

Article 10. WHO Pathogen Access and Benefit- Sharing System And Proposal for Open Source Dividend

Knowledge Ecology International
Comments on the World Health
Organization CA+ ZERO DRAFT



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This note provides paragraph by paragraph comments on Article 10 the WHO CA+ Zero Draft text, concerning the topic of WHO Pathogen Access and Benefit-Sharing System, and also the proposal for Open Source Dividend. The Zero Draft text is available [here](#).

Para 1.

Seems fine.

Para 2.

Not sure how this expands or limits the role of the PABS.

Access to pathogens with pandemic potential

Para 3. (a)

Seems fine.

Para 3. (b)

Seems fine.

Para 3. (c)

Seems fine.

Para 3. (d)

The phrase “in the form received” seems key here, but KEI does not have a problem with it.

Para 3. (e)

Might want an explanation of what this is intended to accomplish. We suggest the following change:

(e) Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws[, subject to and consistent with the provisions in this agreement as regards exceptions to rights.]

If something that clarifies the role of exceptions is not added, this paragraph could be deleted.

Fair and equitable benefit-sharing

Para 3. (f)

Seems okay, however, it may be read to limit other benefit-sharing measures in the agreement. One might consider the following clarification.

f) The Parties agree that benefits arising from facilitating access to pathogens with pandemic potential shall be shared fairly and equitably [in accordance with but not limited to] ~~in accordance with~~ the provisions of the PABS System. Accordingly, it is understood that the production of pandemic vaccines or other pandemic-related products, irrespective of the technology, information or material used, implies the use of pathogens with pandemic potential, including the genomic sequence;

It's worth noting here that the only thing singled out for benefit sharing is access to "pathogens with pandemic potential," even though there are many other things that need to be shared, such as is discussed below, inventions, access to cell lines, manufacturing know-how, access to and rights in data, etc. This is particularly important if the open source dividend approach is used.

Para 3. (g) - (h)

Modeled after the PIP Framework, a Standard Material Transfer Agreement (SMTA) is proposed to bind the recipients of the pathogens or genomic sequences of the pathogens to a set of obligations, selected by the recipient from a menu. The one option elaborated in the draft text concerns the "real time access by WHO to 20% of the production of products." This is not a requirement, only an option, and we don't know what the other options are. Of the 20 percent, 10 percent are a donation and 10 percent are at "affordable prices."

For context on how this might work, an Annex on the PIP Framework is attached. The PIP Framework has three different categories for recipients, two for manufacturers, one for vaccines and antivirals and one for other countermeasures (such as diagnostic kits). A third category is for academic and research institutions. Note that the negotiated contracts for vaccine manufacturers generally involve combinations of donations and reserved products at affordable prices that are 10 percent combined, and not 20 percent, the most common agreements are 8 percent donations and 2 percent of products reserved for WHO at affordable prices. None of the vaccine manufacturers have offered to license the technology, and no manufacturers of antivirals have signed agreements. There are two agreements for other countermeasures, and several for academic and research institutions. The Annex summarizes the commitments reached with the WHO.

The PIP Framework has been successful in the sense that it has obtained agreements with vaccine manufacturers, and companies have agreed to some benefit sharing. The industry is not

enthusiastic about the agreements, and negotiations continue, including a PIP Framework Advisory Group Consultation with Stakeholders on March 29, 2023.

The challenge for using the PIP Framework model for benefit sharing going forward is the possibility that manufacturers will be able to obtain pathogens and sequences outside of the PABS system, and that efforts to police this can result in unwanted restrictions on access to information that is useful in developing new countermeasures.

Recognition of the PABS System as a specialized international instrument

Para 3(i)

Seems fine.

Para 3(j)

Seems fine.

Para 3(k)

Seems fine.

Para 4.

Seems fine.

Reflections on Article 10

While the PABS system can add value, overall, we don't think that benefit sharing should be tied to access to the pathogens or pathogen sequences. Not only can companies obtain pathogens and sequences outside of the PABS system, but the sole focus on access to pathogens and their sequences ignores a large set of targets for which benefit sharing can be useful.

