

Annex 2: Key Comments by MSF on Selected Provisions of the Zero Draft of the Pandemic Accord

Zero draft text of selected provisions	Key Comments
Preamble	
4. “Recalling the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, and that unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger”	The notion that “unequal development in different countries” is a “common danger” paves the way to establishing CBDR and addressing inequity.
25. “Noting that antimicrobial resistance is often described as a silent pandemic and that it could be an aggravating factor during a pandemic”	It describes AMR as “a silent pandemic” and “an aggravating factor during a pandemic”, but does not clarify whether AMR is indeed a pandemic as defined by the accord nor specify the nature of the public health impact of AMR on other pandemics, or vice versa.
32. “Acknowledging that there are significant differences in countries’ capacities to prevent, prepare for, respond to and recover from pandemics”	Paves the way for CBDR.
No text recalling the WHA 72.8 transparency resolution.	Transparency resolution WHA 72.8 should be recalled in the preamble.
Chapter I. Introduction	
Article 1. Definitions and use of terms	
1. For the purposes of this WHO CA+: (b) “pandemic” means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality, and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control”	Criteria such as “overwhelming health systems” and “social and economic interruptions” have no objective or commonly used metrics, which as a result may be interpreted subjectively based on diverse methodologies and context. This suggests that it may be inappropriately difficult to trigger this accord, thereby increasing the likelihood of delaying the use of mechanisms under the accord for emergency response and resource mobilisation.

<p><i>Footnote:</i> <i>“The INB is encouraged to conduct discussions on the matter of the declaration of a “pandemic” by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with the International Health Regulations and other relevant mechanisms and instruments. In this connection see Article 15.2 hereof.”</i></p>	<p>The ambiguity in the current definition of “pandemic” also increases the risk of limiting the use of mechanisms established under the accord to only in the most exceptional situations. Particularly, provisions to increase and ensure equity included in the accord should not be considered exclusive to PPR, but should be considered as the baseline provisions to ensure access to all medical products for all.</p> <p>The modalities and terms of the declaration of a pandemic, as referenced in the footnote to the definition of “pandemic” and in relation to Article 15.2, will require clarity not only on the declaration of a pandemic, but also on the determination of when a pandemic has ended, similar to those undertaken under Articles 12 and 49 of the International Health Regulation (IHR).</p>
<p>(c) “pandemic-related products” means products that may be needed for pandemic prevention, preparedness, response and/or recovery, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;</p>	<p>The scope of the definition of “pandemic-related products” [Article 1(c)] should be expanded, and incorporate subject matter also proposed under the IHR amendment process. For example, components, materials, parts, antibiotics, data and know-how needed for production should all be included in this definition. In addition, the scope should include existing products tackling possible new outbreaks of existing pathogens and new variants, including repurposed medicines.</p>
<p>Article 4. Guiding principles and rights</p>	
<p>6. Transparency</p> <p>“The effective prevention of, preparedness for and response to pandemics depends on transparent, open and timely sharing, access to and disclosure of accurate information, data and other relevant elements that may come to light (including biological samples, genomic sequence data and clinical trial results), for risk assessment and control measures, and development of pandemic-related products and services, notably through a whole-of-government and whole-of-society approach, based on, and guided by, the best-available scientific evidence, consistent with national, regional and international privacy and data protection rules, regulations and laws.”</p>	<p>The scope of this principle is very limited and does not include elements critical to ensuring accountability and equitable access to medical products. It does not establish an obligation for states to create a legal and regulatory framework to make important information publicly available, nor recognise people’s right to information. This limited scope is not in line with the World Health Assembly 72 resolution on transparency (WHA 72.8), and weakens other provisions in the draft, particularly Articles 6.3(b), 7, 9.2, 9.3 and 9.7 in Chapter III.</p>

