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**Written Comment Re: Implications of Access and Benefit Sharing (ABS)  
Commitments/Regimes and Other Proposed Commitments  
in the WHO Pandemic Agreement**

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**Introduction**

I am a law professor at Northeastern University School of Law and have written about, consulted, and worked on access to medicines for over twenty years, but this comment is my own and does not reflect the position of Northeastern or of the School of Law. I am a volunteer Senior Policy Analyst for Health Global Access Project, which was formed 25 years ago to confront systematic barriers to life-saving HIV treatment and care, and this Comment is submitted on its behalf. Although this comment will mainly focus on responding to the specific questions put forth for comment, I will preface this comment by drawing brief attention to domestic and regional policies and proposals put forth and implemented by the U.S. and E.U. that should, at a bare minimum, be authorized or even mandated in the WHO Pandemic Agreement. As my further comments will make clear, I also propose measures that go beyond U.S. and E.U. policies and proposals that nonetheless should be adopted in the Agreement.

As a baseline recommendation, the U.S. should be willing to put forward new proposals at the WHO that would allow developing countries to use the same kinds of flexibilities that the U.S. used during the COVID-19 covid pandemic to shield companies that use other companies' patents from liability for production of medical products that the U.S. needs. Acknowledging that it has the easiest-to-use "government use" licenses in the world pursuant to 28 U.S.C. sec. 1498, the U.S. proposes that other governments can use simple contractual language to immunize biopharmaceutical manufacturers from liability for patent infringement. [The U.S. government used this authority dozens of times during the covid pandemic](#) to insulate its contracted COVID-19 suppliers from IP infringement claims. Similarly, the U.S. used its powers under the Production Defense Act to support U.S. producers manufacturing covid-related medical products and has just announced another Defense Production Act initiative "to enable investment in domestic manufacturing of essential medicines, medical countermeasures, and critical inputs that have been deemed by the President as essential to the national defense." In addition, President Biden has recently announced [a new effort to use federal "march-in" rights](#) arising from taxpayer-funded inventions to allow alternative producers to manufacture and sell medical products when the needs of U.S. patients are not met because of inadequate supplies or unreasonably high prices. Under the Bayh-Dole Act, 35 U.S.C. sec. 202(c)(4), the U.S. can also use march-in rights to secure "a nontransferable, irrevocable, royalty-free license to practice or

have practiced the invention for or on behalf of the United States throughout the world.” ([Combining use of march-in and sec. 1498 rights would be particularly powerful.](#)) Finally, the U.S. has recently begun to impose very modest fair pricing terms, including “most favored nations clauses” in some of its pharmaceutical R&D funding agreements, [including with Regeneron](#); and the [Administration for Strategic Preparedness and Response](#) has made fair pricing a standard part of its R&D deals.

The E.U. is also proposing new legislation that should be replicated the Pandemic Agreement, particularly its proposed legislation [creating a new regional compulsory licensing system](#) to allow “generic” producers to manufacture and sell emergency-related medical products in all E.U. countries without having to go through onerous, country-by-country processes. Not only will the generic producers have freedom to use another company’s patents, they will also have [access to trade secrets and know-how](#) needed to produce more complex biologic medicines and vaccines. The aggregated E.U. market will incentivize licensed producers and access will be accelerated for smaller and poorer E.U. member states. The EU’s proposal also provides for data and market exclusivity waivers to ensure no regulatory barriers exist to supply of the products produced under a compulsory license. This same kind of regional compulsory licensing mechanism, or even broader freedom to operate and to export/import could work for developing country regions as well. In addition to its proposed regional compulsory licensing mechanism, the E.U. is recommending non-exclusive licensing of publicly-funded emergency measures and greater transparency concerning public R&D funding.

### **Recommendations for Pandemic Agreement based solely on U.S./E.U.’s Actual Practices, Policies, and Proposals**

- Invest adequate public resources in basic science and pandemic/emergency health technologies, but with access conditionalities attached (US Bayh-Dole Act).
- Impose adequate supply, reasonable pricing, and equitable distribution requirements in publicly funded research and development agreements and purchasing contracts and allow licensed use by other producers when such conditions are not met (US Bayh-Dole Act and fair pricing directive).
- Adopt easy-to-use government use licenses by or for the government (28 U.S.C. sec. 1498).
- License publicly funded patents, research tools, and technology platforms to the Health Technology Access Pool (US licenses to COVID-19 Technology Access Pool) or to authorized licensees in the case of health emergencies (European Commission’s Horizon 2020 R&D Frameworks and Manifesto for EU COVID-19 research).
- Routinely issue government-use/patent-immunity provisions in public procurement contracts for pandemic health technologies to allow entities producing by or for the government to do so without fear of infringement liability (dozens of US procurement contracts).
- Allow use of national security and emergency powers to support domestic and regional expansion of biopharmaceutical manufacturing capacity and to secure supply of needed components (US Defense Production Act).
- Establish and use national and regional compulsory and government-use licensing procedures for pandemics and other health emergencies that allow export of unlimited

quantities of needed medical products to all members of a regional or other collaborative grouping (EU regional compulsory licensing proposal).

- If trade-secret protect know-how and other confidential information or materials are needed to produce health products pursuant to a compulsory or government use license (or even if such licenses are not needed), require the rightholder to share such information and transfer technology with licensed producers (EU regional compulsory licensing proposal).
- Regulatory data establishing safety, efficacy, and quality must also be shared and may be relied upon to register or allow emergency use authorization/listing for the licensees' or permitted producers' equivalent products (EU regional compulsory licensing proposal).
- Transparency of public R&D funding agreements, procurement agreements, and licensing agreements should be increased.

