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IFMSA Policy Document Access to Medicines

Proposed by Team of Officials

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Policy Statement

Introduction:

Access to affordable medicines and vaccines is an essential part of achieving Universal Health Coverage (UHC) and resilient health systems, as mentioned in Sustainable Development Goal (SDG) 3, Target 3.8. However, 2 billion people worldwide currently do not have access to essential medicines.

IFMSA position:

The International Federation of Medical Students' Associations (IFMSA), strongly believes that access to affordable, effective, and safe technologies is a human right. We believe that the current research and development (R&D) system lacks transparency and is driven by commercial interests rather than public health needs, which is in turn reducing the availability of affordable medicines. Publicly funded research, with its publicly-oriented incentives, makes an essential contribution to the development of medicines which should not be appropriated for commercial profit. Global patent monopolies for the protection of intellectual property (IP), as well as Free Trade Agreements (FTAs), such as Trade-Related Aspects of Intellectual Property Rights (TRIPS), are one of the most important barriers to generic medicine production. Additionally, TRIPS plus provisions, included in smaller FTAs, grant data exclusivity which stifles market approval for lower-cost alternatives. We support the use of TRIPS flexibilities as an internationally accepted tool to mitigate these problems.

Call to Action:

Therefore, the IFMSA calls on:

Governments, according to ability, to:

- Ensure financing of essential medicines as an integral part of the healthcare system;
- Monitor and collect data on the affordability, availability, quality and use of medicines at a national level;
- Explore new, cost-saving models for the tendering and procurement of medicines;
- Use their negotiating power to drive down drug prices to a level that is affordable and sustainable to meet global needs;
- Implement policies to encourage prescription and substitution of patented medicines with generic or biosimilar products to increase competition;
- Use TRIPS flexibilities and refrain from using political pressure to deter others from their use;
- Reject the inclusion of TRIPS-plus provisions in future FTAs;
- Implement Open Data and Open Access publishing policies, both for all publicly financed organizations and for the private sector;
- Support the adoption of the WHO roadmap on access to medicines and vaccines 2019-2023 published on December 5th 2018 and include the United Nations High-Level Panel on Access to Medicines recommendations;



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- Support the development of a new approach to biomedical R&D that is sustainable, needs-drive and promotes innovation and access to essential medicines;
- Include data exclusivity waivers in their medicine regulations and legislation to protect public health;
- Apply strict patentability criteria defining what an invention needs to fulfil to be 'new' and patentable and reduce the duration of exclusive IP rights for essential medicines;
- Establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines clinical trials and reinforce rules on clinical transparency;
- Put into effect stricter laws that prevent parallel trade whenever that is expected to contribute to drug shortages in countries with low-priced medicines;
- Explore the implementation of Health Technology Assessment (HTA) processes to guide cost-effective healthcare expenditure, where appropriate.

World Health Organization to:

- Adopt and lead the implementation of the roadmap for access to medicines and vaccines 2019–2023, ensuring clear responsibilities, timeline and resources;
- Assume an international leadership role for priority setting for essential R&D, with due regard for global health needs, and promote multi-sectoral collaboration between all stakeholders in a transparent manner;
- Conduct a de-linkage feasibility study;
- Create a general Essential Medicines Patent Pool;
- Expand the UNITAID Medicines Patent Pool's disease, patent and country coverage;
- Create an updated international database of prices and patent status of all medicines;
- Support low- and middle-income countries in the implementation of TRIPS flexibilities;
- Update the Guidelines for Evaluation of Similar Biotherapeutic Products.

Universities and publicly funded research institutions to:

- Support organisations and initiatives that advocate for access to medicines;
- Adopt the Global Access Licensing Framework;
- Adhere to WHO guidelines on clinical trials results reporting.

Pharmaceutical industry to:

- Better align its R&D priorities with global health needs;
- Develop strategies to make medically important innovations available to all in need;
- Fully disclose the true costs of R&D to the public;
- Comply with legislation on Open Access publishing and support Open Data Initiatives;
- Openly share information on patents and clinical trials.

IFMSA National Member Organizations (NMOs) and healthcare students to:

- Conduct activities and campaigns on access to medicines with other key NGOs.



