KEI Comments on the May 10,2024 INB Draft of the Pandemic Accord

KEI Staff, May 17, 2024,
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Introduction

There is considerable misinformation on social media and from some politicians and other influencers regarding the negotiations for a WHO pandemic treaty.

In order to provide better understanding of what is actually being negotiated, this note provides commentary on several key articles, based upon the INB's May 10 draft text, as published by Health Policy Watch.

https://healthpolicy-watch.news/wp-content/uploads/2024/05/Pandemic-Agreement-Draft-Reflecting-progress-up-to-10-May.pdf

In general, as the negotiations have progressed, in many areas, the obligations have become softer, as the WHO INB pushes for consensus. That said, the text does create norms in several areas, and mandates and mechanisms for cooperation that are potentially important going forward.

The discussion covers Articles 4 through 13bis, and Articles 19, 20, 27, 29, 30 and 31.

Article 4. Pandemic prevention and surveillance

At this point in the negotiations, the measures in the prevention and surveillance chapter are fairly mild. Parties are asked to "progressively strengthen pandemic prevention and surveillance capacities," which I think all governments would like to do even without the agreement.

The numbering is mixed up (some paragraphs have been deleted or moved) and will be redone in a future draft, so these numbers only refer to the May 10 text.

The 10 bullet points for action in what is now numbered 4.4, is illustrative. The chapeau starts with:

> Each Party shall, in accordance with its national laws and subject to the availability of resources, develop, strengthen and implement, comprehensive multisectoral national pandemic prevention and surveillance plans/1/, programmes and/or other actions, that are consistent with the IHR and that cover, inter alia:

This is a "shall" but only to "develop, strengthen and implement" measures "that are consistent with the IHR," a separate and existing WHO agreement, and even then "subject to the availability of resources."

In 4.2bis there is a reference to "environmental, climatic, social, anthropogenic and economic factors may increase the risk of pandemics," but parties only agreed to "shall endeavour to consider these factors" and "as appropriate, in accordance with national law, and subject to applicable international law."

In 4.5, the Conference of Parties (COP) "may adopt" non-binding guidelines and recommendations, and the only thing left to resolve in this chapter is the relationship between 4.5 and 5.3 on One Health.

Everything in Article 4 is now in yellow with the sole exception of the relationship between 4.4 and 5.3, and it is not surprising because the commitments are almost no obligation at all.

On the positive side, Chapter 4 does give a mandate for the Parties and the COP to work on pandemic prevention and surveillance, and this may become more consequential during the implementation of the agreement.

Article 5. One Health approach for Pandemic Prevention, Preparedness and Response

The One Health approach refers to the interconnectedness of animal, human, and environmental health, and given the cause and source of pandemics, quite relevant.

One telling anecdote about the negotiations is that delegates have spent a large amount of time debating whether to use lowercase or title case for One Health, and this is currently unresolved in the text, with brackets on [One Health/one health].

The first paragraph in Article 5 (5.1) begins with a “shall” but it’s only a “shall promote” and refers to an approach “recognizing the interconnection between the health of people, animals and the environment.” Again, there are caveats such as “as appropriate” and “taking into account national circumstances.”

In Article 5.2, the brackets refer to [in line with national law and], but the rest of the paragraph requires actions (shall take measures, as appropriate), relating to interventions and response place, but again “subject to the availability of resources.”

In Article 5.3, there are a series of qualifiers including “subject to the availability of resources,” and “taking into account national and regional contexts,” and only to “take appropriate measures [...] with support, as necessary and upon request, from WHO and other relevant intergovernmental organizations.” There are three subparagraphs, which include “Developing, implementing and reviewing relevant national policies and strategies,” somehow involving “the effective and meaningful engagement of communities,” and “Promoting or establishing joint training and education programmes.”

Article 5.4 is the most bracketed, and does not have any consensus yet, and concerns a possible legal instrument, by May 2026, to contain additional obligations.

