



## **Médecins Sans Frontières (MSF) submission to APPG on Coronavirus Inquiry into the UK Government's handling of the coronavirus outbreak**

As an international medical humanitarian organization, Médecins Sans Frontières (MSF) seeks to ensure that the medical tools urgently needed to respond to COVID-19 are accessible, affordable, and available to all countries equally, including the countries where we work. Today, MSF is responding to COVID-19 pandemic in nearly 60 countries providing treatment and care for people with COVID-19, and ensuring uninterrupted essential health services for people suffering from other diseases.<sup>i</sup> Since the beginning of the pandemic, MSF has witnessed how the lack of access to essential medical supplies undermines our ability to respond. These experiences show that in order to have an effective response to COVID-19, both existing and future treatments, vaccines and diagnostics must be accessible and available for everyone.

In responding to the Call for Evidence by the All-Party Parliamentary Group (APPG), MSF considers that there are critical measures that the UK government must put in place to make this goal a reality, and to make sure that their words<sup>ii</sup> committing to global equitable access of COVID-19 medical products, are followed through by actions. This document is split into four sections covering areas that are each critical to ensure equitable access to future COVID-19 vaccines, diagnostics and treatments:

1. Research and development (R&D) funding for COVID-19 medical products;
2. Transparency and accountability;
3. Global open sharing of COVID-19 technologies, knowledge, and data; and
4. Ensuring global equitable access to COVID-19 technologies.

### **1. Research and Development (R&D) funding for COVID-19 medical products**

#### **Summary of key issues:**

- The UK government has committed over £474.5million to the R&D of potential future COVID-19 vaccines, diagnostics and treatments. Furthermore, the UK has contributed £250million for the Coalition for Epidemic Preparedness Initiative (CEPI) towards international vaccine research efforts for infectious diseases.
- Actions are needed to ensure that these innovations reach all those who need them, including those living in low and middle-income countries.
- With millions of pounds of public money going into the R&D for future COVID-19 medical technologies, it is critical that the final products are sold “at cost”, and that pharmaceutical companies do not profiteer from public funding when governments are required to buy back the products that they initially funded the development of.
- In addition, there is a critical need to scale up geographically diverse manufacturing capacities, in particular in LMICs, so that the necessary quantities of final products can be produced on the scales needed to meet demand once they are approved. There is currently no clear policy from the UK public funding agencies to request that their grantees ensure effective technology transfer, open-sharing or licensing of COVID-19 medical technologies to facilitate diversified and sustainable follow-on development and manufacture globally, especially in LMICs.
- In April, MSF and more than 20 civil society organisations and individuals wrote an open letter to the UK government to demand that any COVID-19 medicines or technologies created with public funds are available to all, patent-free.<sup>iii</sup> Following this, over 130 cross-party parliamentarians led by the APPG *Vaccination for All*, wrote to the government urging them to ensure equitable access to a COVID-19 vaccine.<sup>iv</sup> Furthermore, the British public overwhelmingly support equitable global access to COVID-19 vaccines and treatments.<sup>v</sup>

**Case study/evidence:** Cepheid’s COVID-19 Xpert testing cartridge was developed using \$3.7million of public funding from the US Biomedical Advanced Research and Development Authority (BARDA). MSF’s analysis estimated that this cartridge cost \$3 to manufacture and could be sold at profit for \$5.<sup>vi</sup> Instead, Cepheid has priced these cartridges at \$19.80 – forcing the public to pay four-fold for a product that was initially developed using public funding.<sup>vii</sup>

**Recommendations:** It is critical that the UK government ensures that publicly funded R&D contributions ensure equitable access to COVID-19 medical products by attaching the following conditions to R&D funding:

- Final products are sold “at cost”, and are accessible to all, including low and middle- income countries.
- Recipients of R&D funding are transparent about their costs, prices and data (see recommendations below).
- Exclusive rights are not granted for the final products, in order to facilitate production, supply and ensure affordability. All products should be openly licensed.