	<p>In addition to transparency requirements outlined in WHA 72.8, transparency requirements should also include the following:</p> <ul style="list-style-type: none"> • Full research and development (R&D) costs, including clinical trial costs – including but not limited to public funding contributions. • Full contractual terms of R&D funding, supply and purchase agreements (without confidentiality provisions which limit disclosure of terms and conditions). • IP licensing, sub-licensing and technology transfer agreements. • All information pertaining to IP, including but not limited to patent information. • Costs of production. • Information on supply capacities, forecasts and delivery schedules. • Information on supply, stock management, allocation and coordination. • Governance documents of global health institutions and other relevant bodies involved in PPR.
<p>8. Common but differentiated responsibilities and capabilities in pandemic prevention, preparedness, response and recovery of health systems</p> <p>“All States are responsible for the health of their people, including pandemic prevention, preparedness, response and recovery, and previous pandemics have demonstrated that no one is safe until everyone is safe. Given that the health of all peoples is dependent on the fullest cooperation of individuals and States, all Parties are bound by the obligations of the WHO CA+. States that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, should bear, where appropriate, a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery. With the aim of supporting every Party to achieve the highest level of proven and sustained capacity, full consideration and</p>	<p>Including CBDR as a key guiding principle for the INB negotiation is fully justifiable whereby achieving equity is both a principle, an objective and substantively articulated under Chapter III.</p> <p>However, this important principle needs to be more clearly articulated in subsequent provisions.</p> <p>Explicit language concretely differentiating responsibilities between developed and developing countries specific to issues of transfer of technology, removing IP barriers, increasing R&D capacities, increasing local and regional manufacturing capacities, supporting national action plans on AMR and financing for PPR, under Chapter III, V, VI is currently missing. Introducing such provisions in greater detail will clarify the</p>

<p>prioritization are required of the specific needs and special circumstances of developing country Parties, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities to respond to pandemics; and (iii) potentially bear a disproportionately high burden.”</p>	<p>nature of states’ obligations and may provide useful guidance to meet those obligations.</p>
<p>Article 5. Scope</p> <p>“The WHO CA+ applies to pandemic prevention, preparedness, response and health systems recovery at national, regional and international levels.”</p>	<p>Whether the accord addresses only future pandemics or present inequities also is unclear. For ongoing outbreaks/known pathogens, there are existing challenges related to equitable access to technologies and medical tools needed to tackle them.</p>
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<p>Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems</p>	
<p>Article 6. Predictable global supply chain and logistics network</p>	
<p>2. “The WHO Global Pandemic Supply Chain and Logistics Network (the “Network”) is hereby established.”</p>	<p>Missing throughout Article 6 and other articles is any provision to address the issue of hoarding of health products.</p> <p>Hoarding can be conceived as a reactive action, leading to obtaining or retaining more of a critical health product or technology in limited supply than is reasonably necessary to meet domestic needs at a time insufficient supplies are available to meet immediate needs elsewhere.</p>
<p>3. The Parties shall support the Network’s development and operationalization, and participate in the Network, within the framework of WHO, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic. In that regard, the Parties shall:</p> <p>(a) “determine the types and size of products needed for robust pandemic prevention, preparedness and response, including costs and logistics for establishing and maintaining strategic stockpiles of such products, by working with relevant stakeholders and experts, guided by scientific evidence and regular epidemiological risk assessments”</p>	<ul style="list-style-type: none"> • The current language does not specify the scope of “products”, namely whether it includes existing products, products in the development pipeline and potential future products, or only covers some of these categories. • It does not clarify the coordination between global and national stockpiling of scarce resources that are widely needed during a pandemic or other public health crisis, particularly with countries who have more resources and/or host key suppliers. • It is unclear how “relevant stakeholders and experts” will be selected and how it will be ensured that the most affected countries play leading roles in decision making.

