WG ACCORD ON THE PANDEMIC AND IHR REFORM

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The "zero draft" of the international pandemic agreement: rhetoric, inaccuracies, and gaps limit progress

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Abstract

This technical note critically scrutinizes the "zero draft" of the new international agreement on pandemics (WHO CA+) that is being negotiated within the World Health Organization (WHO) through an Intergovernmental Negotiating Body (INB), whose fourth meeting will take place in Geneva from February 27 to March 3, 2023. Built upon a call for contributions from members of the WG Agreement on Pandemics and IHR Reform (Fiocruz/USP), after an introduction that provides background information on the ongoing negotiation, this note offers eleven sections that address: the persistent uncertainty about the legal nature of the instrument; issues related to the Preamble; the definition of pandemic and the new declaration mechanism proposed in the CA+; the need to expand the definition of surveillance; the limits of the new provision on human rights; the institutional structure; control and accountability mechanisms; issues related to intellectual property; the proposal of the creation of a Global Public Health Emergency Force; references to the issue of antimicrobial resistance (AMR); and issues related to the participation of non-state actors. At the end, a synthesis of the conclusions is presented in a propositional way to contribute so that the rhetorical character and several inaccuracies and gaps can be overcome, ensuring effective advances in the global response to pandemics.

The WG Pandemic Accord and IHR Reform is an initiative of the Oswaldo Cruz Foundation, Fiocruz (Center for International Relations, CRIS) and the University of São Paulo, USP (Institute of International Relations, IRI; and Faculty of Public Health, with the Postgraduate Program in Global Health and Sustainability and the Center for Study and Research in Health Law, CEPEDISA). It has a multidisciplinary nature, encompassing specialists and guests from the academic community, the health sector, civil society, parliament, and state organs related to the theme. Aimed at the consolidation of a Global South, and particularly a Brazilian perspective of Global Health regulation, the WG intends to provide subsidies to society and the Brazilian State to critically monitor the ongoing negotiations and eventual formulation of proposals, as well as to promote and disseminate the academic production on this theme. Learn more at www.saudeglobal.org

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1. Background

In December 2021, the World Health Assembly (WHA), the highest deliberative body of the World Health Organization (WHO), established an Intergovernmental Negotiating Body (INB), composed of the member states of the organization, to negotiate a new international instrument to strengthen pandemic prevention, preparedness, and response[1]. Figure 1 summarizes the main features of this body.

Figure n. 1 – Main features of INB

Source: Technical Note n. 2 [3]

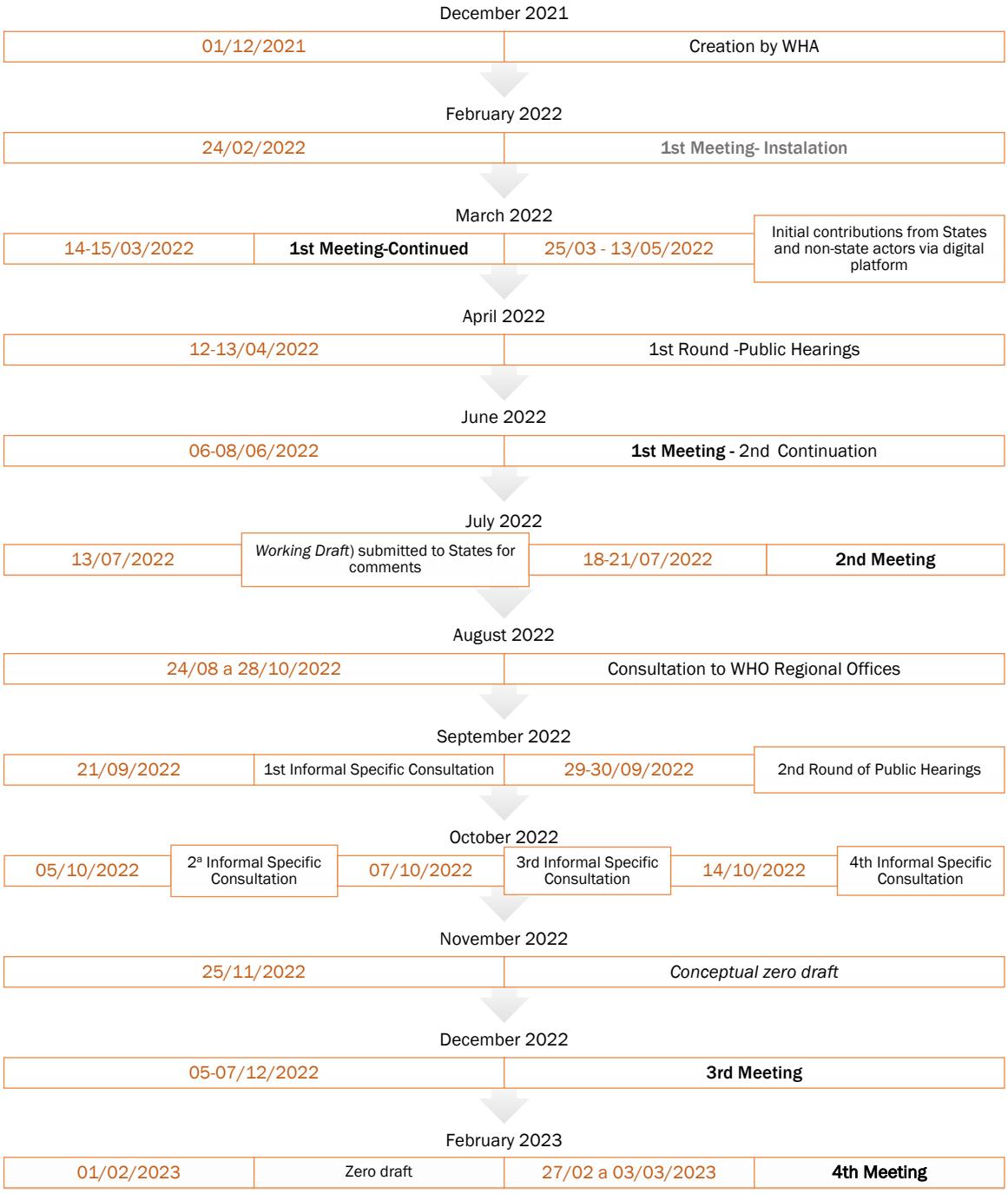
The INB is approaching its fourth meeting, as shown in figure 2, which summarizes the chronology of its main activities.

[1] The negotiations of the new legal instrument on pandemics should not be confused with the reform process of the International Health Regulations, which run in parallel; see Technical Note 1 https://saudeglobal.org/wp-content/uploads/2022/10/gt-NT-001-1.pdf

[2] WHO, SSA2(5) The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response, Genebra, 01/12/2022.