**Supporting document:** [Technical Brief: Achieving equitable global access resulting from the ACT Accelerator](#)

## **2. Transparency and Accountability**

**Summary of key issues:**

- There is currently very little transparency in the pharmaceutical industry. Despite millions of pounds of UK public funding subsidizing COVID-19 R&D, the government is not currently making requirements for transparency or public disclosure of any of the following information:
  - **R&D costs, public funding contributions, production costs, prices they charge in different countries:** This information is critical not only to ensure responsible use of public money including through affordable prices of final products, but also to ensure the public are not paying twice for COVID-19 technologies (first through upfront R&D, and secondly when the products are bought back by the government for the population). It enables a fair negotiation between the government and pharmaceutical companies for a fair price, rather than the government effectively negotiating “blindfolded” without this information.
  - **Clinical trial data:** This allows independent and public scrutiny of safety and efficacy data. This is particularly pertinent for COVID-19 technologies since R&D processes have been accelerated.
  - **Relevant patents and their status, supply capacities and license agreements:** This information is crucial to determine supply capacities and to expand production capacities globally. Patents and exclusive licenses can block other suppliers entering the market, limiting global supplies and keeping prices high (see recommendation below for further information on these issues).

**Case study/evidence:** Oxford’s Jenner Institute own a leading COVID-19 vaccine candidate. Despite early assurances from Oxford researchers that they aimed to maximise access to their vaccine through open-licensing,<sup>viii</sup> they later signed an exclusive license with UK-based company AstraZeneca.<sup>ix</sup> This deal has not been made public, and the terms that have been agreed with AstraZeneca are not known. Furthermore, AstraZeneca claim they will not make a profit from the vaccine during the pandemic period, however, there have been no assurances about the price after the pandemic is declared “over”. The terms of sub-licenses AstraZeneca signed with other vaccine developers on are also unknown, making it difficult to assess the sustainability of supply globally. Since it is likely the vaccine will be needed long after the acute pandemic period, including a need for “booster” doses,<sup>x</sup> AstraZeneca could make exorbitant profits through a vaccine which has been completely funded with public money.<sup>xi</sup>

**Recommendations:**

- Through attaching conditions to COVID-19 R&D funding, the government should require the following to be published in the public domain:
  - R&D costs, public funding contributions, production costs, prices they charge in different countries.
  - Clinical trial data (including genetic data, promising compounds, clinical trial protocols and results).
  - Relevant patents and their status.
  - Supply capacities and license agreements.
- The government should implement the 2019 World Health Assembly (WHA) resolution entitled ‘*Improving the transparency of markets for medicines, vaccines, and other health products*’.<sup>xii</sup> The resolution requests public

disclosure of net prices, public funding of R&D, relevant patents, marketing approval status, clinical trial data, marketing costs and sales revenue. If implemented, this would be relevant to all health products (not just COVID-19). At the time of the resolution (May 2019), the UK government disassociated from this resolution, demonstrating their lack of commitment to improving transparency in the pharmaceutical industry and bringing down prices for medical products.<sup>xiii</sup>

