



Pandemic Accord: MSF's Comments on Equity Provisions in INB Proposal for Negotiating Text

Introduction

On 16 October 2023, the World Health Organization (WHO)'s Intergovernmental Negotiating Body (INB) released its proposal for the negotiating text (A/INB/7/3) of the WHO Pandemic Agreement (commonly known as "pandemic accord" and hereinafter referred to as "the accord").ⁱ

Médecins Sans Frontières/Doctors Without Borders (MSF) has closely followed the accord process and provided comments and recommendations via an analysis of the zero draft and a position paper on pandemic prevention, preparedness and response (PPR).^{ii,iii} In this briefing document, we analyse INB's proposal for negotiating text of the accord with a focus on provisions that have implications for equity in access to medical products.

In our view, the INB's proposal represents an improvement over previous drafts in some key respects. It recognises the need for transparency in some critical areas, establishes governments' responsibility to use public health flexibilities and agreements on intellectual property (IP) waivers, and creates a mechanism by which WHO can stockpile and allocate medical products based on public health needs during pandemics.

However, several shortcomings remain, which could impede the effectiveness of the final outcome of the negotiation in truly ensuring and enabling equity of access to lifesaving medical products, and in changing the deficiencies in PPR governance and accountability that have characterised past outbreaks. These include, but are not limited to, insufficiencies in the clarity and scope of the definitions of "pandemic" and "pandemic-related products"; underrecognition of needs of people in humanitarian settings; a continued reliance on voluntary measures in place of obligations for member states concerning transparency, transfer of technology, and know-how; lack of explicit obligations on attaching enforceable access conditions to publicly funded R&D; and lack of prohibitions on detrimental liability and indemnity clauses in purchase and donation agreements.

There is also an overall absence of reference to existing international legal and medical ethics frameworks to ensure patients' protection and benefit sharing of research outputs, including to ensure registration, access and availability of pandemic-related products particularly in and for developing countries and communities that participate in research and with health needs.

These improvements and shortcomings, among others, are detailed in an article-by-article analysis of selected provisions of INB's proposal in the following pages.

Text of selected provisions	Comments
Preamble	
<p>10. Recognizing that protection of intellectual property rights is important for the development of new medical products, and recalling that intellectual property rights do not, and should not, prevent Member States from taking measures to protect public health, and further recognizing concerns about the effects of intellectual property rights on prices,</p>	<p>Though the text is copied from the TRIPS Agreement/Doha Declaration, the accord and the TRIPS Agreement belong to different fora with different objectives. The focus here should be on recognising the impact that IP has on medical products broadly, beyond high prices, and how it is a barrier to the full realisation of the right to health for all. The structural flaws in ensuring access to medical products that came out during the COVID pandemic have to be acknowledged. Thus, a mere copy-paste job will only strengthen the existing norms set at a different forum.</p> <p>The existing text should also be strengthened by replacing “recalling” with “reaffirming”. Beyond this, it might be worthwhile to change the word “prices” to “availability” or “accessibility.”</p>
<p>11. Underscoring the importance of promoting early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens with pandemic potential, as well as the fair and equitable sharing of benefits arising therefrom, taking into account relevant national and international laws, regulations, obligations and frameworks, including the International Health Regulations, the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and the Pandemic Influenza Preparedness Framework, and also mindful of the work being undertaken in other relevant areas and by other United Nations and multilateral organizations or agencies,</p>	<p>Given that patients and affected communities play critical roles in contributing to clinical research, it is important that the preamble include language on the protection of patients’ rights and compliance with ethical guidelines and protocols based on existing international mechanisms, including to ensure benefit sharing of the research outputs and post-trial access to medical products.</p> <p>Particularly, there should be a clear reference to international medical ethics, notably principles of doing no harm, acting in the best interest of patients, respecting patients’ wishes and right to medical confidentiality, consent, autonomy and bodily integrity.</p>
Article 1. Use of terms	
<p>(e) “pandemic” means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control;</p>	<p>Criteria such as “overwhelming health systems” and “social and economic interruptions” have no objective or commonly used metrics, which as a result may be interpreted subjectively based on diverse methodologies and context. This suggests that it may be inappropriately difficult to trigger this accord, thereby increasing the likelihood of delaying the use of mechanisms under the accord for emergency response and resource mobilisation.</p> <p>It remains unclear how the definition will be coordinated with the definition of a public health emergency of international concern (PHEIC), which is under discussion in the Working Group on Amendments to the International Health Regulations (2005) (WGIHR) process. Issues of equity in access to medical products are also under discussion in the IHR amendment process.</p>

