

**Submission from Médecins Sans Frontières to the OHCHR analytical study on key challenges in ensuring access to medicines, vaccines and other health products (HRC resolution 50/13)**

**(a) What are the major obstacles at the national, regional and international levels to ensure equitable access to medicines, vaccines and other health products?**

Médecins Sans Frontières/Doctors Without Borders (MSF) is an international medical humanitarian organization working in more than 70 countries. Daily, we witness that our patients and the communities where we work are often without the life-saving medical tools they need because they are either not developed, not adapted to the low-resource contexts, unaffordable or not accessible. Exclusive intellectual property rights, keeping the price high and the supply low, and perverse R&D models that are solely based on profit means that people in low- and middle-income countries are often left without the needed medicine, vaccines or other health products. Whether it is millions of people in low- and middle-income countries (LMICs) dying from HIV/AIDS despite the availability of lifesaving treatments; thousands of people dying from Ebola while promising vaccine candidates were deprioritized and left to gather dust in labs; or TB still killing someone on the globe every 20 seconds despite being declared a global emergency in 1993. As such, it is urgent that concrete actions are taken and transformative norms are set to change the status quo so that lifesaving medical innovations and technologies are developed, produced and provided to people in need in a timely and equitable manner.

**(b) Please elaborate on the specific barriers, if any, that women and girls, older persons, children, persons living in poverty, or other persons or groups in situations of vulnerability or marginalization face in accessing medicines, vaccines and other health products.**

People living in resource limited settings and marginalized communities:

In responding to many infectious disease outbreaks, epidemics and pandemics, MSF has repeatedly witnessed the lack of availability, affordability and accessibility of lifesaving medical products in a timely and sufficient manner, particularly for the most marginalized communities and people living in developing countries and other resource-limited settings.[[1]](#footnote-1) These injustices and flaws include, but are not limited to:

* Unrepresentative and imbalanced global health governance and accountability mechanisms, which marginalize or exclude developing countries, civil society organizations, and affected communities.
* An overreliance on “market dynamics” and voluntary actions by the private sector to resolve access issues, while downplaying state responsibility, including through – where relevant – international assistance and cooperation;
* Deficient utilization of all available law and policy options to overcome monopolies on lifesaving medical products in order to facilitate more independent production and supply in and for developing countries;
* The absence of binding norms and enforceable conditions to ensure adequate and equitable public investment for research, development and production of, and equitable access to, lifesaving medical products;
* Insufficient transparency and restricted access to information undermine efforts to ensure governance and accountability of global PPR initiatives; and
* Inadequate global mechanisms to prioritize and ensure equitable allocation of scarce medical products for humanitarian contexts during public health emergencies.

Persons living in conflicts and other humanitarian settings

Following the COVID-19 pandemic, there has been a significant backsliding in immunization coverage.[[2]](#footnote-2) The double-whammy of humanitarian crises and the pandemic has left a growing number of children in many countries where we work at a high risk of contracting life-threatening diseases like measles, diphtheria or pneumonia that could be prevented by vaccines. Therefore, it is important to ensure continuation of immunization services. In addition, more efforts are needed to ensure children above the age of 2 have access to vaccines. This includes ensuring that countries update their immunization schedules to align with the World Health Organization (WHO) guidelines for delayed and interrupted immunization and that Gavi, the Vaccine Alliance, aligns its vaccine support with these WHO guidelines.

While attempts at setting aside specific quantities of COVID vaccines for humanitarian contexts were made through the establishment of the COVAX Humanitarian Buffer, MSF’s experience with this instrument made clear that it was fundamentally flawed and not fit for the purpose of providing rapid supply in an emergency situation. After months of complex negotiations and upon the unreasonable request for MSF to take over product liability from private companies, MSF’s attempt to use the Buffer in 2021 was not successful. [[3]](#footnote-3)

The neglected needs of children and adolescents affected by tuberculosis:
Although tuberculosis is preventable and curable, it is estimated that more than 60% of all children with TB worldwide are never even diagnosed with the disease, and 96% of children who die from TB are never put on treatment, 80% of them younger than 5 years old.[[4]](#footnote-4) The diagnostic tests available for adults with TB are not adapted for use in children, as they lack the sensitivity to detect the low levels of TB bacteria that make children sick. This has resulted in the fact that even in the most resourced settings, it is only possible to confirm TB in a minority of children.

