



73rd World Health Assembly – May 2020

Médecins Sans Frontières (MSF) briefing on agenda item: COVID-19 Response

Background

The COVID-19 pandemic caused by a new coronavirus, SARS-CoV-2, poses an unprecedented global health crisis for all countries and stakeholders. To date, Médecins Sans Frontières (MSF) is responding to COVID-19 in more than 70 countries, supporting health authorities to provide care for people with COVID-19, protecting people living in vulnerable conditions, and ensuring the uninterrupted essential health services for people suffering from other diseases as much as possible.¹ It is absolutely crucial to protect health workers and patients both in COVID-19 care centres and in all other centres providing vital health services, but global shortages of the medical tools and personal protective equipment needed to respond to COVID-19 have strained countries and treatment providers worldwide. Having access to these tools becomes more and more urgent as COVID-19 spreads in countries with limited financial resources and manufacturing capacity.

MSF considers that a successful global response to the pandemic must be built on enforceable actions that ensure universal access to effective COVID-19 medicines, diagnostics and vaccines, including sufficient production and equitable distribution.

The current monopoly-based pharmaceutical research and development (R&D) system fails to develop, produce and distribute lifesaving medical tools in the interest of public health. Patents and other forms of intellectual property give pharmaceutical corporations exclusive rights to make and sell a product with no fear of competition. With control over the market as a result of patents or other exclusive rights, or even the way in which global production and supply chains are organised, pharmaceutical companies have the decision-making power to determine who ultimately has access, including the right to determine who can produce medicines and where they can be supplied. Furthermore, having only a limited number of producers can threaten supply, and can result in shortages. When global demand outstrips production and supply capacity, medical tools are often allocated not based on public health need, but on the ability to pay high prices.

Patents also allow pharmaceutical companies to maintain control over knowledge and research results, where raw materials can be produced and sourced, and where the finished products can be registered and supplied through different contracts and license agreements. The terms and

conditions of these agreements, however, are often negotiated confidentially and kept secret. This is problematic as these agreements may allow only a few generic companies to supply to a limited number of low- and middle-income countries, while the patent-holding pharmaceutical corporation continues to supply and charge high prices in high-income or upper-middle-income countries. Many middle-income-countries with manufacturing capacity are often left out. In such a model, access to affordable medicines for all is often compromised.²

MSF has repeatedly witnessed how exclusive rights, monopolies, high prices, and pharmaceutical corporations' failure to register essential medical products in different countries have forced our staff to waste precious time negotiating for lower prices, challenging intellectual property and pushing for local registration with pharmaceutical corporations.³ For example, in the past, access to treatment for HIV/AIDS, tuberculosis (TB), hepatitis C and cancer has been blocked for many countries who were forced to pay high prices for patented medicines and were also excluded from the scope of voluntary licenses signed by pharmaceutical corporations. These barriers are never acceptable, especially during a global pandemic.

As repeated over the past few weeks by heads of state, international institutions and philanthropies, COVID-19 medical tools should be considered "global public goods" and should be "affordable, safe, effective, easily administered and universally available for everyone, everywhere."⁴ MSF welcomes, in principle, the initiatives that aim to accelerate the R&D and equitable access to the medicals tools needed to treat, prevent and diagnose COVID-19, including the launch of the Access to COVID-19 Tools (ACT) Accelerator, the substantial funding commitments from governments and other global health actors, and the proposals for the open sharing of technologies and intellectual property by the World Health Organization (WHO). We welcome both the draft resolution on the COVID-19 response for the 73rd World Health Assembly (WHA) and the United Nations resolution A/74/L.56 titled 'International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19'⁵ that recognise the lead role that WHO and Member States play in ensuring global equitable access to COVID-19 medical tools through international collaboration.

However, **MSF is deeply concerned about the overall lack of binding and enforceable actions in these initiatives and resolutions.** Since the start of the COVID-19 outbreak, there have been several concerning examples of countries acting in their self-interest and pharmaceutical corporations seeking patents and other exclusivities and protections. This "business as usual" approach by pharmaceutical corporations is unacceptable: there should be no patents in a pandemic, and we cannot rely on pharmaceutical companies' willingness, even in exchange for massive public funding, to address public health needs and to deliver an effective global response to the COVID-19 pandemic.