[3] https://saudeglobal.org/wp-content/uploads/2022/12/GT-NT-2_2022-1.pdf

Figure 2 - INB timeline (not exhaustive)



Source: Technical Note n.2[4] , updated by the authors

[4] https://saudeglobal.org/wp-content/uploads/2022/12/GT-NT-2_2022-1.pdf

The Chair of the INB presented, on 1/02/2023, a "zero draft" of the new legal instrument on pandemics (zero draft of the WHO CA+). This is the third version of the text that is being discussed by the negotiators - the first version was a working draft, presented in July 2022, and the second was the conceptual zero draft, presented in November 2022. The zero draft will be discussed at the fourth meeting of the INB, which will take place in Geneva (Switzerland) between February 27 and March 3, 2023.

The purpose of this technical note is to critically analyze the zero draft. It is a result from a call for contributions from members of the Pandemic Accord and IHR Reform WG (about the WG, see box on p.1).

After an introduction that provides background information on the negotiation, this note offers eleven sections that address: the persistent uncertainty about the legal nature of the instrument; issues related to the Preamble; the definition of pandemic and the new declaration mechanism proposed in the CA+; the need to expand the definition of surveillance; the limits of the new provision on human rights; the institutional structure; control and accountability mechanisms; issues related to intellectual property; the proposal for the creation of a Global Public Health Emergency Force; references to the issue of antimicrobial resistance (AMR); and issues related to the CA+ drafting group. At the end, a synthesis of the conclusions will be presented in a propositional way.

2. Persistent uncertainty regarding the legal nature of the instrument

As we have already pointed out in our technical note n.2[5], the INB has indicated its preference for article 19 of the WHO Constitution as the foundation of the new instrument on pandemics. This means that we would have a new WHO convention or agreement, to be adopted by the WHA by a two-thirds majority of its votes, which could cover any matter within the competence of the Organization. The conventions enter into force for each member state after being incorporated into its national legal system, in accordance with its constitutional rules. The involvement of society, parliaments and local governments in the rites of transposition of norms is decisive for their future effectiveness, favoring the adaptation of national legislation and public policies to the dictates of the new international agreement. The only convention adopted to date within the WHO, on tobacco control, adopted in 2004, is considered a successful experience, with great transcendence in national health policies, and can serve as a valuable example for the INB including in relation to the obstacles that this norm currently faces in terms of implementation.

[5] https://saudeglobal.org/wp-content/uploads/2022/12/GT-NT-2_2022-1.pdf

However, the INB still keeps open the possibility of adopting a Regulation, based on Article 21 of its Constitution, which significantly limits the matters on which the WHO can adopt this type of instrument[6]. In addition, when it comes to WHO Regulations, the consent of States follows the opting out mechanism: instead of express adherence, the silence of a State is equivalent to consent, and within a certain period of time, States may submit reservations to some provisions or reject the Regulations in their entirety, without having to go through the incorporation process.

We need to reiterate that the persistence of uncertainty about the legal nature of the instrument is detrimental to the progress of the negotiations, as it increases the confusion already existing between the parallel processes of drafting the new pandemic agreement and the reform of the International Health Regulations, the main standard developed on the basis of Article 21 of the WHO Constitution. The pandemic agreement is expected to have markedly greater political relevance than is usually attributed to health regulations, and thus to address issues that go beyond the matters on which the WHO Constitution allows regulations to be adopted. The uncertainty also makes it difficult to disseminate the negotiations to opinion makers, including the political class at the national level and the international scientific community, since an instrument referred to in technocratic jargon (such as WHO CA+) obscures the importance of the negotiated topic and does not invite participation.

Despite these uncertainties, the zero draft of the Presidency of the INB refers to the future instrument by the acronym CA+, the name adopted in this note.

3. Comments on the preamble

From the conceptual project to the zero draft, the preamble of the CA+ goes from 44 to 49 considerations, with few changes, most of them limited to wording adjustments. There has also been a shift in the item devoted to the role of WHO from number 43 to number 5.

Although the preamble is a fundamental instrument for the interpretation of international treaties, it draws attention to the length of the text when compared to other instruments such as the 1998 Rome Statute, which created the International Criminal Court, whose preamble has 11 lines; or even the 2004 Framework Convention on Tobacco Control, which contains 23 items in its preamble.

Items 24, 26, and 27 should be unified, since they deal precisely with the need to work on One Health in a synergistic way[7]. Contrary to conciseness, the zero draft split the former item 25 into two items: the current 26 and 27.

[6] These are: a) Sanitary and quarantine measures and other procedures to prevent the international spread of diseases; b) Nomenclatures for diseases, causes of death and public health measures; c) Standards concerning diagnostic methods for international use; d) Standards concerning the safety, purity and action of biological, pharmaceutical and similar products in international trade; and e) Advertising and labeling of biological, pharmaceutical and similar products in international trade.

[7] "**One Health** is a global multi-sectoral, transdisciplinary, cross-cultural, integrated and unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants, and the environment (including ecosystems) are intimately linked and interdependent.", Brazil, Ministry of Health, Saúde de A a Z, Saúde Única https://www.gov.br/saude/pt-br/assuntos/saude-de-a-a-z/s/saude-unica

It is also important to highlight that there is no preambular paragraph dedicated to climate change, which evidences the predominance of the biologicist content of the instrument, partially coherent with the scope restriction to infectious disease pandemics, which will be treated in the following section. The only reference to climate change found in the zero draft is in article 18 on One health, when characterizing it as one of the generating factors of emerging/reemerging diseases related to the human/animal/environment interface. Keeping this direction, the CA+ does not recognize the effects of climate change on the production and dissemination of epidemics and pandemics, already demonstrated by the Intergovernmental Panel on Climate Change (IPCC) in several reports[8].

On the other hand, item 16 of the preamble (formerly item 15 of the draft conceptual document) maintains a generic reference to "people affected by conflict and insecurity" who risk being "left behind" during a pandemic, without elucidating what kind of conflict or insecurity it refers to. In these terms, this is mere rhetoric. If it refers to armed conflicts and other situations of insecurity, however, it could have a purpose as an interpretative guideline.

In the same vein, it should be noted that International Humanitarian Law (IHL) is not mentioned in the zero draft. The CA+ should institute IHL obligations of states in the context of pandemic prevention, preparedness and response. In Article 6.5, humanitarian access[9] is considered only from the point of view of supply and logistics of access to medicines, diagnostics and vaccines, but not from the point of view of the broader care of the population concerned. A specific article on humanitarian situations would be appropriate, which could be linked to Article 14.2 on human rights (see section n.6 of this technical note).

Regarding intellectual property and access to technologies, instead of maintaining the different text options that were listed in items 38 and 39 of the preliminary conceptual draft, the zero draft simply listed and numbered paragraphs with different formulations of the same provision, ranging from inconsistency to contradiction (see section 9 of this note on this issue).