<p>(c) “develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs”</p>	<ul style="list-style-type: none"> • It is unclear whether “the fair and equitable allocation” mechanism only addresses allocation of the supplies from the strategic stockpile of the WHO Network, or if it also covers additional supply sources from national and regional procurement mechanisms. • It is also unclear how priorities of this mechanism will be determined so that the needs of vulnerable and at-risk groups, such as health workers, and of people living in humanitarian contexts, are prioritised from the very beginning.
<p>Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how</p>	
	<p>Article 7 lacks provisions on transparency of IP information, licensing and technology transfer agreements, and does not include measures to ensure sustainable support for and maintenance of manufacturing and supply capacities, including those to address access challenges for existing medicines.</p> <p>There should be a new clause added under Article 7 to specify the transparency requirements.</p>
<p>1. “The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed.”</p>	<ul style="list-style-type: none"> • It does not specify who makes decisions on manufacturing, nor mention the need to address the root cause of inequity: technology ownership associated with IP, including patents and non-patent IP such as trade secrets, and licensing practices. • It focuses only on manufacturing, and misses the dimensions of “supply” and “distribution”. • Limiting the need to increase manufacturing capacity to “pandemic-related products” alone is problematic. • It is important to address the issue of maintaining these capacities and addressing access challenges around existing health products.
<p>2. “The Parties, working through the Governing Body for the WHO CA+, shall strengthen existing and develop innovative multilateral mechanisms that promote and incentivize relevant transfer of technology and know-how for production of pandemic-related products, on mutually agreed terms, to capable manufacturers, particularly in developing countries.”</p>	<p>Establishing a treaty obligation on technology transfer, which primarily applies to states, based on “mutually agreed terms” mostly with the private sector, is inappropriate. Such language should be deleted.</p>

<p>3. During inter-pandemic times, all Parties commit to establish these mechanisms and shall:</p> <p>(a) “coordinate, collaborate, facilitate and incentivize manufacturers of pandemic-related products to transfer relevant technology and know-how to capable manufacturer(s) (as defined below) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to address the needs to develop new pandemic-related products in a short time frame”</p>	<ul style="list-style-type: none"> • Establishing a treaty obligation on technology transfer, which primarily applies to states, based on “mutually agreed terms” mostly with the private sector, is inappropriate. Such language should be deleted. • The division of “inter-pandemic” and “pandemic” is problematic for technology transfer because it is not only needed during inter-pandemic times, but also during the pandemic.
<p>(c) “encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for pre-pandemic and pandemic-related products”</p>	<ul style="list-style-type: none"> • The current wording of states obligation to “encourage” risks repeating the shortcoming under other international instruments concerning technology transfer, such as Article 66.2 of the TRIPS Agreement. Article 66.2 of the TRIPS Agreement only requires developed country WTO members to provide “<u>incentive</u>” to enterprises in their territories “for the purpose of <u>promoting and encouraging</u> technology transfer to least-developed countries” (emphasis added). The multiple layers of concessions have resulted in the overall absence of a more direct and concrete obligation to require and ensure the transfer of technology beyond encouraging voluntary actions, and therefore led to a relatively low level of effective implementation of technology transfer. • MSF’s experiences have repeatedly shown that when pharmaceutical corporations are the main decision makers on the terms and conditions for dissemination of health technologies, it is inherently challenging to ensure access based on health needs of people. • Non-exclusive licensing is not only needed during inter-pandemic times, but also during the pandemic
<p>4. In the event of a pandemic, the Parties:</p> <p>(a) “will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products”</p>	<ul style="list-style-type: none"> • the inclusion of “intellectual property rights” is positive as it could enable the removal of all major IP barriers, and not just patents • The wording is not singling out any particular type of product. This is a useful improvement on the decision made during the 12th Ministerial Conference of WTO on the TRIPS Agreement in June 2022, which covered a limited scope of products. • It should be clarified whether “waivers” would release states from their obligation to implement certain IP protections under their

