Medicines Law & Policy
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Thank you for the opportunity to provide comments on "the implications of access and benefit sharing (ABS) commitments/regimes and other proposed commitments being considered under a WHO convention, Agreement or other international instrument on pandemic prevention, preparedness and response."

Comments are prepared by Medicines Law & Policy and focus on elements contained in Article 9, 10 and 11.

Article 9, Research and Development

Comment on 4th bullet question: Transparency is crucially important to instil and strengthen public confidence in measures taken to combat or prevent a pandemic as well as confidence in pandemic countermeasures. Transparency is also key in fighting misinformation. Therefore, information about measures, in particular those taken by the government, should be as much as possible openly available. This includes the terms and conditions of public funding for the development and supply of pandemic products as outlined in Article 9.4. This comment is also relevant for Article 10(b).

Comment on 6th bullet: Government funded research and product development should contain conditions that ensure the sharing/licensing of intellectual property, know-how, and materials such as cell-lines necessary to product the products that are the result of the funded project. In case of commercial companies, this should not create a disincentive because the R&D expenditures are de-risked by the public financing. If such a provision is contained in the new pandemic instrument, all member states that provide research funding would be bound by it. Therefore, to respond to your question under bullet 6, we do not think that such provisions would disincentivize partnering with the US government.

We also recommend encouraging reasonable royalties in case of licensing which might help allay any concerns with regards to disincentivising commercial actors.

Article 10, Sustainable Production

Comment on 1st and 2nd bullet: Article 10 (a) We do not advocate for royalty-free licenses. Reasonable royalties can be helpful to encourage licensing and counter resistance to sharing of IP and know-how by rights holders. This comment is also relevant for Article 11(b).

Publication of the terms and conditions (Article 10 (b)) is not expected to have any negative effects. The Medicines Patent Pool, since its inception has published full text of licensing agreements. The MPP's transparency has caused no harm for licensors or licensees and has helped to strengthen confidence in the work of the MPP and its commercial partners.

Article 10(c): Licensing and technology transfer is essential to expand production capacity in general including in between pandemics. This was also recognised by the recently held World Local Production Forum. It would therefore be important to establish a robust and well-resourced global licensing and technology transfer mechanism. Public funding for R&D

should be used to incentivise the licensing to such mechanisms. The WHO Covid-19 Technology Access Pool (C-TAP) was established for this purpose in the early days of the Covid-19 pandemic but never received sufficient support to fulfil its mission. C-TAP should be expanded and sufficiently resourced for the purpose of expanding production capacity for pandemic preparedness. Collaboration with the Medicines Patent Pool, which played an important role in securing licenses for therapeutics during the Covid-19 pandemic and in supporting the mRNA technology transfer hub in South Africa, will be essential. See also: the report of the Expert Working Group, A pandemic treaty for equitable global access to medical countermeasures: seven recommendations for sharing intellectual property, know-how and technology published in the BMJ Global Health. This comment also relates to Article 11.

Article 11, Transfer of Technology and Know-How

Comment on 1st bullet: see paragraph on licensing and technology transfer above under heading Article 10(c).

Comment on 3rd bullet: The Covid-19 pandemic has shown that there is a lack of transparency concerning information and know-how needed for manufacturing of countermeasures mostly as a result of the refusal by the holders of such knowledge to share such knowledge. This should not be allowed in a pandemic situation. Collaboration with pooling mechanisms should be compulsory when needed to expand production. Article 11 should include a provision to that effect.

Comment on Article 11.3 (a). It might be helpful to acknowledge that under the TRIPS Agreement WTO Members have the right to use a variety of flexibilities including under Art. 31, 44.2 TRIPS("compulsory licensing") and Art. 73 (b)(iii) TRIPS ("security exception") to override patents and other intellectual property rights. It would be important to include a specific provision in the WHO Pandemic Agreement, that states that member states will refrain from challenging the use of the TRIPS flexibilities, including the security exception when used for pandemic preparedness and response.

Another key comment relates to the treatment of 'undisclosed information' in Article 11(c)

Pharmaceutical products have extended beyond the traditional 'small molecule' medicines to include more complex 'biological' medicines which are grown rather than synthesised. It can be very difficult to produce such biological medicines at scale without more information than is provided in published patent specifications. The key additional information is typically kept secret by the patent owner as one type of 'undisclosed information' (Art. 39.2 TRIPS), more commonly referred to as know-how/trade secrets. It is important to appreciate that the grant of a compulsory patent licence does not, by itself, include any obligation for the patent owner to share any such additional 'undisclosed information', even if the patented medicine cannot be made at scale without it. In order to provide access for all to necessary pandemic countermeasures (including such complex products) as rapidly and widely as possible, we have therefore highlighted the importance of ensuring that third

party manufacturers distributed around the world have timely access to any necessary 'undisclosed information' held by the originators of those countermeasures.