### **3. Global Open Sharing of COVID-19 Technologies, Knowledge and Data**

#### **Summary of key issues:**

- In January 2020, the scientific community welcomed publishing of the SARS-CoV-2 viral genome, which was anticipated to set a precedent for international global collaboration. However, ensuring global equitable access to COVID-19 tools and technologies has proven much more problematic.
- MSF welcomes the establishment of global frameworks, such as the WHO COVID-19 Technology Access Pool (C-TAP)<sup>xiv</sup> that intend to facilitate global access through the global voluntary sharing of COVID-19 knowledge, intellectual property (IP) and data.<sup>xv</sup> However, MSF has long experience with the shortcomings of voluntary measures in IP management regarding access to medicines.<sup>xvi</sup> In this pandemic, enforceable measures adapted by governments are needed to realise global open sharing of IP, data and knowledge and the uninterrupted right to use, produce and supply globally needed medical tools.
- Since we are likely to see unprecedented global demand for any successful future treatments or vaccines for COVID-19, we need to ensure that production of these products can be scaled up as rapidly as possible. Enforceable measures related to the sharing of IP, data and knowledge are therefore critically needed to ensure that IP monopolies do not limit access to future COVID-19 medical tools due by blocking the scale up of supply, or due to high prices.
- MSF has repeatedly witnessed how IP monopolies result in lack of access to such health tools for the people we care for.<sup>xvii</sup> In the past and today, high prices of patented medicines have undermined access to treatment for people with HIV/AIDS,<sup>xviii</sup> tuberculosis,<sup>xix</sup> and hepatitis C.<sup>xx</sup> Barriers due to IP have limited the availability of more affordable pneumonia vaccines for children in low- and middle-income countries.<sup>xxi</sup> Already, there have been a number of patent disputes on COVID-19 vaccines, delaying the development of potentially effective tools.<sup>xxixxxiii</sup>
- MSF has extensive experience of overcoming pharmaceutical company monopolies to expand access to essential medical tools. A critical lesson from these experiences is that *voluntary mechanisms for licensing*, such as the Medicines Patent Pool (MPP) and now as proposed for WHO C-TAP, do not permit companies or national governments to be held to account.
- Previous experiences with voluntary licensing of patents through the MPP have demonstrated the inherent limitations of relying on pharmaceutical companies' willingness to address public health needs.<sup>xxiv</sup>
- Whilst the UK government has expressed to us its support for voluntary measures, it is through the mandatory sharing of IP, knowledge and data that it can be guaranteed that no monopolies are attached to the technologies, and the data shared is accessible to all.

**Case study/evidence:** Remdesivir, developed by US pharmaceutical corporation Gilead Sciences, with considerable public funding<sup>xxv</sup> and government support for clinical trials, is one of the antiviral drugs to enter clinical trials for the treatment of COVID-19. Gilead holds primary patents on the drug in more than 70 countries that may block entry of generic producers until 2031. In May 2020, Gilead announced that it had signed voluntary licenses with five generic manufacturers in India and Pakistan that can market generic versions of the drug in 116 countries and 11 territories.<sup>xxvi</sup> In June, two more companies based in India and one in Egypt were added to the license. These voluntary licenses, however, exclude nearly half of the world's population,<sup>xxvii</sup> including countries such as Brazil and Russia, and most of the South America countries, where coronavirus cases are surging. Having been negotiated in the dark, there is no transparency around the terms and conditions of these licenses, including whether or not they are aligned with global public health needs.

**Recommendations:** The UK government should:

- Suspend all patents and exclusivities related to COVID-19 technologies in the UK.

- Attach conditions to funding agreements to mandate companies to:
  - Share the concerned technologies, data and knowledge with a global open platform.
  - Not seek secondary patenting or additional regulatory exclusivities.
  - Share any additional IP sought by the original technology back into the pool or platform under the same terms.
- Implement the recommendation from the UK International Trade Committee's report, which calls on the government to adjust IP provisions to allow for compulsory licensing of drugs or vaccines for COVID-19 to ensure they are "made available as quickly, widely and cheaply as possible."<sup>xxviii</sup>

#### Supporting documents:

- [MSF Access Campaign position paper on the sharing of technologies for COVID-19 to ensure equitable access for all](#)
- [MSF Access Campaign Technical Brief: Overcoming intellectual property monopolies in the COVID-19 pandemic](#)