	<p>national laws, or if they aim to suspend exclusive rights associated with IP.</p> <ul style="list-style-type: none"> • The wording of “<u>adequacy of affordable</u> pandemic-related products” (emphasis added) is confusing.
<p>(b) “will apply the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement”</p>	<ul style="list-style-type: none"> • The division of “inter-pandemic” and “pandemic” is problematic for TRIPS flexibilities because they can be used not only during pandemic, but also inter-pandemic times. • Flexibilities should not be limited to specific clauses under the TRIPS Agreement. Instead, a more open-ended approach could be more helpful and support the use of all types of flexibilities contained in the TRIPS Agreement and other international laws based on national discretion.
<p>Article 9. Increasing research and development capacities</p>	
	<ul style="list-style-type: none"> • There should be a new provision that strengthens WHO’s role in coordinating the priority setting of R&D based on public health needs, providing guidance to funding priorities accordingly, and supporting international clinical trials. Developing countries and regional bodies should be supported to play a leading role in this process. • The zero draft lacks responsibilities directed towards R&D and access activities carried out by NSAs, the private sector, funding agencies, product development partnerships and other global health actors that are also often recipients of public funds for R&D. Particularly for PPR, it is important that organisations such as CEPI, Gavi, BMGF and other private and philanthropic organisations that carry out R&D and/or procure health products are also held accountable by the clauses and principles of the PPR accord.
<p>2. “With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received”</p>	<ul style="list-style-type: none"> • Transparency requirements should not be limited to “the extent of the public funding received”. These limitations may lead to challenges in implementation because it is common to have mixed funding sources, and disclosing information based on the extent of certain types of funding may turn out to be impractical. • Instead of basing transparency requirements solely on the proportion of public funding received, disclosing this essential information at all

	<p>times when public funds are contributed should be a stand-alone accountability provision.</p>
<p>(b) “endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms”</p>	<ul style="list-style-type: none"> • “Terms” and “conditions” under (b) and (e) are overlap, yet the relationship between the two sub-sections is unclear. • The text should go beyond requiring states to “endeavour” to include “appropriate” access conditions to publicly funded R&D. Instead, states should require a set of minimum binding and publicly available access conditions to be adopted by all funders. This should include, in particular: <ul style="list-style-type: none"> ○ Affordable and transparent pricing requirement of end products (a cost of goods plus reasonable margin or no profit-no loss during a public health emergency can serve as models) ○ Non-exclusive licensing/technology transfer requirement to ensure diversity of manufacturing and supplying ○ Funders’ retention of rights linked to the research funded, including those that would mandate them to license technology, IP and know-how if the manufacturer’s supply doesn’t meet demand in a timely manner or is not reasonably priced (taking reference to the so called “march-in rights”) ○ Transparency requirements, including publication of full R&D costs, clinical trial costs, clinical trial protocols and disaggregated preclinical and clinical trial results data, subsequent IP licensing, sub-licensing and technology transfer agreements, prices and costs of production, and information on supply capacities and delivery schedules. Critically, the full contractual terms of the R&D funding agreement itself should be published in their entirety. ○ Access plans and transparent indicators which encompass registering and making available the drugs, vaccines or diagnostics, particularly where the clinical trials have been hosted ○ Timely access to comparator drugs, tests, assays or vaccines needed for comparison studies, regulatory approvals and/or R&D