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Position Paper

Background information:

Equitable access to health products is a global priority, and the availability, accessibility, acceptability, and affordability of health products of assured quality need to be addressed in order to achieve the Sustainable Development Goals (SDGs), in particular Target 3.8. Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care and rehabilitation. Currently, 2 billion people worldwide do not have access to essential medicines [1].

Access is a global concern, given the high prices of new pharmaceuticals and rapidly changing markets for health products that place increasing pressure on all health systems' ability to provide full and affordable access to quality health care. The high percentage of health spending on medicines impedes progress for the many countries that have committed to the attainment of Universal Health Coverage (UHC). Furthermore, it is known that a large proportion of the population in low-income countries (LICs) pay out-of-pocket for medicines. With the rise in noncommunicable diseases – many of which are chronic conditions that require long-term treatment – the financial burden on both governments and patients will become even greater.

Improving access to health products is a multidimensional challenge that requires comprehensive national policies and strategies. These should align public health needs with economic and social development objectives and promote collaboration with other sectors, partners and stakeholders; they also need to be aligned with legal and regulatory frameworks and cover the entire product life cycle, from research and development (R&D) to quality assurance, supply chain management and use.

Discussion:

1. Availability and rational use

1.1 Essential medicines

The WHO defines essential medicines as 'those that satisfy the priority healthcare needs of the population'. [2] This term is not all-encompassing - medicines are defined as 'essential' by the WHO on the basis of disease prevalence, evidence of clinical efficacy and cost-effectiveness of the medicine, and other public health concerns. Towards this end, the WHO produces Model Lists of Essential Medicines, that have been updated every two years since 1977. The current versions are the 20th WHO Essential Medicines List (EML) and the 6th WHO Essential Medicines List for Children (EMLc) updated in March 2017. [3]

1.2 Affordability and pricing

Availability suffers with the lack of affordability of medicines worldwide. Broadly speaking, affordability can be defined as being able to purchase some necessary product in appropriate quantities without suffering financial hardship. Across the world, several problems make medicines unaffordable to parts of the population. Total Pharmaceutical Expenditure (TPE) represents 1 out of every 4 dollars spent on health in LICs and lower-middle income countries, and 1 in 5 in upper-middle income countries. For some specific diseases, expenditure is rising faster than total health expenditure. [4]

The pharmaceutical industry presents its prices as value-based, which means they amount to the cost to society if a disease is left untreated or is treated with a second-best therapy. However, this is not the case. Considering current incentives to short-termism in investment decisions, justifying future prices with current prices creates a positive feedback loop of fast-growing medicine prices. As an example, the price of phenytoin sodium in the United Kingdom recently suffered 2600% annual increase due to



changes in pricing regulation, something not justifiable by a value-based method. Using a “Fair Value” approach faces additional challenges: different patients have different desired outcomes; cheap, old medicines keep adding great value and are much cheaper than recent high-tech medicines that add little value.

Most pharmaceutical companies justify current medicine prices with the need to recover investment costs in R&D. However, if one looks at how pharmaceutical companies invest their profits, we see that a great share is dedicated to marketing and share buybacks, a process through which pharmaceutical companies inflate their stock price through the purchasing of their own shares. [5] This practice of share buybacks is further proof that current incentives are mostly financial and short-termed, and not health and patient-oriented. Share buybacks and marketing expenditure should be limited and/or regulated.

Another source of high prices and inequities in access is dysfunctional health systems, which have people buying their medicines via out-of-pocket payments. It's important that medicines are available at the point of care without inducing a risk of unpredictable and catastrophic health expenditures.

Risk-pooling is an essential strategy to increase availability by increasing affordability. If a proper health system is in place, governments can use large volume procuring and pooled procurements to lower prices. Examples of large volume procuring successes are abundant with new hepatitis C drug, sofosbuvir, negotiations, i.e. in Australia, Egypt and Portugal. [6,7,8], and the Global Drugs Facility, which lowered the price of multi-drug resistant tuberculosis treatments by 26% [9], is a good example of pooled procurement strategies. In the latter, it's ideal to look for international cooperation with a neutral multilateral coordinator of the procedure. Risk-sharing agreements, based on patient-reported outcomes, and Public-Private Partnerships, especially in health emergencies, are other alternatives.

