



Pandemic Accord: MSF's Comments on Equity Provisions in Zero Draft

Introduction

In light of the global impact of the COVID pandemic and the need to ensure better preparation for and a more effective response to future pandemics, the World Health Organization (WHO)'s 194 member states established a process to draft and negotiate an accord on pandemic prevention, preparedness and response (PPR). On 1 February 2023, the zero draft of the accord was published by the Intergovernmental Negotiating Body (INB).¹ Recognising the lack of solidarity and equity that marked the response to the COVID pandemic, the zero draft emphasises equity as “a principle, an indicator and an outcome” of PPR.

While the inequities witnessed during the COVID pandemic are staggering, they are hardly new. As an international medical humanitarian organisation working in more than 70 countries, Médecins Sans Frontières/Doctors Without Borders (MSF) has witnessed this time and time again – whether it is millions of people in low- and middle-income countries (LMICs) dying from HIV/AIDS despite the availability of lifesaving treatments; thousands of people dying from Ebola while promising vaccine candidates were deprioritised and left to gather dust in labs; or TB still killing someone on the globe every 20 seconds despite being declared a global emergency in 1993. As such, it is urgent that we work towards a more just global PPR infrastructure which requires concrete actions and transformative norms to change the status quo, so that lifesaving medical innovations and technologies are developed, produced and provided to people in need in a timely and equitable manner.

With this in mind, MSF's comments in this brief focus on the issue of equity as contained in the zero draft. The comments follow the structure of the draft, and pay particular attention to provisions related to transparency, intellectual property (IP), research and development (R&D), stockpiling and access and benefit sharing. They also cover issues related to antimicrobial resistance (AMR) as an integral part of PPR. The definitions in and scope of these provisions, as well as the coherence between them, are key to determining the extent to which the final accord can meaningfully address inequity.

Chapter I Introduction

Article 1 Definition and use of terms [Articles 1(b)(c)(e)(i)]

The zero draft lacks clarity in its definitions, and the resulting ambiguity may hamper the timely and appropriate implementation of the accord. Many key terms, such as “One Health”, remain undefined.

The draft defines “pandemic” as 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 the accord, thereby increasing the likelihood of delaying the use of mechanisms under the accord for emergency response and resource mobilisation.

The ambiguity in the current definition of “pandemic” also increases the risk of limiting the use of mechanisms established under the final accord to only the most exceptional situations. Particularly, provisions to increase and ensure equity included in the final accord should not be considered exclusive to PPR, but should be considered as the baseline provisions to ensure access to all medical products for everyone.

In addition, the division of “pandemic” and “inter-pandemic” periods is not entirely appropriate in supporting the use of measures aiming to increase and ensure equity. Most of the mechanisms that need to be established at the national, regional and international levels to strengthen systemic capabilities, particularly those under Chapter III, need to be done regardless of this division.

Furthermore, 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).ⁱⁱ This is vital to clarifying both the concept of “inter-pandemic” period and associated measures and the duration of exceptional measures in responding to emergencies, as well as to help challenge arbitrary declarations by relevant stakeholders. For instance, during the COVID pandemic, vaccine suppliers included contractual language around pricing, and in some cases public commitments around IP enforcement; however, without an objective reference for the end of the pandemic, some of these same companies ended or amended such commitments at their own discretion.^{iii,iv} In another example, vaccine manufacturers requested shifting their responsibility for legal liabilities to countries in the event of serious adverse events from vaccinations during the pandemic. There should be clear rules to regulate corporate liability issues during public health emergencies, particularly when sufficient safety data are available.^v

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.

Recommendations

- The definition of “pandemic” should exclude subjective aspects that could cause delay in qualification, and should not lead to limiting the use of mechanisms that need to be undertaken as a matter of routine.
- The division of “inter-pandemic” and “pandemic” needs to be revisited as it may not be entirely appropriate to support measures that need to be undertaken at all times for PPR.
- There should be greater clarity under both Article 1 and Article 15.2 on the procedures of declaration of both the beginning and the end of a pandemic, especially to avoid arbitrary claims by stakeholders.
- The definition of “pandemic-related products” should include components, materials, parts, cell-and-gene therapies, antibiotics, data and know-how needed for production; it should also cover existing products tackling potential new outbreaks of existing pathogens and new variants.

Chapter II Objective, guiding principles and scope

Article 4.6 Transparency (ref. to multiple provisions)

Ensuring transparency is the first step towards achieving accountability and equity. The lack of access to timely, critical information undermined the COVID pandemic response in a multitude of ways; this ultimately undermined accountability and the attainment of equity.

As it stands, transparency is included in the draft as a guiding principle, and in multiple subsequent provisions in the draft. However, the principle and subsequent provisions are narrow and insufficient, and miss the opportunity to cement the need for transparency and access to information as a critical gateway to accountability and equity.

Transparency as a guiding principle (Article 4.6)

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.^{vi} The guiding principle and these subsequent provisions should be revised and expanded to encompass transparency requirements, including those in WHA72.8, as detailed in Annex 2.^{vi}

The need for full transparency of contracts, license and sub-license agreements: The case of the Oxford/AstraZeneca license on COVID vaccine

The Oxford-AstraZeneca COVID vaccine received over US\$2 billion in public funding to support its development and as part of advance purchase agreements.^{vii,viii,ix} Despite early assurances from researchers and published guidance at University of Oxford^x that they were committed to maximising access to their vaccine through non-exclusive IP^{xi} licensing on the vaccine technology to enable production and supply, they later signed an exclusive IP license with the UK-based pharmaceutical corporation AstraZeneca.^{xii} This exclusive license was not made public, so the terms that were agreed with AstraZeneca were not known. While AstraZeneca claimed that they would not make a profit from the vaccine during the pandemic period, there was no evidence to substantiate these claims, and there were no assurances given about the price after the pandemic was to be declared "over".ⁱⁱⁱ Following the exclusive license agreement with Oxford, AstraZeneca went on to agree multiple sub-license agreements with other vaccine manufacturers, including the Serum Institute of India (SII) and Fiocruz in Brazil. The terms of these sub-licenses were also unknown. This made it impossible to understand the global supply landscape for this vaccine, sustainability of supply, technology transfer arrangements, which countries were in the license agreements, and what the price of the vaccine would be.