<p>(e) “establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies.”</p>	<p>See above.</p>
<p>3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by:</p> <p>(b) “making it compulsory for manufacturers that receive public funding for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics, taking into account the extent of the public funding received”</p>	<ul style="list-style-type: none"> • The concept of “manufacturers” is too narrow and should be expanded to encompass research and procurement organisations (public or private), including when R&D is carried out through product development partnerships, by the private sector and other international organisations, such as UNITAID, CEPI, GAVI etc. • Requirement for disclosure only to “the extent of the public funding received” is insufficient.
<p>(c) “encouraging manufacturers that receive other funds, external to the manufacturer, for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics.”</p>	<p>See above</p>
<p>7. “In the conclusion of contracts for the supply or purchase of pandemic-related products, each Party shall endeavour to exclude confidentiality provisions that serve to limit disclosure of terms and conditions.”</p>	<p>Limiting this provision to “endeavour to exclude” only is contradictory to the guiding principle of transparency.</p> <p>States should prohibit the inclusion of confidentiality provisions in public supply and procurement contracts, particularly during public health emergencies. This should be extended to prohibiting confidentiality clauses in IP licensing and technology transfer agreements concerning health technologies, particularly those signed with public entities, including government agencies, universities and other public research institutions.</p> <p>There should be a positive obligation for states to review national laws concerning freedom of information, trade secrets and confidentiality, to ensure sufficient safeguards for the public interest and the public’s right to information.</p>
<p>10. “The Parties acknowledge the need to take steps, individually and collectively, to develop strong, resilient national, regional and international</p>	<p>Missing entirely under Article 9 on transparency in the R&D context is the requirement for disclosure of clinical trial costs by all research entities.</p>

<p>clinical research ecosystems. In that regard, the Parties, as appropriate, commit to:”</p>	<p>A sub-section to mandate disclosure of clinical trial costs needs to be added to Article 9.10 concerning clinical trial governance.</p>
<p>(c) “supporting transparent and rapid reporting of clinical research and clinical trial results, to ensure evidence is available in a timely manner to inform national, regional and international decision-making”</p>	<p>The accord provides an opportunity to strengthen existing WHO mechanisms in relation to transparency on R&D. Especially, the WHO Observatory on Health Research and Development should be mandated to capture and publish disaggregated costs of clinical trials, while its current mandate remains limited in this regard.</p>
<p>Article 10. WHO Pathogen Access and Benefit-Sharing System</p>	
<p>1. “The need for a multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with pandemic potential and genomic sequences, and benefits arising therefrom, that applies and operates in both inter-pandemic and pandemic times, is hereby recognized. In pursuit thereof, it is agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the “PABS System”) under this WHO CA+. The Parties are mindful that the PABS System, or parts thereof, could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The terms of the PABS System shall be developed no later than XX with a view to their provisional application consistent with Article 35 hereof.”</p>	<p>It is not appropriate, as the zero draft outlines, that the PABS mechanism proposed is to be “developed no later than XX” and not within the negotiations timetable of the INB, as well as without clarity around which body/structure of WHO would negotiate and develop the mechanism.</p>
<p>2. “The PABS System shall cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits arising therefrom, and ensure that it operates synergistically with other relevant access and benefit-sharing instruments.”</p>	<ul style="list-style-type: none"> • For the R&D of health technologies, materials that hold value go beyond pathogens and genomic sequences. Particularly, samples, data and information, including different materials within blood samples such as plasma and white blood cells, are collected from patients and used for R&D. Therefore, the scope of materials to be included under PABS should be expanded to include biological materials/samples, data and information.