4. Definition of pandemic and declaration mechanism

Among the provisions inserted in the zero draft that raise the greatest concern among experts is the concept of pandemic and its respective declaration mechanism. The definition of a pandemic included in Article 1 includes, in addition to the global spread of a communicable disease, the criteria of severe morbidity and increased mortality. This inclusion is not in accordance with some definitions adopted in the international scientific literature[10], and may generate restrictions for the recognition that important threats are, in fact, pandemics. An example of this was the Zika virus Congenital Syndrome (ZCS) crisis, declared as an PHEIC in

[8] Available at https://www.ipcc.ch/
[9] Humanitarian access concerns the ability of humanitarian actors to reach crisis-affected populations, as well as the ability of an affected population to access humanitarian assistance and services.
[10] e.g. Last JM, editor. A dictionary of epidemiology, 4th edition. New York: Oxford University Press; 2001; e Barreto ML, Teixeira MG, Carmo EH. Infectious diseases epidemiology. J Epidemiol Community Health. 2006 Mar;60(3):192-5. doi: 10.1136/jech.2003.011593

2016. The disease had a high magnitude, high spread and severity (although restricted to ZCS and Guillain Barré), but had low lethality when considering the affected population as a whole.

Also, in the influenza A(H1N1) pandemic, the severity, as measured by its lethality, after initial estimates of high levels, turned out to be similar to that of seasonal influenza, except in young patients. The inclusion of the severity criterion for pandemic definition was adopted by the WHO during the 2009 A(H1N1) pandemic[11], which was criticized at the time, including through accusations that were subject to review by a Review Committee[12].

At this point, it is worth going back to the critique we made of the scope of CA+ in our technical note n. 2, in the section "Scope of the new agreement: beyond infectious diseases"[13]. The question arising is: will there be a new instrument to deal with PHEICs of a non-infectious nature, especially those related to climate change? Or will there be a broader revision of the IHR itself? While the second option seems natural, the IHR reform that is underway tends to be focused on specific, less far-reaching amendments, as we will comment on in a future technical note. If the goal of the CA+ is to improve prevention, preparedness, response and recovery capacities of services for pandemics (by infectious diseases), these same capacities are (or should be) developed in an integrated way for events of another nature.

Moreover, the definition of "pandemic-related products" (art. 1.c of the zero draft) should dialogue with the proposals made in the IHR review process, i.e., "health products", including components, materials, parts, cell and gene therapies, as well as data and know-how.

But it is not only the definition of pandemic included in the zero draft that may create obstacles to the international response to pandemics. The new article 15.2 provides for the CA+ to determine the conditions under which a pandemic will be declared by the WHO Director-General. Two footnotes to the zero draft invite the INB to discuss the modalities and conditions for declaration of a pandemic by the WHO Director-General, as well as the relationship between the CA+ and the IHR. To understand what this rule represents, it is necessary to remember that every pandemic necessarily corresponds to the concept of ESPII provided by the IHR, but the reciprocal is not true. For example, the Ebola outbreaks in West Africa between 2014 and 2015, and in the Democratic Republic of Congo between 2019 and 2020 were international emergencies, but fortunately did not turn into pandemics.

Under the current IHR, in order to declare a PHEIC, the WHO Director-General does not need the prior or subsequent consent of states in any form. The Director-General relies on the advice of an emergencies committee to make this decision, which is his sole responsibility, and can be renewed or reversed periodically, depending on the evolution of the emergencies.

[11] Kelly H, 2011. The classical definition of a pandemic is not elusive. Bull World Health Organ. 2011 Jul 1; 89(7): 540–541.

[12] AMS. A64/10. Implementation of the International Health Regulations (2005) Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 05/05/2011 https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf?ua=1

[13] https://saudeglobal.org/wp-content/uploads/2022/12/GT-NT-2_2022-1.pdf

In the same vein, it is up to the Director General to declare that a disease has reached the pandemic level. In the case of infectious diseases, the declaration of a PHEIC is expected to prevent an outbreak from becoming an epidemic or a pandemic. However, unlike PHEICs, there is no specific procedure for this declaration. What does exist is a technical classification of the levels of evolution of certain diseases.

When covid-19 was declared a pandemic, about 40 days after the PHEIC declaration, the current WHO Director-General Tedros Adhanom said:

> *Pandemic is not a word to use lightly or carelessly. It is a word that, if misused, can cause unreasonable fear, or unjustified acceptance that the fight is over, leading to unnecessary suffering and death. Describing the situation as a pandemic does not change WHO's assessment of the threat posed by this virus. It doesn't change what WHO is doing, and it doesn't change what countries should do [14].*

At that time, as of March 11, 2020, there were 118,000 cases of covid-19 in 114 countries and 4,200 deaths. Despite intense international mobilization since January 30, 2020, the WHO was criticized for being late in recognizing that outbreaks of the disease already constituted a pandemic.

Thus, if the provision of Article 15.2 comes to fruition, there would be two different declaration processes, based on different legal regimes:

- one for pandemics, regulated by CA+;
- and another, foreseen in the IHR, for those PHEICs that are not considered pandemics (and may be in the future).

What would be the advantage of having a specific regulation for the declaration of pandemics by the WHO Director-General? Apparently, it is a matter of restricting the autonomy of the organization that, as already mentioned, currently has the eminently technical competence both to declare an PHEIC and to recognize that a disease has reached pandemic status.

As already mentioned, this technical capacity can be limited by the adoption of a narrow concept of pandemic. Moreover, considering the characteristics of the institutional structure presented in the zero draft, still anachronistic and cast in stone, any link between the WHO and these bodies could greatly delay the declaration of a pandemic. What is expected from the international community, however, is the opposite: greater agility in recognizing that a disease has reached the range of a pandemic and greater autonomy for the WHO.

[14] WHO characterizes COVID-19 as a pandemic. 11/03/2020 https://www.paho.org/en/news/11-3-2020-who-characterizes-covid-19-pandemic

5. Definition of surveillance

In its article 1(f), the zero draft leaves pending the definition of what "One Health surveillance" would be[15]. Genomic surveillance is explicitly mentioned in Article 11.3, but it is only one part of the broad field of health surveillance.

It would be important for the CA+ to define surveillance as a set of activities involving pandemic prevention, preparedness and response. This set should include:

(i) digital surveillance;

(ii) artificial intelligence;

(iii) machine learning algorithms;

(iv) genomic surveillance;

(v) observation of the Nagoya Protocol; and

(vi) data sharing.

Only the combination of these actions will allow the earliest possible detection of outbreaks with pandemic potential. All these activities must be covered by the single health approach in order to act at the human-animal-environment interface.

6. Human rights provision: limited progress

The inclusion of article 14 in the zero draft should be celebrated as an important step towards the consolidation of the dialogue between the human rights protection system and global health governance, especially in the context of PHEICs.

In order to compensate for the total or partial absence of human rights approaches in national and local responses to covid-19, dozens of documents drafted by human rights protection bodies have recommended the adoption of urgent measures and public policies to guarantee the rights of the population. The WHO itself has used these documents to stimulate the actions of member states in this field, since covid-19 has highlighted the intersection between these two universes, and the need to go beyond generic statements. Tangible measures for the protection of rights, adopted in different countries by governments and social entities, were able to avoid an even greater number of cases and deaths, as was the case with emergency social protection programs, among many others.