Following multiple Freedom of Information (FOI) requests, and a subsequent formal complaint in the public interest, University of Oxford published a redacted version of their exclusive license with AstraZeneca.^{xiii} Most of the critical information needed to determine global supply, prices and access was redacted. It wasn't until a later leak of the AstraZeneca-Fiocruz sub-license that it became clear that commitments to no-profit prices were not upheld in sub-license agreements, and the "pandemic period" during which they had committed to making no profits, was pre-defined by AstraZeneca.^{xiv} The full terms of the sub-license agreement with SII are still not publicly known. An initial vaccine supply agreement between the UK and AstraZeneca was also published with critical information redacted, despite the UK committing over £88 million for the research, development and manufacture of this vaccine.^{xv,vii}

Eventually, some of the terms that were agreed in these agreements and licenses would become clear - particularly for prices – which, despite AstraZeneca’s early verbal commitments to “no-profit pricing”, seemed to vary from US\$2-\$7 between countries and manufacturers. There was a changing narrative for the reasons for the varying prices, but it was clear that the “at cost” commitment was not consistently upheld in the license agreements.

Despite the Oxford-AstraZeneca vaccine initially being the cheapest vaccine for COVID, it took MSF and other civil society organisations months to try and uncover the terms in these agreements. Information on the terms of licenses and agreements was mostly gathered through FOI requests, investigative journalists and leaks, which is inappropriate and unsustainable. These experiences strongly show the need to have a clear obligation for governments to ensure disclosure of information and to uphold public health interests against the claims for commercial confidentiality over lifesaving medical goods.

Critically, while many provisions related to transparency need to be expanded and strengthened, the zero draft neglects to include the following aspects of transparency altogether:

- Transparency in relation to IP licensing and technology transfer agreements, and information pertaining to IP that may be associated with pandemic-related products and technologies.
- Aside from asking states to “endeavour” to exclude confidentiality clauses in supply and purchase contracts under Article 9.7, there is no provision addressing the overall issues with confidentiality and trade secrets in the context of a public health crisis, particularly pandemics.
- Requirement for disclosure of the full R&D costs beyond those that are publicly funded, to include funding from private funders and product development partnerships.
- Requirement for disclosure of governance documents, full text of access conditions, and other information (see detailed recommendation under Article 9) for private and philanthropic funders, public and private product development partnerships, other global health institutions and relevant bodies involved in PPR.
- The need to review freedom of information/right to information laws at the national level, to incorporate requirements and procedures for public sector entities to disclose, proactively and on request, public health emergency related contracts, agreements and other information.

Recommendations

- The guiding principle of transparency should be revised to include requirements from the WHA 72.8 transparency resolution and beyond.
- The transparency-related obligations included in the zero draft need to be strengthened as outlined in detail in Annex 2.
- There are a number of transparency provisions that are entirely missing from the zero draft and need to be added. These include provisions to address:

Confidentiality and trade secrets:

- A positive obligation for states to review national laws and practices concerning trade secrets and confidentiality should be added to establish a stronger public interest doctrine and expand exceptions for the purpose of protecting public health.
- Confidentiality clauses especially on pricing, cost, manufacturing capacity and supply schedules, IP and technology licensing terms, in public procurement and supply contracts, IP licensing and technology transfer agreements, should be restricted, and prohibited during pandemics.

Freedom of information/Right to information:

- A positive obligation should be introduced for states to review national laws and practices to establish stronger requirements for governments and other public entities to actively disclose relevant information including on procurement, supply, distribution, cost and pricing, in a public health emergency, and to improve procedures for disclosure of information requested by the public.
- Transparency requirements for all R&D funders and funding recipients, particularly those receiving public funding, including private and public foundations, product development partnerships and other philanthropic organisations.

To address issues identified above and ensure greater consistency, transparency should be established as a separate chapter or article altogether.

Article 4.8 Common but differentiated responsibilities (CBDR) and capabilities to address inequity (ref. to Preamble 4, Article 3, Article 4.8)

There are several principles included in the preamble, guiding principles and objective of the zero draft that provide a positive foundation to address inequity. These include the notion of global solidarity as expressed in the recognition that “unequal development in different countries” is a “common danger” (Preamble 4), the acknowledgement of different levels of development among countries (Article 3) and, most importantly, the principle of “common but differentiated responsibilities and capabilities” (CBDR) (Article 4.8).

CBDR was adopted as a legal principle through the United Nations Framework Convention on Climate Change (UNFCCC) during the Rio Conference on Environment and Development (the 'Earth Summit') in 1992.^{xvi,xvii} It has subsequently been given concrete form through the annexes of the various protocols and agreements emerging from the UNFCCC process to address historical injustice and to pursue equity via an international normative framework. Scholars have also elaborated upon differential responsibilities under various instruments of public international law, as well as on the importance of CBDR in addressing inequity and transforming inter-state relations from those grounded in reciprocity towards those grounded in partnership.^{xviii} Including CBDR as a key guiding principle for the INB negotiation, wherein achieving equity is both a principle, an objective and substantively articulated under Chapter III, is fully justifiable.

However, while Article 4.8 specifies that “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”, and “full consideration and prioritization are required of the specific needs and special circumstances of developing country Parties”, this important principle needs to be more clearly articulated in subsequent provisions of the text and potential annexes.

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 nature of states' obligations and may provide useful guidance to meet those obligations.

Recommendation

- Substantive provisions under Chapters III, V and VI should include explicit language to differentiate responsibilities between developed countries and developing countries.

Article 5 Scope

Article 5 suggests that the accord applies to PPR at national, regional and international levels. However, whether it addresses only future pandemics or present inequities also is unclear from the zero draft. For ongoing outbreaks/known pathogens, there are existing challenges related to equitable access to technologies and medical tools needed to tackle them. The zero draft does not clarify how these challenges would be addressed by the accord.

