

Access and Benefit Sharing

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Bureau Text (Article 12: Option 12A)

- Para 1: “epidemic and pandemic potential as well as [genetic sequence data and relevant information]/[digital sequence information]”.

Comment: scope is unclear. Epidemic ...means scope is much broader

- Para 2: “system could be structured as either a unified or two mutually supportive systems”.

Comment: possible suggestion to de-link access from benefit sharing. (i) Undermining of internationally agreed legal principles of access and benefit sharing. Would not be consistent with CBD and Nagoya Protocol, which is a prerequisite for the outcome to be considered a specialized international instrument on access and benefit sharing. (ii) de-link could lead to providing “access” to pathogens & sequences being mandatory while “benefit-sharing” is optional.

- Para 3: “Parties shall further develop the details” of ABS “through the Conference of the Parties”. “The system(s) shall be operational no later than xxx”.

Comment: No details provided on operation of ABS.

Bureau text: Option 12.B

- Para 1: covers all pathogens with pandemic potential, including their genomic sequences. Additionally one health commitments on sharing of materials and data are included elsewhere, outside ABS provisions (Art. 5)
- Para 2: establishes PABS system under WHO CA+. **Comment: Uncertainty for Members not parties to WHO CA+.**
- Para 2: “PABS system is structure as “[a unified system]/[two mutually supportive systems]”.

Comment: suggestion to de-link access from benefit sharing. (i) Undermining of internationally agreed legal principles of access and benefit sharing. Would not be consistent with CBD and Nagoya Protocol, which is a prerequisite for the outcome to be considered a specialized international instrument on access and benefit sharing. (ii) de-link could lead to providing “access” to pathogens & sequences being mandatory while “benefit-sharing” is optional

- Para 3: “Parties shall further develop the details” of ABS “through the Conference of the Parties”. “The system(s) shall be operational no later than xxx, in conformity with the provisions below”.
 - requires sharing through an established WHO coordinated laboratory network “subject to conclusion of a Standard Material Transfer Agreement, which will be agreed upon by the Parties”.

Comment: Development of SMTA postponed. What if there is no agreement on SMTA content? Postponing means losing negotiation leverage.

- Requires uploading the genome sequence “to one or more publicly accessible database(s) of its choice”.

Comment: No conditions on use of data (i) lack of transparency, (ii) accountability (iii) inability to operationalize benefit-sharing, (iv) intellectual property may be claimed on the “use” of shared sequence; (v) no way to supervise “gain-of function” research (that promotes pathogenesis and transmissibility).

- para 5(d): no claim any IP or other rights on the pathogens, their genomic sequences, components or related information.

Comments: (i) does not extend to “use” of pathogens, sequences, components, related information; (ii) meaningless in the absence of conditions on the use of the data.

- Para 5(e): access to pathogens with pandemic potential protected by intellectual and other property rights shall consistent with international agreements and with relevant national laws (i.e. with the TRIPS Agreement and national IP laws).

Comment: reinforces existing IP system/private monopolies over pathogens with pandemic potential This means that if developing countries want access to ‘pathogens with pandemic potential’ that may be protected by IP for e.g. for development of vaccines/diagnostics, developing countries will not be able to do so unless they take measures to address IP barriers.

This **suggests a ‘double-standard’ in the INB text**. No action is taken to eliminate IP barriers that hinders pandemic response. Instead para 3(e) supports the continued application of IP barriers. In contrast, the INB text stresses on sharing of pathogens including sequences with weak references to fair and equitable benefit sharing. Such ‘double standard’ perpetuates inequity.

- Para 6(a): speaks of monetary and non-monetary benefit

Comment: Nothing on monetary benefit-sharing provided.

- Para 6(b): states “Facilitated access shall be provided pursuant to a Standard Material Transfer Agreement...that shall contain benefit sharing obligations”. Then 3 options presented.

Comment: No detailed SMTA provided.

Comment on Benefit-Sharing Options

- Option 6©.X: (i) real time access by WHO (10% donation and 10% at affordable prices); (ii) “collaboration” with manufacturers and WHO initiatives to transfer tech and know-how and strengthen production capacities

Comment: loopholes exists: (i) (one manufacturer may produce multiple products (vaccines, therapeutics), so 10% donation may mean very little goes to WHO. Very imprecise...will lead to complications (ii) what is “affordable price”?. It is dependent on funding available to WHO – which can be a major issue;(iii) risk of all other pharma products available at unaffordable prices (iv) ineffective text on tech transfer and know-how.

- Option 6©.Y: each Party to attach conditions to publicly funded research:
- Option 6©.Z: when DG declares pandemic, then each party shall provide donations and if products in scarce supply “shall make all possible efforts” to reserve for sale.