The most efficient means of sharing any necessary 'undisclosed information' is through voluntary agreements between originators and third party manufacturers. However, originators may decline to enter into voluntary agreements or may be slow in doing so. We have previously noted the example of the World Health Organisation (WHO) 'mRNA Technology Transfer Hub' in South Africa:

> *"Beginning to take steps to avoid the inequity of vaccine supply which marked the Covid-19 pandemic, the Hub is intended to show how sustainable vaccine manufacturing capacity can be boosted in Low- and Middle-Income Countries (LMICs). However, despite being able to make a vital contribution to the operationalisation of the Hub, neither Pfizer nor Moderna agreed to share their know-how/trade secrets relating to the manufacture of mRNA vaccines…Consequently, it has taken Afrigen, the lead South African pharmaceutical firm involved, two years to progress to develop its own equivalent know-how. In the abstract, activities such as inventing 'around' a patent or independently developing know-how can themselves lead to valuable contributions to research and development. However, even if it were possible, there will be no luxury of time to spare in a future pandemic."*

The consequences of a failure to share necessary 'undisclosed information' with third party manufacturers during a future pandemic could be catastrophic, in terms of human health and life as well as in terms of economic and security considerations. To ensure that the necessary sharing occurs, we therefore suggested the following provision for inclusion in any pandemic instrument:

> *"Where the Director-General of the World Health Organization has determined that: (i) a pandemic outbreak, or the threat of a pandemic outbreak, represents a public health emergency of international concern (PHEIC); (ii) the urgent production by qualified third parties of a pharmaceutical product is necessary to respond to the pandemic outbreak, or the threat of the pandemic outbreak; and (iii) the manufacture is prevented or hindered through lack of access to undisclosed information as defined in Art. 39.2 TRIPS possessed by one or more entities located in one or more Parties, that or those Parties shall compel that or those entities to share the undisclosed information with the third parties."*

This provision preserves the ability of originators and third party manufacturers to reach voluntary agreements. However, if they fail to do so, when the necessary tests are met, the provision obliges the Parties to compel the necessary sharing. For a more detailed discussion of this provision and its justification please see the following Medicines Law & Policy documents: "The WHO pandemic instrument must address the sharing of know- how/trade secrets: a proposal for a new measure" (available here) and "Sharing know-how/trade secrets during a pandemic: We must be planning for it now" (available here).

As included in the present negotiating text, however, the suggested provision is significantly more narrow. The Request for Comments asks:

> "What net impacts, positive or negative, would you envision arising from commitments presently outlined in Article 11.3, including:

> ○ (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"?"

This suggested provision does not oblige Parties to compel the necessary sharing but only obliges them to encourage it. This provision therefore cannot ensure access to any necessary 'undisclosed information' in the circumstances of a future pandemic.

We believe that it would be a mistake for the United States to assume that American firms would hold the key technology in the context of any future pandemic and that it need not therefore be overly concerned about the difficulty of obtaining access to any necessary 'undisclosed information'. To state an obvious example relating to the Covid-19 pandemic, one of the key developers of mRNA vaccines, BioNTech, is a German firm. In fact, given the democratization and spread of technologies such as synthetic biology and machine learning, it is increasingly likely that future pandemic countermeasures and associated 'undisclosed information' could be developed in a range of other High-Income Countries or indeed in present day Low- and Middle-Income Countries. How would the United States guarantee that any necessary 'undisclosed information' would be shared with American firms then? (A similar consideration applies to the European Commission (EC) proposal which would compel the sharing of such 'undisclosed information' by firms over which the EC had sufficient jurisdiction and control. For more discussion, see here.)

We therefore strongly suggest that, both in its domestic interests and pursuant to the following broader outcome sought by the United States in the present negotiations:

> *"Support more equitable and timely access to, and delivery of, vaccines, diagnostic tests, treatments, and other mitigation measures to quickly contain outbreaks, reduce illness and death, and minimize impacts on the economic and national security of people around the world"*

the United States should introduce our suggested provision, or a provision with similar effect, into the negotiations.

A variant of the provision that we have considered could usefully be contemplated:

The provision could be expanded to include other types of information relating to the manufacturing (and use) of pandemic countermeasures. The dossier of 'test or other data' provided by originators to regulatory authorities when applying for marketing authorisation is protected as another type of 'undisclosed information' under Art. 39.3 TRIPS. (It is not required, however, that this dossier include all of the 'undisclosed information' protected as know-how/trade secrets under Art. 39.2 TRIPS) Disclosure of this dossier of 'test or other data' by a regulatory authority is already permitted under Art. 39.3 TRIPS "…where necessary to protect the public…". However, it is possible that although such a dossier exists, it has not yet been submitted to any regulatory authority, or alternatively has not yet been

submitted to a regulatory authority in a particular jurisdiction of interest. Other types of information not rising to the definition of 'undisclosed information' protected under Arts. 39.2 and 39.3 could also be useful too. As appropriate regarding the manufacture (and use) of pandemic countermeasures, the relevant provisions above could therefore either be amended to refer to "undisclosed information (as defined in Art. 39 TRIPS)" or to "information (including as defined in Art. 39 TRIPS)".

Medicines Law & Policy
Amsterdam, 22 January 2024