Briefing Document
April 2024

MSF's Comments on Selected Provisions of the Proposal for the WHO Pandemic Agreement

Introduction

On 22 April 2024, a "Proposal for the WHO Pandemic Agreement" was published by the Intergovernmental Negotiating Body (INB). The proposal will form the basis of negotiations at the "Resumed" 9th meeting of the INB (29 April – 10 May 2024).

The new draft presents some improvements over previous versions that should be preserved and strengthened in the final text. These include provisions on protecting health needs in humanitarian settings, respecting the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS flexibilities), public research and development (R&D) funding agreements, transparency and national stockpiling.

However, a number of provisions that are key to an effective agreement have been diluted, deleted, or are still missing from the draft. These include provisions on:

- **Technology transfer:** The current language does not sufficiently hold governments accountable for ensuring and supporting transfer of technology to ramp up production and supply of medical products needed for pandemic prevention, preparedness and response (PPR).
- **Ensuring access to the end products for communities that support research/clinical trials:** While provisions on improving clinical trial design/implementation and collaboration and rapid sharing of trial data and results are included in the new draft, they need to be accompanied by an explicit obligation to ensure people and communities who support trials get reliable access to the end products. This is needed in order to ensure common standards of access by communities, especially when governments collaborate on multi-centred or internationally coordinated clinical trials. It is also imperative for governments to update national policies and practices concerning ethical management of clinical trials in this regard. Moreover, it will also fill a gap in the WHA resolution on clinical trials (WHA 75.8).
- **Reviewing and updating national laws to incorporate the full range of flexibilities, including TRIPS flexibilities:** This positive provision (Article 11.5) appeared in previous drafts, but has been deleted from the new draft. MSF has repeatedly witnessed how the lack of public health safeguards and flexibilities in countries' intellectual property (IP) laws and regulations has hampered their response to emergencies. To get ready for future pandemics/emergencies, it is essential for countries to review and update their national laws.
- **International stockpiling and equitable allocation:** Several provisions concerning transparency of cost and pricing and establishing earmarked stockpiles for humanitarian settings have been deleted. This leaves the Global Supply Chain and Logistics Network without the guidance needed to be adequately developed following the conclusion of the negotiations.

As the negotiations enter the last stage, Médecins Sans Frontières/Doctors Without Borders (MSF) urges governments to address these issues for a meaningful and effective agreement with international norms that can ensure equitable access to lifesaving medical products for PPR. To this end, in this briefing document we examine selected provisions of the new draft of the Pandemic Agreement, paying close attention to their evolution from previous drafts and analysing their implications for equitable access.

Article-by-article analysis

February text	March text (A/INB/9/3)	April text (A/INB/9/3 Rev.1)	Comments
		Preamble	
		11. Recognizing the importance of rapid and unimpeded access of humanitarian relief in accordance with international law, including international human rights law and international humanitarian law, and the respect of principles of humanity, neutrality, impartiality and independence for the provision of humanitarian assistance, *[NEW]*	*We welcome the new paragraph in the Preamble recognising the importance of rapid access to and provision of humanitarian assistance in accordance with international law, including international humanitarian law and principles. The text should be retained.*
Article 1. Use of Terms	**Article 1. Use of Terms**	**Article 1. Use of Terms**	
(i) "pandemic-related products" means products that are needed for pandemic prevention, reparedness and response, which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;	(g) "pandemic-related products" means products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, vaccines and personal protective equipment;	(d) "pandemic-related health products" means safe, effective, quality and affordable products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, vaccines and personal protective equipment;	*The term is revised from "pandemic-related products" to "pandemic-related health products".* *As noted in comments on earlier drafts, the scope of 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 caused by existing pathogens and new variants, including repurposed medicines.*
(l) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of	(j) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk	(g) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of	*We welcome the revised text of Article 1 (g) as it recognises persons in humanitarian settings under the definition of "persons in vulnerable situations". The text should be*

