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A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology

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Significant shortcomings in the global response to COVID-19 have revealed a long-standing reality: the current international health and intellectual property (IP) laws and practices fail to deliver equitable access to medical countermeasures (ie, vaccines, therapeutics, diagnostics and personal protective equipment) for global health crises. Since 2020, governments worldwide have spent US\$5.6 billion on COVID-19 research and development (R&D) and US\$45 billion on advanced purchase agreements.¹ Yet, these funding agreements have not enabled the transfer of manufacturing know-how to scale up vaccine production and make access more equal. As a result, large parts of the world were left unprotected from the virus, allowing the rise of new variants and prolonging the pandemic for everyone.

On 1 December 2021, the 194 Member States of the World Health Organization (WHO) agreed to begin negotiations towards an international instrument that would better position the world to prevent, respond and prepare for future pandemics.² (This instrument is often called a 'pandemic treaty'.) These Member States recognised that a '(lack of) equity is at the core of the breakdown in the current system' while acknowledging that the challenges in ensuring 'universal and equitable access and distribution' of medical countermeasures could be 'meaningfully addressed under the umbrella of a potential new instrument'.³

A pandemic treaty presents an opportunity to address these challenges and craft a better

Summary box

- ⇒ The COVID-19 pandemic highlighted how current international laws and practices fail to ensure medical countermeasures (ie, vaccines, therapeutics, diagnostics and personal protective equipment) are equitably distributed in a global health crisis.
- ⇒ In 2021, the 194 Member States of the World Health Organization agreed to begin negotiations towards an international instrument that would better position the world to prevent, respond and prepare for future pandemics (often called a 'pandemic treaty').
- ⇒ A pandemic treaty presents an opportunity to address these challenges in international law, and craft a better system, based on solidarity, for the global development and distribution of medical countermeasures.
- ⇒ We recommend that a pandemic treaty ensures sufficient financing for biomedical research and development (R&D), creates conditions for licensing government-funded R&D, mandates technology transfer, shares intellectual property, data and knowledge needed for the production and supply of products, and streamlines regulatory standards and procedures to market medical countermeasures.
- ⇒ We also recommend that a pandemic treaty ensures greater transparency and inclusive governance of these systems.
- ⇒ The aim of these components in a pandemic treaty should be to craft a better collective response to global health threats, consistent with existing international law, political commitments and sound public health practice.

system, based on solidarity, for the global governance of medical countermeasures. This commentary identifies key aspects of a

potential pandemic treaty for the global sharing of IP, know-how and medical technology that would be needed to ensure equitable global access to medical countermeasures in a future pandemic. Online supplemental annex highlights examples of existing laws that could be used as a blueprint.

SHORTCOMINGS OF EXISTING GLOBAL LAW AND GOVERNANCE

Several limitations of international law contribute to the failure to deliver access to the knowledge underlying pandemic countermeasures.

One, while 171 states have committed to realise the rights to health (including the provision of essential medicines) and to benefit from scientific progress in international human rights law, it lacks hard enforcement measures for states that fail to live up to these commitments.

Two, while the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights Agreement has policy space to protect public health and to promote access to medicines for all, compliance with the legal texts requires a sophisticated understanding of both IP and trade law, and an ability to resist pressure from trading partners and rights holders.⁴

Compulsory licensing of patents is a powerful legal tool to deal with patent barriers to access to health technologies, in the absence of voluntary licenses, but have scarcely been used during the COVID-19 pandemic. Some products, including many vaccines, require access to manufacturing know-how, in addition to patents (see box 1).

Three, depending on the country, there are inadequate, underused or no mechanisms to mandate private companies to share the know-how and data needed to manufacture and licence medical countermeasures, even in a public health emergency, and when that knowledge was developed with significant public funding.

Four, the International Health Regulations, a global health law requiring states to prepare for and respond to infectious disease outbreaks, is mute on the matter of developing, financing, and managing access to medical countermeasures and sharing of IP and know-how needed to produce them.³

A pandemic treaty should, in as far as possible, address some of these shortcomings and be consistent with international law.

SEVEN RECOMMENDATIONS FOR GLOBAL ACCESS TO MEDICAL COUNTERMEASURES

Our international expert group recommends that any pandemic treaty addresses seven substantive areas for effective and equitable access to medical countermeasures. Our recommendations consider the current limitations of international law, and the different economic realities of potential state parties to a pandemic treaty.