Chapter III Achieving equity in, for and through pandemic prevention, preparedness, response and recover of health systems

Chapter III addresses equity in five articles. While we find this section to be a positive one overall, substantive revisions are needed to improve the interconnection between these articles, as well as to move beyond relying on voluntary actions to address access to technologies, overcome IP barriers and improve R&D governance, and to provide greater clarity and ambition to establish an effective mechanism on access and benefit sharing.

Article 6 Predictable global supply chain and logistics network

Article 6 suggests the establishment of a global stockpiling mechanism under the WHO Global Pandemic Supply Chain and Logistics Network (the WHO Network), learning from the hard lessons of the recent pandemic when supply from a globally coordinated distribution mechanism to vulnerable people and communities proved inadequate and ineffective.^{xix, xx} While this is a positive development, the current draft needs to be improved by concretely addressing 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.

Missing throughout Article 6 and other articles addressing equity, particularly in relation to stockpiling, is any provision to address the issue of hoarding of health products. 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.

On strategic stockpiling and equitable allocation under Article 6.3(a) and (c)

Article 6.3(a) suggests the establishment and maintenance of strategic stockpiles of “products” needed for PPR, in support of the WHO Network. However, several significant questions about this proposal remain.

First, the current language in Article 6 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.

For existing products tackling potential outbreaks and new variants, the current draft contains no provisions that explicitly address existing obstacles to ensure adequate supplies, including through stockpiles, at the global level. Article 6.3(a) also does not clarify the mechanism of coordination between national, regional and global stockpiles, where applicable.

MSF’s experience with the development of and access to Ebola therapeutics shows that while the novel Ebola therapeutics could be game changing for the most affected countries on the African continent, the disproportionate share of existing products is currently being stockpiled by the United States.^{xxi} This poses an ongoing challenge to secure supplies for countries in which the disease is endemic (unlike the US) and are otherwise most likely to be affected by future outbreaks. To date, there is no humanitarian stockpile of these therapeutics at the global level, nor any stockpile similar to those under the International Coordinating Group

on Vaccine Provision (ICG), due in part to market distortions generated by the US government's ability to pay extraordinarily high prices for these goods, and to constraints generated by the reliance on a single supplier.^{xxii}

It is unclear how stockpiling at the national level should be governed and coordinated with the WHO Network to ensure that countries do not unilaterally and disproportionately stockpile scarce resources that will have an impact on the needs of other countries and neglected groups.

Member states should examine the experiences and lessons learned in the past to clarify a reliable and enforceable mechanism of coordination between national and international emergency stockpiles. For instance, in the 1980s, WHO started establishing and maintaining the Smallpox Vaccine Emergency Stockpile (SVES). In 2002, WHA resolution 55.16 urged member states and requested the WHO Director-General to develop a collaborative mechanism for stockpiling of smallpox vaccines in preparation for a possible outbreak. Five member states, France, Germany, New Zealand, the United Kingdom and the United States pledged to make smallpox vaccines immediately available to the SVES on request. While such arrangements between member states and WHO are positive, it would be important to revisit the shortcomings and gaps as the SVES arrangement has not resulted in concrete sharing of supplies from member states. This was in evidence during the 2022 mpox (monkeypox) outbreak, where stockpiles of smallpox vaccine effective against mpox and held by countries pledging stocks to the SVES were not shared with WHO nor with endemic countries for this alternate indication.^{xxiii}

For products in pipeline and potential future products, clearer language is needed to connect Article 6 with subsequent provisions on requirements under publicly funded R&D (Article 9) and the Pathogen Access and Benefit Sharing (PABS) mechanism (Article 10). These provisions, which are discussed later in the brief, could support strategic stockpiling ambitions at the global level.

Second, developing countries should take a more leading role in governing and deciding the priorities and allocations of strategic stockpiling at the international level. While Article 6 states that strategic stockpiles will be determined “by working with relevant stakeholders and experts”, it is unclear how these entities will be selected and how it will be ensured that the most affected countries play leading roles in decision making. Based on our experience with Ebola, developing countries that are most affected by the virus remain marginalised in decision making when it comes to setting R&D priorities, as well as in determining and establishing a global stockpile to prepare for future outbreaks.

Article 6.3(c) indicates the development of a “fair and equitable allocation” mechanism. However, 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. MSF's experience with the humanitarian buffer during the COVID pandemic made clear that the mechanism was fundamentally flawed. Instead of pushing supply needs in humanitarian contexts to the back of the queue, it is imperative to explicitly reserve stockpiles for humanitarian contexts within the global mechanism.

On transparency requirement under Article 6.3(b)

Article 6.3(b) indicates that states shall promote “transparency in cost and pricing of all elements along the supply chain”, but only in the context of supporting the WHO Network. While transparency in cost and pricing is positive, it should be ensured in all circumstances, regardless of whether it is within the WHO Network or not. In addition, in the context of supply, transparency in contractual terms of procurement agreements, manufacturing capacity, supply schedules, and information about strategic stockpiling and equitable allocation should be required.

Recommendations

- There should be measures to reject hoarding. Binding commitments to reserve a portion of domestic supplies for global stockpiles, akin to the SVES model, in emergency circumstances are one potential consideration.
- Article 6.3 (a) needs to be revised with the following considerations:
 - Strategic stockpiling at the global level needs to address present access challenges to existing products that tackle possible new outbreaks and new variants
 - It should specify that states shall coordinate with each other and with the WHO Network to plan stockpiling at the national and regional levels, to ensure proportionality in national and regional stockpiling and to prioritise sufficient global stockpiles dedicated to supplying resource-limited settings, countries most affected, vulnerable and at-risk people and communities, and humanitarian contexts
 - Clearer synergy is needed between global strategic stockpiling under this provision and increasing supply options addressed under Article 9 and 10
 - Developing countries, particularly those most affected, should be included in the design of any mechanism to manage strategic stockpiles at the global level
- Article 6.3(b) should be revised to incorporate transparency requirements beyond the context of the WHO Network, and to encompass an expanded scope of information.
- Article 6.3(c) needs to specify what is being allocated, who is setting priorities, and how the needs of vulnerable people and communities, particularly those living in humanitarian contexts, will be accommodated within the “equitable allocation mechanism”.