infection, severity, disease or mortality in the context of a pandemic, including vulnerability due to discrimination on the basis of race, colour, age, sex, language, religion, political or other opinion, national or social origin, property, birth or other status;	of infection, severity, disease or mortality in the context of a pandemic	infection, severity, disease or mortality in the context of a pandemic. This is understood to include persons in fragile and humanitarian settings;	*retained.*
Article 2. Objective and scope	**Article 2. Objective**	**Article 2. Objective**	
1. The objective of the WHO Pandemic Agreement, guided by equity, the right to health and the principles and approaches set forth herein, is to prevent, prepare for and respond to pandemics, with the aim of comprehensively and effectively addressing the systemic gaps and challenges that exist in these areas, at national, regional and international levels. 2. In furtherance of its objective, the WHO Pandemic Agreement applies at all times.	The objective of the WHO Pandemic Agreement, guided by equity, and the principles and approaches set forth herein, is to prevent, prepare for and respond to pandemics.	1. The objective of the WHO Pandemic Agreement, guided by equity, and the principles further set forth herein, is to prevent, prepare for and respond to pandemics. 2. In furtherance of this objective, the provisions of the WHO Pandemic Agreement apply both during and between pandemics, unless otherwise specified	*We welcome the reinstatement of the clause clarifying that the agreement is applicable both during and between pandemics, for it covers many issues where measures in advance of a pandemic are imperative.* *To ensure that the agreement is implemented effectively, it is important that the text provide as clear and actionable language as possible concerning states' obligations.*
Article 3. Guiding principles and approaches	**Article 3. Principles**	**Article 3. Principles**	
			The text should include clear language on respecting international medical ethics as a guiding principle. *Please refer to our earlier comments on this issue here: https://msfaccess.org/pandemic-agreement-msfs-comments-selected-provisions-revised-draft-negotiating-text*

		3. full respect of international humanitarian law for effective pandemic prevention, preparedness and response;	*We welcome the inclusion of the principle of full respect of international humanitarian law. The text should be retained.*
		5. solidarity with all people and countries in the context of health emergencies, inclusivity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics, recognizing different levels of capacities and capabilities; and	*Transparency is no longer a standalone principle, but mentioned as one of several aspects under the revised Article 3.5.*
7. Common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems – Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures. Given the unequal global development in the promotion of health and control of diseases, especially communicable disease, is a common danger, developed countries that hold more capacities and resources relevant to pandemics should bear a commensurate degree of differentiated responsibility regarding global pandemic prevention, preparedness, response	4. common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems;	*[Deleted]*	*CBDR as a principle has been deleted.* *Paragraph 2 of the Preamble and Article 3.5 of Principles include language on the recognition of differences in capacities and capabilities. This should be treated as the basis to pursue equity across several provisions of the agreement, including those concerning transfer of technologies.*

and recovery through effective means of implementation, such as technology transfer and know-how as well as financial resources			
Article 7. Health and care workforce	**Article 7. Health and care workforce**	**Article 7. Health and care workforce**	
1. Each Party, in line with its respective capacities, shall take the necessary measures to safeguard, protect, invest in, retain and sustain a skilled and trained health and care workforce, with the aim of increasing and sustaining capacities for 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 national law and practice: ..... (c) increase the safety of the health and care workforce, including through priority access to pandemic-related products during pandemics, minimizing disruptions to the delivery of good quality essential health services, and developing and integrating effective measures to prevent and address harassment, violence and threats against health and care	1. Each Party, in accordance with its national circumstances, commits to take, where appropriate, the necessary measures to safeguard, protect, invest in, retain and sustain an adequate, skilled and trained health and care workforce, with the aim of strengthening capacities for pandemic prevention, preparedness and response, while maintaining quality essential health services and essential public health functions during pandemics. To this end, each Party commits, where appropriate, to: (a) protect the safety and security of the health and care workforce, including through strengthening decent work conditions, addressing mental health and wellbeing, ensuring priority access to necessary tools and supplies, including to pandemic- related products	2. Each Party shall take appropriate measures to protect and ensure the continued safety, wellbeing and capacity of its health and care workforce, including by ensuring priority access to pandemic-related health products during pandemics, thereby minimizing disruptions to the delivery of good quality essential health services.	*We welcome the text on protecting and ensuring the safety and wellbeing of the health and care workforce, including their priority access to health products, in Article 7.2. The provision should be retained in the final text.* *However, the clause is weaker than the previous version without explicit language on addressing harassment, violence and threats against health and care workers. The need to protect the safety and security of hospitals and other facilities where health care workers carry out their duties is also missing.*