In this sense, article 14 urges the parties to include the protection of human rights during pandemics in their national legislation. While this is a step forward in instituting a human rights approach to pandemic response, albeit a limited one, the provision requires improvement in at least six aspects.

[15] See footnote 7

6.1 Social protection must become an international obligation

Article 14 of the zero draft makes a timid reference to the need for the integration into national legal orders of provisions on maintaining social protection policies and ensuring access to "basic necessities products" during pandemics.

What is expected of the CA+, however, is that it establishes an international obligation of inseparability between the adoption of measures restricting human rights and social protection measures, which should be enshrined as a principle of international health law[16]. In addition to human rights, social protection is an imperative for the efficiency of the response to pandemics, because in its absence, adherence to containment measures is made difficult or impossible for huge contingents of low-income populations, especially in the case of informal workers.

The incipient proposals of the zero draft on this point is surprising, given that social protection programs were the rule rather than the exception during the covid-19 pandemic. By April 2021, at least 126 states had introduced or adapted social protection measures due to covid-19[17]. This does not mean that they have been sufficient.

To make up for the absence of or to supplement emergency social protection programs during the pandemic, a vast social protection network was created or expanded in peripheral communities in all regions of the world. In Brazil, for example, the organization G-10 Favelas (inspired by the Group of 7 - G7, which gathers the richest countries in the world) developed a model of response to covid-19 based on the experience of the Paraisópolis Complex, São Paulo, SP, which was disseminated in more than 100 Brazilian communities, having among its main axes the provision of basic food baskets and lunch boxes[18].

At least in terms of political discourse, there is consensus in the international community about the decisive role that social protection must play in the response to pandemics. An example of this is that an Interagency Cooperation Council on Social Protection was created around the G20, bringing together 25 international agencies, including the World Bank, which recognizes the need to promote adherence to prevention measures through various initiatives, including emergency income programs and exemption from payment of essential services such as electricity, gas, and water[19]. It is essential that this consensus be reflected in the text of the CA+.

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[16] VIEGAS, Leandro; VENTURA, Deisy; VENTURA, Miriam. A proposta de convenção internacional sobre a resposta às pandemias: em defesa de um tratado de direitos humanos para o campo da saúde global. Cadernos de Saúde Pública 2022, v. 38, n. 1, e00168121 https://doi.org/10.1590/0102-331X00168121

[17] International Labour Organization. Social Protection Inter-Agency Cooperation Board https://www.ilo.org/newyork/at-the-un/social-protection-inter-agency-cooperation-board/lang--en/index.htm

[18] https://g10favelas.com.br/

[19] https://www.ilo.org/wcmsp5/groups/public/---ed_protect/---soc_sec/documents/genericdocument/wcms_740551.pdf

6.2 The guarantee of non-discrimination is insufficient

Article 14 is based on the principle of non-discrimination and of preferential attention to people in vulnerable situations. Despite its undeniable importance, the text does not contemplate other pillars of human rights and, in particular, of international health law. Considering WHO's own definition[20], in order to adopt a true rights approach to public health, Article 14.1 should set as an objective of measures to contain public health emergencies of international concern the realization not only of the right to health, but of all human rights, including equality, social participation, responsiveness, civil and political rights, and other economic, social and cultural rights.

At the same time, consolidated aspects of the right to health in international law should also be contemplated in this article, and in particular its universal character. Covid-19 highlighted that no definition of security, whatever it may be, in any country, can be achieved when the population is forced to pay for tests, basic care, essential medicines and vaccines during a public health crisis.

It is also imperative to go back to the principle of non-retrogressive rights in the context of pandemics, as was done in the Global Compact for Safe, Orderly and Regular Migration, adopted in 2018 under the UN[21] . An example of the practical application of this principle is the situation of migrants and refugees in Brazil with regard to access to health care. The principle of non-regressivity guarantees, for example, that the universal access offered by SUS to every person in the national territory, including in an irregular migratory situation, cannot be restricted temporarily or permanently for economic or security motivations related to a health crisis. In other words, measures adopted in the context of a pandemic cannot be allowed to promote a regression in the guarantee of the population's human rights.

6.3 The previous recommendations of international human rights protection systems with regard to pandemics

During the last few years, the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Human Rights Council[22], and the Inter-American Commission on Human Rights (IACHR), among others, have produced concrete recommendations for fighting the pandemic of COVID-19 from a human rights perspective, as well as detailed reports analyzing the responses of States. At the UN level alone, its various bodies for the protection and promotion of human rights have issued more than 40 pronouncements, dozens of press releases, and 14 "special guides" for States[23]. This body of theory and practice needs to be recovered in the negotiation process of the CA+.

[20] https://www.who.int/publications/i/item/9241545690

[21] https://documents-dds-ny.un.org/doc/UNDOC/GEN/N18/244/47/PDF/N1824447.pdf?OpenElement

[22] See Special Procedures https://www.ohchr.org/EN/HRBodies/SP/Pages/COVID-19-and-Special-Procedures.aspx and https://www.ohchr.org/EN/HRBodies/Pages/COVID-19-and-TreatyBodies.aspx

[23] https://www.ohchr.org/EN/NewsEvents/Pages/COVID-19.aspx

According to the OHCHR, "respect for human rights in all their dimensions including economic, social, cultural, and civil rights will be fundamental to the success of the public health response and recovery from the pandemic"[24]. The OHCHR provides details on such dimensions, in particular on the right to health care, emergency measures, adequate housing, access to information and participation, discrimination, food, among many others.

In April 2020, the WHO presented the document Addressing Human Rights as Key to the covid-19 Response[25], in which it addresses key themes of this intersection, such as stigma and discrimination, gender equality, support for populations in situations of vulnerability, quarantine and restrictive measures, among others. According to WHO:

> *Protecting human rights can help address these public health concerns, by requiring, for example, that proactive measures such as ensuring accurate information is made available and that stigmatizing and discriminatory behavior and practices are identified and stopped*[26].

As such, it is necessary to have these previous recommendations integrated in the CA+, through a synthesis of the contributions of international human rights protection bodies, or at least a reference to such documents.

6.4 Inclusion of the protection of migrants and refugees in the regulation of health measures related to the movement of persons

During emergencies, the WHO recommendations concerning the free movement of persons are among those most resisted by states. The Review Committee that analyzed the operation of the IHR during covid-19[27] concluded that never before had so many health measures related to international traffic been adopted: by the end of January 2020, some 20 countries had closed their borders to people coming from China; seven months later, all countries had implemented health measures related to international travel. According to the same Committee, these measures were often adopted for political reasons, without technical basis, and through decision-making processes that are outside the scope of action of health authorities[28]. This finding is worrisome because, from a public health point of view, depending on the situation, the closing of borders may bring more disadvantages than advantages. Not only does it hinder international cooperation actions, including the movement of health professionals and volunteers, but it also encourages the irregular entry of migrants and refugees in destination territories, hindering the health care that should be provided at entry points, and hindering both migration control and epidemiological surveillance.