There has been resistance among some countries to include Article 5 in the agreement, or to insist on external funding and technical support to meet its obligations.

KEI suggested to some negotiators that the agreement consider an opt-in protocol that would provide a transition period for countries that currently lack the capacity and resources to implement the provisions in Article 5, where those countries would receive assistance before the obligations, as they are, would become binding. Several transition periods were available in the

WTO TRIPS Agreement, for developing countries and countries in transition, and least developed country members of the WTO are still benefiting from an extended waiver of obligations to grant patents on pharmaceutical drugs. However, no delegation has made such a proposal for a special transition period option for Article 5.

Article 6. Preparedness, readiness and health system resilience

This Article begins with an obligation in 6.1 that “Each Party, within the means and resources at its disposal, shall take appropriate measures to develop, strengthen and maintain a resilient health system, particularly primary health care, for pandemic prevention, preparedness and response, taking into account the need for equity and in line with Article 19, to achieve universal health coverage.” This is “within the means and resources at its disposal,” and refers to “appropriate measures,” and reflects goals that governments have already embraced many times, while often falling short of achieving those goals. In any case, it is considered “green”.

Paragraph 6.2 largely elaborates on 6.1, repeating the “within the means and resources at its disposal” and “appropriate measures” qualifiers, and has several non-controversial statements on what a good health system should include.

Paragraph 6.3 and 6.3alt both refer to health information systems. Paragraph 6.3 has the most brackets and more detail on the timely sharing of health data. Both versions refer to standards and interoperability, which are important. Paragraph 6.3alt has green text for “in accordance with national or domestic law,” and both versions are merely obligated to language like “shall endeavour towards developing, strengthening and maintaining” the information systems, something that every Party undoubtedly wants to do.

Paragraph 6.4 is all green and requires Parties to monitor and assess its readiness.

Paragraph 6.5 is highly bracketed and refers to the COP creating or considering creating evaluations of national systems.

Article 7. Health and care workforce

This section is all in yellow with no brackets and contains a series of agreements to treat its labor force with respect to safe and decent working conditions.

This is how each of the 5 paragraphs begin:

7.1 Each Party, in line with its respective capacities and national circumstances, shall take the appropriate measures …

7.2 Each Party, taking into account its national circumstances, and in accordance with its international obligations, shall take appropriate measures …

7.3 Each Party shall endeavor …

7.4 The Parties shall collaborate, as appropriate, and in accordance with their national laws, through multilateral and bilateral mechanisms, ….

7.5 The Parties, taking into account national circumstances, shall take appropriate measures…

Article 8 was deleted

Article 9. Research and development

There are 5 paragraphs, and several brackets. This is one of the areas where there have been hopes that concerns over equity would be addressed, but as it stands, that is not clear.

Unlike the central point of earlier proposals for a WHO biomedical R&D treaty, there are no specific obligations to fund anything. Instead, the five paragraphs include a number of soft promises to cooperate, strengthen, and sustain a variety of measures, in accordance with national and/or domestic laws.

In paragraph 5.1 there are brackets on the words [open science].

In paragraph 5.2 there are brackets on [open innovation].

In paragraph 5.2 in a discussion of what the Parties “shall promote” there are brackets on research relating to [epidemiology, factors, and impacts of emerging diseases, and public health and social measures.]

Paragraph 5.3 on clinical trials has brackets around key provisions, including [comparator] [products needed to carry out trials], and [and access for] such study populations of [to] the safe and [effective/efficacious] products that result from these trials.

Paragraph 5.4 includes, in yellow, an obligation to “support the transparent and public sharing of research results.” But also these brackets: [The Parties in accordance with [international standards,] national and/or domestic law and policies shall facilitate the rapid and transparent publication of results and research including the results of clinical trials, related to the implementation of this Agreement.]