For example, pharmaceutical corporation Gilead's approach to potential COVID-19 treatment remdesivir provides scant assurance that the pharmaceutical industry can be trusted to act in the public interest. Following intense public criticism,⁶ Gilead recently gave up a special designation from the United States Food and Drug Administration that would have allowed for extended monopoly control over the 20-year patents it has filed for in more than 70 countries for remdesivir.⁷ Further, after ignoring demands from civil society organisations⁸ calling for non-enforcement of its patents, Gilead proceeded to secretly sign voluntary licensing agreements with specific manufacturers of its choosing. Negotiated in the dark, there is no transparency around the terms and conditions of the agreements, including whether or not they are aligned with public health needs, and there is no space for accountability with respect to the corporation's actions.⁹

Ensuring global equitable access to COVID-19 medical tools requires enforceable mechanisms. Without defined roles and clear obligations for all stakeholders and without binding mechanisms, the actions and promises behind the global solutions and initiatives being developed risk not be implemented. Additionally, **transparency across the board is essential to ensure access**, and is especially important considering the gravity of the pandemic and the considerable amount of public and philanthropic money behind the development of COVID-19 medical tools. Technologies, data and know-how must be shared on a mandatory basis with the right to use and produce recognised for all countries. Any plans and decisions concerning COVID-19 medical tools need to be presented publicly. The agreements between stakeholders, the conditions attached to public and philanthropic funds, and the costs and prices at all stages of development, production and distribution must be transparent. Finally, the rules for ensuring equitable allocation must be set and made public. Only under these conditions can we ensure that lifesaving COVID-19 medical tools will be shared equitably.

Establishing these conditions requires that the central responsibilities of WHO and its Member States not be side-lined. WHO should have a leading role in establishing the collective governance of COVID-19 medical tools – one where all contributors, including low- and middle-income countries and civil society, are represented.

MSF recommendations

MSF recommends that Member States and WHO further strengthen the overall approach to the COVID-19 response, including the draft resolution at the 73rd WHA, and provides the following suggestions for action:

- 1. Adopt binding and enforceable measures to ensure universal access to effective COVID-19 medicines, diagnostics and vaccines**

A binding and enforceable mechanism should be created to ensure that technologies, data and know-how are shared transparently on a mandatory basis, and that the right to use and produce any COVID-19 medical tools are recognised worldwide on a non-exclusive basis for the response to the pandemic. Beyond facilitating and boosting research, these measures will help to ensure a sufficient supply of quality COVID-19 medical tools by allowing massive decentralised manufacturing efforts in different countries, including in developing countries. A binding and enforceable mechanism should also establish at the international level the rules for equitable allocation of medicines, diagnostics, vaccines and other medical tools needed for the COVID-19 response, including personal protective equipment.

The principle of technology sharing has been captured in the present WHA draft resolution and other WHO initiatives. However, the current initiatives in the form of declarations and resolutions,^{*} based primarily on the call for voluntarily sharing, are insufficient to guarantee an uninterrupted worldwide right to use, produce and supply COVID-19 medical tools, and to guarantee their equitable allocation.

Past experiences with voluntary measures, for example voluntary licences, highlight how this type of mechanism leaves the decision-making power with patent-holding pharmaceutical corporations. With a voluntary license, governments have no power to request which countries and what intellectual property should be included in the agreement – ultimately it is the pharmaceutical company that decides whether or not to license the patent and to whom. Further, when companies choose to license, they place restrictions on the scope of countries included in the agreement – often excluding most middle- and high-income countries with manufacturing capacity who could benefit from the license in the form of sourcing finished formulations or sourcing of raw materials. For example, Gilead notoriously set the price for a hepatitis C treatment at an exorbitant US\$1,000 per pill in 2013 in the US. Gilead then negotiated bilateral voluntary licenses with Indian manufacturing companies that excluded high- and middle-income countries like Brazil and China from receiving generic supply, leaving these countries to negotiate directly with the company, largely in secret, and having to pay higher prices. In another example, pharmaceutical corporations J&J and Otsuka failed to license patented drug-resistant TB (DR-TB) medicines bedaquiline and delamanid respectively, despite appeals from civil society to the Medicines Patent Pool and even after South Africa, India and other high DR-TB burden countries adopted these new medicines into their national DR-TB guidelines. The Ministry of Health in India was ultimately unsuccessful in purchasing delamanid from Otsuka – the only manufacturer – after lengthy negotiations to try and reduce the price from US\$1,700 for a six-month treatment course, meaning people who needed the drug were unable to access it.

