceutical R&D as a Global Public Good, advocating for constructing alternative business models better aligned with public interests (Moon *et al.*, 2022). Other promising proposals to reduce extremely high prices include incentivising or mandating non-exclusive licences or attaching access and affordability conditions to products developed with public funds (Vokinger *et al.*, 2023).

6. Initiatives to improve global access to medicines

A rising number of initiatives challenge the traditional mainstream pharmaceutical business model. The Global Health Center and Geneva Graduate Institute have recently launched the 'Knowledge portal on innovation and access to medicines' (Knowledge Portal, 2023) with a database of alternative R&D initiatives that deliver both innovation and global access. The database includes 130 experiences led by not-for-profit organisations (46), academic and other research institutions (25), for-profit organisations (31), national government agencies (18), and intergovernmental organisations (6). All these initiatives differ from the traditional business model in one or more of its characteristics such as prioritising unmet health needs, promoting open science, public–private collaboration, data sharing, no patenting, non-exclusive licencing, public or philanthropic financing, involvement of academic institutions in late clinical development, manufacturing, distribution strategies, or even pricing of final products.

While some of these initiatives are recent and still in progress, others have a long trajectory and proven results. One well-known barrier to effective treatment is the absence of medicines for the so-called neglected diseases, such as Chagas, dengue, leishmaniasis, chikungunya, and others, which affect more than one billion people mainly in Latin America and Africa (Mundo Sano, 2023). While rare diseases that affect few patients in HIC have financial incentives for their development, neglected diseases lack commercial interest. This led to the creation of DNDi, the

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Drugs for Neglected Diseases initiative (DNDi, 2023), a non-profit endeavour founded in 2003 by MSF, WHO, and other institutions worldwide to address this challenge under an alternative innovation model that ensures equitable access to treatments. So far, DNDi has developed 12 treatments for 6 diseases and has a wide portfolio of new chemical entities under research.

Medicines Patent Pool (MPP) is an initiative started in 2010 by Unitaid and other institutions to improve access to affordable essential medicines in LMICs (Hoen, 2016). This is achieved through voluntary licencing of the patent owners to a common pool and multisource procurement from generic companies, which assures competition. Currently, MPP distributes 23 medicinal products to more than 100 developing countries, facilitating access to high-quality, low-cost essential medicines. Initially, created to facilitate access to HIV, tuberculosis, and hepatitis C treatments, it has extended its mandate to develop paediatric formulations and fixed-dose combinations and, recently, to biological medicines and technologies such as mRNA (MPP, 2023).

Another alternative model has produced the first CAR-T cell therapy developed in Europe through an academic initiative with public financing. The Hospital Clinic de Barcelona-IDIBAPS has developed ARI-0002h for the treatment of patients with multiple myeloma resistant to standard treatments and with a price five times lower than the commercial option (Fernández-Larrea *et al.*, 2021).

A disruptive innovation with huge potential to increase access to medicines is the Health Care Utility model developed by Civica Rx in the USA (Dredge and Scholtes, 2021), a new business genre with a unique structure and organisation. The term 'utility' refers to other commonly shared basic services, such as water or electricity, making an essential service accessible to everyone. Started in 2018 by a group of health systems and philanthropies to face drug shortages and high prices, Civica is a generic manufacturer that now provides near 60 generic medicines to more than 50 health systems, 1.400 hospitals representing over 30 per cent of all inpatient hospital capacity, the Veterans Administration and the Department of Defense in the USA, achieving aggregate prices 30 per cent lower than in the previous market. Civica has also expanded to the retail market with CivicaScript and plans to launch three low-cost insulins in 2024 (CivicaRx, 2023). Although this new model is complex to implement and useful only to address certain market competition failures, it demonstrates again the potential for increasing medicines access when using an alternative business model to that established by the pharmaceutical industry.

Finally, Torreele *et al.* (2023) discuss the urgent global need for pandemic PPR plans with the proposal of an end-to-end model for delivering medical countermeasures with equitable access when and where they are needed. This comprehensive model, with six building blocks, might also inspire solutions for global access in normal non-epidemic situations. Some of the building blocks, such as the African mRNA technology transfer hub, could be directly applied if agreed upon.