Box 1 Access to intellectual property (IP) for pandemic countermeasures

The commonly accepted rationale for protecting IP is to provide a reward to successful innovators in order to induce investments in research and development, while also making the new product or process available for the public to use. The 1995 World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Agreement globalised norms for the protection of IP that WTO Members (ie, countries) are required to implement in their national law.

Access to three forms of IP is critical for the production of pandemic countermeasures. The first is patents on inventions. Patents generally provide the rights holder with the right (for a minimum of 20 years) to prevent others from making, importing, exporting and selling a product, subject to some limitations and exceptions. One of those exceptions is where a government or court permits the production, trade, or sale of the product without the rights holder's permission, and subject to royalty payments. (This is called non-voluntary use, and it includes compulsory licensing). Access to patent rights alone, while necessary, may be insufficient to stimulate the production of generic or biosimilar products, where the manufacturing know-how is required, or other barriers exist.

Undisclosed information, including manufacturing know-how, is a different type of IP.¹⁰ Know-how is a broad body of information that is of commercial value, and in many cases, is important to efficiently manufacture vaccines and other health products. Know-how can include (but is not limited to) trade secrets, technical specifications and training, instructions, process controls and quality control procedures. Rights holders can voluntarily share this knowledge to help efficiently and effectively manufacture products in a process called technology transfer.

Another important form of IP is the right to rely on the evidence from tests (including both preclinical and clinical trials) that demonstrate products are safe and effective. This is often referred to as 'test data' and generic and biosimilar manufacturers may need to obtain the rights to rely on such data for regulatory approval.

Finance biomedical R&D

Policies for access to effective medical countermeasures start with government-led measures to directly or indirectly finance, subsidise, reward and derisk their development. It is generally understood that private investments in vaccines and therapeutics for potential pandemic pathogens are inadequate, particularly in the period before a disaster strikes.

A pandemic treaty should create global norms to ensure and enhance both pre-pandemic and crisis-related funding for relevant R&D, and set standards for managing R&D funding. A critical component will be measures in a treaty to ensure there are sufficient resources from all sources (public and private), and for all stages of R&D. A pandemic treaty should offer a variety of management arrangements allowing states to meet these R&D funding norms (eg, national R&D programmes, cross-border collaborations, contributions to global initiatives, and a diversity of funding mechanisms including direct funding, subsidies and incentives).

There should be provisions for coordination and collaboration among R&D funders (regardless of the source). These provisions should recognise the importance of R&D funders having agency over how their resources are used and managed. Achieving this degree of cooperation would be aided by a pandemic treaty that provides incentives to collaborate and address priority public health needs. A treaty should balance decentralised decision making and control, with mechanisms for cooperation and scaling benefits.

Another aspect of a treaty should be the creation of standards and mechanisms to report on R&D funding (see below on transparency)

Create conditions for government-funded R&D

A major criticism of the R&D process for COVID-19 countermeasures is that public funders bore significant financial risks while private companies controlled access to the largely publicly funded knowledge needed to make the resulting products.

A pandemic treaty should establish norms for conditions and binding provisions (in contracts) when any government has funded the R&D of countermeasures. A critical component is to obtain sufficient rights to ensure that patents, data, know-how and biological resources can be shared as needed to replicate the innovation by qualified entities, subject to appropriate safeguards and conditions, including when appropriate, remuneration. The Medicines Patent Pool, a United Nations-backed institution that aims to increase access to medicines through patent licensing, could provide models for such licences.

These norms should also require the public disclosure of a range of information (see below on transparency') including clinical trial data, research results, and costs in open access platforms. These steps would help realise the global consensus for greater transparency of biomedical R&D costs, units sold, sales revenue and net prices by country.⁵

Mandate technology transfer

The lack of technology transfer from vaccine producers in high-income countries to manufacturers (particularly in low- and middle-income countries (LMICs)) has been a major hurdle to rapidly growing the global COVID-19 vaccine supply.

