Briefing Document
March 2024

Pandemic Agreement: MSF's Comments on Selected Provisions of Revised Draft of Negotiating Text

On 8 March 2024, ahead of the 9th meeting of the World Health Organization (WHO) Intergovernmental Negotiating Body (INB9, 18-28 March 2024), a revised draft of the negotiating text of the WHO Pandemic Agreement was distributed to relevant stakeholders.[1]

In our reading, and compared to the previous draft text (distributed on 19 February 2024 by the INB Bureau via email), the current text contains several improvements concerning stockpiling and allocation, reemphasises the need for respecting the use of flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and contains improved language concerning key provisions to be included in public funding agreements for R&D to help ensure access and equity. The improvement is also noticeable in the deletion of "voluntary and on mutually agreed terms" across provisions concerning transfer of technology and licensing of government-owned or funded technologies. Provisions concerning transparency across supply chains and in public procurement agreements have also improved.

However, there are outstanding issues that need to be addressed in the INB9 negotiations. Specifically:

- Revised language on provision of humanitarian assistance is restricted to only "recognized" humanitarian organisations, which risks undermining the principles of independence and impartiality contained in international humanitarian law (IHL) (Article 13bis.4);
- Revised text on liability and compensation contains no clear framework and redlines to clarify limitation and exceptions (Article 15);
- Important provisions on ensuring access to end products by communities joining biomedical research, compliance with an ethical framework, and on access to comparator products for research and development (R&D) have been deleted (Article 9); and
- The obligations concerning transfer of technology and non-exclusive licensing remain weak, despite notable improvement of the language as mentioned above (Article 11).

In this publication, we compare selected provisions of the new INB9 draft text with the previous text, analysing their implications for equitable access to medical products. This analysis can be read alongside our comments on earlier drafts as well as on specific topics in the negotiations:

- INB Proposal for Negotiating Text (October 2023)
- Zero Draft (April 2023)
- From TRIPS to PPR: Addressing Intellectual Property Barriers on Lifesaving Medical Products (September 2023)

February text	March text (A/INB/9/3)	Comments
Preamble		
		A reference to the IHL legal framework or to a sentence found in UNSC resolution 2565 (2021) that pandemics can exacerbate the negative humanitarian impact of armed conflicts and exacerbate inequalities, should be made in the preamble.
Chapter I Introduction		
Article 1 Use of terms		
(i) "pandemic-related products" means products that are needed for pandemic prevention, preparedness 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;	*As noted in comments on earlier drafts, the scope of the definition of "pandemic-related products" should be expanded to include underlying technologies, components, materials, parts, antibiotics, data and know-how needed for production. In addition, the scope should include existing products tackling possible new outbreaks 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 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;	(j) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of infection, severity, disease or mortality in the context of a pandemic	*The current definition of "individuals in vulnerable situations" as outlined in article 1(j) has significant shortcomings since it does not consider individuals residing in conflict-affected or other humanitarian settings. These individuals are particularly vulnerable during pandemics. These populations face unique challenges in accessing essential services, and they should be explicitly acknowledged in the text.*
Article 2 Objective and scope	**Article 2 Objective**	
1. The objective of the WHO Pandemic Agreement, guided by equity, the right to	The objective of the WHO Pandemic Agreement, guided by equity, and the	