7. Discussion

This paper examines the main barriers to achieving UAM, a fundamental aspect of the human right to health that remains unattainable for nearly half of the global population. The outlook for LICs is particularly grim, with access to medicines expected to stagnate during the next five years. Even more concerning is the fact that such stagnation risks jeopardising the success of other health policy initiatives in LICs (IQVIA, 2023).

We argue that UAM is hampered by a series of barriers such as governance, the business model of the pharmaceutical industry, the regulation of intellectual property rights, and the presence of significant market barriers such as quality regulation, shortages, and high prices resulting from market power and limited competition. However, we have pointed out that some of such barriers can be overcome fully or partially by various initiatives. Some promising initiatives like the Drugs for Neglected Diseases initiative (DNDi) and the MPP, spearheaded by civil society organisations or non-profit institutions with support from national or global health agencies, illustrate that

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achieving global access to medicines is feasible. These initiatives utilise alternative models of innovation and procurement, diverging from the mainstream pharmaceutical industry approach, which effectively manages intellectual property to better align with the right to health and public health priorities.

Nonetheless, the UAM today is today still an incomplete pursuit, largely determined by the pharmaceutical industry's priorities regarding research, production, and market pricing, rather than by broader public health criteria. Market access decisions are often made with minimal oversight from payers and governments. The industry's role extends far beyond that of a drug supplier, as it actively shapes the prevailing models of innovation and marketing. While its incentive-driven framework has proven effective in delivering new medicines (Costa-Font *et al.*, 2015), such success is frequently achieved in partnership with the public sector and primarily benefits a limited portion of the population, neglecting the Human Rights Guidelines for Pharmaceutical Companies on Access to Medicines (OHCHR, 2023). Despite these shortcomings, the intellectual property-based model has become the dominant paradigm in mainstream economic systems.

The overarching principle of maximising shareholder value through short-term return policies has redefined the purpose of global pharmaceutical corporations, shattering their social contract (Ciepley, 2020). Indeed, in the last decades, we have envisaged a wave that has swept through the pharmaceutical industry, which has led to significant returns. More specifically, over the last decade, from 2007 to 2016, the 19 companies in the S&P 500 index spent 297 billion dollars repurchasing their own shares, equivalent to 61 per cent of their combined R&D expenditures during that period (Tulum and Lazonick, 2018)[4].

Similarly, multilateral organisations and governments have failed in their pursuit of regulating pharmaceutical markets to ensure patient access to essential medicines and activating the individual's right to health. Most government have focused instead on limiting their actions to partially fixing market failures. Regulatory capture by the industry is largely to blame. To date, the pharmaceutical industry leads lobbying efforts in both the USA (5.4 billion dollars from 1998 to 2022 for health and pharmaceuticals) (Statista, 2023) and the EU. The Corporate Europe Observatory (CEO) documents declared expenditure on the EU Transparency Register (CEO, 2023) at 36 million euro in 2022 by 40 companies plus another 15 million by consultancy firms, with 290 lobbyists employed, resulting in privileged access to European Commission decision makers. Furthermore, the CEO (2023) reveals that during the pandemic, European Commission officials met with pharmaceutical executives 140 times, 18 with generic companies, and 1 with pro-waiver of COVID-19 countermeasures groups.

Although governments are increasingly taking a more active role to correct the inequities that were profoundly exacerbated by the pandemic, a more balanced approach to pharmaceutical regulation would be desirable if governments were more involved in shaping the innovation and business model for medicines with a vision of the common good. Notably, the position paper from the Benelux governments submitted to the EU EPSCO (Health) Council (Note to the EU Council, 2023) states that 'the time has come to think of new systems, allowing for a change in business models', emphasising a stronger focus on both societal and patient needs over supply chain goals. This can be achieved with a more strategic use of public research funding, alongside market incentives for those technologies with the highest health needs, namely, those with the highest willingness to pay for specific types of medicines. Models have been proposed to ensure access and affordability by design at every stage of the process starting with discovery Mazzucato & Roy, 2023. This requires a new legal intellectual property framework that better balances private incentives with public common interest and health-focused innovation. There is an urgent need to establish conditionalities for public return when public funds are invested in the discovery and development of new medicines. This could involve making march-in-rights effective, introducing

[4]This has contributed to the trend of externalising R&D and manufacturing (Mazzucato and Li, 2021).