Technology transfer should become the norm in the pandemic preparedness and response phases, not the exception. To achieve this, a pandemic treaty should create two types of obligations on governments that are triggered with the declaration of a Public Health Emergency of International Concern. One, governments should condition public R&D funding of medical countermeasures on agreements to provide meaningful technology transfer (see above conditions for government funded R&D). Two, governments should cooperate to provide mandates, subsidies and incentives to the private sector to engage in technology transfer to qualified entities, even when that knowledge is not financed

by the public sector. This can include voluntary or non-voluntary buyouts, with governments sharing the costs, or requirements that government procurement contracts mandate technology transfer.

Governments should provide sufficient financing for technology transfer. The Montreal Protocol, an international treaty designed to protect the ozone layer, offers an example of a global fund for such purposes (see online supplemental annex).⁶ If background IP and know-how are important for technology transfer, then buy-outs of such assets (in which the government purchases the IP rights over an asset in order fulfil a particular policy objective) could play a role.^{7,8}

The success of technology transfer goes hand-in-hand with building and maintaining adequate manufacturing and regulatory capacity in all regions of the world (see below on regulatory standards), and facilitating (global) trade. Some of these steps should be taken in the pandemic preparedness phase.

Require IP and knowledge sharing

The COVID-19 pandemic has shown that current voluntary mechanisms for sharing the IP and knowledge underlying medical countermeasures are insufficient.

A pandemic treaty should require governments to prepare their national laws for sharing the rights to inventions, data and access to know-how and biological resources before a pandemic strikes. These legal tools should include compulsory measures that are triggered by a Public Health Emergency of International Concern (PHEIC), such as tools for the rapid, efficient and effective waiver of monopolies on relevant technology needed for pandemic response (see the broad exceptions to exclusive rights for patents in the 2020 German Epidemic Protection Act, and the mandatory exceptions to copyright in the World Intellectual Property Organization (WIPO) Marrakesh Treaty for the Blind, described in online supplemental annex). A pandemic treaty should acknowledge the growing importance of sharing know-how, particularly as the technology behind countermeasures becomes more complex.

A pandemic treaty should address potential conflicts between the public health need to rapidly share the IP of medical countermeasures in a crisis, and obligations to protect IP, established in other international trade and investment agreements, including bilateral and plurilateral trade and investment agreements. To do this, the pandemic treaty could require that states be required to not to enforce provisions in those agreements when they conflict with a pandemic treaty obligation to share know-how and scale manufacturing of affordable countermeasures.

Streamline regulatory standards and procedures

Regulating the safety, quality and efficacy of medical countermeasures is an important aspect of global access. Pharmaceutical regulation usually takes place on a national or regional basis, leading to a high potential

for fragmentation, duplication, and inefficiency as new medicines are marketed during a pandemic.

A pandemic treaty should provide for a global repository of the applicable regulatory standards and procedures, and the transparency and sharing of regulatory data. A treaty should set up a process to progressively address some of the known problems in regulation, such as: inconsistent approval standards and/or application of emergency use provisions; excessively restrictive or otherwise inappropriate pathways for more complex and/or novel technologies; and progressively eliminate unnecessary regulatory barriers to safe and effective products that are affordable, on a timely basis when dealing with an emergency.

A pandemic treaty should identify or create financing mechanisms for the above actions.

Greater transparency

International cooperation in global health crises is stifled by a lack of information sharing at all levels of medical countermeasure development, financing, procurement and use.

A pandemic treaty should have a distinct and ambitious chapter on transparency that addresses the need for transparency on a range of issues including: pathogens; scientific research; R&D funding agreements (in all sectors)*; regulatory standards and procedures*; patent landscapes and regulatory status landscapes*; licences of inventions, data, know-how and biologic resources*; clinical trial designs, outcomes, costs and subsidies*⁹; R&D costs (this could be designed as a requirement for regulatory approval)*; public funding of R&D including grants, research contracts, advance purchase agreement, tax exemptions and credits and other measures of monetary value*; performance data from diagnostic tests*; manufacturing costs*; supplier/manufacturing capacity; country and multicountry procurement contracts including the list and net prices paid for medical countermeasures*; terms of the non-disclosure agreements between suppliers, government and private employers; volumes of vaccines/treatments procured and available nationally/regionally; price structures/components; manufacturing and acquisition costs of diagnostic tests*.