Comment: (i) These are not benefit sharing, as benefit sharing is from manufacturers that utilize materials and sequence and develop products. (ii) attaching conditions to publicly funded research should be an obligation but this act by a Party cannot be considered benefit sharing; (iii) in any case these options do not offer any certainty of access and neither do they operationalize equity. They are ad hoc, optional and voluntary.

US Proposal:

- Delinks access to pathogens and sequences from benefit-sharing. **Comment: Inconsistent with CBD and the Nagoya Protocol. Does not qualify to be a specialized international instrument.**

On Access to Biological Material

- Scope: "biological material including human and potential zoonotic pathogens particularly those with epidemic and pandemic potential". Includes environmental samples. **Comment: Scope is open-ended, and thus very broad.**
- Providing access to biological material is obligatory. **Comment: obligatory to share with *all* laboratories and networks presumably on request.**
- SMTA is attached: **Comment: Use is optional. Content is inadequate.**
- Sharing of sequence is obligatory.... 'in public databases that can be accessed by the global scientific community with appropriate biosecurity practices, without a requirement to track and trace the use of human and potential zoonotic pathogen GSD'. **Comment: no conditions attached to use, no way to know if those accessing have appropriate biosecurity practices. No way to operationalize benefit sharing. No accountability.**

On Benefit Sharing

- Propose to develop at a later stage a multilateral benefit sharing system through a multistakeholder approach. **Comment: WHO is an intergovernmental authority and the adoption of a successful PIP framework through intergovernmental process, reinforces that an ABS system should be developed by an intergovernmental process. Further the weakness of multistakeholderism is visible in the weakness of ACTA-A/COVAX that failed to deliver equitable response.**
- Proposed benefit sharing is by Parties and suggests that all actions of governments are benefits even the sharing of biological materials, national response measures. Parties will urge WHO to urge manufacturers to set aside a portion of production cycle for procurement, for tier pricing, publish access plans etc. **Comment: Nothing tangible and concrete as fair and equitable benefit sharing. No commitments from manufacturers to provide access, and licensing to diversify production. Action by Parties is NOT benefit sharing. US is twisting the whole concept of access and benefit sharing.**

EU Proposal

- Scope: pathogen samples, pathogen genomic sequence data and other relevant information related to pathogens obtained through their surveillance and detection activities. Additionally one health commitments on sharing of materials and data are included elsewhere, outside ABS provisions. **Comment: very broad scope.**
- Sharing through “Secretariat or other existing mechanisms”
- States “parties should use...model agreements...as appropriate”
- COP to adopt no later than 2 years rules or guidelines to facilitate and support access to and sharing of pathogen samples, sequence, information etc. “in accordance with international law”. **Comment: delays adoption of SMTAs.**
- COP “shall consider the establishment or development of one or more international repositories of pathogen samples and pathogen genomic sequence data” and adds “Data repositories shall comply with global norms and standards established by WHO”. **Comment: interestingly proposal foresee a global data repository, where access and use subject to terms and conditions.**
- Countermeasures to be decided by Expert Committee as soon as possible after declaration of pandemic, on characteristics of pandemic. Committee will decide if there is scarce supply. **Comment: leaves decision-making too late. At that moment, negotiations with manufacturers may take very long. No guarantee manufacturers will comply. There may not even be agreement as to whether there is scarce supply e.g. COVID-19.**
- Benefit sharing – places obligations on State Parties and WHO - when there is scarce supply HIC Parties “shall make all possible efforts” , to get manufacturers to reserve for sale in LIC and MIC. WHO to develop allocation and support countries through partnership, donations, pricing guidelines, promote quality countermeasures, cooperate with respect to stockpile, voluntary transfer of tech and know-how. **Comment: No commitments from manufacturers to provide access, and licensing to diversify production. Action by Parties and WHO is NOT benefit sharing as envisaged by CBD & NP.**

- No. SMTA. Suggests bilateral transfer agreements which covers data and material, affordability and availability of countermeasures to all countries. **Comment: unclear when agreement to be signed. Also how can one country obtain benefits for multilateral use. Encouraging bilateral approach fragments emergency response.**
- Does not address monetary benefit sharing