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fair pricing clauses, or retaining a golden share of patents or other provisions attached that guaranteed access and affordability (Mazzucato and Li, 2021).

Intellectual property is the 'elephant in the room' of how we manage and ensure healthcare for all, and it should be treated as such. It is part of a complex framework of regulatory dispositions, legal concepts, and administrative clauses that govern any complex system where the public and private sectors collaborate, interact, and negotiate. We need a conversation where rights and duties are on equal footing and health is, finally, taken as seriously as other fundamental human rights (Vidal, 2022). Public accountability from reference patent offices (United States Patent and Trade Office, (USPTO), European Patent Office (EPO), and others) is fall short of expectation, which enables an environment that favours the pro-patent community (industry/applicants, attorneys, examiners), leading to the granting of patents that increasingly are too broad, strong, and upstream regardless of their technical merits, at the expense of patients, consumers, and public common interest. This should be urgently addressed by governments and other competent authorities to require that patentability criteria are more stringent and rigorous. A counterbalancing albeit minor, step forward could be the dialogue between the FDA to USPTO following a Presidential Executive order to promote competition and address drug pricing concerns in the USA (FDA, 2021; USPTO, 2022).

Improving global access to medicines requires new governance in the health and pharmaceutical areas. This involves redefining the roles of agents; establishing new rules of play, especially regarding intellectual property; sharing research and manufacturing capacities globally; and leading with a focus on the common good by the public sector. WHO and WTO should properly balance health and trade. The ongoing processes of dialogue and legislative action offer good opportunities to incorporate these needs: global negotiations for a pandemic response treaty, new European pharmaceutical legislation, EU Global Health Strategy, OMI, MC12 TRIPS for therapeutics, or the ongoing international trade negotiations; all provide windows of opportunity to advance in global access to pharmaceuticals. Stakeholders involved have the legal and moral responsibility to enforce and preserve this human right.

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References

Almuzaini T, Choonara I and Sammons H (2013) Substandard and counterfeit medicines: a systematic review of the literature. *BMJ Open* **3**, e002923.

Ciepley D (2020) How America's Corporations lost their public purpose and how it might be (partially) restored. *Accounting, Economics, and Law* **10**, 0088.

CivicaRx (2023) Home | Civica Rx | Nonprofit Generic Drug & Pharmaceutical. Available at https://civicarx.org (accessed 31 July 2023).

Corporate Europe Observatory (2023) *Big Pharma's Lobbying Firepower in Brussels: At Least €36 Million a Year (and Likely Far More)*. Brussels: Corporate Europe Observatory.

Correa (2005) TRIPS agreement and access to drugs in developing countries. *Sur International Journal on Human Rights* **3**, 25–37.

Costa Font J (2016) Deregulation and access to medicines: the Peruvian experience. *Journal of International Development* **28**, 997–1005.

Costa-Font J, McGuire A and Varol N (2015) Regulation effects on the adoption of new medicines. *Empirical Economics* **49**, 1101–1121.

Deaton A (2013) *The Great Scape: Health, Wealth and the Origins of Inequality*. Princeton, New Jersey: Princeton University Press.

DNDi (2023) *Drugs for Neglected Diseases Initiative*. Geneva: DNDi.

Dredge C and Scholtes S (2021) The health care utility model: a novel approach to doing business. *NEJM Catalyst* **2**, 1–9.

Durán CE, Cañás M, Urtasun MA, Elseviers M, Andia T, Vander Stichele R and Christiaens T (2021) Regulatory reliance to approve new medicinal products in Latin American and Caribbean countries. *Revista Panamericana de Salud Pública* **45**, 1–10.

https://doi.org/10.1017/S1744133125000040 Published online by Cambridge University Press

European Alliance for Responsible R&D (2022) Together for Access to Medicines. European Alliance for Responsible R&D and Affordable Medicines. Available at https://medicinesalliance.eu/together-for-access-to-medicines/ (accessed 27 February 2023).

European Commission (2021) *Reform of the Pharmaceutical Legislation*. Brussels: European Commission.

FDA (2019) *Drug Shortages: Root Causes and Potential Solutions*. Maryland: US Food and Drug Administration.