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.	principles and approaches set forth herein, is to prevent, prepare for and respond to pandemics.	*The March revision deletes the statement that the agreement applies at all times, thereby restricting the scope of the provision.* *Given that the agreement covers preparedness, prevention, response and health system recovery, and that the provisions therein need governments' engagement at all times, it is preferable to retain the clarification that the agreement is applicable at all times.*
Article 3 Guiding principles and approaches	**Article 3 Principles**	
Missing principles: ***Respect for international humanitarian law:*** *There is no language in the general principles specifically referencing IHL. IHL contains obligations directly relevant to the prevention and control of infectious diseases, protecting persons and facilities involved in pandemic response, and preventing outbreaks among specific groups of conflict-affected populations. It is imperative to introduce clear language on respecting IHL as a guiding principle in Article 3.* ***Respecting international standards of medical ethics:*** *The text should include clear language on respecting international medical ethics as a guiding principle, especially the principles of "do no harm", acting in the best interest of patients and respecting patient wishes, and the rights to consent, autonomy, and bodily integrity. These principles are directly relevant to an effective and accountable pandemic preparedness, prevention and response (PPR) mechanism, particularly for improving R&D and medical interventions in PPR contexts.*		
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	4. common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems;	*We welcome the retention of CBDR as a principle, but it needs to be established more clearly in relevant provisions, especially those concerning transfer of technology and achieving equity.*

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 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**	
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 workers, their means of transport and equipment, as well as hospitals and other medical facilities, when carrying out their duties; and	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 during pandemic emergencies, as well as addressing harassment, violence and threats against health and care workers;	*We welcome 7.1 (a) on protecting the safety and security of the health and care workforce, and their priority access to medical products.* *The text should be improved by including the need to restate the preventive aspect and address undue criminalisation of health and care workers and organisations, and the protection of hospitals and other facilities where they work.*

Article 9 Research and development	**Article 9 Research and development**	
3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop, strengthen and sustain clinical trial capacities at the national, regional and international levels, including by:	3. The Parties shall, in accordance with national circumstances and mindful of relevant international standards, 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.	*The chapeau text suggests a progressive realisation of the concerned obligation. The text can be improved by referring to the respective capacities of Parties in order to provide greater clarity.*
(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	*The deletion of Article 9.3 (d), 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.* *MSF continues to witness the devastating consequences of non-compliance with medical ethics for individuals who participate in, and communities that, support research.* *For instance, international medical ethics guidelines -- to ensure access to the products in countries where clinical trials were conducted, and by patients and survivors who joined trials -- not being followed is one of several factors contributing to the lack of timely access to the new Ebola treatments in endemic countries,. While the development of the treatments directly benefited from the participation in clinical trials of patients and Ebola survivors in endemic countries, the companies involved delayed the submission for regulatory approvals, which is an essential condition to enable availability of the treatments for people in need.*[2]

		The lack of binding norms to uphold medical ethics is one of the key reasons for the situation mentioned above. *We call on governments negotiating the agreement to reinstate Article 9.3 (d) on post-clinical trial access to the end products by people and communities who participate in and host research.* *The agreement needs to ensure good ethical practices and compliance with ethical standards (such as the CIOMS guidelines) to promote and ensure respect for all human subjects and protect their health and rights.* *More details of the rationale and feasibility in this regard are included in MSF's technical note on post-clinical trial access requirements.*
(f) developing national policies to support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications, while protecting privacy and health identifiers.	Deleted	*Article 9.3 (f) has been deleted in the March draft.* *Assuming the issues covered in this section can be consolidated in Article 9.4 in the latest draft, we suggest improvements in our comments on 9.4 below.*
(h) promoting access to comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies.	Deleted	*The deletion of Article 9.3 (h) on access to comparator products to support rapid development of products and technologies is a huge drawback.* *As recently reported, the pharmaceutical corporation Pfizer denied the non-profit Drugs for Neglected Diseases initiative (DNDi) access to its anti-COVID drug Paxlovid for the ANTICOV clinical trial, a large study in 10 African countries that aims to find treatments for mild to moderate COVID.[3] Pharmaceutical corporations often block such access to needed comparator drugs, vaccines and tests to*