^{*} Declarations and resolutions are frequently adopted by WHO Member States. They are not treaties, however, and are not binding.

The effectiveness of the global response depends on enforceable and rule-based mechanisms. One possibility is to consider triggering the normative process within the power of the WHA as enshrined under the WHO Constitution.¹⁰ Further details on the key considerations for mandatory mechanisms can be found in the Annex ('Essential considerations and principles on mandatory open sharing of technologies for COVID-19 to ensure equitable access for all').

2. Encourage Member States to explore and use fully the existing policy and legal measures to ensure access to COVID-19 medical tools, including flexibilities under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Doha Declaration on TRIPS and Public Health

First, we suggest that the language regarding "international treaties" in the WHA draft resolution be strengthened to explicitly encourage the use of flexibilities under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health. International treaties* is a broad term that could include agreements signed bilaterally and regionally for trade and investment matters. Some of these trade and investment agreements contain provisions that can significantly undermine the rapid removal of access barriers at national and international levels. For instance, provisions requiring second medical use patents or methods of treatment patents could allow pharmaceutical corporations to apply for additional exclusive rights on repurposed medicines or on the way vaccines are administered. Other provisions that require statutory exclusivity on test data by drug regulatory agencies could effectively impede the international collaboration, data sharing and rapid regulatory process in multiple countries that is needed to accelerate the entry of generic and biosimilar products. Therefore, it is important to encourage Member States in the draft resolution to use legal public health safeguards as allowed under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, and the actions available to mitigate the detrimental impacts of TRIPS-plus provisions in bilateral and regional agreements.

Second, we suggest making an explicit reference in the WHA draft resolution to Recommendation 16 of the WHO Secretariat on the overall programme review of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI).[†] This recommendation details the full range of public health safeguards and measures under intellectual property and regulatory laws that can be used by Member States.¹¹ These measures would include, but are not

* A treaty is an agreement between sovereign states, and in some cases, international organisations, that is binding under international law. Treaties can be bilateral (between two states) or multilateral (between three or more states). A treaty may also be known as an international agreement, protocol, covenant, convention, pact, or exchange of letters, among other terms. See 'Treaty, International Relations' in Encyclopedia Britannica.

[†] Recommendation 16 states: "The WHO Secretariat, in collaboration with other international organizations working in intellectual property, to advocate for the development of national legislation to fully reflect the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement."

limited to, governments issuing compulsory licenses, waiving and suspending existing patents and other exclusive rights, and not granting new patents and other exclusive rights on test data and new medical indications related to COVID-19 medicines, diagnostics and vaccines. These measures can be used in order to rapidly remove or avoid any barriers to ensure that COVID-19 medical tools are produced in sufficient quantities at the national and global level and allocated according to public health needs. We especially encourage Member States to explore regional and international legal and policy interventions that can remove barriers to achieving a sufficient supply and equitable access for all.

Furthermore, we strongly recommend adding a specific note¹² for the countries that have opted out of the protocol amendment (Article 31*bis*) of the TRIPS Agreement to restate their eligibility to the amendment in order to be able to import under the special form of compulsory license. This will facilitate global collaboration for the production and transportation of medicines, diagnostics, vaccines and other medical supplies.

3. Ensure full transparency of all R&D funding agreements with explicit and binding obligations to ensure that any resulting medical tools are made available and accessible for all and affordable for government and treatment providers

We note the proactive funding commitments and contributions from governments and global health actors to accelerate the development and delivery of effective treatments, diagnostics and vaccines against COVID-19. However, we are concerned that the overall lack of transparency of the R&D funding agreements makes difficult any accountability mechanism. It is imperative that these agreements are made publicly available, including the full terms and conditions. All R&D funding agreements should have binding obligations to ensure that the agreement and data (including genetic data on the virus, promising compounds, and clinical trial protocols and results) are published in the public domain, and that the outputs of such R&D will not generate private monopolies and will instead be accessible and affordable for all governments and treatment providers.