	To ensure coherence and make sure that equity issues are sufficiently addressed in all types of global public health emergencies, governments should clarify the relationship between “pandemic” as defined in the accord and “PHEIC” under the IHR amendment process.
(f) “pandemic-related products” means products that are needed for pandemic prevention, preparedness and response, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;	The scope of the definition of “pandemic-related products” should be expanded to include underlying technologies, components, materials, parts, antibiotics, data and know-how needed for production. In addition, the scope should include existing products tackling possible new outbreaks of existing pathogens and new variants, including repurposed medicines.
(i) “persons in vulnerable situations” means individuals, groups or communities with disproportionate increased risk of infection, severity, disease or mortality in the context of a pandemic, including vulnerability due to discrimination on the basis of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status;	<p>The definition should include the vulnerability of individuals affected by armed conflict and other humanitarian situations. As recognised in UNSC resolution 2565 (2021), pandemics can exacerbate the negative humanitarian impact of armed conflicts and exacerbate inequalities.^{iv}</p> <p>The notion of protecting persons affected by armed conflicts, natural disasters and other humanitarian situations and the need to respect existing obligations under international humanitarian laws should also be added to Article 2.2 and Article 3.1.</p>
(m) “WHO PABS Material” means pathogen with pandemic potential, as defined herein, and the genetic sequence data of such pathogens with pandemic potential	For the R&D of health technologies, materials that hold value go beyond pathogens and the genetic sequences of pathogens. Specimens containing pathogens will also hold plasma proteins, white blood cells, and other material of human origin that will provide insight in the host response. Specimens may be accompanied by clinical data pertaining to their origin: e.g., patient signs and symptoms at time of collection. The host material and clinical data provide valuable context for the specimen, which will be of great importance for investigating host-pathogen interactions and developing countermeasures. Therefore, the scope of WHO PABS Materials should be expanded to include biological materials/samples, data and information.
Article 3. General principles and approaches	
3. Equity – Equity is at the centre of pandemic prevention, preparedness and response, both at the national level within States and at the international level between States. It requires, inter alia, specific measures to protect persons in vulnerable situations. Equity includes the unhindered, fair, equitable and timely access to safe, effective, quality and affordable pandemic-related products and services, information, pandemic-related technologies and social protection.	<p>The principle of equity should also expressly include language on “benefit sharing”. This should include governments promoting the sharing of end products of R&D in a timely and adequate manner in order to achieve equity.</p> <p>To ensure equity and access, the principle should also refer to the need for governments to agree on and set up negotiation redlines for supply, procurement and purchase agreements, and to ensure that manufacturers do not shift the product liabilities to</p>

	<p>purchasers, developing countries or humanitarian agencies that need to access the products for developing countries during an emergency.</p> <p>The current text includes a mention of “pandemic-related technologies,” which should be included in the definition of “pandemic-related products” under article 1(f).</p>
<p>4. Responsibility – Governments have a responsibility for the health of their peoples, and effective pandemic prevention, preparedness and response requires global collective action.</p>	<p>To ensure a concrete and effective mechanism to achieve equity at the global level in PPR, it is important to include direct language to specify that international collaboration and coordination is a positive responsibility for governments.</p> <p>This includes the responsibility for governments to coordinate in overseeing and taking actions towards activities of the private sector that may have detrimental effects on access to medical products beyond their own national borders, and the responsibility for governments to request proactive action by the private sector for the purpose of achieving equity in access to medical products, including on issues concerning transfer of technologies and know-how to ensure diversified production and supply at the global level.</p>
<p>5. Recognition of different levels of capacity – Countries have varying levels of pandemic prevention, preparedness and response capacities, which presents a common danger, such that support to countries with capacity needs is required, within means and resources available.</p>	<p>The recognition of the differences in capacities among countries and the need to support countries with fewer PPR capacities is welcome. The principle of common but differentiated responsibilities is now effectively split across principles 4 and 5, but the connection between the two principles should be kept and translated into more explicit substantive clauses in the text. How responsibilities are to be differentiated based on differences in capacity to ensure equity of access to medical products has not been clearly articulated in relevant articles of the accord (articles 9, 10, 11, 12, 13, 16, 19 and 20).</p>
<p>7. Transparency – The effective prevention of, preparedness for and response to pandemics depends on transparent, open and timely sharing of, access to and disclosure of accurate information, data and other relevant elements that may come to light, for risk assessment, prevention and control measures, and research and development of pandemic-related products and services, including reports on sales revenues, prices, units sold, marketing costs and subsidies and incentives, consistent with national, regional and international privacy and data protection rules, regulations and laws.</p>	<p>The differentiation between “sharing of,” “access to” and “disclosure of” is useful as it can help lead to substantive obligations in each of these distinct aspects of transparency.</p> <p>However, the scope of this principle needs to be improved. Although some items from the World Health Assembly (WHA) transparency resolution are included, key elements such as the costs of clinical trials and patent status information are missing. The transparency principle should be revised to incorporate all elements included in the WHA transparency resolution, as well as numerous other elements that are not considered but are essential, including:</p> <ul style="list-style-type: none"> • R&D costs, including clinical trial costs; • terms and conditions of IP and technology licensing agreements; • terms and conditions of public funding and public procurement agreements; and • patent and other IP status and information. <p>This principle of transparency should also apply to the different stakeholders, including global health institutions and procurement agencies such as Gavi, the Vaccine Alliance</p>

	<p>and UNICEF, involved along the entire supply chain of medical products. It should also make a reference to WHO’s public calls for increased transparency in medical research, including the joint statement on public disclosure of results from clinical trials.</p> <p>Notably, even information that is currently included in the scope of the principle is not accompanied by strong enough provisions to ensure their disclosure.</p>
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Chapter II. The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response