FDA (2021) *FDA Letter to USPTO*. Maryland: US Food and Drug Administration.

Fernandez de Larrea C, Gonzalez-Calle V, Cabañas V, Oliver-Caldes A, Español-Rego M, Rodriguez-Otero P, Reguera JL, Corral LL, Inogés S, Martin-Antonio B, Paiva B, Rosinol L, López-Diaz de Cerio A, Tovar N, Lopez Parra M, Rodríguez-Lobato LG, Varea S, Sanchez Salinas A, Ortiz-Maldonado V, Perez-Simon JA, Prósper F, Juan M, Moraleda JM, Mateos M-V, Pascal M and Urbano-Ispizua Á (2021) Results from a pilot study of ARI0002h, an academic BCMA-Directed CAR-T cell therapy with fractionated initial infusion and booster dose in patients with relapsed and/or refractory multiple Myeloma. *Blood* **138**, 2837.

Gostin LO (2005) World health law: toward a new conception of global health governance for the 21st century. *Yale J. Health Pol'y L. & Ethics* **5**, 413.

Gostin, LO and Taylor AL (2008) Global health law: a definition and grand challenges. *Public Health Ethics* **1**, 53–63.

Gostin LO, Moon S and Meier BM (2020) Reimagining global health governance in the age of COVID-19. *American Journal of Public Health* **110**, 1615–1619.

Health Action International (2022) *Introducing the TRIPS Flexibilities Navigator and TRIPS Flexibilities Navigator*. Amsterdam: Health Action International.

Hoen E (2016) *Private Patents and Public Health*. Amsterdam: Health Action International

i-MAK (2022) *Overpatented, Overpriced*. Lewes, DE: i-MAK.

India National Health Portal (2023) Drugs and pharmaceuticals. Available at https://www.nhp.gov.in/drugs-and-pharmaceuticals_pg (accessed 27 February 2023).

IQVIA (2023) *The Global Use of Medicines 2022*. Durham, North Carolina: IQVIA.

Kanavos P, Costa-Font J and Seeley E (2008) Competition in off-patent drug markets: issues, regulation and evidence. *Economic Policy* **23**, 500–544.

Knowledge Portal (2023) Database of Alternative R&D Initiatives. Available at https://www.knowledgeportalia.org/database-of-alternative-r-d-initiatives (accessed 3 July 2023).

Lobo F (2019) *La Economía de la I+D en la Industria Farmacéutica: un Resumen. Medicamentos, Innovación Tecnológica y Economía*. Madrid: FUNCAS.

Londeix P and Martin J (2023) Pénuries de médicaments : « En trois ans, il doit être possible de poser les bases solides d'un plan industriel pharmaceutique » (accessed 5 January 2023).

Mazzucato M (2018) *The Entrepreneurial State: Debunking Public vs Private Sector Myths*. London: Penguin Books, UK.

Mazzucato M and Roy V (2019) Rethinking value in health innovation: from mystifications towards prescriptions. *Journal of Economic Policy Reform* **22**, 101–119.

Mazzucato M and Li HL (2021) A market shaping approach for the biopharmaceutical industry: governing innovation towards the public interest. *Journal of law, Medicine and Ethics* **49**, 39–49.

Mazzucato M and Roy V (2023) *A Collective Response to Our Global Challenges: A Common Good and 'Market-Shaping' Approach*. London: UCL Institute for Innovation and Public Purpose.

MPP (2023) *Medicines Patent Pool*. Geneva: MPP.

Moon S, Vieira M, Alonso A and Navarro D (2022) *New Business Models for Pharmaceutical Research and Development as a Global Public Good: Considerations for the WHO European Region*. Geneva: WHO.

Mundo Sano (2023) *Mundo Sano - Enfermedades Desatendidas*. Madrid: Mundo Sano.

Note to the EU Council (2023) Applying a needs-driven approach to pharmaceutical innovation. Available at https://www.politico.eu/wp-content/uploads/2023/06/13/st09967.en23.pdf (accessed 3 July 2023).

OHCHR (2023) *Office of the High Commissioner in Human Rights. Access to Medicines and the Right to Health*. Geneva: OHCHR.

Perehudoff K (2020) Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators. *Global Health Action* **13**, 1699342.