Paragraph 5.5 now has 17 brackets and nothing is yellow. One hope for this paragraph was that the Parties would agree to conditions on publicly funded research regarding affordable access and technology transfer. This is how the paragraph stands now:

> Each Party shall develop and implement[, as appropriate,] national [and/][or regional] policies [regarding the inclusion of] /[to include]/[on the inclusion of] provisions [in [publicly funded research and development agreements][particularly with private entities]/[with private and budgetary entities]/ [in research and development agreements in case of public-private partnerships/contracts] DEL] for the development of pandemic-related health products that promote timely and equitable global access to such products [during [public health emergencies of international concern and DEL] pandemics/[pandemic emergencies] DEL], and the publication of such terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) [voluntary] technology transfer [on mutually agreed terms]; (iv) publication of relevant information on research [inputs and DEL] outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.

One bright spot is the possible agreement that there will be an obligation for each Party to develop and implement policies in funding agreements “that promote timely and equitable global access to such products [during [public health emergencies of international concern and DEL] pandemics/[pandemic emergencies] DEL], and the publication of such terms.

The attempt to include [voluntary] and [mutually agreed terms] in a sentence dealing with terms that a Party “may include” in a public funding agreement, is one of the areas of controversy in the negotiations, since it can be read to exclude the use of take it or leave it provisions in funding agreements, particularly since funding agreements are always voluntary by their nature.

Article 10. Sustainable and geographically diversified local production

This article has 395 words in three paragraphs with no brackets, but a patchwork of white and yellow text.

Paragraph 2 includes six subparagraphs that begin as follows:

(a) take measures, as appropriate, to provide support, and/or strengthen…
(b) facilitate…

(c) actively support, as it deems appropriate…
(d) endeavour to promote and incentivize…
(e) encourage international organizations and other relevant organizations to establish…
(f) during pandemics, in cases where the capacity of facilities does not meet demand, take measures…

Article 11. Transfer of technology and know-how for the production of pandemic-related health products

This is one of the most challenging articles to conclude. It now has 1,446 words, 51 brackets, and no paragraphs that are all yellow.

Everywhere that technology transfer or know-how is discussed there are controversies over the attempts to insert mutually agreed terms (aka MAT) or voluntary mutually agreed terms (aka VMAT).

KEI has written extensively on this issue, and there was also an important vote on the topic on May 2, 2024, at the UN General Assembly, which rejected an amendment by Switzerland to insert VMAT into a paragraph on technology transfer in a resolution on global health.

- KEI comments on six references to “mutually agreed terms” in the WHO pandemic agreement negotiating text: A/INB/9/3 Rev.1, 22 April 2024. https://www.keionline.org/39741

- The WHO Pandemic agreement, language on mutually agreed terms for technology transfer, and claims under investor-state dispute resolution (ISDS). https://www.keionline.org/39762

- Letter to Anne Yu, Director for Global Pandemic Preparedness, NSC, on negotiations for WHO pandemic agreement. https://www.keionline.org/39776

- UN rejects amendment to limit technology transfer to “voluntary and mutually agreed terms” in resolution on global health. https://www.keionline.org/39781

There have been proposals by some negotiators to clarify that any language on technology transfer or the transfer of know-how that uses “mutually agreed terms” with or without the word voluntary, are without prejudice to other measures a Party may take that have a mandatory nature.

It is the case that the US Defense Production Act (DPA) and the new European Union regulation on compulsory licensing for crisis management both give governments the power to mandate

the transfer of know-how and to provide access to cell lines and other ancillary measures when voluntary measures are not available or are inadequate.

Regarding the EU proposed regulation, see recites 32a and 32b in Resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)).

> 32a "Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. . . . It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee. . .
>
> 32b ". . . While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how."