Article 7 Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how

Article 7 sets up a problematic division between “inter-pandemic” and “pandemic periods” whereby some important measures might be treated solely as exceptional mechanisms. While encouraging provisions are included in supporting transfer of technology, the draft nonetheless relies on “mutually agreed terms” with the private sector and voluntary actions, even during pandemic periods. The article also 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.

To revise and improve Article 7, the accord needs to establish stronger obligations for states based on CBDR to ensure access to technologies and support the development of local and regional capacities in R&D, production and supply.

On lacking transparency requirement

Article 7 contains no language about transparency. This misses important information that needs to be governed by transparency requirements, including information related to all types of IP and know-how associated with needed health products and technologies, contractual terms of IP licensing agreements, and technology transfer agreements.

Apart from licenses signed with Medicines Patent Pool (MPP) and WHO COVID Technology Access Pool (C-TAP), the terms and conditions of all bilateral IP licenses and technology transfer agreements signed between commercial entities on vaccines, therapeutics and diagnostics during the COVID pandemic are not publicly available.

There should be a new clause added under Article 7 to specify the transparency requirements.

On issues of the division of “inter-pandemic” and “pandemic” periods (Article 7.3 and 7.4)

The current construction of Article 7 indicates that measures covered by the provisions would be differentiated between “inter-pandemic” and “pandemic” periods. This approach is problematic in addressing access to technologies.

For instance, technology transfer and IP licensing are only covered under measures during “inter-pandemic” time (Article 7.3), and not “in the event of a pandemic” (Article 7.4), when they are also needed. The use of TRIPS flexibilities for safeguarding public health is only mentioned under Article 7.4 as measures “in the event of a pandemic” even though these flexibilities should be considered to facilitate access to technologies during inter-pandemic periods. This interpretation risks limiting the applicability of TRIPS flexibilities to emergencies only, which goes against the existing rights of governments to use these flexibilities whenever needed for the protection of public health and access to medicines, as enshrined by the Doha Declaration on TRIPS and Public Health.

The division of TRIPS flexibilities should be removed and states’ right and ability to make use of them during both emergency and normal times to increase and enable access to technologies should be reaffirmed.

On the need for a positive obligation to establish and use public health flexibilities under Article 7

As noted above, states can make use of public health flexibilities under the TRIPS Agreement and Doha Declaration at their discretion, during as well as outside of emergency situations. However, to do so, these flexibilities need to be incorporated into national law. Article 7 can therefore be improved by the introduction of a positive obligation for states to establish and use public health flexibilities.

During the COVID pandemic, several states took urgent steps to review and revise national laws to ensure the availability of the full range of flexibilities.^{xxiv} At the same time, not all states have these flexibilities incorporated in their national laws. In addition, challenges remain when unilateral or bilateral trade and investment negotiations undermine or threaten to undermine the ability to use these flexibilities.^{xxv} These practices need to be addressed in the accord to provide a meaningful foundation for the effective use of flexibilities. Therefore, before reaffirming the right to use public health flexibilities, it would be important to introduce a positive obligation for states to:

- review and revise national laws and regulations to ensure full incorporation of all relevant IP flexibilities protecting access to medicines
- refrain from introducing IP provisions beyond TRIPS requirements in unilateral actions and bilateral/regional trade and investment negotiations and agreements that could undermine the ability to use TRIPS flexibilities for access to medicines

Article 7.4(b) can also be improved by not limiting its scope 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.

On increasing manufacturing capacities under Article 7.1

While increasing manufacturing capacity is critical to addressing inequitable access, Article 7.1 lacks a number of important elements.

First, it is important to specify the objective of establishing and improving the overall capacity for manufacturing and supply at national and regional levels. The current wording – “increased manufacturing capacities that is more equitably, geographically and strategically distributed” – 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”, which are the final steps of bringing medical tools to people who need them. The wording could also be interpreted as focusing only on expanding manufacturing sites geographically; this can be achieved through a contract manufacturing model, where decision making and technology capacity remains in the control of IP and technology holding companies and is not more equitably distributed.

Second, limiting the need to increase manufacturing capacity to “pandemic-related products” alone is problematic. The recent lessons from the COVID pandemic show that there is a need to have a long-term strategy to establish and improve the overall capacities of R&D, manufacturing and supply, particularly in developing countries.

Third, while increasing manufacturing capacity to prepare for future pandemics is necessary, it is important to address the issue of maintaining these capacities and addressing access challenges around existing health products. The cholera vaccine is a clear example of an existing product whose production remains insufficient even as the need for the vaccine has increased. The draft currently does not address or clarify how it will ensure necessary manufacturing and supplying capacities are not only established, but maintained and used in the inter-pandemic period in order to ensure their sustainability and continued availability to respond to future pandemics.

On issues with “mutually agreed terms” under Article 7.2 and 7.3(c)

Article 7.2 suggests states “strengthen” and “develop” multilateral mechanisms that “promote” and “incentivize” transfer of technology and know-how, based on “mutually agreed terms”, to capable manufacturers in developing countries. There are several problems with this construction and its possible implications.

First, 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 to redirect the strategic objective of this article towards ensuring access to technologies as part of state obligations.

Second, Article 7.3(c) touches on the important issue of technology transfer, but regrettably stops at mandating states only to “encourage” manufacturers to transfer technology based on “mutually agreed terms”, “particularly” when they received “significant public financing”. The several concessions put forward could significantly undermine the effectiveness of the provision. Article 7.3(c) misses the strategic opportunity to connect with the technology transfer requirement under public funding agreements as articulated under Article 9.