Summary of MSF recommendations

1. Adopt binding and enforceable measures to ensure universal access to effective COVID-19 medicines, diagnostics and vaccines:
 - Make the open sharing of technologies, data and know-how, and the worldwide right to use, produce and adapt COVID-19 medical tools on a non-exclusive basis for the response to the COVID-19 pandemic mandatory.
 - Establish rules at the international level for the equitable allocation of medicines, diagnostics, vaccines and other medical tools and personal protective equipment needed for the COVID-19 response.

2. Encourage Member States to explore and use fully the existing policy and legal measures to ensure access to COVID-19 medical tools, including flexibilities enshrined under the TRIPS Agreement and Doha Declaration:

- Make an explicit reference in the WHA draft resolution to Recommendation 16 of the WHO Secretariat on the overall programme review of the GSPA-PHI, which details the full range of public health safeguards and measures available under intellectual property laws and regulatory laws that can be used by Member States.¹¹
- Add a specific note¹² for the countries that have opted out of the protocol amendment (Article 31*bis*) of the TRIPS Agreement to restate their eligibility to the amendment in order to be able to import under this special form of compulsory license.

3. Ensure full transparency of all R&D funding agreements with explicit and binding obligations to ensure that any resulting medical tools are made available and accessible for all and affordable for government and treatment providers:

- Ensure that R&D funding is conditional on agreements and data (including genetic data on the virus, promising compounds, clinical trial protocols and results) being published in the public domain.
- Ensure that R&D funding is conditional on technology owners committing to either not enforcing their existing intellectual property, or to sharing their knowledge and intellectual property by licensing it on a non-exclusive basis globally.

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Annex: Essential considerations and principles on mandatory open sharing of technologies for COVID-19 to ensure equitable access for all

How could a global platform for the open sharing of technologies help fight the COVID-19 pandemic more efficiently?

In the context of the current pandemic, the world urgently needs **effective medical tools, including diagnostics, medicines and vaccines, to be available and accessible in all countries**. Concretely, this requires the research and development (R&D) of new tools, decentralised and rapid scale-up of manufacturing and supply capacities, transparent and affordable prices for governments and treatment providers, and free access for people at the point of care.

The open sharing of technologies, knowledge and data is a **powerful way to boost the R&D of new medical tools. If terms and conditions on the right to use and produce these technologies allow, it can also expand and diversify production and supply capacities by enabling multiple manufacturers to produce. Furthermore, this can also facilitate the management of costs and bring prices down.**

However, a key challenge of this approach is ensuring that **all needed technologies, knowledge and data are shared in such a way that guarantees the right to use and produce by all competent entities worldwide**. A critical risk is that the entities retaining exclusive rights will limit their use. For instance, relying on the willingness of the holders of these technologies, often pharmaceutical companies, risks leading to restricted use of selected rights or knowledge.

Voluntary patent pools between companies is common practice in many technological fields, including in the pharmaceutical industry. A typical voluntary patent pool allows members who join the pool to access, use, exchange and contribute relevant technologies and information under pre-defined terms and conditions. While pooling patents can, to a certain degree, save time and money, the effects of pooling through forming business clusters can also trigger anti-competitive concerns. Patent pools where rights and information are only of use to the pool members may encourage collusion between competitors that share information, such as on pricing, marketing strategies, or R&D information. In addition, while in the short term a patent pool can facilitate lower prices, a lack of transparency on the terms and conditions of the licences and restrictions on their use can enable a company to take the upper hand over competitors and have stronger control over the global market.

Previous experiences with voluntary mechanisms in the medical field, such as the voluntary licensing of patents, including through the Medicines Patent Pool (MPP), **have demonstrated the inherent limitations** of relying on pharmaceutical companies' willingness to address public health needs. Challenges with voluntary approaches have arisen because companies ultimately retain the

rights to determine which entities can access information or knowledge, and/or which entities can produce medicines and where they can be supplied. For example, many middle-income countries with manufacturing capacities, and all high-income countries, were excluded from the licenses as part of the current voluntary patent pool mechanism for HIV and/or hepatitis C medicines.