		protect their commercial interest, which results in key health research and clinical trials being prevented altogether, or getting delayed. *Particularly in the context of global public health emergencies, where there is a need for critical research questions to be answered quickly to support rapid development of comparator technologies and products, establishing clear rules on ensuring access to comparator products will contribute to enabling the relevant clinical trials.* *We therefore call on the governments negotiating the accord to reinstate Article 9.3(h) on access to comparator products.*
4. Each Party shall develop and implement national policies to support the transparent, open public sharing of research inputs, outputs and processes from publicly funded pandemic related products R&D.	5. Each Party shall, in accordance with national law, support the transparent and public sharing of research inputs and outputs from research and development of government-funded pandemic-related products, including scientific publications with data shared and stored securely.	*The revised Article 9.4 reads vague and open to interpretation and does not reflect the scope of, and the merits previously contained in, Article 9.3 (f). The following revisions are needed to improve 9.4:* • *Requirements for public sharing of clinical protocols and results should be included.* • *Transparency requirements should not be restricted only to pandemic-related R&D and publicly funded R&D – this should be applied to all R&D, including R&D initiatives that may not be immediately or clearly linked to a pandemic. This is important considering that the relevance of research to a pandemic may only become apparent when pathogens are tested.* • *The wording of "in accordance with national law" should be removed as it could lead to misunderstanding and diverse interpretations on the level of obligation concerned.*

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-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.	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 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.	*Compared to the February draft, the current text contains both improvements and drawbacks.* *First, instead of establishing a direct obligation as in the previous draft, the current text only requires each Party to develop national policies on including access provisions in government-funded R&D agreements. Therefore, even if the earlier qualifying words of "in accordance with its national laws and considering the extent of funding provided" are removed as a positive step, the overall obligation in the current text is weaker.* *Second, Article 9.6 (a) contains improvements compared to 9.5 (a) in previous draft as it includes examples of provisions that can be attached to government-funded R&D agreements.* *Further improvements can be made to 9.6 (a) by:* • *Including transparency requirements for information such as costs of production and prices of medical products as part of the public funding provisions. MSF has published more 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* • *Removing "on voluntary terms" from (iii) as it is confusing and unnecessary. Provisions in government funding agreements should*

		unambiguously require recipients of funding to carry out technology transfer. • *Removing "during pandemic emergency or PHEIC" when introducing 9.6 (a) to avoid misunderstanding on the applicable timeframe of the obligation. Access provisions are needed at all times, both before and during a pandemic/PHEIC, so that these provisions can safeguard equitable access to relevant R&D outputs or resulting products rapidly. If access provisions are attached only after an emergency occurs, it may be too late.* *Finally, on 9.6 (b), we welcome the retained text, and suggest improvement by removing "during a pandemic" so that publication of relevant terms of public funding agreements is required at all times as a key strategy to ensure preparedness.*
Article 11 Transfer of Technology	**Article 11 Transfer of Technology and Know-how**	
1. In order to enable sufficient, sustainable, and geographically-diversified production of 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;	1. In order to enable sufficient, sustainable and geographically-diversified 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	*We welcome the removal of "voluntary and on mutually agreed terms" in Article 11.1 concerning transfer of technology and licensing. However, the overall obligation is still not strong enough.* *On 11.1 (a), governments should be able to ask public funding recipients to carry out transfer of technology and know-how more directly, and not merely "promote" it. A stronger obligation here can also reinforce the effectiveness of Article 9.6 concerning including provisions in government-funded R&D agreements.*

	received public funding for their development;	
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;	*Stronger wording should be used to replace "promote".* *The wording of "in accordance with national laws" should be removed to avoid diverse interpretations and inconsistent implementation.*
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	*The wording in this sub-section can be improved by removing "on mutually agreed terms" in order to provide greater clarity to the text.* *The term "government-owned pandemic-related products" is questionable compared to the term "technologies" used in the previous version. Governments may have ownership of underlying technologies, platforms and other technological elements that are necessary to support product development and productions, which can be licensed. For instance, during the COVID pandemic, the Spanish National Research Council and the National Institute of Health of the United States licensed important technologies they owned to the WHO C-TAP.*[4,5] *Therefore, we recommend the term "products" be replaced by "technologies".* *The wording of "in accordance with each Party's national laws and regulations" should be removed to avoid diverse interpretations and inconsistent implementation.*