Timely sharing of pathogens and sequences is important, but so too is sharing and access to inventions, theories, information from experiments, other biologic resources including cell lines, know-how, data, rights in regulatory data, etc.

KEI proposes consideration for a separate Article on benefit sharing that introduces a mechanism modeled after the Open Source Dividend proposals, first proposed in the context of MSF's work on

a TB diagnostic prize, and later by bills in the U.S. Senate, and by several proposals by Bolivia, Barbados, Bangladesh and Suriname in the WHO negotiations over new approaches to funding R&D.

The basic idea in the context of this agreement is to impose a levy or fee on the sale of highly profitable countermeasures, for example, products with sales exceeding \$100 million or a different threshold, equal to from 1 to 5 percent of sales, depending upon the incentive desired, and then returning this money to persons, communities or entities that openly share pathogens, sequences, data, ideas, inventions, other biologic resources, manufacturing know how, rights in regulatory data, etc, when such sharing was considered material and significant in the development of the countermeasure. This creates a powerful economic incentive to share.

Once untethered from access to pathogens or their sequences, the scope of the remunerated sharing can be expanded, and designed in a variety of different ways that meet negotiators' or administrators' notions of which incentives are the most useful and most fair.

The Open Source Dividend Proposal

In June 24, 2022, KEI provided a comment to the WHO INB titled, "The open source dividend as a model for incentives to share biological resources, inventions, data, and other inputs." ([link](#)) This submission to the INB provides background on the development of the proposal, and the rationale.

Within the WHO CA+ Zero Draft text, there is a benefit sharing mechanism tied to access to pathogens in **Article 10**, and also a number of references to other areas where the sharing of knowledge and knowledge goods is to be encouraged or mandated.

Article 4, *Guiding principles and rights*, **paragraph 6** (dealing with transparency) refers to the importance of the open and timely sharing of information, data, biologic resources, and best available scientific evidence. **Paragraph 16** in Article 4 refers to the importance of science, evidence and findable, accessible, interoperable and reusable data.

Article 7 paragraph 3(a) of the Zero Draft calls upon parties to "incentivize manufacturers of pandemic-related products to transfer relevant technology and know-how to capable manufacture," and in **3(c)**, to encourage entities that conduct research and development to grant license "to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for pre-pandemic and pandemic-related products."

Article 7 paragraph 4(c) says that parties "shall encourage all holders of patents related to the production of pandemic-related products to waive, or manage as appropriate, payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for production of pandemic related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so;" and in **paragraph 4(d)** "shall encourage all research and development institutes, including manufacturers, in

particular those receiving significant public financing, to waive, or manage as appropriate, royalties on the continued use of their technology for production of pandemic-related products.”

Article 9, *Increasing research and development capacities*, contains a series of provisions including an obligation for parties in **paragraph 2(a)** to promote the free, public dissemination of the results of publicly- and government-funded research for the development of pandemic-related products; in **paragraph 2(b)** to endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms; and in **paragraph 4**, to encourage non-State actors to participate in and accelerate innovative research and development for addressing novel pathogens, pathogens resistant to antimicrobial agents and emerging and re-emerging diseases with pandemic potential.

As demonstrated above, the text has many requirements for parties to encourage and provide incentives to share knowledge, biologic resources, data, inventions, etc, but outside of the limited PABS mechanism, few concrete measures to ensure it happens.

Illustration of an open source dividend approach

The open source dividend proposal could be introduced as a separate article, or included under Article 9, Article 19 or even in Article 7 or 10. An example of how it might be addressed follows.