workers, their means of transport and equipment, as well as hospitals and other medical facilities, when carrying out their duties; and	during pandemic emergencies, as well as addressing harassment, violence and threats against health and care workers;		
Article 9. Research and development	**Article 9. Research and development**	**Article 9. Research and Development**	
(d) ensuring that clinical trials are conducted in accordance with international ethical guidelines, including by guaranteeing: i. equitable representation, considering racial, ethnic and gender diversity across the life cycle, and are designed to help to address geographical, socioeconomic and health disparities, to promote a better understanding of the safety and efficacy of pandemic-related products for population subgroups; and ii. access to safe, effective, and quality assured interventions or products developed for the population or community in which the research is carried out;	*[Deleted]*	*[Deleted]*	*The deletion of Article 9.3(d) from the February text, which stated that clinical trials are to be conducted in accordance with international ethical guidelines, including by guaranteeing access to the end products for populations and communities supporting the research, represents a huge step back. We therefore call on governments to reinstate the text.* *More details of the rationale and feasibility in this regard are included in MSF's technical note on post-clinical trial access requirements.*
(h) promoting access to comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies.	*[Deleted]*	*[Deleted]*	*The deletion of Article 9.3(h) on access to comparator products to support rapid development of products and technologies is a drawback. We shared our concerns in*

			earlier comments here: https://www.msfaccess.org/pandemic-agreement-msfs-comments-selected-provisions-revised-draft-negotiating-text
		3. The Parties shall, in accordance with national circumstances and mindful of relevant international standards and obligations, take steps to strengthen international coordination and collaboration to support well-designed and well-implemented clinical trials, by developing, strengthening and sustaining clinical trial capacities and research networks, at the national, regional and international levels, and facilitating the rapid reporting and interpretation of data from such trials. *[NEW]*	*We welcome the inclusion of the new Article 9.3 concerning well-designed and well-implemented clinical trials in the context of strengthening international coordination and collaboration. It should include explicit language on ensuring access to the end products for communities in which clinical trials are conducted.* *The inclusion of explicit text on ensuring post-clinical trial access in Article 9.3 will fill a gap in the WHA resolution on clinical trials (WHA 75.8) by establishing a well-balanced obligation for governments alongside rapid reporting and interpretation the clinical trial data.*
5. Each Party shall, in accordance with its national laws and considering the extent of funding provided: a. include provisions to promote equitable access to pandemic-related products in government-	6. Each Party shall develop national policies to: (a) include provisions in government-funded research and development agreements for the development of pandemic-related products that	4. Each Party shall ensure that government-funded research and development agreements for the development of pandemic-related health products include, as appropriate, provisions that promote timely and equitable	*Compared to the March text, the language introducing Article 9.4 is improved slightly by "shall ensure" replacing "shall develop national policies". However, "as appropriate" may be read as a concession and could dilute the obligation.*

funded R&D agreements and in licensing of government-owned technology for such products; and b. publish relevant terms of government-funded R&D agreements for pandemic-related products, in particular, information on pricing policies for end-products; licensing to enable the development, manufacturing and distribution of pandemic-related products; and terms promoting equitable and timely access to such products during a pandemic emergency.	promote timely and equitable global access to such products during public health emergencies of international concern and pandemics. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer on voluntary terms; (iv) publication of relevant information on research inputs and outputs; and/or (v) adherence to product allocation frameworks adopted by WHO; and (b) publish relevant terms of government-funded research and development agreements promoting equitable and timely access to such products during a pandemic emergency.	access to such products and shall publish the relevant terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) 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.	*The "on mutually agreed terms" wording in Article 9.4(iii) should be removed as it dilutes what the funding agreement provision should require more directly.* *On transparency: "publication of relevant information on research inputs and outputs" in Article 9.4 (iv) is vague on what needs to be published. Transparency requirements in public funding agreements should include information such as costs of production and prices of medical products.* *While the chapeau text retains the text on publishing the funding agreement, it is limited to "relevant" terms only. The full agreement should be published.* *MSF has published detailed suggestions on key information for which transparency is needed, which can be referred to here: https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text*
Article 11. Transfer of Technology	**Article 11. Transfer of Technology and Know-how**	**Article 11. Transfer of technology and know-how for the production of pandemic-related health products**	
1. In order to enable sufficient, sustainable, and geographically-diversified production of	1. In order to enable sufficient, sustainable and geographically-diversified	1. Each Party shall, in order to enable the sufficient, sustainable and geographically diversified	*The reintroduction of "on mutually agreed terms" is problematic and unnecessary.*