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[24] https://www.ohchr.org/Documents/Events/COVID-19_Guidance.pdf
[25] https://www.who.int/publications/i/item/addressing-human-rights-as-key-to-the-covid-19-response
[26] Ibid.
[27] Regarding this committee, see: https://www.who.int/teams/ihr/ihr-review-committees/covid-19
[28] A74/9 Add.1 5 May 2021. WHO's work in health emergencies - Strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005) https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_9Add1-en.pdf

In the zero draft of the CA+, the rights of migrants, refugee and asylum seekers are cited in article 4.13 among the "guiding principles and rights" that should guide the action of states, along with other "high-risk and vulnerable groups." However, this provision makes no reference to the closing of borders and other measures restricting movement, merely pointing to the need to remove legal and regulatory obstacles to these people's access to health services. In interpreting this article, it is necessary to consider not only people who are already in the territory of the States, but also those who are in transit during emergencies, because of the health crisis or for other reasons.

On the other hand, it is worth noting that article 4.13 does not translate into tangible obligations for states in the other sections of the CA+, not even in article 14 which deals with human rights.

An article dedicated exclusively to the rights of migrants, asylum seekers and refugees during pandemics would be important to clarify, among other things, how these people should be treated when they are close to a Country border during a pandemic. In the absence of a separate article, at least one specific clause could be included in Article 14.2(a), in order to place an obligation on States to adopt provisions in their national legislation to prevent derogations from the rights of migrants and refugees during pandemics, in particular from the principle of non-refoulement, widely recognized in international law and national legal orders, under the pretext of containing the spread of a disease. Moreover, there should be an express prohibition of deportation or expulsion procedures during a pandemic.

6.5 Protection of Health Care Workers

Although health care workers are mentioned in three preamble items of the zero draft, including to acknowledge the disproportionate impact of the pandemic on them, they appear in only one article, Article 12.

This provision could include specific obligations to protect health workers during pandemics, drawing, for example, on the WHO Charter for Safety[29], which urges governments and health care facility managers to protect health workers from violence, improve their mental health, protect them from physical and biological hazards, promote national health worker safety programs, and link health worker safety policies to existing patient safety policies.

[29] https://cdn.who.int/media/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf?sfvrsn=2cb6752d_2

6.6 Institutional Capacity and Emergency Response

Ensuring human rights during pandemic response depends on a robust follow-up mechanism that can account for this complex connection. To this end, Article 14.2(b) merely states that each Party to the CA+ should endeavor to establish an Independent Advisory Committee, albeit not clarifying what the character of this committee's action in terms of human rights protection and promotion would be. Would it be a body responsible for assessing concrete situations of risk and threats to rights at the present time in order to issue recommendations? Or would it be a body destined to guide the respective governments in the development of protective measures during a pandemic and/or in between? These are classic questions regarding such mechanisms.

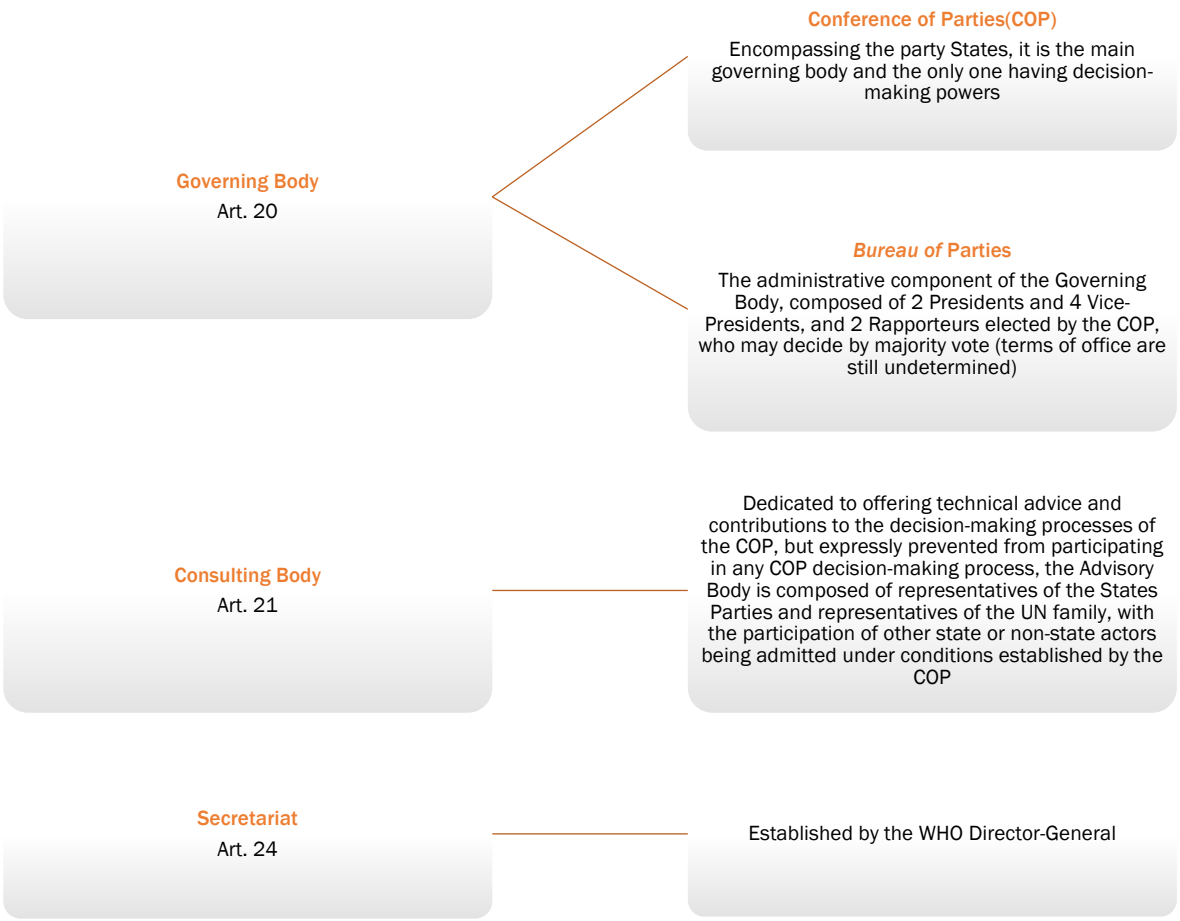
Importantly, the zero draft shifts the task of building and managing a human rights approach to pandemics to states. In fact, these national advisory councils could be replaced or complemented by a collective mechanism that would integrate the institutional structure of the CA+, based on experiences such as the SDGs follow-up mechanism or the Human Rights Council's Universal Periodic Review, both aimed at the progressive monitoring of the implementation of commitments and measures adopted to safeguard them. They could also reflect the composition of existing human rights bodies and mechanisms and, in particular, be composed of members of the human rights treaty bodies and special procedures of the Human Rights Council, possibly led by the Special Rapporteur on Health and the Committee on Economic, Social and Cultural Rights, experts on the specific topic. Such a composition would be the realization of the dialogue that Article 14 is intended to strengthen.