Parties agree

- (a) To create an Open Source Dividend fund within the WHO, to reward and provide incentives to individuals, communities or entities that openly and freely share access to ideas, inventions, data, rights in regulatory data, manufacturing know-how, pathogens or their sequences and other biologic resources including cell lines, that are used and useful for the development of countermeasures;
- (b) To contribute to the Open Source Dividend fund an amount initially set at 2 (or some other number) percent of the gross sales revenue for any pandemic-relevant vaccine, therapeutic or diagnostic countermeasure, for which global sales exceed \$100 million in any consecutive four quarters. The Governing Body of the CA+ may adjust the contribution percentage from time to time, in order to achieve revised incentive and benefit sharing objectives.
- (c) That the Governing Body of the CA+ shall develop procedures for the management of the Open Source Dividend Fund, which are transparent and mindful of the need to avoid conflicts of interest, and are designed to provide effective and fair benefit sharing from commercial products to individuals, communities and entities that openly shared inputs that are used and useful in the development of countermeasures.

Relationship between PABS and Open Source Dividend

The Open Source Dividend can exist as a complement or a substitute to other benefit sharing approaches. One difference between the approaches concerns the beneficiaries.

The WHO is the direct beneficiary of the PABS system, and indirectly, it is expected that the WHO would use its donations and reserved products to benefit persons living in low income countries.

The PABS requires parties to share pathogens with the WHO coordinated laboratory network. The agreements from companies are voluntary negotiated contracts, and companies may be able to obtain pathogens or sequences outside of the PABS system, setting some constraints on the ambitions of the benefit sharing obligations contained in the SMTA contracts. Company engagement is likely to be higher when obligations are lower, and lower when obligations are higher.

The Open Source Dividend beneficiaries are more diverse, including researchers, research institutions, companies and others who voluntarily share, openly and at cost or for free, inputs that will be considered used and useful in countermeasures. The inputs include pathogens and sequences, but also many other knowledge goods and services and biologic materials.

Annex: *The PIP Framework SMTA2*

The WHO administers the [Pandemic Influenza Preparedness \(PIP\) Framework](#). The agreement came into effect on May 24, 2011, after adoption by the 64th World Health Assembly. The agreement, similar to the proposed PABS system in Article 10 of the WHO CA+ Zero Draft text, conditions access to pathogens to benefit sharing agreements.

The PIP Framework currently uses the Standard Material Transfer Agreement 2, or SMTA2. A copy is available here:

- [https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2))
- <https://cdn.who.int/media/docs/default-source/pip-framework/smta2/smta2-eng.pdf>

The Obligations of the Recipient are set out in SMTA2 Article 4, and in particular, in Article 4.1.1.A. and Article 4.1.1.B, and Article 4.1.1.C. These are referred to as categories A, B and C.

SMTA2: Category A

In 4.1.1.A., **Manufacturers of vaccines and/or antivirals** must commit to “at least two” of six available options, set out in A1 through A6.

- **Sharing vaccines:** A1 and A2 are 10% donated and 10% affordable priced vaccines.

- **Sharing antivirals:** Option A3 is a negotiated number of donated antiviral medicines to the WHO, and option A4 is a negotiated number of antiviral medicines at affordable prices.
- **Sharing IPR:** A5 is to license to manufacturers in developing countries, on affordable royalties, the technology and know-how for which it holds intellectual property rights for the production of vaccines, adjuvants, antivirals or diagnostics. A6 is to provide royalty-free licenses to manufacturers in developing countries, or the WHO, non-exclusive, sublicensable rights on IPR.

No manufacturers of antivirals have signed agreements.

In the past, influenza vaccine manufacturers have avoided options A5 and A6, and only offered a combination of donations and vaccines reserved for WHO at affordable prices.

In **Table 1** below, the specific commitments made by **vaccine manufacturers** are listed, along with the dates of the agreements. The WHO has 14 contracts on its web page, and in 12 of the 14 agreements, the combined total of donations and products reserved for WHO at affordable prices is 10 percent, the most typical being 8 percent donation and 2 percent reserved, although there is considerable variance. In the Seqirus agreement, the commitment is 10 percent donation and 2.5 percent vaccines reserved, and the Sanofi agreement is 7.5 and 7.5. In no cases did companies agree to percentages in the options set out in SMTA2.