Regarding the US Defense Production Act, see the definitions in 50 USC 4552:

> (3) **Critical technology.** The term "critical technology" includes any technology designated by the President to be essential to the national defense.
> (4) **Critical technology item.** The term "critical technology item" means materials directly employing, derived from, or utilizing a critical technology.
> (6) **Domestic industrial base.** The term "domestic industrial base" means domestic sources which are providing, or which would be reasonably expected to provide, materials or services to meet national defense requirements during peacetime, national emergency, or war.
> (8) **Facilities.** The term "facilities" includes all types of buildings, structures, or other improvements to real property (but excluding farms, churches or other places of worship, and private dwelling houses), and services relating to the use of any such building, structure, or other improvement.
> (12) **Industrial resources.** The term "industrial resources" means materials, services, processes, or manufacturing equipment (including the processes, technologies, and ancillary services for the use of such equipment) needed to establish or maintain an efficient and modern national defense industrial base.
> **(13) Materials.** The term "materials" includes—
> (A) any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and
> (B) any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.

The US Defense Production Act was used extensively by the US government during the COVID-19 Pandemic.

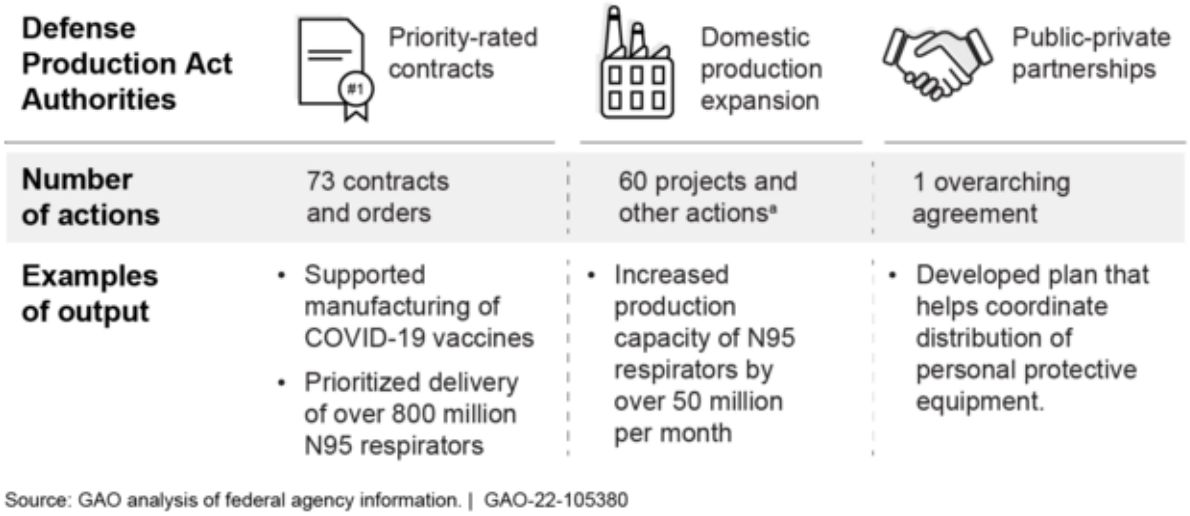
See:

Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues: GAO-21-108, Published: Nov 19, 2020. Publicly Released: Nov 19, 2020. https://www.gao.gov/products/gao-21-108

COVID-19: Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities, GAO-22-105380, Published: Dec 16, 2021. Publicly Released: Dec 16, 2021. https://www.gao.gov/products/gao-22-105380

Among the U.S. Government Accountability Office (GAO) Findings:

> "Federal agencies used the Defense Production Act (DPA) and other actions over 100 times to help address COVID-19 medical supply needs through September 2021. Agencies used DPA authorities to 1) prioritize contracts so those orders can get preference over others, (2) fund projects to expand domestic production of supplies, and (3) enter into partnerships with private companies (see figure)."



Defense Production Act Authorities	Priority-rated contracts	Domestic production expansion	Public-private partnerships
Number of actions	73 contracts and orders	60 projects and other actions[a]	1 overarching agreement
Examples of output	• Supported manufacturing of COVID-19 vaccines • Prioritized delivery of over 800 million N95 respirators	• Increased production capacity of N95 respirators by over 50 million per month	• Developed plan that helps coordinate distribution of personal protective equipment.