In 2021, the WHO released new rapid guidance recommending that children of all ages with drug-resistant tuberculosis (DR-TB) have access to all-oral treatment using the drugs bedaquiline and/or delamanid. However, adopting these new recommendations in high TB burden countries requires access to the paediatric formulations of bedaquiline (produced by Johnson & Johnson) and delamanid (produced by Otsuka and its local partner Viatris). The high prices of medical due to the lack of more affordable generic alternatives, and the lack of registration of these medicines continued to pose barriers of access for children living in resource-limited setting.[[5]](#footnote-5)

Neglected diseases
Diseases like snakebite, Chagas, kala-azar and sleeping sickness, although they are all life-threatening, are neglected. The people most severely affected live in poor and marginalized communities where access to healthcare is limited. And research for new drugs and tests remains inadequate. Snakebite kills an estimated 100,000 people every year, and disables or disfigures many victims.[[6]](#footnote-6)

**(c) Are there any legal or regulatory challenges that impact the accessibility and affordability of medicines, vaccines and other health products?**

Monopolies backed by intellectual property and other exclusivities

The absence of public health protections in national IP laws and policies has a drastic impact on access to lifesaving medical products even beyond pandemics. For instance, despite the expiry in July 2023 of the primary compound patent on bedaquiline—a medicine that has become the backbone of WHO-recommended regimens for drug-resistant tuberculosis (DR-TB) treatment—held by pharmaceutical corporation Johnson & Johnson (J&J), many countries with a high burden of DR-TB will not get access to generic bedaquiline immediately. This is predominantly due to the unmerited secondary patents on bedaquiline held by J&J, often granted due to lenient patentability criteria and lack of rigorous patent examination, that remain in several high burden countries. The accessibility of the drug is further delayed in countries where patent term extensions are granted, beyond international rules, to prolong the monopoly period of the primary patent.[[7]](#footnote-7)

Lacking transparency and accountability to ensure access to medicines

Ensuring transparency is an essential first step towards achieving accountability and equity in access to medical products. While this was exemplified starkly during the COVID pandemic, lack of access to information has been a consistent challenge witnessed by MSF in tackling access barriers to key medical products.

In August 2023, MSF asked ViiV Healthcare to withdraw conditions in negotiations for a purchase agreement that are holding up procurement of the preventative HIV drug cabotegravir long-acting (CAB-LA) for key and vulnerable populations\*, due to the pharmaceutical corporation’s last-minute insertion of terms that are not acceptable in MSF purchase agreements. This includes conditions that undermine supply security for patients because ViiV retains the power to terminate the contract or refuse the purchase order without just reasons, and a confidentiality clause, akin to a Non-Disclosure Agreement (NDA), on the drug’s price and supply terms.[[8]](#footnote-8)

**(d) Please elaborate on the impact of research and development models for pharmaceuticals and other health technologies, including emerging digital technologies, on the access to medicines, vaccines and other health products?**

The mainstream biomedical R&D models are inadequate:

Failing to deliver for diseases that aren´t lucrative - The current biomedical innovation system is overwhelmingly driven by financial interests. Pharmaceutical companies choose to develop drugs based on the likely profit that a product will offer, through sales. The result is a severe lack of investment in medical tools – drugs, diagnostics and vaccines – to meet the needs of people who can’t afford to pay high prices, or who don’t constitute a sizeable or lucrative market under the current system, particularly people affected by NTDs. MSF frontline health workers have witnessed the lack of a treatment or a vaccine for Ebola virus as the outbreak engulfed Guinea, Sierra Leone and Liberia in 2014 is a poignant illustration of this problem. But the problem of inadequate or non-existent treatments and vaccines was a challenge for MSF long before 2014. Since 1999, MSF has treated people with Chagas disease, which is the leading cause of infectious heart disease (cardiomyopathy) in Latin America. Yet, the existing treatment was developed over 40 years ago, carries significant side effects, and has limited efficacy.