Africa Group proposal

- Scope: All pathogens with human pandemic potential, including their genomic sequence data, as well as fair and equitable benefit-sharing arising therefrom (without affecting the functioning of PIP framework). Covers pathogens and sequence covered by IHR as well.
- Defines PABS Materials: pathogens with human pandemic potential, whether wild-type or modified, including their biological materials and parts thereof, clinical specimens, genomic sequence data including associated data (meta and clinical data).
- Sharing through WHO Coordinated laboratory network and authorised national laboratories subject to SMTA 1 (SMTA 1 details conditions of use (e.g. no IPRs) and annexed).
- Sharing with “qualified entities” i.e. manufacturers of diagnostics, vaccines, therapeutics and other medical products subject to signing of SMTA 2 (SMTA 2 detailing conditions for use (e.g. no IPRs, benefit sharing commitments) annexed).
- Sharing of sequence with WHO database. Access to database allowed to institutions and other databases subject to acceptance of click-wrap agreement and data use conditions.
 - Users have to agree to terms and conditions including benefit sharing commitments - from SMTA 1 and 2 as well as monetary contribution.
 - No sharing of data with persons or entities who are not registered with PABS database system.
 - Agree to report “gain of function” research and user agrees to comply with any conditions that may be imposed by WHO, to safeguard public health.

Scope of benefits required:

- **Monetary benefits:** X% of annual revenue for each product or service developed and commercialized using the PABS System. Annual revenue includes all financial benefit such as income from sales and royalties.
- **Non-monetary benefits (in SMTA 2) to be provided by qualified entities (i.e. developers and manufacturers).**
 - General Commitment:
 - Comply with allocation mechanism developed by WHO and ensure supply of vaccines, therapeutics and diagnostics at affordable prices to developing countries during a PHEIC or pandemic. “Affordable pricing” defined: for developing countries: a price no higher than marginal cost per unit +10% profit margin, while for developing countries categorised by the United Nations as least developed countries at “no profit no loss”.
 - Deposit of biological materials in WHO Cell bank for use for production during PHEIC/pandemic including for manufacturers in developing countries.
 - In Addition:
 - 20% of real time production of vaccines, diagnostics, therapeutics as in-kind benefit sharing to WHO
 - Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of vaccine development and production, **for sublicensing to manufacturers in developing countries** for the production and supply of vaccines needed in a PHEIC/pandemic.
 - On request by WHO share the complete regulatory dossier including the full technical know-how, with the sublicensees of WHO.
- Traceability mechanism
- Outlines Governance – PABS Advisory Group, Responsibilities of WHO Secretariat & WHO Members in ensuring compliance with PABS. **Comment: Sets out a comprehensive PABS system that commits users to fair and equitable benefit sharing.**

Other proposals (e.g. Brazil, Indonesia, Bangladesh): vary in level of detail. Some similarities with certain aspects of AG proposal.

Bureau Text	US Proposal	EU Proposal	Africa Group Proposal
<ul style="list-style-type: none"> ▪ Inconsistent with CBD & NP ▪ Does not treat “access” and “benefit sharing” on equal footing. ▪ minimal legal certainty on benefit sharing. 	<ul style="list-style-type: none"> ▪ Inconsistent with CBD & NP ▪ Delinks access from benefit sharing. ▪ Does not treat “access” and “benefit sharing” on equal footing. ▪ Benefit sharing concept misrepresented: considers everything that parties and WHO do – as benefit sharing. No legally binding commitments required of users esp. manufacturers. ▪ No concrete detailed SMTAs... ▪ No certainty of fair and equitable benefit sharing 	<ul style="list-style-type: none"> • Inconsistent with CBD & NP • Does not treat “access” and “benefit sharing” on an equal footing. • promotes signing material transfer agreement bilaterally. • complicated approach. Will fragment emergency response. • Benefits unlikely to be delivered in timely manner as subject to negotiations 	<p>Consistent: Comprehensive ABS system. Certainty of benefits and thus emergency response.</p>

Some additional points:

- Should sequences be left to CBD? Response: No. that would be a strategic mistake.
- Is voluntary benefit sharing ok? Response: No. Voluntary and optional means status quo. Why negotiate, if outcome is status quo. Emergency Preparedness and response has to have certainty, esp of supplies.
- Should benefit sharing obligations be on States or manufacturers?. Response: It should be on the recipients and users in particular on manufacturers because manufacturers dictate the production, supply and access.
- Will imposing data governance conditions discourage current open science ecosystem that promotes innovation? Response: No. Access can be subject to conditions and these are important to ensure transparency, accountability, maintain openness (i.e. not appropriated through IP system) and protect public health. While Bureau text, US & EU proposal refuse to effectively address the IP barriers, allow licensing to diversify production , speaking about openness is really hypocrisy. Further for science to be useful during emergency, there must be legally binding commitments for access. Otherwise science only benefits the developed countries as seen during COVID-19, Ebola etc.
- One Health implications of ABS. Is it Practical of having a separate system under WHO, when one health involves so many other institutions?: Response: Need to be cautious in accepting One Health approach. WHO is the main health authority.
- What is Specialized international instrument? Response: Article 4(4) of NP “Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument”. It allows for multilateral benefit sharing.