In addition, the current language of Article 7.3 (c) 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 “incentive” to enterprises in their territories “for the purpose of promoting and encouraging technology transfer to least-developed countries”. 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 have therefore led to a relatively low level of effective implementation of technology transfer.

The INB process should avoid repeating the same mistakes and take the opportunity to establish firmer obligations for technology transfer. Limiting mechanisms for transfer of technologies and know-how to those based on “mutually agreed terms” also reinforces the existing problems and limitations of voluntary licensing practices by the private sector on health technologies. 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.

During the COVID pandemic, there were three licenses between pharmaceutical corporations and the MPP on COVID therapeutics. Instead of ensuring a global scope as MSF advocated for, all three licenses contained undesirable restrictions:

- All three licenses offered by companies Merck, Pfizer and Shionogi exclude many middle-income countries from the license territories, blocking people in these countries from getting more affordable generic alternatives produced under the licenses.
- Merck’s license on molnupiravir contains an unacceptable clause that undermines the legitimate right to challenge the validity of patents held by the licensor.
- Pfizer’s license on nirmatrelvir excludes the majority of Latin American countries and other middle-income countries such as China, Malaysia and Thailand from its territory. The company also reportedly chose not to amend its conditions in the license to enable emergency local supply by generic licensees in China during the surge of COVID in early 2023.

In the current internal norm-setting process, WHO member states should move away from relying on the goodwill of the private sector to determine the terms and conditions of ensuring access to health technologies, particularly by and in developing countries. Instead of reducing the treaty obligations of states to “mutually agreed terms” with the private sector, the accord should develop common standards to ensure licensing practices on health technologies by the private sector are adequately regulated and subject to public scrutiny.

On improving the provision concerning IP waivers under Article 7.4(a)

Article 7.4(a) suggests states “take appropriate measures to support time-bound waivers of intellectual property rights” during a pandemic. This is a welcome step and reflects the need for expeditious measures to enable the removal of all major IP barriers and related legal uncertainties for the rapid development of relevant health products.

While the inclusion of “intellectual property rights” is positive as it could enable the removal of all major IP barriers, and not just patents, it should be clarified whether “waivers” would release states from their obligation to implement certain IP protections under their national laws, or if they aim to suspend exclusive rights associated with IP. The wording of “adequacy of affordable pandemic-related products” (emphasis added) is confusing.

The wording is also inclusive of “pandemic-related products”, rather than 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. During the COVID pandemic, MSF has called for a meaningful global waiver that covers all major types of IP and all products needed, and that is applicable for all countries, to facilitate more diversified and sustainable production and supply.^{xxvi}

Recommendations

Article 7 should be improved by:

- Introducing new provisions to specify transparency requirements for IP information, including but not limited to patent status, landscaping analysis, non-patent IP information, IP licensing and technology transfer agreements.
- Introducing a positive obligation for states to review and revise national laws and regulations to fully incorporate public health flexibilities.
- Introducing a new provision to specify that states should refrain from introducing TRIPS-plus provisions and requirements through unilateral actions, or bilateral and regional trade and investment agreements.

- Introducing measures to ensure maintenance of manufacturing and supplying capacity, once established, for both existing medicines and future pipeline products.
- Removing the division of “inter-pandemic” and “pandemic” periods in Article 7.3 and 7.4, particularly for measures that need to be available for use at all times.
- Removing the exhaustive list of flexibilities allowed under Article 7.4 to keep an open-ended construction enabling states to use all flexibilities they need for protecting access to medical products.
- Clarifying the strategic connection between Article 7 and Article 9 so that technology transfer requirements under public funding agreements, as articulated under Article 9, can be supportive of, and facilitate access to, technology under Article 7.

Article 9 on increasing R&D capacities

Article 9.1 contains important elements for building and strengthening capacities of institutions for innovative R&D of pandemic-related products, particularly in developing countries. However, it is important that this article be encapsulated in a CBDR lens, emphasising the role of developed countries in promoting technology transfer, capacity building and health/scientific diplomacy towards developing countries.

On lacking provisions on R&D priority and agenda setting

Article 9.10(a) misses an important opportunity to address global coordination on R&D priority setting. WHO should be mandated to exercise a stronger role in driving and monitoring health innovation based on public health needs, including through the work of the WHO Observatory on Health Research and Development^{xxvii} and WHO R&D Blueprint.^{xxviii} Countries, regional health institutions, civil society organisations and affected communities should be consulted in this process, and there should be an emphasis on strengthening the leadership of developing countries, particularly those more vulnerable to pandemics/epidemics, therein. Public and private R&D funding for clinical trials should be driven by the priority setting assessment carried out at WHO HQ, regional and national levels.

The WHO Solidarity trial during the COVID pandemic showed that research can be driven by public health priorities rather than commercial considerations, with the weight of WHO behind it. The trial was marked by significant international collaboration and received inputs from an independent panel of researchers. Such coordination and prioritisation of research and clinical trials is particularly key for neglected tropical diseases.

On access conditions to publicly funded R&D under Article 9

Articles 9.2 and 9.3 suggest several conditions and requirements to be included in public funding research agreements concerning IP licensing, technology transfer and disclosure of key information. The provisions in this section need to be strengthened, going beyond requiring states to “encourage” and “endeavour” to include “appropriate” access terms and conditions. Additionally, a set of minimum binding access conditions should be explicitly included in the substance of the accord.

Such access conditions need to be in place for health technologies to tackle existing pathogens with pandemic potential. This entails a commitment that existing contracts, material transfer agreements, IP, know-how and overall governance of such health products need to be reviewed and renegotiated. This would prevent, for instance, a single supplier/owner having a monopoly on a relevant health technology that has implications for PPR.

Article 9.3(b) and (c) stipulate that “manufacturers that received public funding for the production” of pandemic-related products should disclose key information. This is too narrow and should 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, Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance (Gavi), etc.