Failing to prioritize health needs – The lack of research efforts on areas of critical public health needs as well as recent examples of pharmaceutical companies withdrawing from R&D efforts from entire key public health areas, such as infectious disease, vaccines and antibiotic resistance are some examples. In 2012, Pfizer announced that it would completely close down its anti-infective R&D programme. In 2014, AstraZeneca closed its facility in Bangalore, ending all early-stage R&D for tuberculosis, malaria and neglected tropical diseases, before announcing a further withdrawal from all early-stage R&D across the field of anti-infectives in 2015. Novartis also withdrew from TB R&D as part of a corporate restructuring in 2014, and in 2015, Bristol-Myers Squibb announced it would close its anti-viral discovery operations. In making these decisions, drug companies are responding to financial incentives enabled by the current innovation model and divesting from areas of critical social need simply to boost the share price and executive compensation, regardless of the public health consequences. These different aspects are all testament to how the public sector’s failure to take responsibility for priority setting leads to the R&D system’s failure to prioritise according to medical need.

Failing to deliver affordable diagnostics, medicines and vaccines - pharmaceutical industry claims that patent monopolies and high prices are necessary to recoup the investments that are made in R&D, and to finance future innovation. Evidence suggests that in practice, drug prices are not reflective of R&D costs - whether claimed or estimated. Repeated high price scandals and a WHO Report on pricing of cancer[[9]](#footnote-9) drugs have exposed with great clarity how little pricing has to do with R&D costs, and is in fact primarily determined by what the market can bear. Ensuring equitable access and affordability should be considered from the very beginning of the R&D process. This requires governments to attach concrete and enforceable conditions when they support or fund R&D, including clinical trials.

Failing to use scientific and financial resources efficiently and effectively – During the research and development stages, reliance on market exclusivity pushes scientists and companies to work in isolation from, and in competition with, one another. Secrecy and lack of transparency is encouraged in order to gain first to market advantage. Information around R&D costs and methods are kept hidden, discouraging follow-on innovation that can drive prices down or improve health outcomes; instead of learning from others’ mistakes, poor investment decisions are made simultaneously by multiple companies. Also the system for incentivizing drug development is inefficient because governments that significantly invest in R&D efforts, particularly in an early and risky stage, are failing to demand on a fair return in exchange for the exclusivity and monopoly rights granted to industry.

**(e) From your perspective, what are the main challenges in terms of international cooperation, partnerships and collaboration to ensure access to medicines, vaccines and other health products?**

There is clear failure of international cooperation, partnerships and collaboration to adequately address access issues or address gaps in global R&D prioritization. The international response to COVID-19 is an ample example of this failure, characterized by a lack of global solidarity, political will and adequate governance. While high-income countries secured an abundance of supply and pharmaceutical companies reaped the profits, people in LMICs were left largely empty handed during the height of the pandemic. The failure to decide on a meaningful TRIPS-waiver, temporarily waiving intellectual property right on all COVID-19 medical tools in order to scale up supply, demonstrates this failure. While more than 100 countries as well as CSOs, academics and human rights groups called for this waiver, it was blocked by just a handful of countries, i.e. countries that did not bear the brunt of the global inequity of access to COVID-19 medical tools.

Throughout international partnerships that exist to accelerate access to vaccines and other medical tools there is a clear lack of inclusive decision-making, accountability and transparency. For example, ACT-A, established to act as the central global mechanism to address access issues, failed to deliver true multilateral collaboration. Instead of ensuring equal representation and decision-making of all countries, ACT-A was designed and established by a few institutions and donors, backed by a small group of HICs, without the opportunity for meaningful participation of LMICs and civil society organisations in its governance. Furthermore, ACT-A, including COVAX, failed to be transparent in its operation and governance. Critical information, including prices, manufacturing capacity, delivery schedules and agreements with pharmaceutical corporations is not made public, limiting public accountability.[[10]](#footnote-10) Yet, HICs often presented their financial support to COVAX as a demonstration of cooperation and international solidarity, while their prioritisation of nationalistic interests leading to excessive accumulation of COVID-19 vaccines undermined the very nature of a global coordinated commitment to tackle the pandemic. Similar lack of transparency and enforceability of agreements related to equitable access commitments were also present in international organizations that carry out or fund R&D activities.

Currently, during INB process at the WHO for the negotiation of a Pandemic Treaty, the same lack of international collaboration is evident, with many countries sticking to a health security narrative rather than a rights-based approach based on equity, justice and accountability.