The COVID-19 pandemic will affect all countries regardless of their socio-economic status. It will likely have serious health, social and economic impacts worldwide, disproportionately affecting vulnerable populations and exacerbating existing vulnerabilities within health systems. In such a context, **governments and UN bodies have the responsibility to ensure that monopolies and other exclusivities do not limit the development and use of health technologies needed to combat COVID-19.** There are examples of non-voluntary pooling mechanisms in other technical fields which have successfully created pro-competitive conditions whilst sharing techniques. An emblematic example is the Manufacturers Aircraft Association, which, during the first world war, was forced by the US government to form a patent pool. Whilst MSF supports the principles of open sharing and open science to facilitate sustainable and equitable access to medical tools, it is imperative that **any initiative or platform aiming to share technologies in the context of COVID-19 are designed and organised in such a way that ensures the right to use and produce such technologies by all competent entities world-wide.**

Public funding will play a large role in the funding of R&D of technologies to prevent or treat COVID-19, but governments also have the legal means to **impose mandatory sharing, as well as require transparency of production, prices, stockpiles, and supply capacities to ensure access to all people in need across the world.**

In the midst of the COVID-19 pandemic, it is important to reaffirm the core responsibility of governments and the World Health Organization (WHO) to adopt mandatory measures and direct interventions. This is including, but not limited to, adopting binding agreements at the international level under the WHO Constitution, the use of compulsory licensing and the suspension and cancellation of exclusivity protections. These measures would accelerate the development of diverse and sufficient manufacturing and supply capacities, and enable equitable distribution of COVID-19 diagnostics, treatments and vaccines for all in need.

Essential considerations for initiatives aiming to pool or share technologies

1. Mandatory sharing through global suspension or fast-track compulsory licensing of patents and exclusivities by all governments would ensure no monopolies on COVID-19 medical technologies and data: The profound impact of the COVID-19 pandemic at the global level needs to be addressed through collective action and commitments from all governments. As such, direct legal and policy interventions are critical. Governments are able to suspend patents and

exclusivities, or issue compulsory licenses, and mandate companies to share the concerned technologies, data and knowledge with a global open platform. This would ensure that no monopolies are attached to the technologies, and the data shared through the platform is accessible to all.

2. Explicit binding obligations related to the sharing of technologies should to be put in place in all funding agreements concerning COVID-19: It is essential to ensure public funding agencies and governments hold sufficient power over decision-making to ensure that technologies are shared in a global open platform with favourable terms and conditions. This needs to be explicitly stated and required ahead of funding allocations to ensure the open sharing of technologies.

3. Ensure inclusion of all countries in the territory of any agreement related to access and use: Previous experiences with voluntary licensing has revealed the constant and ongoing challenge of ensuring all countries, especially middle-income countries with manufacturing capacity, are included in the territory of the license agreements with the right to produce and supply. It is critical that all countries, due to the nature of the pandemic, are included in the scope of the agreement.

4. Full transparency and disclosure of the participation of key stakeholders, including governments, in negotiations between the MPP, WHO and rights holders: To avoid the pitfall of unfair terms and conditions being negotiated in the business-as-usual bilateral and confidential negotiation settings for voluntary licenses, it is critical to ensure full transparency and disclosure of the participation of key stakeholders, especially governments, in negotiations. Full agreements should be made public.

5. Worldwide, royalty-free, non-exclusive obligations: Any agreements or terms and conditions to be established in the proposed mechanism, including through the possible administration of those terms and conditions by the MPP, should be non-exclusive and ensure global coverage of production and supply. It should be royalty-free for low- and middle-income countries, with reasonable remuneration terms for the other countries.

6. Binding obligations to prevent secondary patenting and additional exclusivities, and ensuring the continued open sharing of technologies: To ensure that no exclusivities and/or secondary patents arise in the future development of COVID-19 medical tools, it is critical to set up explicit, upfront obligations requiring that: 1) original technology holders will not seek secondary patenting or additional regulatory exclusivities; 2) any additional intellectual property sought by the original technology holders should be shared back into the pool or platform under the same terms and conditions as the original agreements. In addition, explicit open source licensing terms could be considered. This would require all contractual parties to agree on the binding obligations to

share/grant back any development, improvement or adjustment of the original technologies with the same terms and conditions set out in the original license, in order to ensure the continuation of the open sharing mechanism.