Article 6. Preparedness, readiness and resilience

<p>2. Each Party shall, in accordance with applicable laws, including, where appropriate, the International Health Regulations, adopt policies, strategies and/or measures, as appropriate, and shall strengthen and reinforce public health functions for:</p> <p>(a) the continued provision of quality routine and essential health services during pandemics;</p>	<p>Compared to Article 11.4(a) of the zero draft and Article 6.4(a) of the bureau’s text, some important elements have been deleted, including explicit mention of “clinical and mental health care and immunization, primary health care and community-level interventions, and management of the backlog of and waiting lists for the diagnosis and treatment of, and interventions for, other illnesses, including care for patients with long-term effects from the pandemic disease.”</p> <p>There is no reference to sexual and reproductive rights services. “Gender equity” has been deleted from general principles, and the issue of “gender inequalities” is only addressed under Article 7 on health workforce and Article 16 on international cooperation and collaboration.</p>
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<p>3. The Parties shall cooperate, within available means and resources, to provide financial, technical and technological support, assistance, capacity-strengthening and cooperation, in particular in respect to developing countries, in order to strengthen health emergency prevention, preparedness, response and health systems recovery, consistent with the goal of universal health coverage.</p>	<p>To ensure concrete actions are taken, measured and accounted for, the language should be strengthened by specifying that a robust preparedness strategy include measures to ensure transfer of technology and know-how, require full transparency, overcome IP barriers, support diversified independent production, attach access conditions to R&D funding, and provide a benefit-sharing mechanism, as included in the following clauses of Chapter II.</p> <p>The need for strengthening laboratory biosafety and biosecurity capacities in developing countries should also be included.</p>
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Article 7. Health and care workforce

<p>1. Each Party, in line with its respective capacities, shall take the necessary steps to safeguard, protect, invest in and sustain a skilled, trained, competent and committed health and care workforce, with the aim of increasing and sustaining capacities for</p>	<p>Article 7.1(c) should specifically include access to pandemic-related products for priority campaigns at the national level by frontline humanitarian workers during pandemics.</p>
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pandemic prevention, preparedness and response, while maintaining quality essential health services and essential public health functions, during pandemics. To this end, each Party shall, in accordance with its national law:

...

(c) strengthen efforts to address the safety of the health and care workforce, including by ensuring priority access to pandemic-related products during pandemics, minimizing disruptions to the delivery of quality essential health services, developing and integrating effective measures to prevent and address violence and threats against health and care workers, their means of transport and equipment, as well as hospitals and other medical facilities, when preventing and responding to pandemics;

Article 8. Preparedness monitoring and functional reviews

4. The Parties shall establish, no later than 31 December 2026, a global peer review mechanism to assess pandemic prevention, preparedness and response capacities and gaps, as well as level of readiness with the aim of promoting and supporting learning among Parties, best practices, actions and accountability, at the national, regional and global levels, to strengthen national health emergency preparedness and readiness capacities.

The global peer review mechanism should open for participation and contribution by civil society organisations and the most-affected communities. Clear and measurable indicators should be established to review the status of issues covered under articles 9, 10, 11, 12 and 13 to ensure concrete progress.

Article 9. Research and development

1. The Parties shall cooperate to build, strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, and shall promote research collaboration and access to research through open science approaches for rapid sharing of information and results.

There is no reference to medical ethics, benefit sharing of the research outcomes, including to ensure post-trial access to products, and patients’ protection throughout Article 9 on R&D.

Increasing R&D capacities and collaboration cannot be at the expense of patients. It is important to balance the urgency to find new treatments/vaccines with respect for individuals participating in clinical trials, notably when it comes to consent, transparency about risks and compensation for adverse effects. There should also be explicit language about benefit sharing as part of the research collaboration, including ensuring post-trial access.

Overall, this article should reference international medical research law and ethics. This includes the benefit-sharing considerations under the Nagoya Protocol of The Convention on Biological Diversity, the Council for International Organizations of Medical Sciences’ (CIOMS) “International Ethical Guidelines for Health-related Research Involving Humans,” the World Medical Association (WMA) Declaration of Taipei on Research on Health Databases, Big Data and Biobanks, the WMA Declaration of Helsinki on Ethical

	<p>Principles for Medical Research Involving Human Subjects, and other relevant WHO guidelines.^{v,vi,vii,viii}</p> <p>To ensure equity and accountability in R&D, there should also be a reference to WHO’s public calls for increased transparency in medical research, including the joint statement on public disclosure of results from clinical trials.^{ix} When providing funding support, reviewing research protocols and plans or providing other public policy support for research activities carried out in developing countries, governments should ensure participation by institutions, scientists, affected communities and other public health bodies.</p>
<p>2. To this end, the Parties shall promote:</p> <p>...</p> <p>(b) technology co-creation and joint venture initiatives, actively engaging the participation of and collaboration among scientists and/or research centres, particularly from developing countries;</p>	<p>While the clause contains some positive ideas such as collaboration with scientists and research centres from developing countries, overall, it lacks reference to national, regional and international legal and medical ethics frameworks that are needed to ensure sufficient protection of patients, communities and clinical trial participants.</p> <p>In particular, it is important to include the notion of “benefit sharing” to ensure timely, sufficient and equitable access to the end products of R&D, based on health needs, as an integral element of strengthening national and regional research and development governance.</p>
<p>3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop and sustain, strong, resilient, and appropriately resourced, national, regional and international research capabilities. To this end, the Parties shall:</p> <p>...</p> <p>(d) strengthen international coordination and collaboration in respect of clinical trials, through existing or new mechanisms, to support well-designed and well-implemented clinical trials;</p> <p>(e) develop national policies to 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, while protecting privacy and health identifiers; and</p> <p>(f) support new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical guidelines, including during a pandemic.</p>	<p>The current text of the clause lacks sufficient equity and access considerations.</p> <p>Although the need to develop national policies to support transparent and public sharing of clinical trial protocols and results is included, explicit requirements for disclosure of disaggregated costs of clinical trials, in line with the WHA transparency resolution, need to be added.</p> <p>The current text also lacks reference to international legal and medical ethics frameworks for patient protection and R&D benefit sharing.</p> <p>While it is important to strengthen collaboration and data sharing in clinical trials involving multiple countries, sufficient ethical and legal obligations are needed to ensure adequate sharing of benefits of R&D outcomes, particularly with developing countries and communities participating in clinical trials.</p> <p>At the international level, for example, the CIOMS’ “International Ethical Guidelines for Health-related Research Involving Humans” has long stated the importance of ensuring post-clinical trial availability of any intervention or product developed for the population or community in which the research is carried out, and for fair distribution of the benefits of research, including investment towards building local research capacity.^{vi} These non-</p>