An extremely important price-lowering strategy is the use of generic medicines. Policies and practices for the use of generic medicines have been more comprehensively executed and monitored in high-income countries; it is less clear which policies are applicable in LMICs where regulatory frameworks may be weaker but the need for reduced healthcare costs is greater. [10]

Promoting competition between pharmaceutical companies for substitutable medicines is another mechanism with which to lower prices. However, a range of price and non-price policies, such as the size and saturation of the market; regulatory requirements for generic/biosimilar medicines; and enforcement of fair and transparent competition policies (e.g. to prevent tacit or actual collusion), will impact on the success of competition as a means to reduce prices. [11]

2. Research & Development

2.1 Problems with current R&D system

2.1.1 High unmet medical need

The global standard of R&D for biomedical innovation has done little to ensure the affordability of medicines for those in need. Larger R&D expenditures occur only for drugs with higher expected returns. [11] Developing nations, which carry the largest burden of neglected tropical diseases (NTDs), have very low purchasing power to effectively incentivize drug and vaccine development. [12] This profit driven system has resulted in skewed priorities, highlighted by the fact that NTDs, despite representing 14% of global disease burden, continue to receive the least private R&D money with a total of \$511 million compared to at least \$159.9 billion spent on overall health R&D [13]. Owing to the consistent underfunding, only a small number of drugs ever make it to the market. Between 2000 and 2011, only 37 of 850 (4%) of newly approved products were for NTDs. [14]

An example of how the current R&D system failed to adequately respond to a major health crisis is the West African Ebola crisis. Promising therapies languished in preclinical R&D for over ten years without funding [15] indirectly leading to the deaths of over 11,000 people [16] and an estimated economic impact of \$2.6 billion. [17] Another example of the failure of the current R&D system to address the



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most urgent challenges in global health is the lack of innovation in antimicrobial development. Since newer antibiotics have to be used judiciously, they have low profit potential. This has led to few investments and currently, despite the obvious global need, only 24 major companies are researching antibiotics. [18]

On the other side of the spectrum are the increasing accessibility, availability and affordability issues encountered with cancer medication. [19] Over 80% of children diagnosed with cancer in HICs will be cured of the disease, in contrast to rates as low as 10% among children diagnosed with cancer in LMICs, which, despite having almost 80% of the burden, are estimated to have less than 5% share of global resources for combating cancer. [20] By 2014, the average cost of a new orally administered cancer medicine exceeded \$135,000 a year — up to six times the cost of similar drugs approved in the early 2000s, after adjusting for inflation. [21] There is a lack of adequate access to both new and off-patent essential cancer medicines, with high prices cited as a main contributory factor. [20]

2.1.2 Profit driven practices

The incentives of the current R&D system and regulatory environment lead to inefficiencies. Many newly developed drugs offer no or very little added therapeutic value compared to drugs already on the market, but have enough modification to be patentable. An analysis of medicine approvals in Europe between 2000 and 2014 showed that about half of newly approved medicines did not offer additional health benefits, but were modified versions of already approved medicines. [22] This practice focuses R&D resources on drugs for conditions for which treatment options currently exist, while neglecting other conditions of more pressing public health importance. [23] Consequently, there is an increasing trend for extremely expensive medicines, many of which are used in a very small patient population. [24] Branded drugs, which tend to be heavily marketed, are almost always more expensive than generics, which can have huge implications on the consumers and the health-care system as a whole. [25]

Additionally, patent holders often make minor modifications to existing approved medicines or inventions to be applicable for a secondary patent and thus extend the monopoly position, a practise known as *evergreening*. On reviewing 1,304 patent claims listed in the US Food and Drug Administration (FDA) Orange Book, a study found that the average patent life extension was more than 6 years. [26] Evergreening results in delayed market access for generics as well as high drug prices for a longer duration. [27]