Article 9.2(b) and (e) suggest that when states provide public funding, they “shall” “endeavour to include terms and condition” (b) and “establish appropriate conditions” (e) such as “price of products”, “transfer of technology”, “pricing policies”, “publication of contract terms” and “distributed manufacturing”. While these conditions overlap in the two sub-sections, the relationship between them is unclear. Access strategies and post-trial availability, particularly in low-resource settings, must be in place from the very start of the R&D process regardless of the origins of the funds received (whether public, philanthropic or private).

In order to make access strategies an integral part of R&D, we suggest making access-related issues a firm part of milestone reviews along the R&D process, to trace, account for and monitor the effective implementation of access conditions. To enable a follow-up review and monitoring, a baseline landscape of existing access conditions of health technologies (developed or under development) to tackle known pathogens with pandemic potential should be mandated and resourced to be carried out through WHO’s Observatory on Health Research and Development.

Finally, clearer language should be added to specify that these sections under Article 9 are complementary to Article 7 and can enable states to go beyond relying on voluntary actions of the private sector to ensure access to technologies.

On transparency aspects under Article 9.2, 9.3, 9.7 and 9.10

Articles 9.2 and 9.3 include encouraging language under several sub-sections concerning requirements for transparency and access principles under public funding agreements. However, the shortcoming of these subsections should be addressed so that such requirements are not limited to “the extent of the public funding received”. As in the above section, weak language such as “encouraged”, “promoting” and “endeavour to include” should be revised. For other funding, Article 9.3 suggests states shall only “encourage manufacturers” to disclose information on prices and the contract terms of public procurement agreements in a pandemic period.

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 times when public funds are contributed should be a stand-alone accountability provision.

In addition, 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.^{xxvii}

Missing entirely under Article 9 on transparency in the R&D context is the requirement for disclosure of clinical trial cost by all research entities. A sub-section to mandate disclosure of clinical trial costs needs to be added to Article 9.10 concerning clinical trial governance.

The need for transparency of clinical trial costs

Recognising the critical need for more publicly available information about clinical trial costs, MSF is taking steps to publish the costs of clinical trials that we are involved in. In October 2022, MSF approved and published its first Clinical Trial Transparency Policy (CTTP). This policy is a commitment to publishing research protocols, registering clinical trials on appropriate registries, and subsequently publishing clinical trial data in open access formats, in line with the WHO joint statement on public disclosure of results from clinical trials, to which MSF is a signatory. Critically, this policy also includes commitments to publishing a minimum set of cost items for clinical trial costs. The cost items suggested for reporting draw on published reporting guidance.^{xxxix}

MSF has been involved directly in a number of clinical trials, including the endTB and TB-PRACTECAL clinical trials, both aiming to evaluate the safety and efficacy of new treatments and treatment durations for drug-resistant tuberculosis (DR-TB).^{xxx,xxxi} As a first step towards implementing the CTTP, MSF aims to publish the costs of the TB-PRACTECAL clinical trial later in 2023.

By reporting clinical trials costs, MSF supports itself and other entities to generate reliable predictions for future R&D ventures and make proportionate and rational investments – especially for research in low-resource settings. Transparency of clinical trial costs could therefore support innovation and involvement in clinical trials especially from non-traditional actors. In addition, MSF will join Drugs for Neglected Diseases Initiative (DNDi) as the only actors involved in clinical trials to publish some of their costs – contributing to knowledge around the real costs of clinical trials and R&D more broadly.

These initiatives contribute substantially to developing an understanding of the true costs of clinical trials because the overall landscape of available information is so sparse. Mandatory requirements to disclose the costs of clinical trials are needed to ensure this happens more broadly by all actors involved in the funding and delivery of clinical trials.

On confidentiality provisions

Article 9.7 suggests that states shall “endeavour to exclude” confidentiality provisions in supply and purchase contracts. Limiting this provision to “endeavour to exclude” only is contradictory to the guiding principle of transparency.

This obligation should be strengthened by specifying that states shall 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. States should also be mandated 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.

On lacking accountability for R&D funders and entities

Article 9.4 indicates that states should encourage non-state actors (NSAs) to participate in and accelerate R&D. However, beyond provisions addressing public funding for R&D, 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, the Bill and Melinda Gates Foundation (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.

Recommendations

- 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 for funding priorities accordingly, and supporting international clinical trials. Developing countries and regional bodies should be supported to play a leading role in this process.
- Articles 9.2 and 9.3 should go beyond requiring states to “encourage” and “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:
 - 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.
- On transparency:
 - Transparency should be the norm when public funds are involved and not limited to “the extent of the public funding received”. This should be mandatory and should be applied at all times, regardless of the source of funding.
 - Confidentiality provisions should not be included in key agreements that govern R&D and access to health technologies, particularly when public funds are involved and when the technologies are for tackling pandemics. States should prohibit the inclusion of confidentiality provisions in public supply and procurement contracts, IP licensing and technology transfer agreements.
 - A sub-section to mandate disclosure of clinical trial costs should be added to Article 9.10.
 - Governance documents of global health institutions and other relevant bodies involved in PPR, including R&D, should be published in full.
- The obligations in Article 9 towards access conditions and transparency as mentioned above should be applied to R&D carried out by NSAs, the private sector, funding agencies, product development partnerships and other global health actors.
- States that fund and/or host such organisations and clinical trials/research activities in their territories should mandate and oversee the implementation of needed governance changes, access conditions, transparency principles and participation of LMICs, including CSO representatives, for greater accountability.
- Access conditions for technologies already developed through public funds for known pathogens of pandemic potential need to be renegotiated/reviewed and new terms publicised, including when carried out through Product Development Partnerships, private sector and other international organisations.

Article 10 on WHO Pathogen Access and Benefit Sharing Mechanism

Article 10 proposes the establishment of a novel WHO Pathogen Access and Benefit Sharing (PABS) mechanism. The inclusion of access and benefit sharing (ABS) provisions is a positive step. However, ABS provisions under Article 10 need to be improved substantively. 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.