	<p>binding guidelines should be incorporated as binding obligations to strengthen R&D provisions in the accord.</p> <p>References from other international legal and ethical frameworks such as the Nagoya Protocol of The Convention on Biological Diversity, the WMA Declaration of Taipei on Research on Health Databases, Big Data and Biobanks, the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, and other relevant WHO guidelines, should also be included.^{v,vii,viii}</p>
<p>4. Each Party shall, in accordance with its national laws and considering the extent of public funding provided, publish the terms of government-funded research and development agreements for pandemic-related products, including information on:</p> <p>(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;</p> <p>(b) the pricing of end-products, or pricing policies for end-products;</p> <p>(c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and</p> <p>(d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.</p>	<p>The chapeau text of 9.4 contains the same shortcoming as the previous draft.ⁱⁱ Transparency requirements should be applied across all R&D activities rather than being based on the proportion of public funding.</p> <p>While the requirement to “publish” terms of funding agreements is a welcome introduction, compared to the zero draft the scope of information to be included in these terms has shrunk.</p> <p>This clause should be revised by reintroducing language to specify the types of information that need to be included in government R&D funding agreements, alongside the requirement to publish these terms.</p> <p>The terms and conditions should include transparency requirements, including publication of full R&D costs (including full disaggregated clinical trial costs), clinical trial protocols and disaggregated preclinical and clinical trial results data, subsequent IP licensing, sub-licensing and technology transfer agreements, costs of production, prices and information on supply capacities and delivery schedules. Critically, the full contractual terms of the R&D funding agreement should be published in their entirety.</p> <p>Instead of generally referring to “pricing” or “pricing policies” under 9.4(b), there should be more explicit conditions on the types of pricing to ensure affordability, such as the “cost of goods plus reasonable margin” or “no profit-no loss” models.</p> <p>Overall, we reiterate recommendations to include key conditions, especially</p> <ul style="list-style-type: none"> • Affordable and transparent pricing requirements for end products (such as the “cost of goods plus reasonable margin” or “no profit-no loss” models); • Non-exclusive licensing/technology transfer requirement to ensure diversity of manufacturing and supply; • Retention of rights by funders linked to the research, in the event that the manufacturers’ supply does not meet demand in a timely manner or is not reasonably priced (so-called “march-in rights”); • Transparency requirements, as outlined above;

	<ul style="list-style-type: none"> • Access plans and specific, transparent and disaggregated indicators which encompass registering and making available the drugs, vaccines or diagnostics, particularly where clinical trials were hosted; and • Timely access to comparator drugs, tests, assays and vaccines needed for comparison studies, regulatory approvals and/or R&D.ⁱⁱⁱ <p>When providing funding support, reviewing research protocols and plans or providing other public policy support for research activities carried out in developing countries, governments should ensure participation by and collaboration with national research institutions, scientists, affected communities and other public health bodies.</p> <p>In addition, while conditions upon receiving public funding have been considered in other clauses of this draft, there should be improved coherence and more explicit language to make the connections.</p> <p>For instance, Article 10.1(d) encourages manufacturers who receive public funding to engage in non-exclusive, royalty free licensing on IP and technologies with manufacturers in developing countries. This should be strengthened by placing it as an obligation, rather than as encouragement, and by including it in the terms and conditions under Article 9.</p> <p>Overall, the obligations towards access conditions and transparency as mentioned above should be applied to R&D carried out by NSAs, the private sector, funding agencies, product development partnerships and other global health actors.</p> <p>Access conditions for technologies already developed through public funds for known pathogens of pandemic potential need to be renegotiated/reviewed and new terms publicised, including when carried out through product development partnerships, the private sector and other international organisations.</p>
<p>Article 10. Sustainable production</p>	
<p>1. The Parties, with a view to achieving a more equitable geographical distribution of the global production of pandemic-related products, and increasing timely, fair and equitable access to safe, effective, quality and affordable pandemic-related products, thereby reducing the gap between potential demand and supply at the time of a pandemic, shall:</p>	<p>While there are multiple levels of connections between Article 10 and other articles, particularly articles 9 and 11, these connections should be made more explicitly to ensure they are mutually supportive.</p> <p>Sustainable production should not be treated as a standalone issue. As currently drafted, the article relies primarily on voluntary measures. It should be revised with a view to supporting more independent and diversified production and supply that reduces the reliance on private sector decision making.</p>

