Briefing Document
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Pandemic Agreement: MSF's Comments on Selected Provisions of the Draft Proposal Text

On 27 May 2024, an updated draft of the World Health Organization (WHO) Pandemic Agreement was published during the 77th World Health Assembly (WHA). As the Intergovernmental Negotiating Body (INB) negotiations for the agreement did not conclude by WHA77 as originally planned, the process has been extended with a view to concluding the negotiations and submitting their outcomes for consideration by the 78th WHA in 2025.[1] The draft text represents the interim outcome of the negotiations.

It includes several equity-related provisions on which member states have reached consensus, known as "green text". These include:

- principles guaranteeing respect for dignity, human rights and international humanitarian law (Article 1);
- obligations ensuring decent work, protecting safety of health workers and facilitating their priority access to health products (Article 7); and
- new international standards for disclosure of relevant terms of purchase agreements for pandemic-related health products, and for procurement and stockpiling of health products taking national and international needs into consideration (Article 13bis. 1,3,6).

However, several other key equity-related provisions still lack consensus. These include provisions on ensuring access to humanitarian assistance during health emergencies according to international humanitarian law; ensuring transparency and transfer of technologies and know-how; linking public funding for research and development (R&D) and communities' contributions to clinical trials with the requirement to ensure access to health products; collaborating on production, supply, stockpiling and allocation efforts; and establishing a global mechanism for pathogen access and benefit sharing.

This article-by-article analysis provides comments on selected equity-related provisions that will be negotiated further. MSF urges governments to build on the progress made thus far in the negotiations and commit to stronger obligations in these provisions.

[1] The 77th World Health Assembly decision extending the mandate of the INB: https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_(20)-en.pdf

Article-by-article analysis

The highlighted text is based on the WHO official version with different colours and formats representing different status of the text:

- green: text for which initial agreement was reached;
- yellow: text for which initial convergence was reached;
- without highlights: text for which no convergence was reached;
- [brackets]: text for which there were divergent views.

May text (A77/10, Annex)	Comments
Article 1. Use of terms	
(d) [["pandemic-related health products" [means [safe, effective, quality and affordable] health products, including medicines, vaccines, medical devices including diagnostics, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies that are needed to respond to public health emergencies of international concern, including pandemic emergencies;] [means the safe, effective, quality and affordable products that are needed for pandemic prevention, preparedness and response, [which may include, without limitation (DEL)/(RETAIN)/including], diagnostics, therapeutics, vaccines and personal protective equipment [and ancillary supplies [[and other health technologies] (DEL)];]]	The definition of "pandemic-related health products" is not yet agreed, with the wording of "other health technologies" still under debate. As noted in our earlier comments, "pandemic-related health products" should also include technologies, components, materials, parts, antibiotics, data and know-how needed for their production. The definition of "relevant health products" under Article 1.1 of the International Health Regulations (2005), as amended in 2024 (hereinafter "amended IHR"), includes "other technologies" in its scope. This should be used as a reference to guide the finalisation of the definition of "pandemic-related health products".
(g) "[persons (DEL)/(RETAIN)] [people] in vulnerable situations" means individuals, [as well as persons in] groups or communities with a disproportionate increased risk of infection, severity, disease or mortality [, as well as those likely to bear a disproportionate burden owing to social determinants of health] in the context of a pandemic. This is understood to include persons in fragile and humanitarian settings;	We welcome the retention of "persons in fragile and humanitarian settings" as part of this definition. This important inclusion provides a clear underpinning for several operational provisions across the instrument, such as Article 13.2 (c) on ensuring the needs of persons in fragile and humanitarian settings are met as part of the functions and mandate of the Global Supply Chain and Logistics Network (GSCL Network).
(new j) "Transfer of technology" For the purposes of this Agreement, references to the transfer of technology implies consensually negotiated and accepted terms among the contracting parties without prejudice to other measures that State Parties may take pursuant to their domestic legislation, provided that such	This new text defining "transfer of technology" provides a balanced account and clarifies that transfer of technology can be initiated in accordance with domestic legislation, alongside voluntary actions. This is a welcome proposal.

legislation and actions are consistent with relevant international norms regarding intellectual property.	
(new k) "Know-how" For the purpose of this agreement, the transfer of technology is understood to include the sharing of know-how which covers knowledge and skills required to manufacture and control the resulting product according to international standards.	This new text defining "know-how" as a component of transfer of technology, and including knowledge and skills, is a welcome proposal.
Article 9. Research and Development	
3. Each Party shall, in accordance with their national [or domestic] circumstances and law, and taking into account relevant national and international ethical guidelines and relevant guidance, promote the conduct of well-designed and well-implemented clinical trials in their jurisdiction, including by promoting representative study populations and [facilitating] access to [comparator][products needed to carry out trials] [and access for] such study populations of [to] the safe and [effective/efficacious] products that result from these trials. [ALT 3. Each Party shall, in accordance with their national [or domestic] circumstances and law, and taking into account relevant national and international ethical guidelines and guidance, promote, [[especially] during pandemics], the conduct of well-designed and well-implemented clinical trials in their jurisdiction, including by promoting (i) representative study populations; (ii) access to safe and [effective/efficacious] products that result from these trials for such study populations; and (iii) access to comparator products required to conduct clinical trials;]	We welcome both options in the draft text for their inclusion of the need to ensure access to comparator products for clinical trials as well as access to end products of clinical trials for study populations. However, compared to Article 9.3(d) of the February 2024 draft, the obligation here is significantly weaker. Both options require each Party to "promote" access, while the previous text required "guaranteeing" access. In addition, "communities" as a category is no longer included. (See page 6 of the text comparison in MSF comments on the INB draft text published in April 2024). We call on governments to reinstate a stronger obligation by going beyond requiring Parties to only "promote" post-clinical trial access. It is also imperative to add "communities" back alongside study populations to enhance the health impact of this provision.
5. Each Party shall develop and implement[, as appropriate,] national [and/][or regional] policies [regarding the inclusion of] /[to include]/[on the inclusion of] provisions [in [publicly funded research and development agreements][particularly with private entities]/[with private and budgetary entities]/ [in research and development agreements in case of public-private partnerships/contracts] DEL] for the development of pandemic-related health products that promote timely and equitable global access to such products [during [public health emergencies of international concern and DEL]	The inclusion of "as appropriate" and "regarding the inclusion of" would lead to weaker and vague obligations in this provision, which establishes an important leverage for Parties to ensure public funding recipients comply with conditions that are beneficial to global access to health products. The concessions should be deleted to provide greater clarity to and strengthen the obligation.

pandemics/[pandemic emergencies] DEL], and the publication of such terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) [voluntary] technology transfer [on mutually agreed terms]; (iv) publication of relevant information on research [inputs and DEL] outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.	The strengthened obligation under this provision should apply to all public funding agreements, regardless of whether the funding recipients are public or private entities or public/private partnerships. Therefore, we recommend revising language that would limit this section's applicability only to R&D agreements with public-private partnerships. The "*[in [publicly funded research and development agreements][particularly with private entities]"* option is better, and can be improved by adding "including and" before "particularly". The words "voluntary" and "on mutually agreed terms" should be deleted from Article 9.5 (iii) as they dilute what the funding agreement provision should require more directly. Given the need for timely and equitable global access to health products during both pandemics and public health emergencies of international concern (PHEIC), both should be retained in the text. Limiting the provision's applicability to pandemics alone would limit its impact.
Article 11. Transfer of technology and know-how for the production of pandemic-related health products	
1. Each Party shall, in order to enable the sustainable and geographically diversified production of pandemic-related health products for the attainment of the objective of this Agreement, as appropriate: (a) Promote and otherwise facilitate or incentivize transfer of technology, skills and [know-how] [which may include know-how, as appropriate,] on [voluntary and mutually agreed terms, without prejudice to other measures a Party might take,] for pandemic-related health products, in particular for the benefit of developing countries [and for technologies that have received public/government funding for their development], through a variety of measures such as licensing, capacity building, relationship facilitating, incentives or conditions linked to research and	We reiterate our earlier comments on Article 11.1 (a) and call for stronger obligations for ensuring transfer of technologies.[2] We welcome the inclusion of "conditions linked to research and development" among measures that can be used to facilitate or incentivise transfer of technologies. This can be improved by: - making an explicit reference under Article 11.1 (a) to Article 9.5 so that both provisions can reinforce each other when implemented; and - deleting "voluntary" and "on mutually agreed terms" under Article 9.5 (iii).

[2] See pages 7 and 8: https://msfaccess.org/msfs-comments-selected-provisions-proposal-who-pandemic-agreement

development, procurement or other funding, regulatory policies, and/or fiscal policies; **<u>note</u>: it is to be recalled that the chapeau of article 22 on "Cooperation in the scientific, technical, and legal fields and provision of related expertise" of the FCTC when dealing with transfer of technology, stated the following:** *"1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and Parties with economies in transition. Such cooperation shall promote **the transfer of technical**, scientific and legal expertise and technology, **as mutually agreed**, to establish and strengthen national tobacco control strategies,* plans and programmes aiming at, inter alia:" **Also, the PIP Framework uses similar terminology under article 16:** *"6.13.3 **Technology transfer** should be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time, **on mutually agreed terms**, and be suitable to the…"* **<u>note</u>: another option would be to add a definition on "transfer of technology", either**: 1. Wherever the term transfer of technology is used in this agreement, it implies the transfer takes place under terms and conditions which are conducive to successful transfer; **Or:** 2. Technology transfer is the process of sharing knowledge, skills, innovations, and technologies between governments, organizations, or institutions to ensure scientific and technological developments are available to those who need them. A77/10 Annex 18 **Or:** 3. When transfer of technology, including through licensing agreements, is referred to in this Agreement, such reference is generally understood	We welcome Option 3 proposed by the Bureau on defining "transfer of technologies" and the footnote proposed by member states for VMAT. Both proposals rightly clarify that transfer of technologies can be initiated through measures other than technology holders' voluntary decision making.

to concern transfer of technology consensually negotiated and accepted among the parties. It is recognized that transfer of technology also may take place pursuant to domestic legislation or regulation of WHO members, provided that such legislation or regulation and actions taken pursuant to it is consistent with relevant international norms regarding intellectual property. *Member State proposed footnote for VMAT:* For greater certainty, for the purposes of this Agreement references to the transfer of technology or know-how on voluntary and mutually agreed terms are without prejudice to other measures that Parties may take consistent with the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health. **<u>note</u>: on "know-how", we can add a footnote:** For the purpose of this agreement, the transfer of technology includes the transfer of know-how [required to consistently manufacture and control the resulting product according to international standards].	
(b) [Seek to] make available licences on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries for government-owned pandemic-related technologies, in accordance with national or domestic, and international law and urge private rights holders to do the same;	As the chapeaux text of Article 11.1 introduces a direct obligation for each Party, the obligation in this clause is related to Parties' own conduct and commitment. It can be made more direct by deleting "seek to".
(c) [seek to ensure/take measures to ensure] timely publication of the terms of its licensing agreements relevant to promoting timely and equitable global access to pandemic-related health technologies, in accordance with applicable law and policies, and shall encourage private rights holders to do the same;	The obligation for timely publication of government licensing agreements can be made more direct by deleting "seek to" and "take measures to".
4. The Parties that are World Trade Organization (WTO) members reaffirm that they have the right to use, to the full, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics. The Parties	We support the use of the word "flexibilities" in its plural form in the second sentence. To ensure accuracy and consistency, "flexibility" in the first sentence of this provision should be revised to "flexibilities". The TRIPS Agreement and Doha Declaration on the TRIPS Agreement and

respect the use of the TRIPS flexibilities that are consistent with the TRIPS Agreement [and shall not exercise any direct or indirect pressure [to that effect (DEL)] [to discourage the use of such flexibilities].	Public Health both provide multiple flexibilities that support public health and access to medicines. We recommend including the bracketed text requiring governments not to exercise pressure to discourage the use of TRIPS flexibilities.
6. Each Party should review and consider amending, as appropriate, its national and/or domestic legislation with a view to [using the flexibilities referred to in paragraph 4 and] ensuring that it is able to implement this Article in a timely and effective manner.	We welcome the reintroduction of text requiring each Party to review and consider amending its national legislation to improve readiness to use flexibilities. However, as written, the clause can limit the use of flexibilities to implementing Article 11 alone. This is problematic. In addition to implementing Article 11, more timely and effective use of TRIPS flexibilities is important for the implementation of the Agreement at both preparedness and response stages. Therefore *"ensuring that it is able to implement this Article"* should be deleted.
Article 13. Supply chain and logistics	
1. The Global Supply Chain and Logistics Network (the GSCL Network) is hereby established to enhance equitable, timely and affordable [and unhindered DEL] access to pandemic-related health products [, as well as access to such products in [humanitarian settings DEL] in full respect of international [humanitarian DEL] law [and principles DEL]]. The GSCL Network shall be developed, coordinated, and convened by WHO in partnership with relevant [Parties and other] stakeholders[NOTE define stakeholders in Article 1] under the oversight of the Conference of the Parties. The Parties shall prioritize, as appropriate, sharing pandemic-related health products through the GSCL Network for equitable allocation based on public health risk and need, in particular during pandemic emergencies [at all times DEL].	We welcome the vice-chair's proposal for Article 13.1, which clarifies that WHO shall develop, coordinate and convene the GSCL Network, and that the GSCL Network shall facilitate work to remove barriers to equitable, timely and affordable access to pandemic-related health products. This reinforces Article 13.8 of the amended IHR.[3] We urge governments to agree on explicit wording on access to pandemic-related health products "in humanitarian settings". This is in line with the agreed principle under article 3.3 and should be retained in the final text.

[3] Article 13.8 of the amended IHR states that "WHO shall facilitate, and work to remove barriers to, timely and equitable access by Member States to relevant health products". See: https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF14-en.pdf. See also "Information document on complementarity and coherence between the amended International Health Regulations (2005) adopted by the Seventy-seventh World Health Assembly, and the proposal for the WHO Pandemic Agreement": https://apps.who.int/gb/inb/pdf_files/inb11/A_inb11_INF2-en.pdf

[Vice-chair proposal Art 1. The Global Supply Chain and Logistics Network (the GSCL Network) is hereby established to enhance, and facilitate work to remove barriers to, equitable, timely and affordable access to pandemic-related health products , as well as access to such products in humanitarian settings consistent with international law. The GSCL Network shall be developed, coordinated, and convened by WHO in partnership with relevant [Parties and other] stakeholders [NOTE: define stakeholders in Article 1] under the oversight of the Conference of the Parties. The Parties shall prioritize, as appropriate, sharing pandemic-related health products through the GSCL Network for equitable allocation based on public health risk and need, in particular during pandemic emergencies RESERVE].	
2. The Conference of the Parties shall, at its first meeting, define [by consensus DEL] the structure, functions and modalities of the GSCL Network, with the aim of ensuring the following: … (c) consideration of the needs of developing countries and the needs of [those in vulnerable situations][vulnerable populations (DEL)] [and (DEL)] [persons in vulnerable situations (DEL)], including those in fragile and humanitarian settings; (d) the equitable and timely allocation of pandemic-related health products, based on public health risk and need, including through procurement from the facilities referenced under Article 10; and (e) accountability, transparency, and inclusiveness in the functioning and governance of the GSCL Network allowing for equitable representation of the WHO Regions.	We welcome the inclusion of persons "in fragile and humanitarian situations" in Article 13.2 (c). However, as noted in earlier comments, the language should be strengthened so that the GSCL Network does not merely ensure "consideration" of their needs, but works directly towards fulfilling them. Accordingly, "consideration" should be replaced by "fulfilment", and the phrase "persons in vulnerable situations, including those in fragile and humanitarian settings" should be used, as indicated in Article 1 ("Use of terms").

3. The functions of the GSCL Network may include, subject to further decision making by the Conference of the Parties, for pandemic-related health products, the following: estimation of supply and demand; identification of product and relevant raw material sources; facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10, coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work; promotion of transparency across the value chain; collaboration on stockpiling; and facilitation of equitable [and unimpeded] access, including allocation, distribution, delivery, and assistance with utilization, [including for products provided to the PABS system,] during a PHEIC and a pandemic emergency. (Vice-chair Alt 3.) The functions of the GSCL Network may include, subject to further decision making by the Conference of the Parties, for pandemic-related health products, the following: estimation of supply and demand; identification of product and relevant raw material sources [and barriers to/for their access]; facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10, coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work; promotion of transparency across the value chain; collaboration on stockpiling [both during pandemic emergencies and inter-pandemic periods]; and [the removal of barriers to] [facilitation of [work to remove barriers] for (DEL)] equitable [and unimpeded (DEL / RETAIN)] access, including allocation, distribution, delivery, and assistance with utilization, [including for products provided to the PABS system,] during a PHEIC and a pandemic emergency.	Compared to the February and March 2024 versions of the negotiation text, the current text contains a weaker obligation, specifying key functions that "may" be included.[4] "May" should be replaced by "shall" in the final text of the Agreement. We prefer the Alt 3 text proposed by the vice-chair because it includes "removal of barriers" in access to pandemic-related health products, facilitation of procurement and equitable access during both a PHEIC and a pandemic emergency, as part of the functions of the GSCL Network. Given the clear connection between PHEIC and pandemic emergencies, as clarified in the amended IHR, it is important for all functions of the GSCL Network to apply both to PHEIC and pandemics. The ongoing mpox PHEIC[5] has once again shown the absence of rules and accountability in the coordination of vaccine stockpiles, allocation, distribution and pricing at the global level, including among governments and global health agencies, and the failure of current arrangements to ensure timely, equitable and affordable access for people in need.[6] A framework such as the GSCL Network, but with stronger obligations and greater accountability, and covering both PHEIC and pandemics, is the need of the hour. In addition: - we welcome the inclusion of "transparency across the value chain" but suggest a stronger obligation than "promotion";

[4] See text comparison in MSF's comments: https://msfaccess.org/msfs-comments-selected-provisions-proposal-who-pandemic-agreement

[5] See WHO declaration of mpox public health emergency of international concern: https://www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern

[6] See MSF response to PHEIC declaration: https://www.msfaccess.org/msf-responds-who-declaring-mpox-public-health-emergency-international-concern; see also letter by civil society organisations to Gavi, the Vaccine Alliance, on mpox vaccine supply and pricing: https://msfaccess.org/letter-csos-call-gavi-demand-affordable-price-mpox-vaccine

	- we also welcome the inclusion of "collaboration on stockpiling" but suggest adding "establishing strategic international stockpiling" and "coordinating equitable allocation" as part of the functions; and - An overall review of the use of the terms "PHEIC", "pandemic emergency" and "pandemic" is needed to provide clarity on applicability of the provision under various alert levels.
2. During a pandemic, the rapid and unimpeded access of humanitarian relief personnel, their means of transport, supplies and equipment and their access to pandemic-related health products shall be facilitated in a manner consistent with international law, [including international humanitarian law and the Charter of the United Nations and its purposes and principles, [and the principles contained in Article 3 of this Agreement]] [with respect for sovereignty, and the principle of sovereign equality (DEL) (RETAIN)]].	We welcome Article 13.2 concerning the provision of humanitarian relief. For greater clarity, this text should be retained and revised to explicitly mention governments' obligation to respect principles of humanity, impartiality, independence and neutrality in the provision of humanitarian assistance by impartial humanitarian organisations.
Article 13bis. Procurement and distribution	
1. Each Party shall endeavour, as appropriate, during a pandemic, in accordance with national and/or domestic law and policies, to publish the relevant terms of its purchase agreements with manufacturers for pandemic-related health products at the earliest reasonable opportunity, and to exclude confidentiality provisions that serve to limit such disclosure. The Parties shall take steps to encourage regional and global purchasing mechanisms to do the same.	Article 13bis.1 contains a weakened commitment that Parties "shall endeavour" to publish relevant terms of its purchase agreements instead of "shall" used in earlier versions of the draft text.
2. Each Party shall, in accordance with national and/or domestic law and policies, consider including provisions in its publicly funded purchase agreements for pandemic-related health products that promote timely and equitable [unhindered] [global] access especially for developing countries, such as provisions regarding donation, delivery modification, licensing and global access plans.	We welcome the reinstatement of the provision setting out the practical terms of leveraging public purchase agreements for global access needs. It should be retained in the final text.
3. During a pandemic, each Party shall consider, setting aside a portion of its total procurement of, or making other necessary arrangements for the procurement of, relevant diagnostics, therapeutics or vaccines in a timely	In line with our previous comments, we welcome this positive provision. It should be retained in the final text.

manner for use in countries facing challenges in meeting public health needs and demand. [RESERVE 1 Member State]	
6. During a pandemic emergency, each Party should avoid maintaining national stockpiles of pandemic-related health products that unnecessarily exceed the quantities anticipated to be needed for domestic pandemic preparedness and response.	We support the retention of this important provision in Article 13.6 in relation to avoiding excessive stockpiling at the national level. A similar obligation should also be applicable for all PHEIC.