pandemic related products, each Party ~~[especially developed countries~~], shall collaborate towards: a) promoting and otherwise facilitating or incentivizing the transfer of technology and know-how for pandemic-related products on voluntary and mutually-agreed terms, including through the use of licensing and collaboration with regional or global technology transfer ~~hubs~~ partnerships and initiatives, and in particular for technologies that have resulted from public funding;	production of pandemic-related products each Party, taking into account its national circumstances, shall: (a) promote and otherwise facilitate or incentivize the transfer of technology and know- how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development;	production of pandemic-related health products, and taking into account its national circumstances: (a) promote and otherwise facilitate or incentivize the 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 funding for their development, through a variety of measures such as licensing, on mutually agreed terms;	*Governments should be able to require recipients of public funds to engage in transfer of technologies and know-how more directly. Article 9.4 enables governments to include technology transfer as part of R&D funding conditions; it should be directly activated and not merely be promoted or incentivised.*
b) promoting the publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related health products; without prejudice to applicable national laws	(b) promote the timely publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related products, in accordance with national laws;	(b) publish the terms of its licenses for pandemic-related health technologies in a timely manner and in accordance with applicable law, and shall encourage private rights holders to do the same;	*We welcome the current text of Article 11.1(b) that introduces a direct obligation for governments to publish the terms of licenses it signs and encourages private rights holders to do the same.* *The "in accordance with applicable law" wording should be removed in order to avoid diverse interpretations and inconsistent implementation.* *The previous Article 11.1(c) concerning licensing of government-owned technologies on a non-exclusive, worldwide and transparent basis has been deleted. As a result, there is no longer any text calling on*

			governments to make licenses available before publishing those licenses as stated under Article 11.1(b). *Article 11.1(b) should be revised by reintroducing text requiring governments to "make available licenses on a non-exclusive and worldwide basis" of government-owned technologies. This should be placed before the requirement to "publish the terms of its licenses" to make the clause more meaningful.*
c) license, on a non-exclusive basis and for the benefit of developing countries, government-owned pandemic-related technologies, on mutually agreed terms, and shall publish the terms of these licenses at the earliest reasonable opportunity and to the fullest extent possible in accordance with each Party's laws and regulations	(c) make available licenses, on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries, for government-owned pandemic-related products, and shall publish the terms of these licenses at the earliest reasonable opportunity and in accordance with national laws; and	*[Deleted and partially combined with the Article 11.1 (b).]*	*See comments above.*

		(f) encourage manufacturers within its jurisdiction to share as appropriate, during pandemics, information that is relevant to the production of pandemic-related health products when the withholding of such information prevents or hinders the urgent manufacture of a pharmaceutical product that is necessary to respond to the pandemic	*While we welcome the recognition of the importance of transparency from manufacturers, words such as "as appropriate" and "information that is relevant" weaken the provision.* *Information about manufacturing capacity, production status, supply schedules, and pricing is essential for PPR, especially to manage supply when there are shortages. Governments should require, and not merely "encourage", manufacturers to share this information.*
3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall encourage holders of relevant patents related to the production of pandemic-related products, in particular those who received public funding, to waive/forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products.	3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall: … (b) consider supporting, 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.	3. Consider supporting, within the framework of relevant organizations, appropriate measures to accelerate or scale up the manufacturing of pandemic related health products, to the extent necessary to increase the availability and adequacy of affordable pandemic-related health products during pandemics.	*The explicit wording of "time-bound waivers of intellectual property rights" has been deleted.* *MSF's comments on how IP issues should be addressed in the WHO PPR processes, including by supporting the use of IP waivers, can be found here: https://msfaccess.org/trips-ppr-addressing-intellectual-property-barriers-lifesaving-medical-products*
5. The Parties ~~reaffirm~~ recognize that WTO Members have the right to use to the full, the flexibilities inherent in the TRIPS Agreement,	4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the	4. The Parties that are WTO Members reaffirm that they have the right to use, to the full, the flexibilities in the TRIPS	*We welcome the retention of "shall fully respect the use" of TRIPS flexibilities. This should stay in the final text of the agreement.*

the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and subsequent relevant decisions* which provide flexibility to protect public health including in future pandemics, since the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that it can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. * Reference is made here to what is known as Paragraph 6 System of the Declaration which was an amendment to the Agreement adopted by the WTO General Council on 30 August 2003, that became permanent by the GC Decision on 6 December 2005 and entered into force on 23 January 2017.	TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.	Agreement, including those reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health in future pandemics, and shall fully respect the use of the TRIPS Agreement flexibilities by WTO members.	
6. Each Party shall review and update as necessary its national legislation in order to ensure the implementation of such flexibilities in a timely and effective manner	5. Each Party shall, as necessary and appropriate, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 5 in a timely and effective manner.	*[Deleted]*	*The deletion of the March text's Article 11.5 from the new draft is a huge drawback. We urge negotiating parties to reinstate it in the agreement.* *Reviewing and updating national legislation is critical to ensure the timely and effective use of public health safeguards and flexibilities, including TRIPS flexibilities.*