	There should also be a strategic link between Article 10 and Article 13 to ensure production is connected to global supply chain, stockpiling and allocation.
(d) encourage entities, including manufacturers within their respective jurisdictions, in particular those that receive significant public financing, 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;	<p>The licensing of IP, technologies, know-how, information and knowledge by manufacturers who receive public funding to manufacturers in developing countries is a welcome inclusion.</p> <p>However, this needs to be strengthened by:</p> <ul style="list-style-type: none"> • making it a mandatory requirement rather than merely an encouragement; and • making it part of the conditions needed under Article 9. <p>The current text relies on voluntary mechanisms to pursue sharing of technology and more diversified production and supply. Yet, past experiences have repeatedly shown that relying on “mutually agreed terms” and voluntary mechanisms is insufficient; other mechanisms, particularly the use of legal flexibilities as included in Article 11, are critical to achieving these objectives.</p>
<p>3. Each Party, in addition to the undertakings in paragraph 2 of this Article, shall:</p> <p>...</p> <p>(b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products;</p>	<p>The clause promoting publication of the terms of licensing and technology transfer agreements is a welcome inclusion. It should be strengthened by making it a mandatory requirement, particularly during emergencies and when it involves public funding, in order to ensure accountability.</p>
Article 11. Transfer of technology and know-how	
<p>1. The Parties, within a set time frame, working through the Conference of the Parties, shall strengthen existing, and develop innovative, multilateral mechanisms, 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.</p>	<p>While pooling of knowledge, IP and data is needed, the clause suggests the mechanism will primarily be based on mutually agreed terms and voluntary actions. During the COVID pandemic, major technology and IP-holding entities did not participate in WHO-led initiatives for technology pooling and transfer. Relying primarily on voluntary measures is insufficient.</p> <p>Establishing a treaty obligation on technology transfer, which primarily applies to states, based on “mutually agreed terms” mostly with the private sector, is inappropriate. Such language should be deleted.</p> <p>There should be an explicit reference to “equity” and “benefit sharing” under Article 11 to make it consistent with relevant clauses under Article 12. Transfer of technology and know-how should also be considered, including technologies that can help health systems continue operating outside of pandemics to increase resilience and preparedness.</p>

2. The Parties shall:

(a) coordinate with, collaborate with, facilitate and incentivize the manufacturers of pandemic-related products to transfer relevant technology and know-how to manufacturer(s) on mutually agreed terms as appropriate, including through technology transfer hubs and product development partnerships, and to address the need to develop new pandemic-related products in a short time frame;

(b) 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;

(c) make use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement, and fully respect the use thereof by others;

(d) collaborate to ensure equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities;

(e) develop a database that provides the details of pandemic-related products for all known pandemic-potential diseases, including the technological specifications and manufacturing process documents for each product; and

(f) provide, within their capabilities, resources to support capacity-building for the development and transfer of relevant technology, skills and know-how, and to facilitate access to other sources of support.

3. During pandemics, each Party shall, in addition to the undertakings in paragraph 2 of this Article:

(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;

...

Compared to the zero draft and the bureau’s text, this draft does not restrict measures that governments should take at all times to use during the “intra pandemic” period only.ⁱⁱ

However, technology transfer and non-exclusive licensing under 11.2(a) still primarily rely on voluntary measures and “mutually agreed terms,” which have proven to be insufficient. The mechanism should be strengthened by:

- including technology transfer and non-exclusive licensing as part of the mandatory conditions of receiving public investment, connecting with relevant provisions under Article 9;
- including technology transfer and non-exclusive licensing as part of the mandatory benefit-sharing conditions under Article 12; and
- using legal flexibilities, including flexibilities mentioned under 11.2(c), to support technology transfer and non-exclusive licensing.

The non-exclusive licensing of government-owned technologies and publication of the terms of these licenses in 11.2(b) is welcome. However, the clause should be strengthened by not merely relying on “mutually agreed terms as appropriate.” Instead, governments should treat government-owned technologies as a public good and pursue their broadest possible dissemination with standard non-exclusive licensing terms and conditions for the recipients to engage in transfer of technology and collaboration, particularly with entities in developing countries.

Language obligating governments to make use of TRIPS flexibilities and respecting their use by other countries in 11.2(c) is welcome. The clause should be strengthened by:

- removing the non-exhaustive list of provisions cited from the TRIPS Agreement and Doha Declaration to keep the clause open to any types of legal flexibilities as appropriate; and
- introducing a positive obligation for governments to proactively incorporate public health flexibilities in their national legislations as part of the preparedness strategy.

The retention of IP waivers in 11.3(a) is welcome. However, “commit to agree upon” and “to the extent necessary” carry the risk of initiating the discussion on the necessity of IP waivers only during pandemics, delaying their effective use and impact. Instead, governments should already agree on the use of IP waivers and institute them when a pandemic occurs.

The inclusion of sharing undisclosed information with qualified manufacturers to support urgent manufacture under 11.3(c) is similarly welcome. The clause, however, should be strengthened by not merely relying on encouragement for manufacturers to do so. The text should include mechanisms whereby sharing of undisclosed information with