## 4. Ensuring Global Equitable Access to COVID-19 Technologies

### Summary of key issues:

- Global equitable access to future COVID-19 technologies is essential to tackle this pandemic. People in countries in humanitarian crises where MSF works, and frontline healthcare workers are particularly vulnerable and must be prioritised for treatment and protection.
- MSF is concerned that access to any successful vaccines or treatments may be limited by narrow political or commercial interests. Past experiences have shown that limited supply, nationalistic control and high prices can result in barriers to access, therefore MSF is following these potential access barriers closely:
  - **Inadequate supply:** Due to demand outstripping supply, there are likely to be supply shortages of whatever COVID-19 medical products are first to be approved for use. The failures of the current patent system explained above that have shaped biomedical research for decades could once again hinder scale up and access to affordable vaccines.
  - **Hoarding and nationalistic approaches:** There is currently no globally agreed-upon enforceable framework for equitable allocation of medical tools for COVID-19. Without such an agreement there is a serious concern that governments might hoard COVID-19 treatments or vaccines, or that products developed nationally will be prioritised for their population, rather than allocated globally according to health needs.
  - **Pricing and lack of affordability:** We do not know what the price will be for COVID-19 medical products that may emerge, but some initial indications from companies suggest that price could be a barrier to access in many regions of the world.
- Gavi's COVID-19 Vaccine Global Access (COVAX) Facility and the COVAX Advance Market Commitment (AMC) aim to ensure global equitable access to COVID-19 vaccines.<sup>xxix</sup> However, MSF has concerns about how this Facility will work to ensure real global equitable access, and has a number of critical recommendations to ensure it meets these aims.<sup>xxx</sup> In June, MSF and over 40 other civil society organisations and individuals wrote to the Gavi board, including the UK Gavi board members, requesting urgent changes to the COVAX Facility to ensure equitable access to COVID-19 vaccines.<sup>xxxi</sup>
- To ensure an effective global response, the availability of vaccines for frontline health care workers and social care settings in all countries is a matter of utmost urgency. Although the WHO-led global equitable allocation framework (EAF)<sup>xxxii</sup> spells out these needs, the concrete mechanism to ensure the implementation remains unclear. In addition, as supply will eventually increase, proportional shares of vaccines should be made available for populations in crisis-affected humanitarian settings: refugees, asylum seekers, marginalised populations, and people living in conflict areas. These are populations who have the least access to, or are excluded altogether from, national health services.

**Case study/evidence:** The UK Government has already displayed nationalistic approaches both in the establishment of bilateral vaccine deals and the hoarding of a potential COVID-19 treatment:

- Despite pledging support for the COVAX Facility,<sup>xxxiii</sup> the UK has so far signed bilateral deals for six unproven COVID-19 vaccines. This makes the UK the world's highest per-capita buyer, with 340 million purchased: around 5 doses for each citizen.<sup>xxxiv</sup> With anticipated limited global supplies of COVID-19 vaccines, this leaves other countries with limited or no resources with none or very little of the remaining supply. Shadow Secretary of State for Foreign Affairs, Lisa Nandy, wrote an open letter condemning bilateral deals in the U.S., and encouraged the UK to uphold its reputation as a global leader by championing international cooperation and equal access.<sup>xxxvxxvi</sup>
- Following preliminary data on the use of dexamethasone and the positive impacts on hospitalisation and mortality in June, the UK government immediately put in place an export ban.<sup>xxxvii</sup> This was condemned as 'morally questionable' by MSF and other health campaigners.<sup>xxxviii</sup>

**Recommendations:** The UK government should:

- Require that technologies, data and know-how must be shared on a mandatory basis with the right to use and produce recognised for all countries to maximise supply and access (as above);
- Refrain from export bans on potential COVID-19 products and from bilateral deals for unproven vaccines whilst there is limited global supply capacity. Global collaboration is the only way to ensure equitable access for all, achieved through full cooperation with the WHO EAF;<sup>xxxii</sup>
- Support the realisation of guaranteed access for frontline health workers by committing to share a portion of the vaccines they obtain through advanced purchase agreements with the COVAX AMC starting from the very first vaccine shipment, and contribute doses towards the development of a humanitarian stockpile to meet the needs of populations in crisis-affected humanitarian settings;
- Use its critical position as a donor and board member of Gavi to ensure that COVAX Facility meets its key aim of global equitable access through:
  - Demanding 'at-cost' prices from pharmaceutical companies. Profits should not be made off the back of this pandemic;
  - Transparency: pharmaceutical corporations receiving funding from the COVAX Facility must open their books publicly so it is possible to independently verify how much potential COVID-19 vaccines will actually cost to produce. Additionally, Gavi must share transparently any agreements made with industry;
  - Requiring technology transfer and open licensing: COVAX Facility funding should come with "strings attached" that require companies to participate in technology transfer and open licensing to broaden the manufacturer base, helping improve supply availability; and
  - Including humanitarian organisations and NGOs: Gavi must include non-governmental purchasers in their COVAX Facility so that they can access vaccines at the lowest global price.

**Supporting document:** [COVID-19 Vaccine Global Access \(COVAX\) Facility: Key considerations for Gavi's new global financing mechanism](#)

[MSF statement at the EU parliamentary hearing on COVID-19 vaccines](#)

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