7. Institutional structure

The zero draft changes the institutional structure proposed in the conceptual draft by eliminating the "Expanded Conference of the Parties," which was part of the Governing Body of the CA+, and creating an "Advisory Body." While Article 19.4 of the conceptual draft referred to the Expanded Conference of the Parties as a "multilateral diplomacy body" encouraged to make a "broad contribution to the decision-making process of the Conference of the Parties," the zero draft clarifies that "*to avoid any ambiguity*, it is understood that the Advisory Body will not participate in any decision-making of the Conference of the Parties" (emphasis added). It is hoped that this unusual wording will disappear from the final text of the CA+.

Under the terms proposed by the zero draft, the governance of the CA+ would correspond to the representation in figure n. 3.

Figure n.3 - CA+ institutional structure according to the zero draft



Source: Authors

Although fundamental elements of the design of these bodies are still absent from the zero draft, it is already possible to see that it is an eminently intergovernmental structure, devoid of innovative character, which seems incompatible with the immense challenges surrounding the international response to pandemics, particularly with regard to the participation of non-state actors. A specific study devoted to the institutional framework of the CA+ is due to be issued promptly.

8. Control mechanisms and accountability

One of the most severe criticisms of the WHO is "being toothless," that is, it does not have the power to oblige states to comply with certain norms, or to be accountable for the fulfillment of the organization's recommendations.

Strictly speaking, this criticism should be addressed to states, not to the WHO, since an intergovernmental organization depends entirely on the will of its members when it comes to granting powers. On the other hand, the WHO has been criticized for decades for the opacity of some of its decision-making processes, such as, for example, the very procedure for declaring emergencies or pandemics, as mentioned above.

Both the failure of states to meet their obligations to respond to emergencies and the alleged lack of transparency in the WHO's management of the pandemic were crucial issues in the global response to covid-19. Both find in the CA+ the greatest political opportunity ever for international health law to evolve toward more efficient and equitable responses to pandemics.

However, article 22.1 of the zero draft is limited to stipulating that at its first meeting (therefore after the CA+ has entered into force internationally) the Governing Body will review and approve procedures for cooperation and institutional arrangements to promote compliance with the provisions of the CA+, as well as address cases of noncompliance.

Article 22.2 states that these arrangements will include follow-up and accountability measures, and are not to be confused with dispute settlement mechanisms between the Parties (provided for in Article 36 in classic terms of public international law). Such mechanisms would be instituted by the Governing Body of the CA+, comprising periodic reports and other undetermined actions. Thus, negotiations on ways to ensure compliance with the CA+ would be postponed until after the instrument is in force, without a fixed deadline for such mechanisms to be adopted.

The postponement of this discussion is not a good sign, and may indicate that everyone is already convinced that it will be a merely formal document. On February 5, 2023, Richard Horton, editor of the Lancet journal, commented on the zero draft:

> The absence of any mechanism for independent accountability is a fatal flaw in the zero draft. Whatever the warm rhetoric, without robust and independent monitoring, review, and action, words mean very little. The zero draft, I'm afraid, deserves zero applause[30]

After reflecting on what accountability means, in the next section we will specifically address the mechanisms for monitoring and controlling national prevention and response capabilities.

[30] https://twitter.com/richardhorton1/status/1622180478114533376?s=20

8.1. Accountability: what are we talking about?

The term accountability is usually used as a "silver bullet", whose mere mention would automatically improve political bodies or agents. To avoid purely rhetorical uses, it is important to establish a more solid base for the concept of accountability and to discipline its use.

Accountability exists only in relationships where the decision maker is accountable to others, and where those affected by the decisions have the right or are able to demand accountability for the actions (or lack thereof) of the decision maker. In this sense, the mechanism would have the ability to restrict the autonomy of decision-makers in some way.

From a conceptual point of view, it is a tool that puts two (or more) agents in dialogue. The first agent would be the decision maker (the power holder in accountability jargon). In the case of the pandemic agreement, the power holders would be the states. The second agent is the one who will be affected or who has a legitimate interest in the decisions adopted, called account holder. In the case of the CA+, the account holders are the WHO, on one side, and, indirectly, the other states.

From this concept we realize that neither a positive nor a negative quality can be presumed from the concept of accountability, which has no intrinsic value. For accountability mechanisms to effectively enhance political bodies or agents, its concept needs to be supplemented by normative guidelines, which are external to the concept.

The zero draft only abandons the rhetoric about accountability in article 22, but does so to postpone the creation of such a mechanism. Apparently, the mechanism will serve for the state to submit reports and action plans and for WHO to make technical considerations and provide assistance. The normative orientation of the mechanism has a clear epistemic appeal here, in the sense that its main objective would be to improve the cognitive abilities of the decision-maker and thereby function as a tool to make better choices possible.

The epistemic character, however, should not be the only goal to be reached by mechanisms of this nature. There are other goals that can and should guide Article 22, such as the rationale of democracy, since the future mechanism should be able to incorporate and respond to the wishes of various agents with legitimate interests in the decision-making process, such as civil society and other non-state actors.

8.2 Preparation monitoring, simulation exercises and peer review: relation with the IHR

Article 2 of the zero draft provides that the CA+ and other relevant international instruments, including the IHR, shall be interpreted in a complementary, compatible and synergistic manner, and that the CA+ shall be interpreted in a manner that promotes and supports the implementation and operationalization of the IHR. In this regard, Article 13 could be clearer, so as to avoid confusion and duplication of efforts in relation to already existing monitoring and evaluation mechanisms, especially those concerning IHR implementation[31] .

Given that pandemic preparedness and response, as well as the construction of national plans to this end, are not dissociated from the implementation of the IHR, and that the article provides for the development and implementation by States of a monitoring and evaluation system for pandemic prevention, preparedness and response, with the inclusion of standardized targets and indicators, it would be appropriate for the CA+ text to signal the importance that such monitoring and evaluation systems be implemented in a manner that complements, or incorporates, existing public health emergency preparedness and response capacity assessment mechanisms.

Through confusing wording, Article 13.7 goes so far as to provide for the establishment of a universal peer review mechanism to assess national, regional, and global preparedness capabilities. There are no details about how this mechanism would work.

It should also be noted that the aforementioned uncertainty of the legal character of the CA+ makes this clarification regarding existing capacity assessment instruments even more necessary, seeking a more harmonious relationship between the CA+ and the IHR, avoiding a duplication of efforts.