<p>(c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the 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.</p>	<p>qualified manufacturers comes as a legal remedy following the use of a compulsory license, as recently discussed under the European Commission’s proposal for an EU-wide compulsory license scheme for health emergencies.^x</p>
<p>4. The Parties shall, with a view to effective pandemic response, when engaged in bilateral or regional trade or investment negotiations, take steps so that negotiated provisions do not interfere with the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health.</p>	<p>TRIPS-plus provisions continue to be introduced in bilateral and regional trade agreement and investment treaty negotiations that can hinder access to affordable medicines. Article 11.4 is therefore encouraging.</p> <p>However, the language of 11.4 should be improved by</p> <ul style="list-style-type: none"> • directly obliging governments to refrain from including TRIPS-plus provisions in these negotiations, alongside the requirement for governments not to intervene in the use of full flexibilities; and • obliging governments to review existing free trade agreements (FTAs) and bilateral investment treaties (BITs) to revise, suspend and waive the implementation of TRIPS-plus provisions.
<p>Article 12. Access and benefit sharing</p>	
<p>1. The Parties hereby establish a multilateral system for access and benefit sharing, on an equal footing, the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to pandemic-related products for pandemic prevention, preparedness and response</p> <p>2. The WHO PABS System shall ensure rapid, systematic, and timely sharing of WHO PABS Material, as well as, on an equal footing, timely, effective, predictable and equitable access to pandemic- related products, and other benefits, both monetary and non-monetary, based on public health risks and needs, to strengthen pandemic prevention, preparedness and response.</p>	<p>Consistent with the comment above on Article 1(m) concerning the definition of “WHO PABS Material,” the scope of the materials should be expanded.</p> <p>For the R&D of health technologies, materials that hold value go beyond pathogens and genetic sequences. Particularly, samples, data and information, including different materials within blood samples such as plasma and white blood cells, are collected from patients and used for R&D. Therefore, the scope of WHO PABS Material should be expanded to include biological materials/samples, data and information.</p>
<p>4. The WHO PABS System shall have the following components:</p> <p>(a) WHO PABS Materials sharing:</p> <p>...</p>	<p>The recognition that the WHO PABS System should be consistent with international legal frameworks concerning the collection of patient specimens is important. This current wording, however, lacks more explicit reference to relevant international legal and medical ethics frameworks to ensure sufficient protection of patients’ rights.</p> <p>To strengthen this clause,</p>

ii. The WHO PABS System shall be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote findable, accessible, interoperable and reusable data available to all Parties.

- the implementation of WHO PABS System should also comply with applicable laws and policies of the country of origin, including with respect to obtaining relevant ethical and scientific approvals as required;
- existing non-binding guidelines of the CIOMS should be integrated as enforceable measures in the accord;
- access to biological material and data should be in accordance with applicable ethical standards and approvals, including international best practice relating to medical confidentiality, medical ethics, privacy, medical research, data protection and data access, without limiting the duties to cause no harm to individuals and groups, to respect patients’ autonomy, patient confidentiality and patients’ right to informed consent; and
- the protection and empowerment of communities and patients in the governance and decision making of the WHO PABS System should be specified via additional provisions.

(b) PABS multilateral benefit-sharing:

...

ii. The PABS SMTAs shall include, but not be limited to, the following monetary and non-monetary benefit-sharing obligations:

(a). in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related products for distribution based on public health risk and need, with the understanding that each Party that has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and manufacturers; and

(b). on an annual basis, contributions from Recipients, based on their nature and capacity, to the capacity development fund of the sustainable funding mechanism established in Article 20 herein.

(c) The Parties shall also consider additional benefit-sharing options, including:

(i) encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries through WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products;

12.4(b)ii.(a) is a welcome clause aimed at strengthening WHO’s capacity to operationalise the WHO Global Supply Chain and Logistics Network (WHO SCL Network), including strategic international stockpiling and equitable allocation. There can be a more explicit mention of the intended use of the supplies to WHO, linking with Article 13.

Compared to the zero draft, there is a positive revision to make 20% real-time supply to WHO a minimum requirement rather than a ceiling. However, the pre-estimated percentage may still be insufficient. Focusing on a “minimum” quantity may mislead the estimation for supply and allocation based on health needs. Instead, the clause should include an open-ended approach to facilitate a more appropriate distribution based on a rolling assessment of evolving public health risks and needs, allowing for underreporting of case and death counts in developing countries due to testing constraints.

The inclusion of financial contribution by “Recipients” under 12.4 (b)ii.(b) is a good step, connecting with the financing mechanism discussed under Article 20. However, more details are needed to clarify how the financing mechanism as a whole under Article 20 is to be used to support the WHO PABS system.

Article 12.4(c) contains very important benefit-sharing elements but requires substantive revision to provide greater clarity and effectiveness for the purpose of ensuring equity.

First, the benefit-sharing options herein are for “the Parties” rather than the “Recipients” of WHO PABS Material. This seems to take the clause in a different direction from the previous sub-sections, which focus more on what the Recipients should do under the WHO PABS System.