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.	*We welcome reintroduced text concerning time-bound IP waivers in 11.3 (b).* *MSF's comments on how this can be strengthened can be referred to here: https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text*
5. The Parties ~~reaffirm~~ recognize that WTO Members have the right to use to the full, the flexibilities inherent in the TRIPS 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	4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the 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.	*We welcome the reintroduction of "shall fully respect the use thereof by others" in the language on TRIPS flexibilities. This should stay in the final text of the agreement.* *The removal of the reference to the TRIPS Agreement amendment that entered into force in 2017 is an improvement as mentioning it separately is redundant and can lead to misunderstanding.*

Decision on 6 December 2005 and entered into force on 23 January 2017.		
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.	*We welcome the retention of text in 11.5 concerning reviewing and updating national laws to allow timely and effective use of flexibilities for access. This can be improved by removing the restriction on the use of flexibilities to only those referred to in 11.4 of the TRIPS Agreement, because other international instruments also contain flexibilities on IP that are supportive of the objectives of the agreement.*
	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; (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	*On 12.6 (b), we welcome the text on real-time contribution of supplies by manufacturers in order to support the PABS system during both PHEIC and pandemics as a binding condition. However, requiring a fixed proportion of the total quantity remains questionable.* *While Article 12.4 (4) in INB's October 2023 proposal for negotiating text stated that the 20% contribution is "the minimum", rather than the ceiling, the current text no longer contains this clarification.* *We suggest a more open-ended approach based on a rolling assessment of needs in order to ensure contributions by manufacturers to the PABS system are sufficient. For more details, please see our earlier comments on the issue here:https://msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-inb-proposal-negotiating-text*

	(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.	
	9. During a pandemic, each 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.	*We welcome this very positive provision.* *To improve clarity of the objective of each Article, we suggest moving Article 12.9 into Art 13 (possibly under 13.4 (g)) and cross-referencing it in Article 13bis concerning national procurement.* *Setting aside a portion of national procurement for global access needs can be independent of the PABS system, so it is more suitable to place this text in Article 13. The portion set aside should be considered as one more source for coordinated supply and allocation by the Global Supply Chain and Logistics Network.*
Article 13 Global supply chain network	**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.	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	*We welcome the retention of language concerning "special attention to the needs of developing countries, including those in fragile and humanitarian settings."*

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.	Network shall pay particular attention to the needs of developing countries, including those in fragile and humanitarian settings.	
2. The Network shall develop modalities aimed at ensuring the 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.	2. The Conference of the Parties shall, at its first 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.	*Compared to Article 13.2 in the February draft, the current text clarifies that the Conference of the Parties (COP), instead of the Network itself, is responsible for defining the structure and modalities of the Network. This provides a clearer governance framework.* *However, the structure and modalities will be discussed only at the first COP, which will be organised no later than one year after the entry into force of the agreement (upon ratification by 40 States). The modality to be discussed under 13.2 should also include core responsibilities of Parties and WHO member states, if not yet a Party to the agreement, in supporting and assisting the operation of the Network, and to include mechanisms for civil society to participate in the decision making and governance of the Network.*
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 operationalization of the Network, including the support provided by Parties and other stakeholders during and between pandemics.	*We welcome the retained text on transparency in 13.4 (d).* *It can be improved by:* • *being more explicit or providing key examples of "other data", especially concerning*

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;	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;	*manufacturing capacity, production and supply schedules, relevant licensing and technology transfer agreements, for the purpose of pursuing the maximum level of transparency to support effective coordination and collaboration under Article 13; and* • *making the requirement applicable not only for the Network, but also for the Parties.*
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;	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;	*We welcome the inclusion of earmarked stockpiles for humanitarian settings.*
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;	(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 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;	*We welcome the clear reference to Article 12 and 13bis in the context of equitable allocation.* *Incorporating humanitarian needs as a paramount consideration in the equitable stockpiling, allocation, delivery and use of pandemic-related products is essential.* *The text can be improved by:* • *Including "humanitarian needs" in Article 13.4 (g) as an additional factor to consider for equitable allocation;* • *Moving Article 12.9 into Article 13 (possibly under 13.4 (g)) and by cross-referencing it in Article 13bis concerning national procurement. Setting aside a portion of national procurement for global*