			We have repeatedly witnessed how the lack of legal readiness to overcome intellectual property barriers, including during emergencies, has affected both developing and developed countries and ultimately undermined people's access to lifesaving medical products. The INB negotiations provide an opportunity to recognise the need for proactive action to make sure national laws are fully equipped with all flexibilities for sufficient protection of access to medical products, especially during global health emergencies.
	Article 12. Access and benefit sharing	**Article 12. Access and benefit sharing**	
	6. WHO shall conclude legally binding standard PABS contracts with manufacturers to provide the following, taking into account the size, nature and capacities of the manufacturer: (a) annual monetary contributions to support the PABS System and relevant capacities in countries; the determination of the annual amount, use, and approach for monitoring and accountability, shall be finalized by the Parties;	3. The WHO PABS System shall have, at a minimum, the following components and elements: ..... (b) The fair, equitable and timely sharing of benefits, both monetary and non-monetary, arising from access to PABS Material and information, in accordance with modalities, terms and conditions to be determined and agreed, and which shall include, at a minimum, the following: (i) in the event of a pandemic, real-time access by WHO to 20% (10% as a donation and 10% at	*The text on real-time contribution of supplies to WHO in the event of a pandemic [12.3(b)] is positive.* *However, compared to the March text of Article 12.6, and in the context of the extended timeline for PABS negotiations proposed in the current Article 12.6, whether these "minimum" benefit sharing requirements will be mandatory, and the type of legal agreements to be used in triggering the benefit-sharing requirements, is unclear.* *In addition, non-exclusive licensing and transfer of technologies and know-how are only included as additional voluntary benefit-sharing options under Article 12.4(a). These*

	(b) real-time contributions of relevant diagnostics, therapeutics or vaccines produced by the manufacturer, 10% free of charge and 10% at not-for-profit prices during public health emergencies of international concern or pandemics, to be made available through the Network established under Article 13 for use on the basis of public health risks, needs and demand; and (c) voluntary non-monetary contributions, such as capacity-building activities, scientific and research collaborations, non-exclusive licensing agreements, arrangements for transfer of technology and know-how in line with Article 11, tiered pricing for relevant diagnostics, therapeutics or vaccines.	affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related health products; and (ii) annual monetary contributions from PABS System users shall be administered by WHO, based on modalities, terms and conditions to be defined, per paragraph 6 of this Article; and 4. The PABS System will also have additional benefit-sharing options, which may include: (a) voluntary non-monetary contributions, such as capacity-building activities, scientific and research collaborations, non-exclusive licensing agreements, arrangements for the transfer of technology and know-how of relevant diagnostics, therapeutics or vaccines in line with Article 11, tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for the purchase of pandemic-related health products during public health emergencies of international concern or pandemics; and	*elements should be included as part of the minimum requirements under Article 12.3.* *There should not be a ceiling of 20% for WHO's access to the supply of pandemic-related products; an open-ended approach should be considered to allow adjustment of the quantities based on health needs. For more detailed comments on the issues with a fixed proportion of supply, see: https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text*
	9. During a pandemic, each	*[Relocated to Article 13bis.2]*	

	Party in a position to do so shall, within available resources and subject to applicable laws and in line with Article 13, set aside a portion of its total procurement of relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand for relevant diagnostics, therapeutics or vaccines.		
		6. The modalities, terms and conditions, and operational dimensions of the PABS System shall be further defined in a legally-binding instrument, that is operational no later than 31 May 2026.	*There should be more clarity on what will be further negotiated and defined in the proposed new timeline. It is unclear whether the new deadline will lead to a "legally binding instrument" that is separate from or a part of the Pandemic Agreement instrument.* *To provide clarity and guide further negotiations, the final agreement should include a list of mandatory benefit-sharing requirements. This should include transfer of technology and know-how, non-exclusive licensing and affordable pricing.* *The text should also explicitly retain a connection between Article 12 and 13 such that the supply secured through the PABS System can support the Global Supply Chain and Logistics Network.*