It is also worth noting that the provisions on financing in articles 18 and 22 of the conceptual draft have apparently been merged into a single article, article 19 of the zero draft. The new article moves towards setting minimum ceilings for expenditures on health expenditures related to the objectives of the agreement (19.1.c), as well as an -as yet - undetermined percentage of the gross domestic product of States Parties for investment for the same purpose, particularly for developing countries (19.1.d). The zero draft, however, is still far from presenting an original and potentially efficient financing model for funding its implementation.

[31] https://extranet.who.int/sph/ihr-mef

9. Intellectual Property and Access to Health Technologies

In our second technical note, two sections were dedicated to intellectual property and access to health technologies. In addition to what has already been noted by this WG, we bring the following elements.

It is unclear how CA+ will address the governance of health technologies/products already developed or under development for known pathogens with pandemic potential. The ownership of intellectual property, manufacturing, or contracts related to the financing of such technologies is already largely, disciplined. Therefore, if the CA+ has the scope to regulate only new products, as mentioned in several parts of the zero draft, its application is limited. At a minimum, it is necessary that there be a transition mechanism and an obligation for the member states that eventually financed the development of the technologies in question to renegotiate the conditions of access, technology transfer, licensing for manufacturing expansion, etc.

The concept of a global public good is included briefly in chapter VI on financing, without disciplining how CA+ would contribute to health technologies being developed as global public goods. For example, Articles 7.2 and 7.3 stipulate that access to health technology should also happen on "mutually agreed terms," which may suggest a direction toward voluntary licensing agreements and bilateral technology transfer, absent management as a global public good, and possibly limiting the ability to use compulsory licenses.

The definition of the principle of transparency, contained in Article 4 of the zero draft, is limited to the sharing of information and data for surveillance and development of health tools. Therefore, it does not address several important aspects for the supply chain of health technologies, particularly the disclosure of public investments in research and development, clinical trials, disclosure of procurement contracts and prices charged, among others. It is suggested that the topic of transparency be incorporated across the board in several sections of the CA+.

It is also noted that several entities that fund pandemic-related R&D, including vaccine procurement mechanisms such as GAVI, and philanthropic entities such as the Wellcome Trust and the Bill and Melinda Gates Foundation, are not covered by the provisions in the zero draft. Therefore, there is a risk that the governance of this technology escapes the new international regulations.

Finally, it should be reiterated that the zero draft, in this particular regard, is between distance and dissonance with the equity guideline that, as we commented in our previous note, should be the tone of the whole CA+.

10. Global Public Health Emergency Force

Article 12.3 contains a concrete proposal that Parties "invest in the establishment, sustainment, coordination and mobilization" of a global public health emergency workforce to be "deployed at the request of Parties based on public health need, in order to contain outbreaks and prevent escalation from small-scale spread to global proportions". Article 12(4) then goes on to propose that Parties "will support the development of a network of training institutions, national and regional facilities, and centers of expertise in order to establish common guidelines to enable more predictable, standardized, timely and systematic response missions and deployment of such a global public health emergency force.

Such proposals seem to derive more directly from the white paper prepared by WHO after consultation with member states on strengthening the global architecture for health emergency preparedness, response and resilience, presented to the 75th World Health Assembly (May 2022)[32]. In this document, the WHO recommends assembling a new global health emergency force, which has a leading role in emergency coordination by member states at national, regional and global levels[33].

Although the proposal will most likely imply a commitment from the signatory states in terms of funding and provision of human resources, there has been little discussion on the subject so far. At the third INB meeting, held in December 2022, Norway was the only country to address the issue, indicating that it was interested in exploring the concept of a global force. However, it emphasized that the main strategy should still be to secure a national health workforce.

The broader context inspiring the wording of items 3 and 4 of Article 12 appears to be that of a concern not only about the rapid escalation of covid-19 from a local outbreak to a pandemic, but also about outbreaks of the Ebola virus disease. In fact, the only antecedent for the proposal of a global public health emergency force is the United Nations Mission for Ebola Emergency Response (UNMEER), created by the UN General Assembly in 2014 to contain the outbreak of the Ebola virus in Guinea, Liberia and Sierra Leone. At that time, through Resolution 2177, the UN Security Council considered that the Ebola crisis in West Africa posed a threat to international peace and security, and that UNMEER, as a multidimensional peace mission, should address all dimensions of the health crisis in the region[34].

Therefore, this initiative lacks further detailing in the INB negotiating process, including to inform the Brazilian negotiating position and thus compare Brazilian interests on the subject with those of the other countries of the Global South.

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[32] HORTON, Richard. Offline: Bill Gates and the fate of WHO. The Lancet 2022, v. 399, n. 10338, p. 1853 https://doi.org/10.1016/S0140-6736(22)00874-1

[33] WHO, A75/20, 23 Mai. 2022, Strengthening the global architecture for health emergency preparedness, response and resilience, pp. 8-9 https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_20-en.pdf

[34] SANTOS NETO, Ramiro Januário dos. Da Missão da ONU para a Ação de Urgência contra o Ebola e de seu estabelecimento para combater uma ameaça à paz segundo o artigo 39 da Carta da ONU. *In:* Seminário de Pós-Graduação em Relações Internacionais da ABRI, 5., 2020, evento *on-line*. Anais. pp. 1481-1507. https://www.abri.org.br/download/download?ID_DOWNLOAD=1063

11. Antimicrobial resistance (AMR)

The topic of Antimicrobial Resistance (AMR) has been timidly appearing in the discussions about the new international legal instrument on pandemics, driven especially within the One Health agenda and by some actors who seek to influence the instrument. AMR is mentioned in the preamble of the zero draft as a "silent pandemic," but also as an aggravating factor during pandemics. No other infectious disease or phenomenon is directly mentioned.

In addition to the preamble, AMR also appears in 3 articles:

- Art. 4.14, Principles and rights, unique health - attention to the prevention of epidemics resulting from pathogens resistant to antimicrobial agents;
- Art. 9.4, Capacity building for research and development, R&D - encouraging the participation of non-state actors to accelerate R&D on antimicrobial resistant pathogens, among others;
- Art. 18, One Health - AMR as a possible driver of disease emergence and re-emergence (para. 3), commitment of parties to strengthen surveillance systems and laboratory capacity (para. 6), actions to prevent pandemics of resistant pathogens, national and local actions to identify and control AMR, development of national action plans to address AMR, improved surveillance to identify and report resistant pathogens (para. 7).

In a way, all the pillars that WHO uses to work on addressing AMR are mentioned in the draft (strengthening surveillance and research, infection prevention and control, rational use of antimicrobials, investment in R&D), except the pillar of knowledge dissemination /education /communication.

However, this instrument may be a good opportunity to work these pillars of AMR in an integrated way, that is, they could appear in other articles, for example:

- Art. 8 - Improve and strengthen the regulation of the prescription and dispensation of antimicrobials in human, animal, and agricultural health;
- Art. 11.4(g) - Include strengthening of laboratory capacity in microbiology, especially of LMIC, to identify resistant pathogens;
- Art. 12 - Invest in the training and continuing education of the health workforce, as well as awareness campaigns, in primary health care and hospital settings, to increase the commitment of these professionals to infection prevention and control in normal situations, reinforcing the practice beyond situations of epidemics/pandemics.