There is also a general lack of transparency in the sector and companies publicly share only limited amounts of data, if at all. Only around half of all clinical trials ever conducted have been published or reported and a majority of the clinical decisions about drugs are based on only half of the available evidence. [28] Even where regulatory frameworks do exist, research shows that registration and summary results posting lags behind, including public institutions. [29] The current secretive R&D model drives inefficiency in drug development, resulting in research duplication, high costs in accessing data from previous trials and difficulty in negotiating drug prices due to secrecy in the true R&D costs. [30] Additionally, data exclusivity rights, like those in the European Union (EU), also limit clinical trial data access. [31,32] Although publicly-traded companies are legally required to disclose a range of financial information in their annual report, privately held ones are not. Even when disclosed, the data can be incomplete and difficult to parse and may not be sufficiently disaggregated, e.g. not disclosing price per product or public investment such as research grants. [33]

2.2 Possible solutions

2.2.1 Delinkage and incentives

A possible solution is delinking the cost of R&D, and other such as marketing or approval, from the price of the product. An example of this is the Drugs for Neglected Diseases initiative (DNDi)'s hepatitis C medicine, which reduced the cost of the 12 week course treatment from \$84,000 to \$300. Innovation can be supported by market entry rewards, grants, subsidies or open source dividends. Utilizing such financing mechanisms could support a needs-based innovation system that ensures accessibility and



affordability. Traditional funding depends on 'push' mechanisms which work by mitigating the prohibitive costs of R&D. These are usually in the form of grants offered upfront by public and private investors, equity investment in product development, or tax credits. In recent years, 'pull' mechanisms are increasingly being used for funding and promoting innovation in the R&D sector. For example, through collaboration between the GAVI Alliance, donors like the Gates Foundation, and pharmaceutical companies like Pfizer Inc., the Advanced Market Commitment nearly halved the prices of the pneumococcal vaccines. [34] Another example is the Priority Review Voucher [35] program created by the United States Congress [36] which rewards a quicker review by the FDA for market approval, potentially translating into an early market entry and greater profits. A delinkage feasibility study can be conducted by the WHO to explore the various financing mechanisms and their reliability. [37]

2.2.2 Public investment and public returns

Currently, the public sector largely finances research while profits are largely benefited by the private sector. [38] As an example we can look to the US National Institutes of Health, which have funded every one of the new molecular entities approved between 2010-2016 [39]. Publicly funded research accounts for 49% of global health research and 1/3 of new drugs originate from university research. [40, 41] Most of this investment sees its return flow entirely into pharmaceutical companies. If there is public share in development and investment, a proportionate share of the benefits should also go to the public. Mazzucatto et al [37] list possible mechanisms of doing so, such as "attaching conditions on public funding such as reinvesting profits from innovative products to support future R&D; a commitment to share knowledge and fully disclose data related to R&D, including expenditures and data from failed clinical trials; the possibility of the public retaining a golden share from IPR (and, on occasion, equity of profits); and a requirement that manufacturers supply treatments on reasonable term". Institutions can also ensure that end products of publicly funded research are made available and affordable to the public, licensing them through a transparent strategy. Universities and publicly funded research institutions should implement Global Access Licensing policies. [42]

2.2.3 Stringent patentability criteria

Referring to Article 27 of the TRIPS Agreement, which reads "Patents shall be available for any inventions ... provided they are new, involve an inventive step and are capable of industrial application", governments should ensure that patents are only granted for real innovations, by specifying what 'new' means to them (such as demonstrated additional therapeutic value). [43] Promotion of TRIPS flexibilities and allowing nations to implement regulations that can keep unfair practices in check are essential to protect the public health interest of the population. We have expanded on this in more detail in the section on regulatory systems elsewhere in the document.

2.2.4 Open science and transparency

Open science not only involves the improvement of transparency of ongoing trade practices but also involves open collaboration among academia, companies, governments, philanthropy organizations and other stakeholders to jumpstart innovation.

Open Access and Open Data initiatives are clear routes to ensuring free and equitable access to all research data collected on new and existing drugs. [44] Companies should fully disclose the public and private funding of pharmaceutical R&D. Health systems are also encouraged to publish the price of medicines that they negotiate on behalf of patients. The United Nations (UN) High-Level Panel on Access to Medicines points out that WHO should establish and maintain a countrywise accessible international database of prices and patent status of all medicines and biosimilars in the private and public sectors. Additionally, they also recommend that governments should establish and maintain their own publicly accessible databases. This information should be periodically updated and consolidated with World Intellectual Property Organisation (WIPO) in collaboration with stakeholders to develop an international, easily searchable database which should include standard international common names for biological products; international nonproprietary names for products, either as known at the time of application or after the granting of a patent as well as dates of grant and expiry. [45] Additionally, governments should enforce clinical trial transparency regulations in line with WHO guidelines, including but not limited to clinical trial registration and the publication of summary results 12 months



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after their completion. These practices can potentially drive up the standards of both the research that is conducted and the product that is created. They will also allow both regulators and populations to hold researchers and pharmaceutical companies to account.