Article 13. Global supply chain network	**Article 13. Supply chain and logistics**	**Article 13. Supply chain and logistics**	
Supply chain network provisions: 1. The [Global Supply Chain and Logistics Network] (the Network) is hereby established. The Network shall be developed and operated by WHO in partnership with the Parties and other relevant international and regional organizations and stakeholders, and shall be guided by the principles of equity, transparency, inclusivity, and public health needs. The Network shall consider the experiences of other mechanisms in procurement, allocation and distribution of product placeholder in health emergencies, and shall pay particular attention to the needs of developing countries and others with increased needs, including those in fragile and humanitarian settings. The governance structure of the Network shall be defined in the first meeting of the governing body, allowing for equitable representation of the WHO regions.	1. The Global Supply Chain and Logistics Network (the Network) is hereby established. The Network shall be developed, coordinated and convened by WHO in partnership with the Parties and other relevant international and regional stakeholders, and shall be guided by the principles of equity, transparency, inclusivity, timeliness, fairness and consideration of public health needs. The Network shall pay particular attention to the needs of developing countries, including those in fragile and humanitarian settings.	1. The Global Supply Chain and Logistics Network (the Network) is hereby established to enhance equitable, timely and affordable access to pandemic-related health products. The Network shall be developed, coordinated and convened by WHO in partnership with the Parties and other relevant international and regional stakeholders. The Parties shall prioritize sharing through the Global Supply Chain and Logistics Network for equitable allocation based on public health risk and need over bilateral donation agreements.	*The text on the "needs of developing countries, including...fragile and humanitarian states" has been retained, albeit under Article 13.2(c), which is positive.*
2. The Network shall develop modalities aimed at ensuring the	2. The Conference of the Parties shall, at its first	2. The Conference of the Parties shall, at its first meeting, define	*We welcome the recognition of the needs of persons in vulnerable situations, including*

following: a) collaboration among the Parties and other relevant stakeholders during and between pandemics, b) assignment of functions to stakeholders based competencies and expertise, and c) accountability and transparency in the functioning of the Network.	meeting, define the structure and modalities of the Network, which shall aim at ensuring the following: (a) Collaboration among the Parties and other relevant stakeholders during and between pandemics; (b) assignment of functions to stakeholders based on competencies and expertise; and (c) accountability and transparency in the functioning of the Network.	the structure and modalities of the Network, which shall aim at ensuring the following: (a) collaboration among the Parties and other relevant stakeholders during and between pandemics; (b) the functions of the Network are discharged by the organizations best placed to perform them; (c) consideration of the needs of developing countries and the needs of persons in vulnerable situations, including those in fragile and humanitarian settings; (d) the equitable allocation of pandemic-related health products; and (e) accountability and transparency in the functioning and governance of the Network.	*those in humanitarian settings.* *However, the word "consideration of" should be deleted in order to provide a clear mandate for the Network to ensure the needs of developing countries and persons in vulnerable situations, including those in fragile and humanitarian settings, are not merely "considered" but fully met.* *More detailed comments from MSF on this issue can be found here: https://msfaccess.org/pandemic-agreement-msfs-comments-selected-provisions-revised-draft-negotiating-text*
3. The Parties shall periodically review the operationalization of the Network, including the support provided by Parties and other stakeholders [during and between pandemics]. The functions of the Network shall include: d) promoting transparency in cost, pricing and other relevant data on products, including raw materials,	3. The Parties shall periodically review the operationalization of the Network, including the support provided by Parties and other stakeholders during and between pandemics.	3. The Parties shall periodically review the operations of the Network, including the support provided by Parties and other stakeholders during and between pandemics. *[Previous Subsection 4 is Deleted]*	*The March text's Article 13.4, on the functions of the Network, has been deleted from the latest draft. This is a significant drawback.* *Article 13.4(d) included specific language on transparency in cost, pricing and other relevant data, which are foundational to the effective coordination, operation and accountability of the Network.* *It also provided practical content concerning stockpiling, allocation and delivery,*