[https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)/list-of-signed-agreements-cat-a](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)/list-of-signed-agreements-cat-a)

Table 1: Agreements signed with manufacturers of vaccines and/or antivirals (Category A)

Company	Date signed	Obligations regarding real-time access to vaccines
China National Biotech Group	May 23, 2016	Donate 8 percent, reserve 2 percent at affordable prices
Denka Seiken, Japan	May 9, 2017	Donate 8 percent, reserve 2 percent at affordable prices
Glaxo Group Limited, England	May 26, 2022	Donate 8 percent, reserve 2 percent at affordable prices
The Government Pharmaceutical Organization (GPO), Thailand	Jun 24, 2020	Donate 5 percent, reserve 5 percent at affordable prices
Green Cross Corporation, Korea	Apr 14, 2017	Donate 7 percent, reserve 3 percent at affordable prices
Kitasato Daiichi Sankyo Vaccine Co., Ltd., Japan	Jan 26, 2017	Donate 8 percent, reserve 2 percent at affordable prices
KM Biologics Co. Ltd. Japan	Apr 18, 2019	Donate 8 percent, reserve 2 percent at affordable prices
Medimmune, USA	Oct 12, 2016	Donate 9 percent, reserve 1 percent at affordable prices

The Research Foundation for Microbial Diseases of Osaka University (BIKEN), Japan	Mar 24, 2017	Donate 8 percent, reserve 2 percent at affordable prices
Sanofi Pasteur, France	Feb 4, 2014	Donate 7.5 percent, reserve 7.5 percent at affordable prices
Seqirus UK Limited	Mar 14, 2017	Donate 10 percent, reserve 2.5 percent at affordable prices
Serum Institute of India	Oct 1, 2013	Donate 8 percent, reserve 2 percent at affordable prices
Sinovac Biotech Co. Ltd. China	Mar 13, 2017	Donate 8 percent, reserve 2 percent at affordable prices
Takeda Pharmaceutical Company Limited, Japan	Mar 16, 2018	Donate 8 percent, reserve 2 percent at affordable prices

SMTA2: Category B:

Category B obligations are set out in In 4.1.1.B. Manufacturers of products other than vaccines or antivirals are required to choose ONE of six options, including the A5 or A6 licensing options, or options B1, B2, B3 or B4.

Donating diagnostic tests. Option B1 involves a negotiated number of diagnostic kits to be donated to the WHO, as needed for a pandemic.

- **Providing affordable diagnostic tests.** Option B2 requires that a negotiated number of diagnostic kits be made available to the WHO at affordable prices.
- **Strengthen laboratory and surveillance capacity.** Option B3 is a negotiated commitment to support the strengthening of influenza laboratories and surveillance capacity in developing countries.
- **Support technology transfer.** Option B4 is a negotiated commitment to support the transfer of technology know-how and/or processes for pandemic influenza preparedness and response in developing countries.

Only two companies in Category B have signed agreements. The obligations are set out in Table 2.

[https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)/list-of-signed-agreements-cat-b](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)/list-of-signed-agreements-cat-b)

Table 2: Manufacturers of diagnostics & other pandemic-related products

Company	Date signed	Obligations
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Becton Dickinson and Company, USA	May 22, 2018	Donate 25 million syringes needed for influenza pandemics
Quidel Corporation, USA	August 5, 2016	Reserve at least 250,000 diagnostic kits at affordable prices

SMTA2: Category C

Obligations for academic & research institutions are negotiated, and may involve donations of products, affordable pricing, transfer of technology and processes, granting sublicenses to the WHO or laboratory and surveillance capacity building.

In reviewing the Category C commitments, every agreement we reviewed has exactly the same vague and non-binding commitment.

Shall consider contributing to the measures listed below:

- Donations of vaccines;
- Donations of pre-pandemic vaccines;
- Donations of antivirals;
- Donations of medical devices;
- Donations of diagnostic kits;
- Affordable pricing;
- Transfer of technology and processes;
- Granting of sublicenses to WHO;
- Laboratory and surveillance capacity building.

A link to each of the agreements is available here:

[https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-\(smta2\)/list-of-signed-agreements-cat-c](https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/standard-material-transfer-agreement-2-(smta2)/list-of-signed-agreements-cat-c)