		access needs can be independent of the PABS system so it is more suitable to place this text in Article 13. The portion set aside should be considered as one more source for coordinated allocation by the Network; and • *Making a reference to Article 10 (sustainable and geographically diversified production) so that improved production capacity can contribute to the Network.*
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;	(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	*We welcome the inclusion of "humanitarian settings" in the context of delivery and distribution.*
	Article 13*bis*: National procurement- and distribution-related provisions	
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.	*This is a welcome provision.* *Compared to the February draft, the obligation to exclude confidentiality provisions in public procurement agreements has been improved by deleting "endeavour to" and "unwarranted".* *We also welcome the "encourage regional and global purchasing mechanisms to do the same" language as it is an important step towards consistency in practice. To further improve this provision, the text could go beyond "encourage" as it is feasible for governments to leverage*

		their role in relevant regional and global purchasing mechanisms to establish transparent publication of purchase terms and exclusion of confidentiality as a standard practice. *To avoid diverse interpretations and provide greater certainty, the qualifying wording of "in accordance with applicable laws" could be removed.*
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 the products.	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 the products.	*We welcome the provision to set out practical terms of leveraging public purchase agreements for global access needs.*
	4. The Parties commit to ensure rapid and unimpeded access of humanitarian relief personnel, as well as their means of	*We welcome the reinstatement of the provision concerning ensuring humanitarian assistance, which had been deleted in the February draft.*

	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.	*However, it is imperative to **avoid any potential setback from previous versions of the draft** (Article 13.8 of the October 2023 version INB draft text, A/INB/7/3) **and the downgrading of IHL**. We suggest refraining from creating a whitelist of "recognized humanitarian organisations," which could compromise the principles of independence and impartiality as enshrined in IHL. Instead, we advocate language that reflects the pre-existing obligations of States with respect to IHL and the organisations covered by it, **by removing the word "recognized" and replacing it with the word "impartial" or similar wording as found in the provisions of IHL and in various UNSC resolutions**.*
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.	*We welcome this provision.* *The text can be improved by deleting "unnecessarily" as it adds a condition that is gratuitous and may lead to litigation that will delay product distribution and reallocation.* *Also, for example, national or biosecurity interests could be considered a "necessary" condition under this provision and would not enable stockpiles to be managed only based on health needs.*
Article 15 Compensation and Liability Management	**Article 15 Liability and compensation 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	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	*Despite the language on special consideration of individuals in humanitarian settings concerning the non-fault compensation (Article 15.2), the new article 15 represents a **huge step backwards** compared to the previous versions for two main reasons :* • *there is no longer any framework/redlines to the transfer of liability from the vaccine manufacturers*

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 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.	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 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.	*to the purchasers. Such transfer of liability seems now to be viewed as an accepted and "normal" practice (no reference to an exceptional measure, no time limitation, no exception for humanitarian actors who do not have the financial capacity to bear such risks, etc.); and* • *the obligations in Article 15 have been significantly softened, shifting from a firm commitment by the parties to mere "encouragements" ("shall consider developing" / "shall develop recommendations").*

Article 29. Reservations	**Article 27 Reservation**	
No reservations may be made to the WHO Pandemic Agreement [unless permitted by other articles of the WHO Pandemic Agreement].	1. Reservations may be made to the WHO Pandemic Agreement unless incompatible with the object and purpose of the WHO Pandemic Agreement 2. Notwithstanding paragraph 1 of this Article, no reservation may be made to Article XX, Article YY, or Article ZZ of the WHO Pandemic Agreement.	*The text has changed from allowing no reservations to the agreement in the February draft to Article 27 in the current version where reservation is allowed.* *It is imperative for the negotiating parties to clarify the essential articles that should not be reserved, according to 27.2.*

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