<p>(ii) tiered-pricing or other cost-related arrangements, such as no loss/no profit arrangements, for purchase of pandemic-related products, that consider the income level of countries; and</p> <p>(iii) encouraging laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.</p>	<p>Second, transfer of technology and know-how should become a mandatory benefit-sharing requirement for the Recipients, rather than as an option to be considered by the Parties, as currently stated in article 12.4(c)(i).</p> <p>Third, Article 12.4(c)(ii) is confusing. It is unclear under which circumstance the Parties shall consider “tiered-pricing” or a “no loss/no profit” arrangement and how this is related to the operation of the WHO PABS System. While the notion of “no loss/no profit” is welcome, it is unclear what “arrangements” means in this context. The inclusion of a tiered-pricing option based on the income level of countries is a problematic norm and should be deleted.</p> <p>In addition, the positive notion of involving scientists from developing countries as part of laboratory collaborations under Article 12.4(c)(iii) should be specified as a mandatory requirement for the Recipient under the PABS framework.</p> <p>The three sub-sections of Article 12.4 (c) should be revised into mandatory benefit-sharing conditions with the Recipient as the duty bearer.</p>
<p>5. In the event that pandemic-related products are produced by a manufacturer that does not have a PABS SMTA under the WHO PABS System, it shall be understood that the production of pandemic-related products requiring the use of WHO PABS Materials, implies the use of the WHO PABS System.</p> <p>Accordingly, each Party, in respect of such a manufacturer operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to require such a manufacturer to provide benefits in accordance with paragraph 4(b)(ii) of this Article.</p>	<p>It is a positive step to include “implied” use of the WHO PABS System by manufacturers who produce pandemic-related products without a standard material transfer agreement (SMTA), and for governments to require the concerned manufacturers to comply with benefit-sharing requirements.</p> <p>However, the clause does not clarify the role and obligations of manufacturers themselves, nor those of governments that are members of WHO but not party to the accord.</p>
<p>6. The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic-related products, based on public health risks and needs</p>	<p>This is an important mechanism that is closely linked to Article 13, particularly concerning establishing, managing and deploying international and/or regional strategic stockpiles.</p> <p>While it is implied that the supplies to WHO under the PABS system (Article 12) should be used to support the operation of WHO SCL Network including international stockpiling (Article 13), this should be expressly stated under both Article 12 and Article 13. Accordingly, the development of the fair and equitable allocation mechanism should also be related to Article 13 explicitly.</p> <p>The clause should be strengthened by including essential criteria for priority allocations, particularly for resource-limited settings and humanitarian contexts.</p>

Article 13. Global supply chain and logistics	
<p>1. The WHO Global Supply Chain and Logistics Network (the WHO SCL Network) is hereby established. The WHO Network will operate within the framework of WHO, in partnership and collaboration with relevant international, regional organizations and other organizations, and be guided by equity and public health needs, paying particular attention to the needs of developing country Parties.</p>	<p>Overall, in Article 13, it is unclear how other organisations, particularly several global health organisations operating outside of the UN system who are now working out their separate PPR plans involving supply, procurement and allocation, will be coordinated formally under the WHO SCL Network to ensure coherence in resource allocation, priority setting and accountability.</p> <p>The article should be revised to clarify the role of these organisations as well as that of governments, especially those that are on the governing body of such organisations, in ensuring that the WHO SCL Network operates optimally.</p>
<p>3. The Parties shall support the WHO SCL Network’s development and operationalization and participate in the WHO SCL Network, including through sustaining it at all times. The terms of the WHO SCL Network shall include:</p> <p>(a) estimating, or, where possible determining, the most likely types and size/volume of products needed for robust pandemic prevention, preparedness and response, including the costs and logistics for establishing and maintaining strategic stockpiles of such products;</p> <p>(b) assessing the anticipated demand for, mapping the sources of, and maintaining a dashboard of manufacturers and suppliers, including surge capacities and relevant necessary raw materials, for the sustainable production of pandemic-related products;</p> <p>(c) identifying the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;</p> <p>(d) working with national authorities to establish and maintain national and/or regional stockpiles of various pandemic response-related products, as well as maintaining the relevant logistical capacities and assessing them at regular intervals, and specifying the criteria to ensure that stockpiling is used only to address public health needs;</p> <p>(e) facilitating the negotiation and agreement of advance purchase commitments and procurement contracts for pandemic-related products;</p> <p>(f) promoting transparency in cost, pricing and all other relevant contractual terms along the supply chain;</p> <p>(g) coordinating to avoid competition for resources among procuring entities, including regional organizations and/or mechanisms;</p> <p>(h) mapping existing, and identifying needed, delivery and distribution options;</p>	<p>The chapeau text’s proposal to sustain the WHO SCL Network “at all times” is welcome.</p> <p>As the WHO SCL Network is now set to start operating before 31 May 2025, it is imperative for governments to agree on the practical aspects of the mechanism to the extent possible in order to ensure its effectiveness and impact.</p> <p>Particular attention needs to be paid to the following aspects:</p> <ul style="list-style-type: none"> • 13.3(a) contains important elements needed to determine and manage strategic stockpiling. However, it will be helpful to specify how the costs would be estimated with sufficient transparency and an accountability mechanism. A transparent and independent methodology and process to estimate costs is important. Transparency requirement in cost and pricing under 13.3(f) should be supportive of the exercise stated in 13.3(a); • 13.3(d) and (g) recognise that stockpiles should only be used to address public health needs and that competition for resources should be avoided. However, it is unclear how a reliable, predictable and accountable coordination mechanism between national, regional and international stockpiling and procurement will be ensured if the sources of supply are limited at the global level when emergencies occur; • While the coordination described in 13.3(g) is necessary and welcome, the clause says nothing about the rules of coordination or any criteria related to stockpiling, nor does it articulate any constraints on individual state behavior when it might be hoarding as compared to stockpiling. • 13.3(f) contains an important mention of transparency in cost, pricing and all relevant contract terms. The language should be strengthened by replacing “promoting” with “requiring” as transparency is the prerequisite to ensuring effective management of supply. The requirement for transparency under this section should be directly applicable for all stakeholders and organisations along the supply chain.