Open collaborative research platforms like Open Source Drug Discovery consortium, enable researchers from various disciplines and countries to work together to solve complex challenges encountered during upstream research. The Medicines for Malaria Venture (MMV) applied the open-source drug discovery model in an initiative called the Malaria Box which assembled 400 diverse molecules active against *P. falciparum*, derived from an extensive screening of libraries held by GlaxoSmithKline (GSK), Novartis, and St Jude Children's Research Hospital. Using an open data-sharing platform, MMV despatched more than 160 of these boxes, free of charge, to researchers in 27 countries, to help catalyse drug discovery and research. [18]

2.2.5 Partnerships (PPPs and PDPs)

Public-Private Partnerships (PPPs) and Product Development Partnerships (PDPs) are the most visible manifestation of the power of collaboration to tackle the current difficulties in more efficient and innovative ways. Products developed through these partnerships should have clear and transparent strategies to ensure access and affordability, providing the best examples of specific features that can ensure broad and affordable coverage. Additionally, they must be suited to the population in need. One good example of such a partnership is the Global Antibiotic Research and Development Partnership which was jointly established by the DNDi and WHO to develop and deliver new antibiotic treatments with prices fixed to be sustainably affordable. [46]

3. Regulatory and supply systems

3.1 Competition and intellectual property laws

Pharmaceuticals and biotechnology are some of the most patent-intensive industries. Companies file patents in order to gain monopoly on the development and sale of specific medicinal products. This prevents access of generics and biosimilars to the market and keeps prices at a high level.

The Medicines Patent Pool (MPP) is a public health organisation funded by UNITAID that works to increase access to treatments for HIV and tuberculosis amongst other diseases in low- and middle-income countries (LMICs). [47] This is achieved by patent holders for drugs agreeing to have their innovations held in a shared "pool" and then allowing generic drug manufacturers who have signed up to the MPP to use the patents and be able to produce the versions of the drugs for use in LMICs. As an example of its impact, in a 36 month period from January 2012, MPP partners distributed pills equivalent to 4.3 million patient years across 115 countries. From the success of this initiative it is clear that action should be taken to increase and strengthen the impact of the MPP by: expanding the number of diseases covered in the patent pool; increasing the number of licensing agreements from patent holders; and increasing the number of countries that can be included in the licenses.

3.2 TRIPS flexibilities

The Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) is formed through the World Trade Organisation (WTO) to set standards for the regulation and protection of IP. [48] TRIPS has restricted the ability for IP to be used by companies to produce generic drugs. [48,49]

There are a number of ways that countries can be flexible in implementing the TRIPS agreement. Compulsory licenses are instances where countries are able to issue licenses for the production of drugs without authorization of the original patent holder. [50] This has been used to great effect by developing countries such as Thailand, India and Brazil to reduce the costs of some medicines. [51] However, the ability for a country to issue compulsory licenses is being challenged as 2003 Doha Implementation Decision addressed the insufficient manufacturing capacity to allow developing countries such as India to issue compulsory licenses to export to these countries. Also, another challenge met by compulsory license is its overstated significance as government-issued compulsory



license serves almost the same function as government-imposed price controls on drugs to limit the profit earned by patent holder. Clearly, implementation of issuing compulsory licenses receives criticism and opposition from right-holder groups and thus we call upon the supporting of TRIPS flexibility mechanisms.

It is essential for moving forward to ensure that TRIPS flexibility mechanisms such as compulsory licenses are protected and actively promoted. Likewise, it is also essential that the exemption of Least Developed Countries to be fully compliant with TRIPS until 2030 be protected as much as possible. [51,52]

Numerous Free Trade Agreements (FTAs) negotiated in recent years, such as the United States-Mexico-Canada Agreement, have sought to strengthen the provisions within the TRIPS agreement, that give powers to companies such as:

- The ability to extend patents on drugs
- The ability to restrict access to data about new drugs (data exclusivity) that prevent generic production
- The ability to sue governments through Investor State Dispute Settlements
- Extending the duration of exclusive right protection for some drugs like the biologics for 10 years instead of 8.

