FUNDACIÓN SALUD POR DERECHO (RIGHT TO HEALTH FOUNDATION)

31st January 2024

Madrid, Spain

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

Salud por Derecho is a non-profit foundation that defends human rights so that all people, wherever they live, can exercise their right to health. We work independently of institutions, religious beliefs, and political ideologies. We receive support from memberships, private donors and foundations. Since the foundation in 2003, Salud por Derecho has created campaigns, formulates proposals and advocates the defense of the right to health from the perspective of social justice and equality. We work on putting the focus on governments and addressing causes and solutions that would tackle the infringement on the right to health in the long run. We work on a national, European and global level from our headquarters in Madrid.

General Comments

The focus of Salud por Derecho is on enhancing the WHO Pandemic Agreement on the areas of, but not limited to, innovation, public interest-based conditionalities of publicly supported research and development (R&D), technology transfer, and equitable access to health technologies. Salud por Derecho's submission respond to the Request for Comment by the HHS regarding article 9, 10, 11 and 12. We have made previous analysis of the different draft and negotiating texts of the agreement here, here and here, including an analysis of the EU domestic policies and proposals that could be extrapolated to the WHO Pandemic Agreement, upon which we base this contribution. In that regard, the Pandemic Agreement should include:

- Ensure commitments, accomplishments and milestones with a full-fledged binding treaty.
- Further strengthen the language by avoiding vague wording and opting for precision to produce a treaty that is robust in its commitments and clear in its mandate.
- Strengthen transparency throughout the health product and technology pipeline, from R&D to pricing.

- Ensure the necessary funding with clear and ambitious targets, as well as shared governance among all treaty parties in an equitable way, addressing the challenges of the treaty in the multilateral as well as national space. Additionally, financing systems should be designed based on the principle of common but differentiated responsibilities (CBDR).
- Conditions for public financing must be attached so that there is effective governance of the pandemic-related products' access throughout the entire life cycle.
- Regarding intellectual property, it is important to guarantee all forms of knowledge and technology transfer across regions, beyond voluntary transfer, and to ensure the application of TRIPS flexibilities.
- Regional R&D and production capacity should be facilitated and favored, especially in areas where industry needs further strengthening. Furthermore, the final pandemic-related products must be shared equitably across regions based on global public health needs.
- Reinforce accountability mechanisms to ensure that the roadmaps for ratifying parties are clear in their goals, commitments and implementation.
- The obligations undertaken within the treaty must reciprocate the benefits they yield. For instance, pandemic-related technologies developed using data collected by surveillance systems of third countries should subsequently be made accessible to those populations.
- Particular attention should be paid to the specific needs of the groups that are identified as vulnerable in the text, particularly those of migrants.

Detailed Comments

Article 9, Research and Development

Public funding of R&D activities should include **conditionalities** that protect public interest in terms of greater accessibility, affordability, knowledge and technology transfer, including know-how, trade secrets and all relevant data. Conditionalities should apply not only during pandemic response phases, but also during the previous stages. From a strict crisis preparedness and prevention angle, if a monopoly is established over breakthrough technologies, such as critical platforms like the mRNA technology, that might prove essential to respond to acute crisis, the WHO Agreement should allow to act preemptively before a crisis occurs.

For this conditionalities to be effective, **transparency** should be the overarching principle governing the whole R&D ecosystem and should be incorporated in every contract, grant, license or any other form of agreement that include public funding.

While in previous versions of the text there was proposals that tried to impose more rigorous conditions that favored access and transparency in the setting of product prices whose R&D had been publicly financed, in the current negotiating text, it has been reduced to an obligation to publish the terms of publicly funded R&D agreements, eliminating the need to incorporate more equitable conditions into those agreements. This setback abandons the principle of recognition of vaccines, medicines, and diagnostics as **global**

public goods and prevents the value of public financing and contributions made by taxpayers from being highlighted.

The text should include elements related to **open science** when discussing public financing of pandemic-related products, a measure that would facilitate and speed up R&D process, which is needed for pandemic PPPR. Collaborative approaches should be additionally included for (pre-)clinical trial network development and early-to-final R&D stages.

Article 10, Sustainable Production

Although we find greater obligation to grant **non-exclusive licenses** for government-owned technologies—although a degree of discretion is maintained with the "as appropriate" formula—it is worth asking why not **establish binding transfer and licensing conditions** for all those products that have been publicly financed, directly or indirectly. Doing this would constitute a crucial tool to protect the public interest in the early stages of R&D, thus ensuring subsequent conditions of equitable access. During the COVID19 pandemic, we have witnessed the lack of support for voluntary initiatives such as the C-TAP. While 43 governmental bodies formally embraced this endeavor, only a few entities have finalized licensing agreements with the C-TAP mechanism. These entities have predominantly consisted of public research institutions. During the initial peak of the pandemic, only the Spanish National Research Council committed to license a complete pandemic-related product, followed then by others such as the United States National Institutes of Health (NIH). Only one private company has concluded agreements with the C-TAP so far. This mechanism now been under reviewed needs to be incorporated in the treaty with a robust governance and financial system ensuring its full accomplishment.

Article 11, Transfer of Technology and Know-How

Avoid the ambiguity of language around the scope of necessity or non-bindingness, which raises concerns about potential interpretations, potentially diluting the impact of intellectual property waivers during pandemics, leaving decisions on exemptions where appropriate to the discretion of the relevant institutions. In this sense, as shown during the COVID-19 pandemic, it is necessary to advance in terms of technology and knowledge transfer, both to have effective responses and fair and sustainable preparations for pandemics. In that sense, the text should include **binding language regarding regional collaboration initiatives to transfer technology and know-how**, including those hubs and patent pools backed by WHO (see also previous comment).

The excessive emphasis on voluntary licenses contrasts with the lack of clarity on how to make them a reality in practice, given the widespread failure to promote this option during COVID-19. It is an insufficient instrument to confront global crises that require agile and equitable responses. More opportune measures would involve establishing compulsory licensing mechanisms that are inspired, for example, by the positive elements of the regulatory proposal that the EU is considering for **compulsory community licenses**, which include trade secrets and know-how. The text should guarantee and acknowledge **the full arrangement of TRIPS flexibilities** and mechanisms that can improve access to

medicines could and should be used if necessary to protect public health, avoiding any unnecessary delay or obstruction attempt. Furthermore, waiving of intellectual property is an important measure to incorporate in the agreement, even if they are time-bound. However, to avoid abrupt cessation of access to health technologies, which could potentially diminish incentives for generic manufacturers to engage in the production under a waiver framework under these specific circumstances, a transitioned, progressive phase-out must be planned so that de-scalation/transition of production is sufficiently seamless.

Article 12, Access and Benefit Sharing

The Pathoten Access and Benefit Sharing should go beyond the current proposals. Donations and sales of countermeasures at affordable prices remain a cornerstone of the system, leaving in the background measures that allow more equitable knowledge sharing and diversification of production. The mechanisms set out in the negotiating text it is insufficient and may not be extrapolated to all contexts. The first of these is to secure 20% of the health technologies developed for the WHO, with 10% to be donated and the other 10% to be purchased by the WHO at an affordable price. However, it does not include other elements which **obligate the sharing of intellectual property or the transfer of technology**. Nor does 20% seem a proportionate figure when we see that rich countries set immediate vaccination goals of 70%. What's more, each case may depend on the pathogen itself, characteristics, infection rates and other context-specific variables.