The content of the Pandemic Agreement should not, however, be limited to current U.S. and E.U. domestic and regional policies, practices, and proposals. The needs of developing countries were clearly not met in the COVID-19 response, and re-codification of the status quo would be a travesty and a violation of the most fundamental principles of global health justice and solidarity. Accordingly, in comments below, I make many recommendations that go beyond minor adjustment to the status quo.

### **Comments on Article 9, Research and Development Questions**

- What approaches or incentives might be provided to governments, research institutions, or the private sector to encourage participation of relevant stakeholders to, as proposed in the Negotiating Text, “accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential”?

**Comment: Governments, public/private research partnerships, research institutes, universities, and charitable research funders need to significantly increase their funding of research into pandemic pathogens and pandemic-related medical products and technologies. In addition, they need to include transparency, open-science, and equitable access conditionalities in their funding agreements. The results of publicly and charitably funded research, including especially research platforms, technology platforms, and medical products, should be considered global public goods that are shared and licensed broadly to capable, regionally distributed manufacturers. The private sector also could play a much more constructive role if it assumed pandemic preparedness and response research and product development responsibilities, including increased funding, that focused on pandemic risks and agreed to engage in full IP licensing and technology transfer agreements in advance of and during the earliest stages of emerging pandemics so that regionally distributed manufacturers could help ensure adequate supplies, affordable prices, and equitable access.**

**Pandemic-related research needs to be collaborative and democratized. The idea of siloed, secret research to prepare for and respond to pandemics has been shown to be deeply problematic. Research should be based on open-science principles of rapid public reporting and publication of research findings, results, and data. Research**

should be broadly and deeply collaborative. [Robust, multisite clinical trial platforms](#) should be established allowing well-powered trials that can where appropriate compare multiple products and regimes. The clinical trial platform should include all regions and ensure representative participation of historically under-represented and excluded populations and populations with co-morbid conditions. Early- and late-stage research partnerships should routinely be established between high-income and low- and middle-income country (LMIC) researchers, with later being given greater voice in setting priorities and in conducting and reporting research.

In addition, R&D should focus on pandemic-related products that are well-adapted for use in LMICs, especially resources poor settings. This research focus would include adaptation of existing products that can be cheaply produced and that are durable and easy-to-use at the community level. Much greater attention needs to be paid on product and manufacturing optimization to simplify manufacture and to lower the costs of production.

Populations most at risk from pandemic outbreaks and relevant community organizations should be mobilized and supported to be involved in the prioritizing pandemic-related research and development, [to help design research and clinical trial protocols](#), and to monitor their results. Those same populations and community organizations should be empowered to help ensure that the fruits of scientific research and progress are equitably shared to all in need.

- What voluntary steps could Research & Development (R&D) stakeholders take that would build capacities and promote more inclusive research collaborations and participation from basic science through advanced development and clinical research, addressing the global calls for equity and inclusion?

**Comment:** In addition to answers to the immediately preceding question, R&D stakeholders, particularly in high-income countries (HICs), need to (a) recognize the talents and capabilities of LMIC researchers, (b) select them more frequently as lead or co-lead investigators and lead authors of scientific publications, and (c) respond to their contextualized knowledge of local needs and priorities. R&D stakeholders should prioritize research on conditions that already or are most likely to burden LMIC regions. Concrete efforts, including resources for LMIC R&D capacity-building, twinning agreements and exchanges, and funding for LMIC R&D activities, must be undertaken. HICs and their R&D stakeholders should avoid contributing to LMIC brain-drain by increasing efforts for LMIC researchers to engage in high-quality, collaborate research in their home countries.

- What national policies might be developed that (as proposed in the Negotiating Text), “support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications”?

**Comment:** All countries have existing capacity and legal freedom to adopt laws, regulations, or policies that require registration and open-access publication of clinical trial protocols and results. Negative results must be reports as well as positive results. Many countries already require open publication, especially for publicly funded research results, though enforcement is often lax or worse. Not only should open publication be required, but redacted data should also be available, especially so that other researchers can conduct mega-studies or seek to verify earlier findings. Open access journals should have reduced or no-fee policies for LMIC researchers.

- What are respective pros and cons of, the following proposed language in the Negotiating Text: “in accordance with national laws and considering the extent of public funding provided, publish[ing] the terms of government-funded research and development agreements for pandemic-related products, including information on: (a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability and reusability principles; (b) the pricing of end-products, or pricing policies for end-products; (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic”? In your view, are there alternative recommended actions or commitments that could be considered?

**Comment:** Transparency is one of the key proposals that should be incorporated into any final agreement for at least five reasons. First, transparency with respect to publicly funded research inputs, processes, results, pricing, licensing and equitable access terms, is critical to government planning before and during pandemics, to government accountability, and to public oversight. Second, public funding should lead to public benefits – to the collective good rather than private gain – and the extent of those public benefits, in terms of open-science, fair pricing, licensing/technology-transfer, and ultimately affordable, equitable and timely access, can only be measured and assured if there is transparency. Third, we have learned the negative consequences of non-transparency during COVID-19 where product rightholders routinely claimed that the information listed above, especially price, was trade-secret/confidential-information protected and just a routinely imposed onerous confidentially and non-disclosure conditions in R&D and procurement/supply agreements (see [South Africa study](#)). Fourth, contrary to industry’s claims, transparency will not have a significant negative impact on innovation incentives. Many R&D funding agreements, including those involving the Gates Foundation, CEPI, DNDi, and others, have included transparency and equitable, access conditionalities as reported in a currently unpublished WHO publication (RECOMMENDED CONTRACT TERMS FOR TECHNOLOGY TRANSFER AND AFFORDABLE ACCESS IN FUNDING AGREEMENTS FOR R&D, CLINICAL TRIALS, AND MANUFACTURING). Moreover, HICs are highly likely to continue paying market rate prices to pandemic product producers, meaning that rightholders have almost nothing to lose from transparency. After all, 81% of global expenditures on by originator brand name biopharmaceuticals occurred in the 10 richest countries in 2023, with an additional 18.5% occurring in other developed and pharmerging countries; less than 9% of such

sales occur in low-income and lower-middle-income countries (excluding Bangladesh, Egypt, India, Pakistan, Philippines and Vietnam, which are consider pharmerging) ([IQVIA, Global Use of Medicines 2024](#), p. 39). Fifth, and with respect to price information, industry claims protection for [final price information that should not even be classified as a trade secret](#).

In addition to transparency on the issues above, there should be transparency on that patent and regulatory landscapes of pandemic-related medical products and their components. At present, despite most of this information theoretically being in the public domain (patents and regulatory approvals are granted by governments), it is virtually impossible to gather this information in one country let alone all countries. Inaccessibility of this impedes access to lawful compulsory, emergency, and government use licenses.

Finally, publicly financed R&D agreements should have an access provision that require the funded entity to timeously and broadly register or seek emergency use/listing authorization of pandemic-related medical products throughout their relevant markets. Global or transnational biopharmaceutical companies should ordinarily be expected to register in all countries, including smaller and poorer countries where they frequently delay or decline to seek regulatory approval. Regional manufacturers should register regionally, national manufactures need only register domestically.

- What is the appropriate role for WHO in facilitating the R&D process in areas focusing on infectious diseases?

**Comment:** At the very least, the WHO should identify pathogens with pandemic potential; keep track of and report on pandemic related R&D and the product pipeline; and provide oversight and guidance on the innovation systems that are sorely needed to fully address pandemic prevention, preparedness and response. However, there are other areas, less frequently addressed, where the WHO could strengthen its contributions. The WHO could significantly accelerate research activity and product development and adaptation in LMICs if it strengthened and accelerate [WHO Prequalification](#) and Emergency Use Listing, expanded use of [WHO Collaborate Registration Procedures](#), and expedited clinical guidance of the use of pandemic-related medical products. Uncertainty and delay in WHO procedures and processes contribute to a sense ennui for LMIC researchers who often see their efforts wither on the vine because of first-mover advantages of HIC researchers tied to multinational enterprises.

The WHO should also be supported in its proposed establishment of a [Health Technology Access Pool](#) (H-TAP) and initiatives like the mRNA Technology Transfer Hub Programme. H-TAP is the proposed successful to the COVID-19 Technology Access Pool. Although C-TAP was not highly successful in negotiating access to COVID-19 technologies, its mandate included trying to gain access to rights and technologies that would promote R&D as well manufacture of final products. In this regard, it received several research tools from US National Institutes of Health. The



**mRNA Technology Transfer Hub Programme is a very intriguing effort to promote open-science and cross-licensing of mRNA developments, including product and process optimization and application of mRNA technologies to new health conditions. The Programme offers a template for additional novel innovation/access partnerships for medical products, including other vaccine platform, monoclonal antibodies, etc.**

- Are there provisions that could reasonably be included in government-funded research or advanced development agreements, or policies related to licensing of government-owned and/or government-funded technology that would promote global access to pandemic-related products, without disincentivizing innovation or partnering with the U.S. government around research and development?

**Comment: In a word yes. In addition to provisions discussed in answers to preceding questions, the following draft principles were developed in WHO expert meetings addressing recommended contractual terms in R&D funding agreements.**

“i. Funders should direct funding principally to public health priorities and identified needs, recognizing that the targets of such funding are global public goods. Funding agreements should assure that the price of any developed products are affordable to public health systems and individuals, with particular attention to underserved or under-represented populations, especially those in lower-income countries. Funding conditions should be based on access-to-products criteria rather than on commercial criteria, taking into account reasonable commercial considerations of funding recipients. Such agreements should restrict the excessive pricing of licensed materials and intellectual property rights and of target products. Consistent with legitimate needs for confidentiality of competitive business information and trade secrecy, such agreements should assure the public availability and transparency of costs of contract performance (including R&D costs, clinical trial costs, regulatory approval costs, and manufacturing and distribution costs), conform to the maximum extent possible with the principles of World Health Assembly Resolution 72.8, and (where not possible to make such costs public), should provide for funder access and ability of funders to audit expenditures, costs, and remuneration (including licensing and sales revenues). Funding agreements should require funding recipients and licensees to publicly report actual sales prices and amounts in all jurisdictions, so as to permit assessments of affordability for access. Funding agreements should provide mechanisms for more specific access and pricing provisions as technology and regulatory approvals develop over time.

ii. Funders should adopt open calls for qualified applicants or other expressions of interest, should perform capabilities assessments of potential funding recipients, and should fund multiple recipients wherever possible to decrease the likelihood of exclusivity requirements. Funding agreements should require submission by funding recipients of plans for how recipients will meet technology development and transfer and affordable access objectives. Such agreements should include requirements for funders to review access plans, should require reporting by funding recipients and licensees (with licensee reporting going to both licensors and funders), and should include terms for reversion of rights and other actions where plans are not followed or technology development and transfer or affordable access objectives are not met. Such agreements should provide for post-funding funder and public assessments of conformity of recipients and licensees to funding agreement requirements and to access and affordability goals, clearly identifying the products of the funding and how they achieved access and affordability goals.

iii. Funding agreements should include terms on whether and under what conditions funding will be provided, continued, or renewed. Such agreements should include evaluative criteria and benchmarks to assure achievement of stated goals for R&D, clinical trials, regulatory approvals, manufacturing, and distribution. Wherever possible, funding

agreements should require that R&D, clinical trials, and regulatory approval data and other information and materials at all stages of product development be published, shared, and conducted on an “open science” basis, in order to permit ongoing, reproduceable, parallel, and incremental innovation. Such agreements thus should require transparency of research activities, should specify where R&D and clinical trials are to be conducted, and should include specific terms for technology transfer that provide for governmental regulatory oversight of technology transfer processes.

iv. Funders should assure that whatever target products ultimately result are made available to the widest possible worldwide publics, by adopting the least restrictive alternatives that assure such access consistent with product development objectives, the nature of the disease targets and disease burdens, and the geographic distribution of those targets. Funders should seek to assure to the maximum extent possible geographically distributed manufacturing and marketing authorization of products.

v. Funding agreements should include “reach-through” provisions to assure downstream access to subsequent patents and trade secrets and any other IP rights (e.g., designs, software, etc.), including assuring the ability to engage in non-exclusive third-party licensing of those rights where needed. Such agreements should prohibit downstream licensing requirements that would condition access to technology on the loss of rights (e.g., geographic sales). Funding agreements also should prohibit downstream licensing restrictions on access to basic supplies and intermediary products, APIs, software, etc.

vi. Funding agreements should promote broad sequential R&D and product development. Such agreements ordinarily should avoid segmentation or differentiation of equitable access options based on geography and demographics, both within countries and among countries, while recognizing that field-of-use restrictions (particularly in technology transfer licenses) and product access requirements may sometimes be required. Consistent with funding objectives and the nature of disease targets, such restrictions should be avoided or limited wherever possible in order to permit follow-on R&D for additional medical indications and for alternative product development.

vii. Funding agreements should seek to assure worldwide access by adopting the least restrictive alternative to assure such access, consistent with funding contract objectives and the nature of disease targets and geographic distribution thereof. Such agreements should preferentially require licensing to entities with broad access goals (e.g., the Medicines Patent Pool). Funding agreements should ordinarily avoid limitation of parallel imports, although market segmentation may sometimes permit increasing the geographic scope of licensing agreements and market differentiation using concessionary pricing and exclusivity sometimes may be a useful tool to achieving affordable access. Funders should document in a publicly transparent manner why specific contractual terms of funding agreements have in fact adopted least-restrictive alternatives.

viii. Funders should perform due diligence to avoid creating regulatory barriers based on quality assurance and thus should carefully evaluate, document, and publicly report any funding agreement restrictions based on quality assurances. Funding agreements should recognize the need to include provisions that assure adequate quality and safety of products, as well as adherence to standards of good manufacturing practice.

ix. Funders should differentiate among research platform development, multi-product technology platforms, and specific types of target products, and should include in funding agreements terms seeking the broadest feasible open science and publication, geographic technology transfer, and geographic distribution of clinical trials and regulatory approvals for such products. Funding agreements should require know-how and materials sharing to assure rapid scale-up of product lines, manufacturing, and regulatory approvals, as well as data sharing and affirmative cooperation requirements (including providing any needed reference and reliance rights in data, materials, and any supplemental regulatory



information to third parties) to assure such worldwide regulatory approval applications can be successful and timely achieved.

x. Funding agreements should specify whether funding is accompanied by any background IP, materials, or data. In general, funding agreements on research platforms should seek to assure open access, and at a minimum should insure open licensing. Funding agreements may require additional funding incentives to assure access to platform technologies, so as to encourage new product innovation, development of sustainable pharmaceutical capacity, and access to particular products.

xi. Funding agreements should detail requirements for mandatory sharing of technology packages, including active cooperation obligations to assure transfers of tacit knowledge, assistance in setting up product lines and regulatory approvals, training of personnel, etc. Wherever possible, such agreements should require that target technologies be made available on a “share-alike” or “open access” basis, and should require grant-backs of developed technology to assure broad access to improvements for further development (including open pooling arrangements). Where such global approaches are not possible, funding agreements should seek to maximize public access to target technologies through mechanisms such as by creating “club goods” among countries willing to share technologies. Funders should seek to assure interoperability of any developed technologies. Consistent with any needs for intellectual property acquisition, funding agreements should require the public transparency of any developed technologies. Complementarily, funding agreements should require, wherever possible, publication of results on an open access model.

xii. Funders should whenever possible provide for non-exclusive funding, and should require pro-competitive, non-exclusive licensing by funding recipients by incorporating in funding agreements contractual terms that control and dictate the terms of downstream licensing of target products. Consequently, whatever contractual terms for licensing are recommended should be included as upstream requirements in funding contracts. However, funding agreement provisions should not be so burdensome as to prevent contracts from being concluded, and should not include unnecessary terms, while recognizing that with greater amounts of funding provided, funders can more readily dictate the terms of downstream licensing requirements.

xiii. Funding agreements should be pro-competitive, and should avoid provisions that harm competition, such as prohibiting sales where not restricted by IP rights or imposing supplier-based restrictions rather than adopting quality-based restrictions. Such agreements should, whenever possible, include provisions that permit follow-on research and development, including for new medical uses and alternative products.

xiv. Funding agreements should address third party beneficiaries of technology transfer and of product availability. Such agreements should include mechanisms for some form of enforcement of third-party beneficiary interests (e.g., governing board oversight). Funding contracts should provide financial terms for buyouts of target technologies and intellectual property, where important for lowering access costs, recognizing that funding for such buyouts may need an international cooperative mechanism but may provide for lower-cost access to the technologies while providing reasonable returns to target technology developers.

xv. In general, funding agreements should require funding recipients to seek full regulatory approvals, as well as any emergency use authorizations needed to assure rapid public access to needed target products. Funding agreements should not provide indemnities to funding recipients, whether for intellectual property rights infringement or for products liability (although funders may rely on governmental compensation programs for vaccine products that provide immunities from products liability suits). Such agreements should clearly identify any warranties, but any warranties or indemnities should not override

contractual requirements to provide to funders and to make publicly available any adverse effects data or similar information. Funding agreements should require that adverse effects and other follow-on studies be completed and be made publicly accessible.

xvi. Funders should implement in agreements all core recommended principles and policies, and funding agreements should not be used to avoid regulatory requirements or policies that would otherwise apply to funding. Funders should clearly justify and publicly document any departures from non-core recommended principles, limiting such departures only to what is in fact necessary. Any such justifications for departures should be clearly, transparently, and publicly made in advance, and some form of public accountability should be maintained to assure that decision-making conforms to the maximum extent possible to the relevant policy criteria.”

**[Copied without express permission from: WHO RECOMMENDED CONTRACT TERMS FOR TECHNOLOGY TRANSFER AND AFFORDABLE ACCESS IN FUNDING AGREEMENTS FOR R&D, CLINICAL TRIALS, AND MANUFACTURING (Sept. 2022). I was an expert working group member.]**

### **Comments on Article 10, Sustainable Production Questions**

- What approaches or incentives might be used to encourage manufacturers and others “to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licenses to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries”?

**Comment: Licensing and technology transfer requirements in R&D funding agreements have been discussed in previous Article 9 comments and are incorporated by reference. In addition, tax credits or deductions could be given to manufacturers that license and transfer pandemic-related technologies to other manufacturers, particularly in developing countries. By defraying properly accounted expenditures on licensing and technology transfer, countries would in effect be subsidizing those expenditure and reducing out-of-pocket costs for transferring entities. Although full tax credits would not be appropriate for purely commercial licensing and technology transfer agreements with manufacturing partners or contract manufacturing organizations, tax credits would be appropriate for such licensing and technology transfer to independent LMIC manufacturers.**

**Countries, especially HICs, could make licensing and technology transfers a condition of advance purchase, capacity reservation, and other procurement agreements, where the guarantee of presumably profitable sales in HICs would provide an incentive for licensing and technology transfer.**

**Countries could offer modest cash payments to help defray not just the costs of licensing and technology transfer but also some of the sunk costs of R&D, including pre-clinical and clinical trials. This would require some disclosure of R&D expenditures and previous and projected sales to understand the degree of existing and**

expected R&D expenditure recoupment. There may be special circumstances where a patent buyout would be appropriate.

Although the question asks about royalty-free licenses, there is an argument that royalties might be imposed, if not for low-income countries, then on a tiered basis for lower-middle and upper-middle income countries. Provisions for non-exclusive grantback licenses in licensing and technology transfer agreements could also provide economic incentives for licensors/transferrors who could thereafter market improved products or take advantage of cost-saving improvements.

The WHO COVID-19 Technology Access Pool has recently published a set of recommendations on [technology transfer incentives](#).

- How helpful or harmful would the following proposed obligations for governments be for public health, business, and innovation interests generally:
  - “(a) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;  
**Comment: Although zero royalties are always cost-saving for procurers and payors, modest royalties are ordinarily not a significant deterrent to access. Again, there could be zero royalties for LICs and pediatric products and modest royalties in L-MICs and U-MICs consistent with the prevailing practice at the Medicines Patent Pool.**
  - (b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products; and  
**Comment: It is highly desirable that these licenses be published and publicly accessible consistent with the practice of the Medicines Patent Pool and now some commercial companies including Gilead.**
  - (c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks.”  
**Comment: Providing for transfer of technology and related know-how and materials is now central to ensuring adequate supply, affordable pricing, and ultimately equitable distribution of more complex medical products, including but not limited to biologics and vaccines. Although technology transfer is often not needed for small-molecule medicines, detailed information and technology transfer concerning complex products, where developing commercial scale production capacity for quality assured products is much harder, time consuming, and more expensive, full technology transfer is extremely important. Some producers may be worried about pandemic field-of-use restrictions on the licensed and transferred technology and about maintaining confidentiality of trade-secret protected know-how, information and materials. These concerns can easily be addressed in licensing and technology transfer agreements.**

As an example of how important technology transfer is, no mRNA producer has yet been able to manufacture the Moderna or Pfizer/BioNTech mRNA COVID-19 vaccine at commercial scale without technology transfer. Tech transfer to partners and contract manufacturers, on the other hand, resulted in duplicating manufacturing capacity in a

**matter of months. The WHO mRNA Technology Transfer Programme started in early 2022 is still in the process of independently developing mRNA commercial scale manufacturing capacity and may take more than a year more to complete that process even with unprecedented assistance of mRNA experts from around the world.**

- How can we work to promote a globally sustainable medical countermeasures (MCM) manufacturing system, including leveraging regional approaches to production and maintaining readiness of facilities between pandemic emergencies?

**Comment:** To develop viable, sustainable, and distributed pandemic-related manufacturing capacity, especially in underserved regions of the world, multiple interventions are necessary. First and foremost, there needs to be substantial and sustained public and private investment in biopharmaceutical manufacturing capacity, infrastructure, and human resources. Second, local and regional manufacturers will need product rightholders to license relevant IP and transfer technology and/or countries will need to overcome IP barriers through compulsory licenses on patents and know-how, not only to create freedom to produce, but also to aggregate viable regional export/import markets. Third, multilateral, international, and other major procurers will need to agree to purchase relevant pandemic products (and other medical products) produced by regional manufacturers even if a premium price is necessary until the new manufacturers mature and reach economies-of-scale. Similarly, LMICs will also need to agree to procure from regional suppliers again, if needed, with at a somewhat higher price at least in the short- to mid-term. Fourth, countries will need to strengthen and harmonize their domestic and regional regulatory systems so that they can oversee relevant clinical trials, inspect manufacturing and distribution facilities, guarantee adherence to Good Manufacturing Practice standards, grant marketing approval, and conduct post-marketing surveillance. Fifth, R&D capacity must be strengthened with priority given to unmet epidemiological needs in the region. Sixth, and as a cross-cutting issue, countries, especially those in a relevant region, must engage in unprecedented collaboration to pick sites of manufacture for components and final products, to broaden and strengthen supply chains, to reach agreements of joint and pooled procurement, and to invest in the development and sustainability of the new biopharmaceutical manufacturing capacity.

### **Article 11, Transfer of Technology and Know-How**

- What measures could be taken, or incentives provided, to “strengthen existing, and develop innovative, multilateral mechanisms [under WHO], including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries”?

**Comment:** The WHO’s recently announced Health Technology Access Pool (H-TAP) and the [Medicines Patent Pool](#) (MPP) are both entities under or associated with the WHO that can negotiate and manage pooling of knowledge, intellectual property and data, and even trade-secret know-how and material transfer for pandemic-related health technologies. These pooled resources can be used both to accelerate

pandemic-related R&D and to license local and regional manufacturers to produce needed quantities of pandemic-related health products. Both institutions can and should be strengthened. The MPP has a thirteen-year track record of licensing infectious disease medicines, primarily for HIV, TB, and HCV, which has resulted in an unprecedented scale-up of generic manufacturing capacity and production of much lower cost medicines. The [MPP has recently broadened its mandate to cover pandemic-related products](#) and to work further upstream on development optimized and combined products and [long-lasting](#) and [pediatric formulations](#). H-TAP's predecessor, [C-TAP](#), struggled to get off the ground and only achieved minimal in-licensing of research platforms and covid-related diagnostics and medicines, but suffered from inadequate resources, limited political support internally or externally, and disparagement and what was effectively a boycott by major biopharmaceutical companies. To succeed with an even broader mandate, H-TAP will need substantially increased resources and political support. Rather than duplicate the MPP existing capacity, H-TAP should rely on the MPP's considerable voluntary licensing expertise while relying on H-TAP's WHO pedigree to garner political support and resources and to negotiate cooperation with owners of key pipeline technologies. H-TAP and MPP together might try to development model licensing terms and principles, with a special focus on territorial inclusion of typically excluded MICs.

Beyond requiring licensing, tech transfer, and equitable access terms in R&D funding and public procurement agreements, governments and charitable entities could directly compensate companies that license and transfer their pandemic-related medical technologies to region manufacturers in LMICs. These options are described in greater detail in a comment addressing Article 10 questions.

Although it may seem counter-intuitive, efforts to incentivize voluntary agreements depend in part of the availability and willingness of countries to use involuntary measures, including compulsory and government use licenses, without fear of industry and HIC retaliation. As extensively documented, the threat and use of compulsory licenses was instrumental in the AIDS response and essential for expanding supply and lowering price. For example, [the U.S. International Trade Commission \(USITC\) report](#) commissioned by USTR on COVID-19 diagnostics and therapeutics found that compulsory licenses are “associated with increased generics and lower prices, and increased access to pharmaceuticals,” while patent protection “has little to no positive effect for innovation in developing countries and negative effects for access and affordability (pp. 16, 64–5).”

- What measures could be taken, or incentives provided, to “make available non-exclusive licensing of government-owned technologies, on mutually agreed terms as appropriate, for the development and manufacturing of pandemic-related products, and publish the terms of these licenses”?

**Comment:** This question has essentially been answered in previous comments. Non-exclusive licensing and transfer of government-owned technologies seems a non-brainer in the context of pandemics where the safety and well-being of domestic

populations is ultimately dependent on the timely and affordable delivery of sufficient supplies of pandemic-related products on an equitable basis to everyone globally. Contributing to artificially limited supply, needlessly high prices, and grossly inequitable commercial distribution by transferring exclusive rights to private entities would seem to be the epitome of bad public policy. It neither protects the tax-paying public from ongoing pandemic risks nor does it provide a return of public investments. Governments shouldn't need any incentives for this eminently reasonable policy proposal.

- In your view, is there a lack of transparency concerning information regarding pandemic-related products, their technological specifications, and manufacturing details? If so, could the establishment of a new mechanism at the WHO effectively address this lack of transparency?

**Comment:** Transparency is undoubtedly a major problem across the whole value chain of pandemic-related medical products. (Rationales for open-publication and open-science have been previously discussed in response to questions on Article 9. Additional answers have been provided with respect to transparency requirements in public R&D funding agreements.) However, this question is narrower and focuses on the need for more product specific information, technological specifications, and manufacturing details and the establishment of a WHO mechanism to create such a transparent database. The need for this database is obvious as it would provide important information to alternative producers that would accelerate and simplify the process of developing, registering, and marketing generic or biosimilar equivalents. Private rightholders treat some of this information as being trade-secret/confidential-information protected. However, regulatory agencies and WHO Prequalification Programme frequently have access to some of this information. There are strong arguments that regulators and WHO should no longer treat this information as trade-secret protected and recognize a trade-secret exception to its inclusion in a public database. This recommendation is discussed further below.