<p>(i) establishing or operationalizing, as appropriate, international or regional stockpiles, consolidation hubs and staging areas;</p> <p>(j) assisting buying countries in meeting the logistical requirements for the utilization of specific pandemic-related products; and</p> <p>(k) facilitating or, as necessary, organizing the efficient delivery and appropriate utilization of pandemic-related products in beneficiary countries or in humanitarian settings.</p>	<p>Overall, we recommend the improvement of Article 13 taking into account the following:</p> <ul style="list-style-type: none"> • Upfront commitments and agreements between governments and WHO to reserve portions of domestic supplies for global stockpiling and allocation, using the experience of the Smallpox Vaccine Emergency Stockpile (SVES) as a reference; • Securing dedicated production and supply for global stockpiling and allocation through a mandatory benefit-sharing condition under global access and benefit-sharing mechanisms and as a mandatory condition attached in public R&D investment agreements; • Governments coordinating with each other and with WHO to plan stockpiling at national and regional levels, to ensure proportionality, and to prioritise sufficient global stockpiles dedicated to supplying resource-limited settings, countries most affected, vulnerable and at-risk people and communities, and humanitarian contexts; • Including regional organisations, governments of developing countries, particularly those most affected, and humanitarian and civil society organisations, in the design and governance of strategic stockpiles at the global level; and • Prioritising humanitarian needs in equitable allocation schemes, with a simplified, transparent, fair and unified process to facilitate rapid supply and access.
<p>5. Each Party shall, at the earliest reasonable opportunity and in accordance with applicable laws, make publicly available online the terms of government-funded purchase agreements for pandemic-related products in those instances in which the Party is directly entering into such purchase agreements.</p>	<p>This is a positive and welcome clause.</p> <p>In order to facilitate its implementation and avoid it being restricted by currently applicable laws, governments should also review national laws to strengthen public interest doctrines, limitation and exceptions to provide stronger legal support to reject non-disclosure claims and to support the full disclosure of public purchase agreements.</p>
<p>6. Each Party shall, in its government-funded purchase agreements for pandemic-related products, to the fullest extent possible and in accordance with applicable laws, exclude confidentiality provisions that serve to limit disclosure of terms and conditions.</p>	<p>This is a positive and welcome clause.</p> <p>In order to strengthen it and avoid concessions brought by restrictions under currently applicable laws, it should be revised to include below aspects:</p> <ul style="list-style-type: none"> • Confidentiality clauses should be directly restricted, and prohibited during pandemics, especially on pricing, cost, manufacturing capacity and supply schedules, IP and technology licensing terms, liability and indemnification arrangements, in public procurement and supply contracts, IP licensing and technology transfer agreements; and • Public interest doctrines, exceptions and limitations should be strengthened in national laws to provide legal support for governments to reject claims of non-disclosure and confidentiality of key information based on commercial interests.

Article 15. Compensation and liability management

2. The Conference of the Parties shall establish, within two years of the entry into force of the WHO Pandemic Agreement, using existing relevant models as a reference, no-fault vaccine injury compensation mechanism(s), with the aim of promoting access to financial remedy for individuals experiencing serious adverse events resulting from a pandemic vaccine, as well as more generally promoting pandemic vaccine acceptance. The Conference of the Parties shall further develop the mechanism(s), which may be regional and/or international, including strategies for funding the mechanism(s), through the modalities provided for in Article 20.

3. Each Party shall endeavour to ensure that, in contracts for the supply or purchase of novel pandemic vaccines, buyer/recipient indemnity clauses, if any, are exceptionally provided and are time-bound.

Article 15.2:

- Non-fault compensation mechanisms (NFC): this section should explicitly refer to individuals in humanitarian settings and specify that they should also have access to NFCs (because of the virtual impossibility for such individuals to seek recourse through national courts).
- Such mechanisms should provide fair and equitable compensation to individuals.
- *“using existing relevant models as a reference”*: the model referred to should be specified as there are different compensation mechanisms in place at national, regional and international levels.

Article 15.3:

- Governments should agree on principles/redlines regarding the supply terms between the manufacturers and the purchasers (i.e. the governments themselves, international platforms like the COVAX humanitarian buffer or other actors, including humanitarian nonprofit organisations) in a pandemic context to ensure that the manufacturers do not systematically seek to transfer the product liability attached to the vaccines/medical products to the purchasers:
 - such transfer of liability should be proposed as an exceptional and last-recourse solution only;
 - it should be limited to real “novel” vaccines/medical products;
 - a clear and restricted definition of “novel” vaccines/medical products should be provided;
 - the transfer of liability should be limited, proportional, evidence-based and time-bound from the outset, with a mechanism to monitor its end date (e.g. time bound from the outset according to safety data available); and
 - **independent humanitarian actors should not be requested to accept such a risk transfer in order to access products (since, contrary to governments, humanitarian actors do not have the financial capability to bear such risks).**
- “shall endeavour to ensure” should be replaced by “shall ensure.”

Article 16. International collaboration and cooperation

2. The Parties shall:

To ensure the full realisation of the principle of equity as articulated under Chapter II, there should be explicit reference to the issue of access to medical products under articles

<p>...</p> <p>(e) assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness, and response in line with the provisions set forth in Article 19 herein;</p>	<p>9, 10, 11, 12 and 13 in the scope of international collaboration and cooperation under Article 16.</p>
<p>Article 19. Implementation capacities and support</p>	
<p>1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Agreement, taking into account especially the needs of developing country Parties. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen sustainable pandemic prevention, preparedness and response capacities of all Parties.</p>	<p>The promotion of transfer of technologies in the context of international cooperation is welcome. The wording of “mutually agreed” is confusing here as governments are pursuing such cooperation through international bodies.</p>

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