Currently some of this information is publicly available, while other information is held confidentially by governments and/or private entities. A pandemic treaty should establish norms for sharing and disclosing information. The information marked with an asterisk should be housed in a global repository mandated by a pandemic treaty.

Inclusive governance

A treaty should provide financial support for low-resourced states to effectively participate in negotiations. The resulting governance mechanism should provide for the meaningful representation of states by region and by level of development. The governance mechanism should not advantage early ratifiers or states with greater

capacity and financial resources. A pandemic treaty should be dynamic (allowing for changes and amendments as needed) and have effective incentives and enforcement provisions, including accountability mechanisms for state parties and, ideally, non-state actors.

Global cooperation to address these six foregoing recommendations would be aided by an ongoing process to build a stepwise global framework with three levels. On the first level, a global framework should bind all governments to harmonise their existing mechanisms related to areas of the strongest consensus. The second level should provide an opt-in for harder-to-agree provisions. These provisions would be legally binding for those countries who join. The third level should develop best practices or soft norms for more novel or experimental provisions, where these norms could be moved 'up' to level two or one over time as support grows.

CONCLUSION

With the WHO Member States' decision to pursue an international instrument on pandemics, the world now has an opportunity to enhance preparedness and cooperation for future global health crises. Our international expert group recommends that the pandemic treaty address seven areas in order to support the global sharing of IP, know-how and technology for equitable access to medical countermeasures. The overarching aim of these components in a pandemic treaty should be to craft a better collective response to global health threats, consistent with existing international law, political commitments and sound public health practice.

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Supplementary Annex - Examples of existing laws regarding access to the intellectual property of technologies needed by society

Related to Commentary: A Pandemic Treaty for equitable global access to medical countermeasures: Seven recommendations for sharing intellectual property, know-how and technology

United Nations Montreal Protocol on Substances that Deplete the Ozone Layer¹

This Protocol was adopted to assist in phasing out ozone-depleting substances, including by deploying replacement substances that may be protected by intellectual property.² An amendment to the Montreal Protocol established a 'Multilateral Fund' to provide financial and technical assistance, to transfer substitute technologies to developing countries that may otherwise be unable to comply with these phase-out rules. Under the Protocol, technology transfer requires states to take steps to ensure the 'best available' technologies are 'expeditiously transferred' to developing countries and that those transfers happen under 'fair and most favourable conditions'.³ This is an example of a mandate for technology transfer and the creation of a global fund supporting developing countries to obtain and use technologies in the global public interest.

WIPO Marrakesh Treaty for the Blind⁴

This Treaty requires its members (currently 84 governments and the European Union are contracting parties) to include exceptions and limitations in their national copyright law in order to reproduce, distribute, and make available accessible copies of copyrighted works for blind or visually-impaired people. The exceptions are consistent with existing copyright treaties and the World Trade Organization's TRIPS agreement, and remedies two problems. First, before the treaty, many countries had inadequate or no exceptions for blind persons in their national copyright laws. Second, treaty members are required to allow the export and import of accessible works, making the exceptions work cross-border, which has led to much greater efficiency in using the exceptions, and a massive increase in the availability of accessible works worldwide.

German Epidemic Protection Act⁵

In March 2020 the German government passed a law that provides for the non-enforcement of patents on medicinal products, active ingredients, medical devices, personal protective equipment, and other

¹ 1987 Montreal Protocol on Substances that Deplete the Ozone Layer.

² Garrison C. Lessons for a pandemic preparedness treaty from previous successes and failures with treaty-based technology transfer. *Medicines Law & Policy Briefing Paper*. 2021. <https://medicineslawandpolicy.org/wp-content/uploads/2021/10/Lessons-for-a-pandemic-preparedness-treaty-from-previous-successes-and-failures-with-treaty-based-technology-transfer.pdf>

³ 1987 Montreal Protocol on Substances that Deplete the Ozone Layer.

⁴ Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled. WIPO. 2013

⁵ Act for protecting the Population in the Event of an Epidemic Situation of National Importance, (*Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite*) <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents>

technologies during a pandemic where these products are important for public welfare or security.⁶ This is an example of how measures allowing access to the intellectual property of medical countermeasures can be included in pandemic preparedness legislation, which is triggered by a public health emergency.

⁶ <https://www.twobirds.com/en/news/articles/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents>