Briefing Document
November 2024

Pandemic Agreement: MSF's Comments on Selected Provisions of November 2024 Draft

On 4 November 2024, the World Health Organization (WHO) distributed a new draft of the Pandemic Agreement reflecting the status of negotiations after the Intergovernmental Negotiating Body's 11th meeting (INB11, 9-20 September 2024) and containing additional proposals by the INB Bureau for negotiation at INB12 (4-15 November 2024).

The draft text builds on the progress made in previous rounds of negotiation, with member states reaching agreement on additional equity-related provisions ("green text"). These include, chiefly, provisions related to the governance and future operationalisation of the Global Supply Chain and Logistics (GSCL) Network.

However, the language used in several key equity-related provisions remains weak and insufficient for ensuring effective implementation and clear accountability. Member states should address these shortcomings in the upcoming negotiations through:

- Stronger obligations under Article 9 on: ensuring post-clinical trial access to products by communities, and including and publishing global access provisions under publicly funded research and development (R&D) agreements;
- Stronger obligations on transfer of technology and know-how, and affirming use of TRIPS "flexibilities" under Article 11;
- Clearer text to ensure equity-related provisions are mutually supportive;
- Clarity on preparatory work and governance of the GSCL Network before the first Conference of Parties; and
- Clarity on the responsibilities of non-party WHO member states to avoid excessive national stockpiles that may compete against global needs.

Additionally, the next steps toward the full implementation of the Agreement should be clarified.

The table in the following pages analyses selected provisions of the new draft and makes recommendations to help ensure timely and equitable access to medical products for effective pandemic prevention, preparedness and response. The highlighted text is based on the official version circulated by WHO, 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
- Blue: Bureau proposals for INB12
- No highlight: Text for which no convergence was reached
- [brackets]: Text for which there were divergent views

Article-by-article comments

Draft text as of 1st November 2024	Comments
Preamble	
11. *Recognizing* the importance of rapid and unimpeded access of humanitarian relief [in accordance (DEL)] [consistent] with international law, including international human rights law and international humanitarian law, [and the provision of humanitarian assistance in line with resolution A./RES46/182.] [and the respect of the [humanitarian (DEL)] principles of [sovereign equality,] humanity, neutrality, impartiality and independence for the provision of humanitarian assistance [with the consent of the affected country and in principle on the basis of an appeal by the affected country] (DEL)],	We urge member states to agree on this important clause recognising the "importance of rapid and unimpeded access of humanitarian relief". The explicit reference to the principles of humanity, neutrality, impartiality and independence should be retained. These are practically connected to protecting humanitarian assistance delivered by impartial humanitarian organisations.
Article 1. Use of terms	
The following terms defined in Article 1 of the International Health Regulations (2005), as amended in 2024, shall apply to the WHO Pandemic Agreement: disease; event; pandemic emergency; public health emergency of international concern; public health risk; relevant health products. Any further amendments or revisions to those defined terms shall apply to the WHO Pandemic Agreement. In addition, for the purposes of the WHO Pandemic Agreement: ..... (c) "pandemic-related health products" means those relevant health products as defined in Article 1 of the International Health Regulations (2005), as amended, that may be needed for prevention, preparedness and response to pandemic emergencies;	The Bureau's text on the use of terms is a welcome addition. It cross-references the definitions of terms under Article 1 of the International Health Regulations (IHR) (2005), as amended in 2024, which rightly includes "other technologies" in the scope of "relevant health products". By defining "pandemic-related health products" in this manner, the text reflects the practical need to facilitate production and supply across the entire value chain of health products. *See MSF comments published in September 2024: Pandemic Agreement: MSF's Comments on Selected Provisions of the Draft Proposal Text | Médecins Sans Frontières Access Campaign*
(e) "persons/those/people in vulnerable situations" means individuals, including persons in groups or in communities or in fragile, emergency and/or humanitarian settings, with a disproportionate increased risk of infection, morbidity, or mortality, as well as those likely to bear a disproportionate burden owing to social determinants of health in the	We welcome the retention of "persons in fragile and humanitarian settings" as part of the definition of "persons in vulnerable situations". It provides a clear basis for several operational provisions across the instrument, such as Article 13.2(c) on ensuring the needs of persons in fragile

context of a public health emergency of international concern, including a pandemic emergency;	and humanitarian settings are met as part of the functions and mandate of the GSCL Network.
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 guidance, promote, during PHEIC and pandemic emergencies, the conduct of well-designed and well-implemented clinical trials in their jurisdiction, including by: (i) promoting representative study populations; (ii) ensuring access to safe and effective products that result from these trials for such study populations, including communities; and (iii) supporting access to comparator products as required in the clinical trial to assess candidate pandemic-related health products.	We welcome the inclusion of "ensuring" access to end products of clinical trials and "supporting" access to comparator products for clinical trials when needed. These should be kept in the final text. To ensure the end products of clinical trials are widely accessible, we suggest reintroducing the formulation used in the February 2024 text for Article 9.3(ii), where "communities" is placed on an equal footing as, and not subsumed within, "study populations".
5. Each Party shall develop and implement national and/ or regional policies regarding the inclusion of provisions in publicly funded research and development agreements, particularly for/of private entities and public-private partnerships, and encourage privately funded research and development entities, for the development of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern including pandemic emergencies, and the publication of relevant provisions. Provisions in the research and development agreements may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer; (iv) publication of relevant information on clinical trial protocols and relevant research results; and (v) adherence to product allocation frameworks adopted by WHO.	The revised Article 9.5 contains several improvements that should be retained in the final text. We welcome the deletion of "voluntary" and "on mutually agreed terms" under Article 9.5(iii). This gives greater clarity that governments may include "technology transfer" as a general condition in a publicly funded R&D agreement. The previous text containing "voluntary" and "on mutually agreed terms" in this section was redundant and confusing. As Article 9.5 deals with a contractual relationship between funders and funding recipients, this relationship is mutually agreed and voluntary by nature. The obligations in Article 9.5 focus not only on the inclusion of provisions conducive to global access in publicly funded R&D agreements, but also extend to encouraging privately funded R&D entities to include the same provisions. This is a positive step towards establishing a new norm for biomedical R&D funding in the future.

	We urge governments to agree on the text of "publication of relevant provisions" at INB12. In the discussions at INB11, we noticed confusion around whether the meaning of "publication" of R&D provisions has been covered by the 2024 IHR amendments. Article 13.9(c) of the IHR establishes a substantively different obligation than Article 9.5 of the INB draft text. The former only requires states parties to "make available" relevant terms of their R&D agreement to WHO or other states who request them. It does not contain a direct obligation for each state to include and proactively publish access provisions in publicly funded R&D agreement. Therefore, "publication of relevant provisions" should be retained under Article 9.5. *(See Annex)*
Article 11. Transfer of technology and know-how for the production of pandemic-related health products	
Proposed New 1(j) footnote under Article 11 for INB12: For the purposes of this Agreement, Transfer of Technology refers to a mutually agreed process where technology is shared consensually. This understanding is without prejudice to measures that Parties may take in accordance with their domestic or national legislation and does not affect any rights they may exercise under it, provided that these measures are in line with their relevant international obligations regarding intellectual property rights. And a New 1(k) Alt on know-how: Know-how refers to knowledge and skills required to manufacture products.	We take note of the efforts made to resolve the meaning of transfer of technology and know-how. Importantly, while the practical steps of how technology transfer is carried out are decided by the technology holder and recipient on mutually agreed terms, governments can ask for or require technology transfer in order to ensure timely and equitable access to health products. The draft New 1(j) footnote tries to strike a balance. We welcome the confirmation that technology transfer can be based on measures taken by governments in line with national legislation. However, there are two issues with the current text: • It still mixes the practical transfer of technology with how the transfer can be initiated and requested, including by governments. • Compared to the text circulated on September 20, the revised Article 11.1(a) no longer refers to Article 9 concerning transfer of technologies that have received public funding for their development. The current text of New 1(j) does not include the meaning of transfer being based on public funding agreement provisions, which could potentially undermine the strength of Article 9.5.

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 and know-how for pandemic-related health products, in particular for the benefit of developing countries, through measures which may include, *inter alia*, licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures; ***Note: Below draft text of Art. 11.1 (a) is from the version circulated by WHO on September 20:*** "Promote and otherwise facilitate or incentivize transfer of technology and know-how 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 in line with Article 9] through measures which may include, *inter alia*, licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures;"	We reiterate our earlier comments on Article 11.1(a) and call for stronger obligations on ensuring transfer of technologies. Compared to the draft text circulated by WHO on September 20, the reference to Article 9 has been deleted in the new version. This is a drawback. We recommend this reference be reinstated so that the leverage created under Article 9.5 can be used to support the implementation of Article 11.
(b) 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 encourage private rights holders to do the same;	We welcome the choice of "Make available" over "Seek to make available" in this section and call on member states to agree on this text.
(c) 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 "take measures to".
3. Each Party shall, within the ~~[existing]~~ framework of relevant international and regional organizations, ~~[consider supporting]~~ ~~[adopts]~~	We suggest deleting "existing" in order to future-proof the instrument.

~~[consider adopting] [review and consider]~~ ~~[endeavour to undertake]~~ [support, as] appropriate, time-bound measures to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability, accessibility and affordability of pandemic-related health products during pandemic emergencies.	
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 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].	We urge governments to agree on the use of "flexibilities" in the entire text of Article 11.4. We reiterate our support for 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 Public Health together 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 ensuring that it is able to implement this Article in a timely and effective manner.	We welcome the requirement for each party to review and consider amending its national legislation. While the clause no longer explicitly mentions TRIPS flexibilities, its objective ("to implement this Article") is directly related to Article 11.4 concerning the use of TRIPS flexibilities.
Article 13. Supply chain and logistics	
1. The Global Supply Chain and Logistics Network (the GSCL Network) is hereby established to enhance, facilitate, and work to remove barriers to, equitable, timely and affordable [and unhindered] access to pandemic-related health products, as well as to enable access to such products in humanitarian settings, in accordance with international law. The GSCL Network shall be developed, coordinated and convened by WHO in full consultation with the Parties, WHO Member States, and in partnership with relevant stakeholders, 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	We welcome the progress made toward agreement on this provision. The text clarifies the governance mechanism of the GSCL Network wherein WHO is responsible for developing, coordinating and convening the network under the oversight of the Conference of the Parties (COP). This is a welcome step towards clearer accountability for equity and access, addressing the gaps in the status quo. To ensure effective implementation, it is important to clarify the obligations of both parties and non-party WHO member states in supporting the

based on public health risk and need, in particular during pandemic emergencies.	operation of the network. We therefore welcome the inclusion of "WHO Member States" under Article 13.4 for this purpose.
2. The Conference of the Parties shall, at its first meeting, define ~~[by consensus]~~ the structure, functions and modalities of the GSCL Network, with the aim of ensuring the following:	The text of Article 13.2 provides a pathway towards continuation of work after the main agreement is concluded. However, considering the time needed to conclude the negotiation, adopt the agreement, wait for the threshold number of ratifications for the agreement to enter into force (Article 35.1), and one more year thereafter before the first COP is organised (Article 21.3), it could mean a few years' delay before the GSCL Network discussions are resumed. Clarity is needed on preparatory work to reduce this delay and mitigate fragmentation.
… (c) consideration of the needs of developing countries and the needs of persons in vulnerable situations, including those in fragile and humanitarian settings;	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 consider their needs but works directly towards fulfilling them.
3. The functions of the GSCL Network shall include, *inter alia*, subject to further decision making by the Conference of the Parties: a) identification of pandemic-related health products and relevant raw material sources including co-sourcing or co-allocation; b) identification of barriers to their access; c) estimation of supply and demand; d) facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10; e) coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work; f) promotion of transparency across the value chain;	We welcome the revised Article 13.3 which contains several improvements: • the reintroduction of "shall" in the chapeaux text, which strengthens the overall obligation; • paragraphs b) on identification of barriers, and h) on facilitation of and working to remove barriers, are welcome additions and could work in complementarity with Article 13.8 of the amended IHR concerning WHO's role of facilitating work to remove access barriers; • paragraphs d) and h) include both PHEIC and a pandemic emergency as part of the GSCL Network's functions on procurement, allocation, distribution, delivery, assistance with utilisation and removing barriers to equitable access. Paragraph f) could have been strengthened by going beyond the "promotion" of transparency across the value chain, and urging member states to continue improving and ensuring transparency instead.

g) collaboration on stockpiling both during pandemic emergencies and inter-pandemic periods; h) facilitation of, and working to remove barriers to equitable, timely and unimpeded access to pandemic-related health products, ~~including~~ through allocation, distribution, delivery, and assistance with utilization, including for products provided to the PABS System, during a PHEIC and a pandemic emergency.	
4. The Conference of the Parties shall periodically review the functions and operations of the GSCL Network, including the support provided by the Parties, WHO Member States which are not parties to the Pandemic Agreement, and relevant stakeholders, during and between pandemic emergencies and may provide further guidance related to its operations.	As noted in our comments on Article 13.1, we welcome the inclusion of "WHO Member States" under Article 13.4 as it can help strengthen the governance of the GSCL Network and ensure its effective operation.
5. During a pandemic emergency and PHEIC, 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 allowed and facilitated in accordance with national and international law, and the principles contained in Article 3 of this Agreement.	We welcome Article 13.5 concerning the provision of humanitarian relief and support the revised draft on the facilitation of humanitarian relief in accordance with "…international law, and the principles contained in Article 3 of this Agreement". We suggest deleting "national and" in this provision for greater clarity on how this obligation is governed by existing international law and principles. For greater clarity and consistency, we strongly suggest that the explicit reference to the principles of humanity, impartiality, independence and neutrality in paragraph 11 of the Preamble also be added here. It is needed to protect 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	Article 13bis.1 contains a weakened commitment that parties "shall endeavour" to publish relevant terms of their purchase agreements compared to "shall" used in earlier drafts.

disclosure. The Parties shall take steps to encourage regional and global purchasing mechanisms to do the same.	
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 global access especially for developing countries, such as provisions regarding donation, delivery modification, licensing and global access plans.	We welcome this provision setting out the practical terms of leveraging public purchase agreements for global access needs.
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 manner for use in countries facing challenges in meeting public health needs and demand.	In line with our previous comments, we welcome this positive provision. It should be retained in the final text.
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 welcome this provision for each party to commit that it should avoid maintaining excessive national stockpiles. A clear compliance mechanism needs to be established to ensure implementation. However, if excessive national stockpiles held by WHO member states that are not parties to the Pandemic Agreement overtake global access needs, Art 13bis.6 may not be sufficient to ensure clear accountability and coordination at international level. We therefore recommend that the text clarify that non-party member states should also have a responsibility to avoid excessive national stockpiles that may compete against global needs.

Annex: Technical Note on Access Provisions in R&D Agreements

A comparison of Article 9.5 of INB draft text and Article 13.9(c) of IHR

In the on-screen draft text of the INB negotiation dated 17 September 2024, Article 9.5 reads:

> *"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] pandemics/ [~~ [including] pandemic emergencies] DEL], **~~and the publication of such terms.~~** Such provisions may include: (i) licensing and/or sublicensing, [including in developing countries,] [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] outputs; and/or (v) adherence to product allocation frameworks adopted by WHO."*

Compared to the earlier draft, the phrase "and the publication of such terms" is put under a strikethrough. This represents a step backwards. The technical note provides an overview of the differences between Article 9.5 of the INB text and Article 13.9(c) of IHR as amended in 2024.

	Article 9.5 of INB draft text (September 17)	**Article 13.9(c) of IHR (**Working Group on Amendments to the International Health Regulations (2005) (who.int)**)**
	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****] ……,* ***and the publication of such terms.*** ***Such provisions may include****:* (i) licensing and/or sublicensing, [including in developing countries,] [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] outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.	*9. Pursuant to paragraph 5 of this Article* and paragraph 1 of Article 44 of these Regulations, and* ***upon request of other States Parties or WHO****,* ***States Parties shall****…****, to collaborate with, and assist each other and to support WHO-coordinated response activities****, including through:……; and* ***(c) making available****, as appropriate,* ***relevant terms*** *of their* ***research and development agreements*** *…….* *(*Article 13.5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO coordinated response activities.)*
Who is the duty bearer?	"Each party" Article 9.5 establishes an obligation for each individual state party at the national level.	"States Parties" Article 13.9 creates a collective obligation for state parties to undertake. It can be done by any state party, for the purpose of

		collaborating with and assisting each other and to supporting WHO-coordinated activities. It does not create an obligation that each state party will implement.
Who triggers the relevant obligations?	"Each Party" itself Each party implements Article 9.5 by developing and implementing its own national policies regarding "inclusion" AND "publication" of access provisions in publicly funded R&D agreements.	"Upon request by WHO or other States Parties" Subsections of Article 13.9 are triggered at the request of WHO or other state parties. This means each individual State Party has an obligation to implement Article 13.9 (c) only when there is a request from WHO or other State Parties and not proactively.
Is there an explicit publication requirement?	Yes When implementing this provision, each party's national policies cover both "inclusion" AND "publication" of access provisions in publicly funded R&D agreements.	No Article 13.9(c) uses the term "making available", which does not create an explicit obligation of "publication". "Making available" upon the request of WHO or other state parties could mean sending a copy to WHO, sharing with WHO or other states confidentially, or other means. It does not ensure entities other than WHO or states who request the terms of R&D agreements would be able to see it publicly.
What kind of agreement do the access provisions apply to?	Publicly funded research and development agreements	Research and development agreements
What kind of access provisions can be included?	Article 9.5 includes a list of examples of key global access provisions that may be included, providing explicit guidance for state implementation.	There is no specific reference to terms and provisions that could be used in R&D agreements for equitable access.

Remarks:

- Article 9.5 of INB text and Article 13.9(c) of IHR create two substantively different obligations. While they are complementary, one cannot be used to replace the other.
- Importantly, Article 13.9(c) of IHR does not introduce a direct obligation for an individual State Party to develop and implement national policies on including and publishing access provisions in publicly funded R&D agreements, nor does it specify the possible access conditions to be included.
- The phrase "*and publication of such terms*" under Article 9.5 should be retained in the text of the Pandemic Agreement.