Source: GAO analysis of federal agency information. | GAO-22-105380

The most recent time the U.S. involved the Defense Production Act was in 2022, in order to enhance U.S. manufacturing of large storage batteries.

> "On March 31, 2022, the president signed a determination permitting the use of Defense Production Act (DPA) Title III authorities to strengthen the U.S. industrial base for

> large-capacity batteries. With this action, the president gave the Department of Defense (DoD) the authority to increase domestic mining and processing of critical materials for the large-capacity battery supply chain." Press Release, Defense Production Act Title III Presidential Determination for Critical Materials in Large-Capacity Batteries, US Department of Defense, April 5, 2022,

In a May 17, 2024 negotiation on the IHR, the United States proposed the following language on a similar provision:

> footnote in Article 13.8(e) that would come right after "mutually agreed terms" and would say the following " "For greater certainty, the reference to voluntary transfer of technology, know-how and expertise on mutually agreed terms is without prejudice to the rights, obligations, and flexibilities that WTO Members have under the provisions of the TRIPS Agreement, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health.""

The proposal by the United States in the IHR negotiations to make reference to the TRIPS Agreement is somewhat helpful, but certainly not as clear as acknowledging that non-voluntary measures are not ruled out for knowledge transfers and access to other inputs to products. The TRIPS does not mention know-how, or deal with mandates to train staff or provide access to cell lines, samples or other ancillary inputs, measures that the US Defense Product Act or the EU regulation on compulsory licensing in emergencies address. The footnote could be read to limit the use of mandatory measures to only those permitted specifically by the TRIPS, and given the limited scope of the TRIPS agreement on topics such as access to biological resources or know-transfers, it creates legal uncertainty.

One bright spot of the May 10 text is the return of language on possible pooling of knowledge resources, in the "Chair's simplified proposal for paragraph 5, following 7 May working group session."

The Chair's version, all in white, is an obligation on the Parties, working through the COP, to create mechanisms

> "that promote and facilitate the transfer of technology with a view to increasing access to pandemic-related products, particularly in developing countries, including through the pooling of intellectual property, know-how and data and transparent, non-exclusive licensing."

The Chapter 11 text includes a proposal for a footnote on know-how.

> **note: on "know-how", we can add a footnote:**
> For the purpose of this agreement, the transfer of technology includes the transfer of know-how [required to consistently manufacture and control the resulting product according to international standards].

Article 12. Pathogen Access and Benefit-Sharing System

The negotiations over the Pathogen Access and Benefit-Sharing System (PABS) have been challenging and may carry over to be fully resolved at a later date.

The PABS is modeled after the WHO Pandemic Influenza Preparedness (PIP) Framework, a system where the WHO facilitates the collection and distribution of influenza pathogens, and provides them to companies and researchers who sign contracts to provide certain benefits, including money to support its operation and benefits specifically designed to increase access to vaccines and enhance the research capacity in developing countries, include percentages of vaccines manufactured that are provided to the WHO for free or at concessionary prices. A WHO web page with links to background information of the PIP Framework is here: https://www.who.int/initiatives/pandemic-influenza-preparedness-framework

It is not straightforward to export the PIP framework to PABS, for several reasons. Unlike the market for seasonal influenza vaccines, where suppliers and demand for products are reasonably predictable, a new virus like COVID-19, Zika, Ebola or monkeypox may involve new firms and researchers that do not have a relationship with the service, the role of public funding for R&D may be more extensive, and demand can have significantly different characteristics. Also, some proponents of PABS want it to address more than access to the samples, they wanta tracking system for sequences or other digital information from the samples and to condition access to the digital information to benefit sharing obligations.

Highly relevant to the PABS is the legal status of pathogens as a genetic resource to be protected under the Convention on Biodiversity (CBD), and whether the PABS would satisfy the requirements of the Nagoya Protocol, which is an agreement within the CBD. The Nagoya Protocol allows parties to create a system of benefit sharing that provides legal certainty regarding benefit sharing obligations, and in the context of the PIP Framework and PABS, the benefits would be global, rather than specific to the country where the generic resources originate.