- What net impacts, positive or negative, would you envision arising from commitments presently outlined in Article 11.3, including:
  - “(a) commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

**Comment:** The case for announcing in advance a time-limited waiver of all relevant IPRs, including patents, trade-secrets/confidential-information, copyright, and industrial designs, covering all pandemic-related health products, their components, and their production methods should be clear. The waiver should not be limited to the narrow, highly-conditioned, and ultimately non-operable decisions reached at the [WTO in June of 2022](#), which covers COVID-19 vaccines only, which truly relaxes on one TRIPS provision, Art. 31(f) dealing with exports of non-predominant quantities, and which limits utilization to Developing Country Members (excluding China). Any waiver proposal should clearly indicate that it is based on the principles of the [broader](#)



**South Africa/India TRIPS waiver proposal. The justification for a waiver is not limited to increasing the availability and adequacy of supply, but also includes increasing affordability and helping to ensure more equitable distribution. Equitable distribution concerns also need to be addressed more directly elsewhere in the Agreement.**

○ (b) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and

**Comment: As previously answer under the first question concerning Article 9, the absence of royalties would be ideal, but moderate royalties on sales in MICs would not be a major problem and might incentivize rightholder cooperation.**

○ (c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, with qualified third-party manufacturers when the withholding of such information prevents or hinders urgent manufacture by qualified third parties of a pharmaceutical product that is necessary to respond to the pandemic”?

**Comment: As previously answered, gaining access to confidential data, manufacturing know-how, and essential materials (especially biologic) is essential to the ability of alternative producers to produce bioequivalent biologic medicines and vaccines. Article 39.2 of the TRIPS Agreement does not prevent countries from requiring disclosure of such information from rightholders if they do so in the public interest. And, clearly, increasing and accelerating biopharmaceutical capacity to manufacture pandemic-related medicines and vaccines is in the public interest. Countries should have the power to compel rightholders to disclose such information to qualified third parties when needed to respond to a pandemic. In this respect it is interesting to note that the U.S. has the power to compel such disclosure under its Defense Production Act and the EU has a current proposal to establish a regional compulsory licensing system in a regional health emergency that includes the right to require disclosure of this same information to qualified licensees if such disclosure is necessary to timely and efficient manufacture. In addition, countries should have express permission to disclose such information that they possess within their national medical products regulatory authority or elsewhere to qualified third party producers.**

## **Article 12, Access and Benefit Sharing**

- The Article 12 negotiating text envisions parties agreeing to set aside certain percentages of pandemic-related products (proposed in the current negotiating text as a minimum of 20%) and facilitating their exportability.

○ What, from your perspective, are the pros and cons of such a requirement?

**Comment: The transactional nature of the access and benefit sharing article is problematic, at least with respect to access obligations. There should be an enforceable central element to the Agreement requiring concerted action to operationalize timely and equitable access to all pandemic-related health products based on need and established allocation principles. Therefore, the setting of an arbitrary 20% minimum set aside of pandemic-related products to the WHO is an inferior solution. Moreover,**

**the 20% figure is itself arbitrary and is not at all proportionate to the predictable populations needs in LMICs.**

○ Would such a requirement advance or hinder rapid research and development efforts?

**Comment: A 20% set aside requirement, particularly one where only 10% is donated at the rest sold at a no-profit price, would not impose an undue economic burden on companies nor would it negatively impact R&D incentives where billions of dollars in profit are likely to be earned in HIC markets during a major pandemic outbreak. For example, biopharmaceutical companies [reaped over \\$90 billion in pure profit on COVID-19 vaccines and medicines from 2021 to 2022.](#)**

- The Article 12 negotiating text further envisions required monetary contributions from recipients of shared samples or data, including researchers and manufacturers, for privileges of access. What in your view is the monetary value of access that would be provided in terms of an annual or percentage-based contribution from your organization? How would requiring monetary contributions from academic, government, or other non-profit research institutions impact, positive or negative, research?

**Comment: As stated previously, the principle of global equitable access should be established rather than payment on a purely fortuitous basis to countries or entities that share samples or data.**

- The Article 12 negotiating text specifies other benefits that should be considered for provision to developing countries, including “(i) encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries . . . to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products; (ii) tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products . . . ; and (iii) encouraging of laboratories . . . to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.”

○ How helpful would these additional measures be in advancing the rapid creation and/or production scale-up of safe and effective vaccines, diagnostic tests, and treatments? What are the risks or potential negative impacts could come from including such provisions?

**Comment: As discussed in answers to previous questions, an effective pandemic response needs both voluntary and mandatory licensing and technology transfer to capable producers, particularly in developing country regions. There should also be provisions encouraging or, better yet, requiring participation of scientists from developing countries in scientific projects associated with pandemic response needs.**

○ What incentives might be provided to stakeholders to encourage/assure participation in such voluntary measures?

**Comment: Although incentives should be needed in these circumstances, incentives for licensing and technology transfer have been addressed in answers to prior questions.**

- What provisions might companies, academic research institutions, and other industry stakeholders look for when assessing voluntary participation in such a proposed Access and Benefit Sharing system? What samples/data are needed the most and how could such a

system improve access to needed resources? What provisions are missing that would incentivize broad participation in the system that Member States should consider?

**Comment: If an access and benefit sharing system is established, participation by companies, academic research institutions, and other industry stakeholders should be mandatory not voluntary.**

### **Article 13, Global Supply Chain and Logistics (SCL) Network**

- The WHO SCL Network proposed in Article 13 envisions performing a range of functions ordinarily left to individual governments, institutions, or organizations.
  - What functions of Access to COVID-19 Tools-Accelerator (ACT-A) should or should not be institutionalized?