	<ul style="list-style-type: none"> • The PABS mechanism should be operationalised such that current access challenges to existing medical products used for known pathogens with pandemic potential can be addressed.
<p>3. The PABS System shall include the following elements and shall be regulated as follows:</p> <p><i>Access to pathogens with pandemic potential</i></p> <p>(b) “The PABS System will be consistent with international legal frameworks, notably those for collection of patient specimens, material and data, and will promote effective, standardized, real-time global and regional platforms that promote findable, accessible, interoperable and reusable data available to all Parties”</p>	<ul style="list-style-type: none"> • There should be explicit commitment to principles that relate to the collection, recording, processing, storage and transmission of biological specimens, material and personal data so that it is undertaken in a lawful and fair manner. These processes should be governed by robust data security mechanisms and controls, benchmarked against national and international standards, to protect the privacy and rights of the data subjects. • Existing non-binding guidelines of Council for International Organizations of Medical Sciences (CIOMS) should be integrated as enforceable measures in the PPR accord. • Access to biological material and data should be in accordance with applicable ethical standards and approvals, including international best practice relating to medical confidentiality, medical ethics, privacy, medical research, data protection and data access, without limiting the duties to cause no harm to individuals and groups, to respect patients’ autonomy, patient confidentiality and the patients’ right to informed consent. • Additional provisions are also needed to specify the protection and empowerment of communities and patients in the governance and decision making of PABS.
<p>(d) “Recipients of materials shall not claim any intellectual property or other rights that limit the facilitated access to pathogens with pandemic potential, or their genomic sequences or components, in the form received”</p>	<p>The notion that IP should not be claimed as it may create barriers to access is welcomed. However, the no-IP strategy should be supported more broadly and ambitiously with the aim of establishing the norms of open science and knowledge sharing.</p> <p>The qualifying phrase, “in the form received”, leaves open the possibility of commercial entities claiming IP on derivative forms of the “materials” received. This is a clear problem with respect to maximising access options to the end product.</p> <p>There are also no further supporting clauses included to specify how compliance by both non-commercial and commercial entities receiving materials from the PABS mechanism can be guaranteed, and how</p>

	<p>traceability of those materials will be ensured to retain vigilance over the possible IP barriers that can limit access to the end products.</p> <p>For tracking and accountability purposes, states should consider introducing requirements of disclosing the origin of the pathogens, materials and/or samples during different steps of the health technology R&D and access, including during filing of patents for health technologies (if appropriate).</p>
<p>(e) “Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws.”</p>	<p>It misses the opportunity to connect Article 10 with the use of IP flexibilities and safeguards to facilitate access to technologies. Additional provisions are also needed to specify the minimum standards of licensing of IP-protected pathogens in the PABS context.</p> <p>In addition, non-exclusive licensing of IP protected technologies or open-source licensing should be considered as part of the benefit sharing obligations, as mentioned above.</p>
<p><i>Fair and equitable benefit-sharing</i></p> <p>(h) “Such options shall include, but not be limited to: (i) real-time access by WHO to 20% of the production of safe, efficacious and effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics, to enable equitable distribution, in particular to developing countries, according to public health risk and need and national plans that identify priority populations. The pandemic-related products shall be provided to WHO on the following basis: 10% as a donation and 10% at affordable prices to WHO; (ii) commitments by the countries where manufacturing facilities are located that they will facilitate the shipment to WHO of these pandemic-related products by the manufacturers within their jurisdiction, according to schedules to be agreed between WHO and manufacturers.”</p>	<p>This is a welcome clause aimed at strengthening WHO’s capacity to operationalise the WHO Network, stockpiling and equitable allocation. However, “20% of the production” may prove insufficient for developing countries’ needs and therefore not address existing inequities.</p> <p>It is important not to make 20% the ceiling, and to instead maintain an open-ended approach to facilitate a more appropriate distribution based on a rolling assessment of evolving needs, especially those of vulnerable and priority groups, including the health workforce.</p> <p>“10% as a donation and 10% at affordable prices” can be problematic due to the inherent limitations of donations.</p> <p>Benefit sharing conditions should go beyond supplying to WHO. Options that can enhance local and regional R&D, access to know-how, manufacturing and supplying capacities, non-exclusive IP licensing, registration of product in countries/regions where clinical trials are carried out, and monetary contributions to establish a R&D fund, should be included as part of a core package of benefit sharing obligations.</p>