KEI is of the view that pathogens should not have been protected as a genetic resource under the CBD, but there is widespread opinion that they are, legally, and the negotiators at the WHO assume that they are.

The IFPMA has signaled it will support some type of benefit sharing in the PABS, but as is the case for everyone else, the details matter, particularly on such topics as the percent shares of free or price controlled products, the monetary contributions and technology transfer obligations, if any.

KEI's views on the PABS are nuanced. In the case of a life threatening or altering pandemic, particularly one that spreads rapidly, it is important that researchers everywhere have access to timely information about the pathogens, including sequences. It is our opinion that it is not burdensome or unusual to attach metadata to sequence data that describes its source, and in general, we have pushed for better standards for metadata in other areas. It is the case that better metadata on sequences enables other policy measures, including those relating to disclosures on patent applications, a topic of a separate WIPO treaty negotiation, but also possible attempts to monetize or restrict access to biomedical sequence data in artificial intelligence services, similar to the European Union opt-out for copyright by commercial entities in its new AI Act.

The percentages of vaccines or other products shared may or may not be set in any agreement by the time of the WHA. The common numbers of 10 percent free and 10 percent at concessionary prices are proposed as a floor by some and a ceiling by others. As a practical matter, the percentages could be different for different pandemics, and percentages that are too high will discourage companies from participating, which has a potentially negative impact on innovation.

If the costs of participating in the PABS are significant, one risk is that the large and/or established companies will have access while smaller or newer companies or independent researchers will not, and this could have negative impacts on industry concentration and innovation.

Some of the motivation for the benefit sharing article is to address the recognition that some pandemics have been huge windfalls for some companies, and to also distribute products first to the highest income customers in times of crisis. The benefit sharing provisions are designed to create more global equity.

Many of the measures to expand access and affordability could be implemented outside of the PABS, reducing pressure on the PABS to restrict access to pathogen information. But as the negotiations have so far demonstrated, the US, the EU, the UK, Japan, and Switzerland have mounted considerable opposition to the equity measures in other parts of the pandemic agreement.

The sense among many developing countries is that they have some leverage in Article 12, where the pharma industry wants legal certainty on benefit sharing obligations under the CBD (a treaty with 196 parties), and almost no leverage in Articles 9, 10, 11 or 13 regarding conditions on publicly funding R&D, local production, technology transfer, and supply chain management. The very countries that complain about onerous conditions for access to pathogen information are the countries that block key equity measures in other parts of the agreement.

Now, a look at the May 10 text.

Paragraph 2 of the PABS system is largely greened, and concerns the provisions governing the PABS system. However, there remains some brackets throughout this paragraph, including what falls within the scope of the PABS System, [,including] [of pathogens with pandemic potential and] Material and Information,]. In addition, whether PABS shall be developed and agreed in a [legally binding] instrument remains bracketed.

Paragraph 3 refers to the modalities of access and benefit sharing. Previous versions focused on the need for legal certainty, but did not have extensive details on the implementation through legally binding contracts. The May 10th version introduces the concept of legally binding terms and conditions. There are also two suggestions for alternate modalities for paragraph 3 b(alt) texts:

> (b. alt.) [the [access and] benefits shall be implemented by [standardized] legally binding contracts between the [WHO and the users of the] PABS system and [private] entities which [voluntarily] conclude such contracts, taking into account the different nature, size and capabilities of such entities;]/[the access will be in accordance with terms and conditions to be agreed in the instrument, refer to paragraph 6']
>
> b (alt) Processes that govern access to PABS Materials and Information and include, inter alia, terms and conditions for monitoring and accountability; processes that govern benefit sharing, including contracts concluded by WHO, and that take into account the nature, size and capacities of entities that decide to enter into such contracts.

The gray text indicated that this subparagraph has no amendments proposed.