12. Participation of non-state actors

In this section, we will complement the analysis made in our technical note n. 2 on the participation of non-state actors in two different dimensions: in the response to pandemics that will be regulated by the future CA+, and in the negotiation of said instrument.

12.1 Participation of non-state actors in the response to pandemics

The zero draft maintains the "whole-of-society" approach to social participation that, as we commented in technical note n.2, considers the private sector and civil society as part of the same field of action, following OECD guidelines.

Considering the already mentioned role of communities and social entities in the response to covid-19, decisive for millions of lives to be spared, it is essential to include specific references to the participation of communities and social organizations in the international response and in the national responses to pandemics. The institutional structure foreseen in the zero draft, already referred to in a previous section, is far from guaranteeing this participation, thus compromising the legitimacy and efficiency of the new governance of pandemics that is supposed to be instituted. In the case of Brazil, for example, social participation is a SUS principle, reflected in the body of national health legislation and has guided, for decades, the country's international action in the health field.

Social participation should be mandatory at least in the national human rights advisory committees proposed by Article 14.2(b), which should advise governments on human rights protection during public health emergencies, and in the universal review mechanism provided by Article 13.6 to assess national, regional, and global preparedness capacities and gaps.

12.2 Participation of non-state actors in the negotiating process

The participation of representatives of organizations of the UN system and other intergovernmental organizations with which WHO maintains effective relations, as well as observers, representatives of non-state actors in official relations with WHO, other relevant stakeholders, and experts in the negotiating process of the CA+ has already been described in our Technical Note No. 2[35] and will be the subject of specific future publications.

In this note, we simply point out that there are no forms of participation of non-state actors in the Drafting Group of the CA+ and in future meetings of the INB[36]. We consider that the forms of participation established so far are insufficient for the new agreement to reflect the expectations of social actors that played a central role in the response to covid-19, such as the scientific community, non-governmental organizations that work in the field of global health, and social entities that worked directly with peripheral communities during the pandemic.

[35] Specifically pages 6 - 8, see https://saudeglobal.org/wp-content/uploads/2022/12/GT-NT-2_2022-1.pdf
[36] A/INB/4/4 - Proposal by the Bureau of the Intergovernmental Negotiating Body (INB) regarding modalities for the INB's fourth and fifth meetings, for consideration by the INB https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_4-en.pdf

13. Closing remarks

In a propositional way, we now present a summary of the main suggestions emanating from the contributions of the WG members who sign this technical note, without prejudice to what has already been recommended in technical note n.2.

Legal nature of the instrument

1. To immediately define that it is a convention within the meaning of art. 19 of the WHO Constitution, putting an end to the confusion between the negotiating processes of the INB and the Working Group analyzing the amendments to the IHR. In addition, when defining the nature of the instrument, use the example of the Framework Convention on Tobacco Control both as a way of disseminating the negotiations and inviting the participation of state and non-state actors, and as an example of mistakes and successes made during the negotiation and implementation of that convention.

Preamble reflected in the provisions of the agreement

2. To amend the absence of reference to climate change, which reflects the limitation of the scope of the CA+ to the control of infectious diseases. Add reference to obligations enshrined in IHL. Promote an effort at conciseness and precision that allows the preamble to fulfill its task of facilitating interpretation of the text of the agreement.

Definition and mechanism for declaration of pandemics

3. To exclude from the concept of a pandemic the criteria of severe morbidity and increased mortality. Delete the reference to the declaration procedure for pandemics by the Director-General, respecting the autonomy of WHO in a highly technical matter, and avoiding overlap with the mechanism for declaring PHEICs provided for by the IHR.

Definition of surveillance

4. To expand the concept of One Health surveillance beyond genomic surveillance to detect outbreaks with pandemic potential as early as possible.

Human rights

5. To improve article no. 14, adding the international obligation of inseparability between the adoption of measures restricting rights and social protection; going beyond the guarantee of non-discrimination that seems to be the keynote of the proposed device to consecrate the integrality of human rights, including the principle of non-reactivity; incorporate the acquis of international human rights systems concerning pandemics; expressly include the protection of migrants, refugees, and refuge seekers in the face of closed borders and other

restrictions on international mobility; insert specific provisions for the protection of health professionals; and detail the composition and mission of the independent advisory committees, in addition to giving them a regional and multilateral dimension.

Control mechanisms and accountability

6. To reverse the postponement of the establishment of control mechanisms for compliance with the obligations provided for in the CA+, including the adoption of accountability measures, so that they appear in the text of the agreement. Clarify the relationship between the follow-up measures provided for in the IHR and those provided for in the CA+.

Intellectual Property and Access to Health Technologies

7. To promote a global revision of the provisions related to this issue in the zero draft, including in the CA+, with mandatory character, the content of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights, among other guarantees to promote equity.

Global Public Health Emergency Force

8. To request from the INB and/or the proponent of Article 12, Items 3 and 4, further information on the concepts of the global public health emergency workforce and the network of training institutions, national and regional facilities, and centers of expertise. Request advice from the relevant areas of the Brazilian government and from Brazilian civil society organizations about the referred items and about eventual Brazilian interests to be presented on the subject.

Antimicrobial resistance

9. To include antimicrobial resistance in new provisions of the CA+, such as articles 8, 11.4(g) and 12, in order to work on this theme in an integrated manner.

Institutional framework and participation of non-state actors

10. To build a more advanced and innovative institutional framework that is up to the challenges brought by the response to pandemics, based on the example of other successful international arrangements that effectively contemplate intersectorality and provide the CA+ with effective mechanisms for participation of non-state actors, especially those who are not committed to the interests of the private sector. Ensure the participation of non-state actors in the next stages of the work of the INB, as an imperative of transparency and legitimacy of an international agreement that will require broad social support when it is incorporated into national orders and its implementation.

Abbreviations list

ABS - Access and Benefit Sharing

C-TAP - Technology Access Pool

CA+ - Legal instrument on pandemics negotiated within WHO

G-10 Favelas - Social Impact Block of Favela Leaders and Entrepreneurs

G-7 - Group of 7

GAVI - Global Alliance for Vaccines

IACHR - Inter-American Commission on Human Rights

IHR - International Health Regulations

IOM - International Organization for Migration

IPCC - Intergovernmental Panel on Climate Change

OHCHR - UN Office of the High Commissioner for Human Rights

PHEIC - Public Health Emergency of International Concern

R&D - Research and Development

RAM - Antimicrobial resistance

SCZ - Congenital Zika Virus Syndrome

SDG - Sustainable Development Goals

SUS – Brazilian Unified Health System

UN - United Nations Organization

UPR - Universal Periodic Review

WHA - World Health Assembly

WHO - World Health Organization

WTO - World Trade Organization

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