across the value chain;			*including language on the establishment of earmarked stockpiles for humanitarian needs [13.4 (f)] and covering humanitarian settings in delivery [13.4 (h)], and contained explicit text on how other provisions of the instrument, including PABS, can be used to supply the Network [13.4 (g)].* *While we appreciate the need to streamline the text and understand that the Network will be operationalised after the adoption of the agreement, clauses concerning the mandate and functions of the Network under Article 13 are important to retain in order to ensure the accountability of the Network.*
f) collaborating with relevant authorities and organizations/institutions, as appropriate, and taking into account national and regional circumstances to establish, strengthen and maintain national, regional, and/or international stockpiles of various product placeholder, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities and assess them at regular intervals;	4. The functions of the Network shall include: ..... (d) promoting transparency in cost, pricing and other relevant data on products, including raw materials, across the value chain; …… f) collaborating with relevant authorities and organizations/institutions, as appropriate, and taking into account national and regional circumstances to establish, strengthen and maintain national, regional, and/or international stockpiles of various product placeholder, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities and assess them at regular intervals; (g) facilitating the equitable allocation of pandemic-related products, including those procured through the facilitation by the Network, acquired through the PABS or donated by countries as		
g) facilitating the equitable allocation of product placeholder based on public health risks and needs, taking into account factors, such as population size, demographic structure, epidemiological situation and health system capabilities of beneficiary countries and their readiness and capacity to utilize such products;			
h) facilitating the most efficient delivery and distribution of pandemic-related health products, including, as appropriate, through regional stockpiles, consolidation			

hubs, and staging areas, while taking into account specific requirements for these products;	referred to in Article 13bis, subparagraph 2, based on public health risks and needs, and taking into account factors, such as population size, demographic structure, epidemiological situation and health system capabilities of beneficiary countries and their readiness and capacity to utilize such products; (h) facilitating the most efficient delivery and distribution of pandemic-related products, including, as appropriate, through regional stockpiles, consolidation hubs and staging areas, while taking into account specific requirements for these pandemic-related products, including in humanitarian settings; and		
		5. 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 relevant provisions of international law, including international humanitarian law, and in respect	*We welcome Article 13.5 concerning the provision of humanitarian assistance. This text should be retained in the final instrument.*

		of the principles of humanity, neutrality, impartiality and independence for the provision of humanitarian assistance. *[NEW, revised and relocated from Art 13bis]*	
		6. A multilateral system for managing vaccine and therapeutic-related compensation and liability during pandemics shall be considered. *[NEW, split and merged from previous Article 15]*	*Article 13.6 is unclear and too broad.* *It is unclear who is the duty bearer and who should consider "a multilateral system".* *It does not differentiate novel/experimental products from routine health products in its scope. This sets up a huge risk for abuse and expansive interpretation. While routine health products may also be used for emergency response, there is no justification for routine health products to be covered by any liability transfer schemes.* *It is also unclear whether the text implies any particular approach to compensation and liability management, which makes follow-up of Article 13 challenging.* *WHO and member states, when discussing any potential multilateral compensation and liability schemes, should thoroughly review the pitfalls and lessons learned from COVID, especially on elements that have affected the effectiveness of the COVAX Non-Fault*

			Compensation Scheme and the issues with liability management and indemnification.
	Article 13bis. National procurement- and distribution-related provisions	**Article 13bis. National procurement and distribution**	
Procurement/Trade/Other provisions 1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic related productions, in accordance with applicable laws, and shall endeavour to exclude unwarranted confidentiality provisions that serve to limit such disclosure.	1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic-related products at the earliest reasonable opportunity and in accordance with applicable laws, and shall exclude confidentiality provisions that serve to limit such disclosure. Each Party shall also encourage regional and global purchasing mechanisms to do the same.	1. Each Party shall publish the relevant terms of its purchase agreements with manufacturers for pandemic-related health products at the earliest reasonable opportunity, and shall exclude confidentiality provisions that serve to limit such disclosure, in accordance with applicable laws, as appropriate. Regional and global purchasing mechanisms shall also be encouraged to do the same.	*This is a welcome provision and should be retained.* *However, the introduction of the words "relevant" and "as appropriate" weaken the obligation, and therefore the language used in the March version of the text should be restored.* *While the "regional and global purchasing mechanisms shall also be encouraged to do the same" language is an important step towards consistency in practice, it can be improved by requiring, and not merely "encouraging", relevant regional and global purchasing mechanisms to establish transparent publication of purchase terms and exclusion of confidentiality as a standard practice. It is feasible for governments to leverage their role in such purchasing mechanisms to require these practices.* *To avoid diverse interpretations and provide greater certainty, the qualifying language of "in accordance with applicable laws" should be deleted.*
		2. During a pandemic, each Party in a position to do so shall, within	*We welcome this very positive provision. It should be retained in the final instrument.*