The scope of materials included in the PABS mechanism is narrow, and should be expanded to include biological materials/samples, data and information.

The benefit sharing options included in the current draft are limited, and should go beyond securing supplies to WHO to include benefits for member states and communities in getting access to technologies.

The Article lacks a clear commitment and mechanism to protect the rights of patients, who own biological samples and patient data, and to do no harm to the individual or the community at large. It does not outline how it will empower disease-affected families and communities, so that benefit sharing obligations can be developed in view of sufficient, adequate and timely access for people more directly.

On definitions and scope of PABS under Article 10.2

Article 10.2 suggests that PABS shall cover “all pathogens with pandemic potential, including their genomic sequences”. However, 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 used in R&D in order to provide a solid foundation for benefit sharing obligations based on patients’ contributions.

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. This would require a review of whether existing medical products for tackling pathogens with pandemic potential have or will abide by ABS requirements established in the PPR accord.

On benefit sharing options under Article 10.3

Article 10.3(h)(i) suggest that benefit sharing options shall include but not be limited to “real-time access by WHO to 20% of the production of pandemic related products” to enable equitable distribution, “in particular to developing countries”. 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. 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.

In addition, the above clause indicates that the 20% supply to WHO will be “10% as a donation and 10% at affordable prices”. This can be problematic due to the inherent limitations of donations. It has been documented that on material transfer agreements on influenza virus, pharmaceutical corporations have chosen almost exclusively to donate treatments when other options such as sharing technology, building capacity and affordability considerations are available.^{xxxii} In alignment with the preamble, ABS provisions in Article 10 should address systemic challenges and not rely on a charity model.

Currently, the benefit sharing options included under Article 10.3 (h) only focus on mechanisms of supply to WHO. While this is an important option, it is very limited compared to options provided under other existing international frameworks such as the Nagoya Protocol on Access to Genetic Resources and the Fair and

Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) and the WHO Pandemic Influenza Preparedness (PIP) Framework.^{xxxiii,xxxiv} Both frameworks contain a comprehensive list of benefit sharing options, including both monetary and non-monetary measures, such as transfer of technology and process, affordable pricing and laboratory/surveillance capacity building.^{xxxv}

However, as these options are voluntary, they should provide an inspiration but not the ceiling for ABS commitments in the accord. In addition, benefit sharing conditions 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.

The accord should also include provisions to encourage states to review and improve national laws and policies to strengthen overall ABS mechanisms at national and regional levels.

On increasing synergy and clarity between Article 10 and other provisions

The PABS mechanism under Article 10 presents the potential to secure dedicated supply for the WHO Network, including strategic stockpiling at the global level as mentioned in Article 6.3(a). However, greater clarity and explicit links are needed to make PABS more directly supportive of strategic stockpiling, thereby addressing inequity at the global level.

In addition, there should also be a clearer strategic connection between Article 10 and Article 7 concerning access to technology, including transfer of technology. Currently, the wording under Article 7 remains vague and limited when it comes to options for generating and ensuring transfer of technology and know-how, while several sub-sections are limited to reliance on “mutually agreed terms” with technology and IP-holding entities. The PABS mechanism should be structured to provide another pathway towards ensuring transfer of technology. Particularly, more benefit sharing options should be added under Article 10.3, with differentiation between mandatory and voluntary choices, and with transfer of technologies as part of the minimum standard of benefit sharing obligations.

On protecting the rights of the patients and communities under PABS mechanism

There should be more explicit obligations under Article 10.3(b) around protecting the rights of patients when collecting and reusing patients’ specimens, material and data. 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) establish important recommendations for the purposes of obtaining consent for carrying out health research and also to ensure benefit sharing. These should be integrated as enforceable measures in the PPR accord.

These obligations should be grounded in the protections afforded under the rights to health, privacy and other relevant rights under international human rights law.

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.

On IP questions under PABS provisions [Article 10.3(d) and (e)]

Currently, Article 10.3(d) and (e) state that

(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” (emphasis added)

and

(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.”

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. In that respect, the current wording under Article 10.3 remains limited.

The qualifying phrase, “in the form received”, in 10.3(d) 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.

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 traceability of those materials will be ensured to retain vigilance over the possible IP barriers that can limit access to the end products.

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).

Article 10.3(e) suggests an approach of managing background IP associated with pathogens. 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.

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.

Recommendations

- Article 10 should go beyond pathogens and their genomic sequences to expand the scope of materials covered under the PABS mechanism to include biological samples/patient specimens.
- Instead of an arbitrary and insufficient ceiling of 20% of pandemic-related products for WHO, a more open-ended approach to benefit sharing based on a rolling assessment of needs should be explored.
- A core package of benefit sharing obligations should be established. This should include training, technology transfer for local production, priority access to end products, affordable prices, joint research, non-exclusive IP licensing, capacity building and other knowledge sharing options.
- Key elements of ethics in health research such as obtaining consent, benefit sharing and post-trial access and registration of health technologies included in the “Guidelines for Health-related Research Involving Humans” of CIOMS should be incorporated in the accord and made mandatory.
- States should review or establish material transfer agreements incorporating the core package of benefit sharing obligations to address challenges of access to existing and pipeline health products tackling existing pathogens with pandemic potential and their new variants.

- States should review and strengthen national and regional legislative, regulatory and policy mechanisms on ABS.
- States should establish requirement of disclosure of origin of pathogens, genomic sequences and other biological materials in patent applications to ensure traceability and accountability.
- States should use IP flexibilities to ensure the full implementation of benefit sharing requirements under PABS

On Antimicrobial Resistance (AMR)

The challenges arising from antimicrobial resistance (AMR) are recognised in the zero draft as an integral element to consider as part of PPR. This recognition is reflected in the preamble and under Article 18 on One Health. While the inclusion of language addressing AMR is welcome, several improvements and clarifications are needed.