Paragraph 3(g), concerning intellectual property rights of PABS Material and Information remains fully bracketed. An earlier version from the agreement added an obligation not to seek or grant intellectual property rights of PABS Materials and Information. Now, the paragraph reads as follows:

> [intellectual property rights of [PABS] Materials and Information [shall be addressed in the instrument referenced in paragraph 2];][DEL]

In Paragraph 4 on the provisions of Benefit Sharing, there is partial yellow text in subparagraph b(ii), which states that "Annual monetary contributions shall be administered by the PABS System[.] [, based on modalities, terms and conditions, to be defined according to paragraph 2b.]

The May 10th text contains a new provision, 12.4(b)(ii bis):

> [(NEW ii bis.) During a PHEIC and/or pandemic emergency, grant to WHO royalty free, non-exclusive manufacturing licences, that can be sub-licensed to manufacturers in developing countries for the production of vaccine therapeutics and/or diagnostics.]

This new obligation on the PABS system is a welcome addition by the Bureau, but its status going forward is not clear.

Article 13. Supply chain and logistics

The chapter on supply chain and logistics is fairly detailed, in seven paragraphs including five subparagraphs in paragraph 2.

At its core is the creation of the Global Supply Chain and Logistics Network (the GSCL Network), to be convened by the WHO and “relevant stakeholders,” a term that might or might not end up being defined in the text, but during the negotiations it includes industry, NGOs, academics, and others.

Article 13 is largely highlighted in yellow. When comparing earlier versions, there were many deletions of delimitations throughout the article (e.g., [at all times DEL], [by consensus DEL]). These deletions seem to have been accepted since they no longer appear in the May 10th version.

The functions of the GSCL are described in paragraph 3 to include:

1. estimation of supply and demand;
2. identification of product and relevant raw material sources;
3. facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10,
4. coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work;
5. promotion of transparency across the value chain; collaboration on stockpiling; and
6. facilitation of equitable [and unimpeded] access, including allocation, distribution, delivery, and assistance with utilization, [including for products provided to the PABS system,] during a PHEIC and a pandemic emergency.”

Paragraph 4.bis regarding sanctions is bracketed as a deletion:

> [4.bis the Parties of the agreement shall not apply any unilateral economic, financial or trade measures not in accordance with international law and the Charter of the United Nations that impede supply, distribution or procurement of any medical or health related goods [, including medicine, medical equipment, spare parts, raw materials, software, access codes etc. DEL] DEL]

[Article 13bis. [National (DEL)] procurement and distribution

At least half of Art. 13bis has been yellowed. Some of the deletions that were made on the distributed May 9th version have been streamlined in the May 10th version. In particular, the

Vice Chair proposals from the May 9th text on subparagraphs 4 and 5 have been largely consolidated and implemented into the May 10th version and largely yellowed. There remains a number of brackets within these two paragraphs, with suggested deletions.

Paragraph 1 includes an obligation to provide some welcome transparency of purchase agreements through the publishing of terms relevant to procurement and distribution, and also to exclude from those agreements confidentiality provisions that limit disclosure. The paragraph is entirely in yellow and has no bracketed deletions or suggestions.

Similarly, paragraph 2 is entirely yellowed and concerns global access provisions in publicly funded purchase agreements. This subparagraph does, however, include a bracket for the term [unhindered] with reference to equitable global access. MSF is among the NGOs that have raised concerns about the risks and dangers to health workers in conflict zones, and KEI has complained about the impact of sanctions on humanitarian supplies including drugs and vaccines. See KEI's letter to the Department of Treasury on exception to sanctions for medical products.

Paragraph 7 alt, 7 alt 2, paragraph 8 and 8 alt all remain neither highlighted in green nor yellow. Paragraph 7 sets out generally that shared products should not be earmarked and that they should come with necessary information to ensure effective use. The bracketed suggestions for paragraph 7 alt and 7 alt 2 further refine paragraph 7 by explicitly mentioning 'expiration dates' or mentioning 'sufficient shelf life' and 'provide recipients with expiration dates'. The provisions further detail that the products that are shared with countries, organizations or mechanisms are usable upon receipt and unearmarked.