Perehudoff K, Durán C, Demchenko I, Mazzanti V, Parwani P, Suleman F and de Ruijter A (2021) Impact of the European Union on access to medicines in low-and middle-income countries: a scoping review. *The Lancet Regional Health-Europe* **9**, 100219.

Peters DH, Garg A, Bloom G, Walker DG, Brieger W and Hafizur Rahman M (2008) Poverty and access to health case in developing countries. *Annals of the New York Academy of Science* **1136**, 161–171.

PTO (2022) PTO Letter to FDA. Available at https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf (accessed 27 February 2023).

Rajkumar SV (2020) The high cost of prescription drugs: causes and solutions. *Blood Cancer Journal* **10**, 71

Rovira J (2015) Precios de los medicamentos: cómo se establecen y cuáles son sus sistemas de control. *Salud Colectiva* **11**, 35–48

https://doi.org/10.1017/S1744133125000040 Published online by Cambridge University Press

Rovira J (2018) *Los Derechos de Propiedad Sobre (activos) Intangibles: Un Peligro Para la Salud*. Barcelona: ATTAC Acordem.
Rovira J and Cortés-Gamba M (2021) *Manual Para Estimar el Impacto de Cambios en Los Derechos de Propiedad Intelectual. Modelo IPRIA*. Bogotá: Misión Salud.
Statista (2023) Leading Lobbying Industries in the United States in 2022, by Total Lobbying Spending. Available at www.statista.com (accessed 27 February 2023).
Torreele E, Kazatchkine M, Liu J, Dybul M, Cárdenas M, Singh S and Clark H (2023) Stopping epidemics when and where they occur. *The Lancet* **401**, 324–328.
Tulum Ö and Lazonick W (2018) Financialized corporations in a national innovation system: the US pharmaceutical industry. *International Journal of Political Economy* **47**, 281–316
UN Secretary General's High-Level Panel on Access to Medicines (2016) *Promoting Innovation and Access to Health Technologies*. Geneva: WHO.
Vidal J (2022) *The TRIPS Agreement Laid Bare*. Amsterdam: Health Action International.
Vokinger KN, Avorn J and Kesselheim AS (2023) Sources of innovation in gene therapies. Approaches to achieving affordable prices. *N Eng J Med* **388**, 292–295.
WHA (2019) *Improving the Transparency of Markets for Medicines, Vaccines, and Other Health Products*. Geneva: World Health Organization.
WHO (2020) *New WHO Guide to Help Countries Expand Access to Essential Medicines*. Geneva: WHO.
WHO (2020) *WHO Guideline on Country Pharmaceutical Pricing Policies*. Geneva: WHO.
WHO (2021) *The mRNA Vaccine Technology Transfer Hub*. Geneva: WHO.
WHO (2023) *Universal Health Coverage (UHC)*. Geneva: WHO.
WHO (2023) *Left Behind in Pain*. Geneva: WHO.
WHO (2023) *International Conference of Drug Regulatory Authorities Regulation and Prequalification*. Geneva: WHO.
WHO (2023) *WHO and Republic of Korea Sign Landmark Agreement to Boost Biomanufacturing Capacity*. Geneva: WHO.
WHO (2023) *Zero Draft of the WHO CA+ for the Consideration of the Intergovernmental Negotiating Body at Its Fourth Meeting*. Geneva: WHO.
Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, Gyansa-Lutterodt M, Jing S, Luiza VL, Mbindyo RM, Möller H, Moucheraud C, Pécoul B, Rägo L, Rashidian A, Ross-Degnan D, Stephens PN, Teerawattananon Y, Hoen E, Wagner AK, Yadav P and Reich MR (2017) Essential medicines for universal health coverage. *Lancet* **389**, 403–476.
WTO (1994) *Marrakesh Declaration of 15 April 1994*. Geneva: WTO.
WTO (2001) *Ministerial Conferences. Doha 4th Ministerial. TRIPS Declaration*. Geneva: WTO.
Zozaya N, Villaseca J, Abdalla F, Fernández I and Hidalgo-Vega A (2022) *El Proceso de Evaluación y Financiación de los Medicamentos en España: ¿dónde Estamos y Hacia Dónde Vamos?* Madrid: Fundación Weber.

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