<p><i>Recognition of the PABS System as a specialized international instrument</i></p> <p>(i) “The PABS System, adopted under the WHO Constitution, is established with a view to its recognition as a specialized international access and benefit-sharing instrument within the meaning of the Nagoya Protocol”</p>	<p>The PABS mechanism should expand benefit sharing options, referring to those under the Nagoya Protocol and WHO PIP framework, including both monetary and non-monetary measures, such as transfer of technology and process, affordable pricing and laboratory/surveillance capacity building.</p>
<p>Article 15. Global coordination, collaboration and cooperation</p>	
<p>2. “Recognizing the central role of WHO as the directing and coordinating authority on international health work, and mindful of the need for coordination with regional organizations, entities in the United Nations system and other intergovernmental organizations, the WHO Director-General shall, in accordance with terms set out herein, declare pandemics.”</p> <p><i>Footnote: Reference is made to footnote 3 (Article 1), which invites the INB to propose and consider the development of modalities and terms for this provision.</i></p>	<p>The modalities and terms of the declaration of a pandemic, as referenced in the footnote to the definition of “pandemic” and in relation to Article 15.2, will require clarity not only on the declaration of a pandemic, but also on the determination of when a pandemic has ended, similar to those undertaken under Articles 12 and 49 of the International Health Regulation (IHR).</p>
<p>Article 18. One Health</p>	
<p>1. “The Parties, recognizing that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, commit, in the context of pandemic prevention, preparedness, response and recovery of health systems, to promote and implement a One Health approach that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives.”</p>	<p>The zero draft makes no reference to the existing Global Action Plan on AMR adopted during the WHA in 2015, which contains many important objectives and mechanisms specifically designed to tackle AMR issues, such as antimicrobial stewardship. The accord should clearly incorporate mechanisms and objectives under the Global Action Plan on AMR.</p>
<p>6. “The Parties commit to strengthen multisectoral, coordinated, interoperable and integrated One Health surveillance systems and strengthen laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spill-over events, mutations and the risks associated with zoonotic neglected tropical and vector-borne diseases, with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic.”</p>	<ul style="list-style-type: none"> • Enhancement of infrastructure and laboratory capacity for surveillance should build on already existing systems, included those established or further developed during COVID. • Laboratory capacity on AMR should not be separate from the overall strengthening of laboratory capacity as specified under Article 11.4(g) in the context of health system strengthening. There should be coherent language used across different provisions. • There should be more concrete obligations and measurable indicators for how laboratory capacity can be strengthened. Obligations to

	address measurable financial and technical support, training of personnel, strengthening surveillance and monitoring systems in resource-poor settings, and developing integrated analysis of data across the human, animal and environment sectors that account for both viral and bacterial threats, should be a key priority.
7. “Each Party shall: (a) implement actions to prevent pandemics from pathogens resistant to antimicrobial agents, taking into account relevant tools and guidelines, through a One Health approach, and collaborate with relevant partners, including the Quadripartite”	The accord should mandate financial and technical support and capacity building to ensure the development, implementation and budgeting for national plans, especially for countries with limited resources. These obligations should be specified with measurable indicators and milestones to ensure accountability of governments and intergovernmental agencies, including the Quadripartite.
“(c) develop and implement a national One Health action plan on antimicrobial resistance that strengthens antimicrobial stewardship in the human and animal sectors, optimizes antimicrobial consumption, increases investment in, and promotes equitable and affordable access to, new medicines, diagnostic tools, vaccines and other interventions, strengthens infection prevention and control in health care settings and sanitation and biosecurity in livestock farms, and provides technical support to developing countries”	The accord should make clear reference to and incorporate the 2015 Global Action Plan on AMR, establishing explicit obligations and measurable indicators for states to implement, particularly to address financial and technical gaps to develop and implement national action plans on AMR.
“(d) enhance surveillance to identify and report on pathogens resistant to antimicrobial agents in humans, livestock and aquaculture that have pandemic potential, building on the existing global reporting systems”	As it is crucial to share pathogen data as stated under Articles 18.7 (d) and 11.4(d), a global framework is needed to ensure that any obligations to share such data are adequately matched with equally strong rights to access to medical products (or other benefits) that may emerge as a result of such data sharing and availability.