**(f) What impact, if any, does the existing intellectual property rights regime have on access to medicines, vaccines and other health products. How can global efforts better address intellectual property rights and technology transfer issues to enhance access to medicines, vaccines and other health products?**

MSF has witnessed and analyzed multiple examples of the detrimental impact of monopolies backed by intellectual property on access to medicines. For example, at least three mRNA vaccine patents have been granted in South Africa to one foreign company, Moderna. These patents and applications pose barriers to production and supply of mRNA vaccines by alternative developers in South Africa. Particularly, they create uncertainties for any outputs of the COVID-19 mRNA Vaccine Technology Transfer Hub in South Africa.[[11]](#footnote-11)

As new vaccines have been developed and recommended for all children worldwide, they have come with high prices, dramatically increasing the cost to fully immunize a child. MSF analysis finds that there are both many types of patents and a significant quantity of patents and patent applications which together pose a threat to access to affordable versions of newer vaccines, like Pneumococcal Conjugate Vaccine and Human Papillomavirus vaccines.[[12]](#footnote-12)

During the COVID pandemic, three pharmaceutical corporations licensed their COVID treatments to the Medicines Patent Pool. However, none of the licenses offered world-wide coverage, excluding many countries from accessing these treatments. In the case of Ebola virus disease, too, exclusive IP licenses on lifesaving new treatments have restricted timely and sufficient access for people in endemic countries.[[13]](#footnote-13)

The production of diagnostic tests can face potential IP-barriers, including copyrights, patents, trademarks, industry design, and undisclosed information such as know-how and trade secrets. Access to know-how is of particular concern for diagnostic production, leading many local manufacturers to pursue technology transfer arrangements with originator manufacturers. Diagnostic companies typically file many patents. Despite the cost of filing for and upholding patents in various jurisdictions, developers prioritise this to discourage competition, attract investors, and support an ‘exit strategy’ of being purchased by a larger company.[[14]](#footnote-14)

1. **(g) What are the main challenges to ensure the quality, safety and efficacy of medicines and vaccines?**
2. MSF witnesses the issue of substandard medical products. While more data on the problem are needed, its root cause is well known: regulatory systems in producing and importing countries.  Key manufacturing countries, particularly low- and middle-income, should participate in the WHO regulatory systems strengthening programme to establish their maturity level (ML) for medicines and vaccines, working towards becoming WHO-listed authorities (WLAs). Importing countries can rely on WHO Prequalification (PQ). For medical products outside PQ scope, ML1/2 countries should consider relying on authorities becoming WLAs.

**(i) What concrete recommendations would you make to enhance access to medicines, vaccines and other health products?**

1. Ensure the full respect of International Humanitarian Law to protect access to care and medical assistance by persons living in conflicts and other humanitarian settings
2. Improve transparency. Countries must start with the implementation of the WHA 72.8 transparency resolution. In addition, countries must take steps to adopt the following transparency measures:
	1. Full R&D costs, including clinical trial costs – including but not limited to public funding contributions.
	2. Full contractual terms of R&D funding, supply and purchase agreements (without confidentiality provisions which limit disclosure of terms and conditions).
	3. IP licensing, sub-licensing and technology transfer agreements.
	4. All information pertaining to IP, including but not limited to patent information.
	5. Costs of production.
	6. Information on supply capacities, forecasts and delivery schedules.
	7. Information on supply, stock management, allocation and coordination.
	8. Governance documents of global health institutions and other relevant bodies involved in PPR.
3. Attach conditions to public funding. These conditions should ensure benefit - sharing and access to resulting medical technologies for LMICs. Funders should also require full disclosure of R&D costs, preclinical and clinical trial data, all relevant IP, licensing and technology transfer agreements from the grantees, with consequences for non - compliance to ensure robust public scrutiny and accountability. Additionally, funders should require globally covered, non - exclusive licensing and sustainable technology transfer by grantees to LMICs.
4. Align R&D with public health needs, including neglected tropical diseases, over national security and profit seeking. Efforts need to be pursued at the international level to address the failures of biomedical innovation on a more systematic basis.
5. Ensure full use of TRIPS-flexibilities. Including by refraining from including TRIPS+ provisions in Free Trade Agreements (FTAs) and ensuring national IP laws reflect the use of TRIPS-flexibilities.

**(j) Please add any other information or data you would like to share that have not been covered above?**

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