**Comment: The ACT-A did not begin with a structure that was fit for purpose. In the absence of a responsive structure and/or a more prepared and capacitated WHO, significantly more attention should have been directed to ACT-A's foundational structures of participation, governance, and accountability. Instead, there was a reliance on a loosely organized handful of northern global health institutions and actors at the expense of a meaningful role for LMICs. Civil society engagement appeared as an afterthought for many but not all partners. Inclusion and transparency are fundamental to meaningful participation, engagement, and accountability. The absence of meaningful inclusion has had a significant negative impact on civil society, communities and compromised the ability of some low- and middle-income countries to meaningfully engage in the ACT-A work. Without the accountability that inclusion and transparency engender, ACT-A was unable to fully realize its potential and legitimacy to serve those most in need. Any successor of ACT-A has the responsibility to be an inclusive, democratic, deliberative, and accountable governance structure.**

**Instead of conceptualizing ACT-A as a short-term collaboration to address only the “acute phase” of the pandemic (erroneously estimated to terminate at the end of 2021) and only a portion of need access in low- and middle-income countries, e.g. 20% of vaccine coverage, 500 million diagnostic tests, and 265 million treatments, ACT-A and any successor initiative should embrace a broader, more urgent, and more equitable goal of accelerating and equalizing global access to the critical health technologies needed to end a pandemic. ACT-A's lack of ambition rested on the assumption that interventions would be needed during the acute phase of the pandemic only (when hospitals threatened to be overrun by sick people and when international travel and trade were unduly disrupted) and that normal market forces would address post-acute phase needs for LMICs. Since it was predictable that status quo responses to the pandemic would result in stockpiling by rich countries, profiteering by industry, and vaccine/therapeutics/PPE/diagnostic/oxygen apartheid, it was magical thinking that the market would right itself to suddenly ensure equitable access, even more so when the threat of new variants materialized.**

**The resource mobilization and distribution model for ACT-A was deeply flawed. The biggest flaw, of course, was the lack of a dedicated source of sufficient and sustained funding, something that is still lacking even as the Pandemic Accord is being negotiated.**

**In addition, fundraising was largely left to ACT-A partner organizations acting on their own behalf to capture needed resources and to the idiosyncratic and disjointed priorities of major donors. Thus, the Vaccine Pillar ended up being overfunded (even though it did not come close to meeting its vaccine delivery objectives) and the Diagnostic, Therapeutics, and Health System Response and Strengthening Pillar were left woefully underfunded. There needs to be a much more rational system for raising need resources for pre-pandemic needs and additional surge resources for full-blown pandemics. Those resources will need to be allocated according to particularized funding needs of the likely pillars in the next response mechanism. With respect to financing, another central issue will need to be decided, will the resources go to an entity like the Medical Countermeasure Platform previously discussed this past year to oversee procurement or will procurement and distribution be overseen by other structures. ACT-A anticipated that it would have resources for significant procurement, but that ultimately proved true only for vaccines.**

**ACT-A needed stronger policies and a more urgent political voice to address the issues of intellectual property, regulatory processes; and supply system barriers to more rapid and expanded production of key COVID-19 health commodities including personal protective equipment, tests, medicines, vaccines, ventilators, and other oxygen supply equipment. The architects of ACT-A were content to accept the status quo protection of intellectual property rights and to pursue concessionary agreements reserving some supplies for lower-cost sales for low- and lower-middle-income countries. Thus, the primary “market interventions” deployed were advance market commitments and capacity reservations with some largely secret arrangement for tiered pricing. Biopharmaceutical and diagnostic rights holders, even when they received product development support from ACT-A partner resources, were left largely free to make decisions about quantities produced, the extent of discount pricing, and the portion of production set aside to supply LMICs. Experienced access-to-medicines advocates, on the other hand, anticipated the problems of artificially restricted supplies, needlessly high prices, and insufficient and inequitable access. They called correctly for bolder intellectual property and market interventions that would have focused on licensing and technology transfer to increase manufacturing capacity and to democratize production in LMIC regions instead of relying on manufacturing and distribution systems centered in the Global North and tightly controlled by rightsholders. In addition, civil society and LMIC advocates would have insisted on forestalling the ability of suppliers to prioritize sales to HIC and instead requiring them to allocate health products equitably.**

**In terms of regulatory issues, very little support was given to WHO to ramp up work within its Prequalification Programme, which resulted in protracted delays, particularly with respect to diagnostic tests and therapeutics. Although WHO sped up its guidance documents somewhat, it was still painfully slow in this regard, with the infamous examples of delayed use-cases and guidance for self-testing, delayed guidance on outpatient antivirals, and a near total failure of attention and guidance on test-and-treat programming.**

**Regrettably, ACT-A did not take a strong position on transparency and its partners entered into multiple non-disclosure agreements with biopharmaceutical companies. As discussed in answers to previous questions, there needs to be a new norm of transparency concerning pandemic-related products across the value chain from beginning to end, including with respect to R&D funding and procurement agreements, if any, licensing and technology transfer agreements, prices and pricing policy, clinical and implementation trial results and data, patent and regulatory landscapes, etc.**

○ Should the U.S. consider incentives to encourage U.S. stakeholders' participation in such an effort and what would compelling incentives be?

**Comment: The U.S. should require U.S. stakeholders to participate when efforts to achieve voluntary participation are unavailing. During the covid pandemic, U.S. efforts to secure voluntary cooperation in licensing and technology transfer were completely unsuccessful despite massive public funding and de-risking of product development, clinical trials, and manufacturing scale-up. The U.S. had to actually seek after-the-fact permission from biopharmaceutical companies to share vaccine doses with the COVAX Facility because of non-diversion provisions in original procurement contracts.**