		its available resources and subject to applicable laws, set aside a portion of its total procurement of relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand. *[NEW, relocated]*	
2. Each Party, in accordance with national laws, shall include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products, such as provisions that: a) permit the donation of such products outside of its territories; b) facilitate potential modifications (e.g., delivery swaps >, in order to address supply gaps around the world; c) incentivize or otherwise encourage licensing and other transfer of technology, in particular for the benefit of low- and middle-income countries; d) incentivize or otherwise encourage the formulation and sharing of global access plans for	2. Each Party, in accordance with national laws, shall include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products, such as provisions that: a) permit the donation of such products outside of its territories; b) facilitate potential modifications (e.g., delivery swaps), in order to address supply gaps around the world; c) incentivize or otherwise encourage licensing and other transfer of technology, in particular for the benefit of low-and middle-income countries;	Deleted	

the products.	d) incentivize or otherwise encourage the formulation and sharing of global access plans for the products.		
	4. The Parties commit to ensure rapid and unimpeded access of humanitarian relief personnel, as well as their means of transport, supplies and equipment, in accordance with international humanitarian law, and to respect the principles of humanity, neutrality, impartiality and independence of recognized humanitarian organizations for the provision of humanitarian assistance.	*[Revised and relocated to Article 13]*	
5. Each Party shall ensure that any national stockpiles do not unnecessarily exceed quantities needed for domestic public health emergency preparedness and response.	5. Each Party shall ensure that any national stockpiles do not unnecessarily exceed quantities needed for domestic public health emergency preparedness and response.	4. Each Party undertakes to avoid having 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 very positive provision. It should be retained in the final instrument.* *The revised text is weakened by "undertakes to avoid" replacing "shall", and "quantities anticipated to be needed" replacing "quantities needed" from the previous version. These changes introduce too wide a margin of discretion for effective implementation. The final text should restore the wording used in the March version.* *The word "unnecessarily" should be deleted in order to avoid disputes over what is necessary, and to ensure that stockpiles are managed only on the basis of health needs.*

		6. 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. *[NEW, split and merged from previous Article 15]*	*We welcome this new provision that makes clear that the indemnity clauses must remain exceptional and not become the "principle".* *However, "shall endeavours" is very soft and a firm commitment from governments is needed on this very important matter.* *Also, Article 13bis should explicitly state that humanitarian actors are exempt from such indemnity clauses.*
Article 15. Compensation and Liability Management	**Article 15. Liability and compensation management**	**Article 15. Compensation and Liability Management**	
1. In order to increase vaccine confidence, each Party shall implement and/or participate in a transparent no-fault compensation mechanism(s), established at a national, regional or global level, for serious adverse events resulting from the use and/or administration of vaccines developed for response to pandemics and shall consider developing strategies for funding the mechanism(s), potentially including through private sector contributions. 2. In order to facilitate timely access to vaccines developed for response to pandemics, each Party shall develop, as necessary and in accordance with national and	1. Each Party shall consider developing, as necessary and in accordance with applicable law, national strategies for managing liability in its territory related to pandemic vaccines and shall make such strategies publicly available. Strategies may include, inter alia, legal and administrative frameworks; no-fault compensation mechanisms, potentially funded by private sector contributions; policies and other approaches for the negotiation of procurement and/or donation agreements. 2. The Parties, within the framework of the Conference of the Parties, in collaboration	*[Deleted; split and integrated into Article 13 and 13bis above]*	*See comments on Article 13.6 and 13bis.6 above.*

regional legislation, national strategies for managing liability in its territory related to pandemic vaccines. Such strategies may include, inter alia, model contract indemnification provisions, insurance mechanisms, policy frameworks and principles for the negotiation of procurement and/or donation agreements including circumstance-based time limitations and building expertise for contract negotiations in this matter. 3. Each Party shall make information about its participation in no-fault compensation mechanism(s) and other strategies for liability management publicly-available, in accordance with national law. 4. WHO, in collaboration with other relevant organizations and entities, shall develop recommendations for the establishment and implementation of regional and/or global nofault compensation funds and for strategies for managing liability during pandemic emergencies, including coverage of individuals that are in a humanitarian setting or vulnerable situations.	with relevant entities and multilateral organizations, as appropriate, shall develop recommendations for the establishment and implementation of national, regional and/or global no-fault compensation mechanisms and strategies for managing liability during pandemic emergencies, including with regard to individuals that are in a humanitarian setting or vulnerable situations.		