Actions such as these are sometimes referred to as “TRIPS-plus” provisions. [53, 54] Among the most crucial issues pertaining to drugs and pharmaceutical products in TRIPS-plus, protection for test data exclusivity, linkages between drug registration and patents, parallel import limitations through contracts with the patent holders and so on have resulted in data and marketing exclusivity which delayed drug accessibility in addition to interfering with the effective use of TRIPS flexibility such as compulsory licensing.

3.3 Market approval and quality assurance

According to the FDA [55], a typical process for approving a medicine's sale in the market consists of the following: analysis of the target condition and available treatments, assessment of benefits and risks from clinical data, strategies for managing risks. When the drug's benefits prove to outweigh its side effects, it's approved. Having a robust system for market approval and quality assurance of medicines is fundamental to ensuring the safety of medicines for the population. While quality assurance and safety requirements are essential in this process, standards set (e.g. by FTAs) that go beyond requirements of safety in order to exclude new market entrants are eventually impeding access to medicines. There may be circumstances where market approval processes should be fast-tracked to ensure rapid access to life-saving medicines.

3.4 Health technology assessment

The health technology assessment (HTA) method is one approach to assessing the value of a new medicine. HTA can have a crucial role in determining, through its “budget impact” variable, which prices are acceptable; however, it is hard to put a price limit in cost-effectiveness analysis (CEA), as a recent example in the NHS has shown. [56] This becomes increasingly relevant when we see studies claiming that a large share of new approved medicines do not show to be clinically beneficial. [57] That's why HTA should go far beyond CEA; it must be a multidisciplinary activity that also looks at safety, clinical efficacy and effectiveness, and organisational and social consequences. HTA programmes have been established in a number of HICs with national health insurance systems. [58] A similar process, described as priority setting, has been cited as essential to achieving UHC.

3.5 Shortages and parallel trade

Parallel trade' in the pharmaceutical industry occurs where drug prices vary from country to country due to national price regulation. In such circumstances, a wholesaler in 'low price' country A will be able to achieve a better price by selling its product in 'high-price' country B rather than on the domestic market in country A.



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Parallel trade contributes to drug shortages in countries characterised by lower medicines prices. Among others, Greece, Romania and Poland are known to export large quantities of pharmaceuticals to higher-income EU Member States. Unfortunately, these exports are on the rise and regularly interfere with domestic needs, causing shortages and preventing access to these medicines for local patients. [59]

3.6 Transparency policies

The current lack of data about pricing deals cut between states and pharmaceutical companies harms evidence-based decision and creates a knowledge gap that is explored by pharmaceutical companies. This gap can be addressed by governments, making the information about agreed prices publicly available. In the US, some states have made it mandatory that price increases are disclosed and justified, including a disclosure of cost breakdown by R&D and marketing expenses and of prices charged in other countries.

4. Intergovernmental collaboration for access to medicines

Intergovernmental collaboration to improve access to medicines is fundamental.

The WHO has been engaged with this topic for a number of years. Most recently, the WHO Secretariat was requested by the 71st World Health Assembly in 2018 to outline a roadmap on access to medicines and vaccines for the period of 2019-2023. [60] Recommendations from the UN High-Level Panel on Access to Medicines warrant inclusion, to ensure consistency in global leadership on this issue. [45]

Current international guidelines are lagging behind the speed of innovation of biotherapeutic products. The use of biotherapeutics, which are produced in living cells rather than through traditional chemical synthesis, has greatly expanded in a variety of disease areas in recent years. However, biotherapeutics on the market currently lack effective competition, making them expensive, inaccessible and burdensome for public health budgets. Obtaining market approval for generic biotherapeutics is extremely cumbersome and compromises access. WHO's Guidelines on Evaluation of Similar Biotherapeutic Products [61] are considered out-of-date, and without strong international leadership on this issue, access to affordable biotherapeutics is likely to be compromised. [62]

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