Overall, the zero draft makes no reference to the existing Global Action Plan on AMR adopted during the WHA in 2015.^{xxxvi} While the 2015 Global Action Plan contains many important objectives and mechanisms specifically designed to tackle AMR issues, its non-binding nature and financial and technical gaps continue to undermine national implementation and the full realisation of these objectives. The PPR accord should clearly incorporate mechanisms and objectives under the Global Action Plan on AMR.

On definition

While paragraph 25 of the preamble describes AMR as “a silent pandemic” and “an aggravating factor during a pandemic”, it 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. The heading of Article 18, “One Health”, also remains undefined in the zero draft. The draft should clearly define AMR within the context of PPR and give greater clarity about binding State obligations to tackle AMR as an integral strategy of PPR.

On R&D and access

Explicit indicators and objectives are needed to practically address concrete antibiotic access and innovation challenges such as gaps in sustainable access to antibiotics and diagnostics and the need for a more collaborative, efficient antibiotic R&D ecosystem – including international clinical trial networks – that is able to surmount significant scientific challenges in developing critical medical tools. It will be critical to establish binding obligations for countries to coordinate and cooperate on R&D, developing and maintaining public capacity to do so, and to uphold equitable and affordable access to antibiotic medical countermeasures. The current draft misses these critical aspects, particularly under Article 18.7, Article 7 and 9.

On supporting the implementation of National Action Plans (NAPs) on AMR

Article 18.7 (c) suggests the obligation to develop and implement a national One Health action plan for AMR addressing both human and animal dimensions. While this is a welcome step, WHO member states should strengthen this through close examination of the unfinished commitments to implement the 2015 Global Action Plan on AMR, including the financial and technical gaps of national implementation particularly in resource-limited settings. To date, less than a third of WHO member states have a fully budgeted or financed action plan established.^{xxxvii}

To address these gaps, there should be more explicit language under Article 18 to 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.^{xxxviii}

Surveillance

The accord should strengthen and support harmonised, multisectoral One Health approaches to surveillance, data-sharing and communication across sectors in ways that mutually benefit PPR and efforts to address AMR, and should include surveillance of antimicrobial consumption, use and access. Enhancement of infrastructure and laboratory capacity for surveillance should build on already existing systems, included those established or further developed during COVID.

Article 18.6 suggests states “commit” to strengthen laboratory capacity to identify and assess the risk and emergence of pathogens and variants. However, 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.

In addition, 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.

In the context of laboratory capacity strengthening, it is crucial to share and report pathogen data as stated under Article 18.7 (d). At the same time 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. Clearer strategic connection needs to be made between Article 18, 10 and Article 6.

Recommendations

- The accord should incorporate mechanisms from the 2015 Global Action Plan on AMR, establishing explicit obligations and measurable indicators for states to implement in order to address financial and technical gaps to develop and implement national action plans on AMR.
- Binding obligations to coordinate AMR R&D financing and priority setting and conditions to ensure stewardship and access are needed across the accord, particularly under Articles 18, 7 and 9.
- Antimicrobial consumption, use and access should be included in surveillance and monitoring. Instead of being treated separately, laboratory capacity for AMR surveillance and diagnostics should be an integral part of the overall laboratory capacity strengthening.
- Pathogen data sharing should follow the principles and mechanisms concerning access and benefit sharing, promoting transfer of technology and know-how and equitable supply and allocation.

Conclusion

The INB zero draft represents the first step towards a legally binding accord that would govern PPR among WHO member states. It includes some positive provisions and principles addressing the key challenge of achieving equity in access to lifesaving health technologies, setting the process in the right direction. However, several outstanding issues need to be addressed as the negotiation progresses.

Definitions of key terms, including “pandemic”, and “pandemic-related products” need to be revised to ensure effectiveness and enforceability of measures established under the accord. Greater clarity and consistency is needed between guiding principles and substantive provisions, especially concerning transparency and CBDR. The draft also needs to clarify whether measures established under the accord are applicable to existing

medical products addressing existing pathogens with pandemic potential. To achieve equity, provisions addressing global supply chain and strategic stockpiling, equitable allocation mechanism, access to technologies, increasing R&D capacity and the new WHO PABS mechanism should be improved by introducing more direct state responsibilities to ensure equity in access based on health needs of people. While the inclusion of AMR is welcomed, the accord should sufficiently incorporate the existing Global Action Plan on AMR to implement obligations and indicators for states to address AMR as an essential part of PPR.

Alongside the INB process and the zero draft, several substantive proposals addressing the issue of equity have been put forward during the Working Group on Amendments to the International Health Regulations (2005) (WGIHR) process.^{xxxix} Many of these proposals provide a valuable reference for INB negotiations, to ensure that the issue of equity is streamlined in both processes.

In addition, there is also an ongoing WHO consultation process for a new global coordination platform for equitable access to medical countermeasures (MCM).^{xl} The concept note sent by WHO to member states for consultation set up an ambitious timeline of moving towards establishing the prototype of a new global mechanism by April 2023, at which point the INB and WGIHR negotiations will inevitably still be ongoing. The concept note only mentions that the proposed platform “will be adjusted once INB has completed its work”, while the process of developing such a platform should already keep pace with and be governed by the INB and WGIHR processes.^{xl} In addition, the High-Level Meeting on PPR during the United Nations General Assembly in September 2023, when possible political commitments are to be made by UN member states, will also take place before the INB/WGIHR negotiations conclude. It remains unclear how and when explicit normative connection and coordination will be developed to ensure adequate oversight and rule-based governance from WHO member states on the MCM initiative and the UNHLM, while major international norm-setting processes are ongoing at the INB/WGIHR processes.

It is imperative that future PPR mechanisms avoid repeating the same mistakes as those used during the COVID pandemic, such as ACT-A.^{xix} Better coordination among these parallel processes is needed to ensure that the PPR processes happening in parallel outside of the multilateral platform of WHO stay within the remit of negotiations in INB/IHR, particularly on the roles and responsibilities of philanthropic funders, global health actors and the private sector. The zero draft should include states’ obligations, either through national laws or international cooperation, to regulate these entities so that PPR initiatives involving them are governed by common norms.

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