Paragraph 8 concerns liability management and is bracketed for deletion. Paragraph 8 alt contains some deletions and provides a different and more detailed approach to liability management. This alternative paragraph emphasizes the role of the WHO in developing and encouraging the adoption of no-fault compensation mechanisms. The focus is thus on creating a global or regional framework to manage liability to ensure fair and swift compensation for adverse effects.

Article 19. International cooperation and support for implementation

Article 19 is one of the places where there are efforts by the US, EU, Japan, UK, Switzerland and other high income countries to insert [voluntary] and [mutually agreed terms] in connection with the obligation to promote technology transfer.

Here again it is important to either reject these additions or to clarify that any voluntary measures are without prejudice to measures a Party may take that are of a mandatory character.

It is important to avoid an interpretation or perception that pandemic agreement creates a global consensus that technology transfer can only be on voluntary and/or mutually agreed terms. (See extended discussion of this topic in Article 11 above).

Article 20. Sustainable financing

Much of Article 20 on sustainable financing has been yellowed. The article is about sustainable and predictable financial support for the implementation of both the WHO Pandemic Agreement and also the IHR (see paragraph 1), but actual financial commitments are not spelled out.

In paragraphs 1 and 2, there are several references to “endeavour”, to “mobilize,” to “promote”, “as appropriate,” and “to the extent feasible,” which reflect a lack of consensus over actual financing commitments.

At the end of paragraph 2 is the addition of 2*bis,* the non-averse measures clauses, which remains neither yellowed nor greened, which seems to refer to economic sanctions.

> [*2.bis* The Parties shall refrain from taking any measures that may adversely affect the sustainable and predictable financing of other Parties for the purposes of this Agreement.]

Paragraph 3, largely yellowed, sets out the establishment of the Coordination Financial Mechanism (the Mechanism) and the operational guidelines of the Mechanism. Much of the text is about identifying needs and possible sources of funding.

Paragraph 3(f) gives a mandate to seek:

> “voluntary monetary contributions for organizations and other entities supporting pandemic prevention, preparedness and response, free from conflicts of interest, from relevant stakeholders, in particular those active in sectors that benefit from international work to strengthen pandemic prevention, preparedness and response.”

Good to see “free from conflicts of interest” in the text, but note that it also refers to “relevant stakeholders” that are “active in sectors that benefit” creating some possible tension. Of concern over anything involving pandemics is the outsized influence that the Gates Foundation and Wellcome Trust exercise, institutions that recently announced a partnership with the Novo Nordisk Foundation and have in the past have aligned themselves with industry rights holders on matters concerning intellectual property rights.

Paragraphs 4, 5 and 6 use the word “consider” twice, “appropriate” four times, “mobilize,” and brackets on “by consensus” and “endeavour,” in text that all adds up to the financing will be decided later.

Article 27. Reservations

The reservations clause in the agreement is all in yellow, and is quite liberal in terms of reservations allowed.

> "Reservations may be made to the WHO Pandemic Agreement unless incompatible with the object and purpose of the WHO Pandemic Agreement."

Article 29. Amendments

There are six paragraphs on amendments to the treaty (paragraphs 1 through 5bis), and Parties can propose amendments to the Conference of Parties. While encouraging consensus, amendments can be adopted by a three quarter approval of Parties both present and voting.

Article 30. Annexes

Annexes to the agreement can be considered an integral part of the agreement, and can be proposed and adopted under the procedures for amendments in Article 29.

Article 31. Protocols

Protocols to the agreement are possible, but the procedures and consequences of doing so are more complex, and are currently set out in eight paragraphs, which include three brackets and a patchwork of yellow and white text. It may be possible for Parties not members of the agreement to join a protocol, although that option is currently bracketed.