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Text Comparison: Provisions on Access and Benefit Sharing (ABS) in the Proposal for Negotiating Text of the WHO Pandemic Agreement Proposal (30 October 2023), in the Proposal of the Africa Group and the Equity Group, and in the Proposal of the EU and its Member States

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Proposal for Negotiating Text of the WHO Pandemic Agreement (30 October 2023)	Proposal of the Africa Group and Equity Group	Proposal of the EU and its Member States
Use of terms		
Art.1 Use of terms For the purposes of the WHO Pandemic Agreement: (a) "genetic sequences" means the order of nucleotides identified in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus; [...] (f) "pandemic-related products" means products that are needed for pandemic prevention, preparedness	Art. 1 Use of terms For the purposes of the WHO Pandemic Agreement: ***(aa) "authorized national laboratories": means laboratories authorized and designated by a Party to provide PABS Materials to the PABS System and recognized as part of the WHO Coordinated Laboratory Network.*** (a) "genetic sequences" means the order ~~of~~ ***or sequence of*** nucleotides identified in a molecule of DNA or RNA ***or amino acids in proteins***. They	For the purposes of the WHO Pandemic Agreement: "Pathogen" shall mean a virus or an organism that causes, or can cause, a disease to its human host and covers unknown pathogens and unknown variants of known pathogens[1]; "Disease" shall mean an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans; "Unknown pathogen" shall mean a pathogen or a new variant of a pathogen that have not been identified and

[1] Possible coverage or exclusion of pandemic influenza pathogens as defined within the Pandemic Influenza Preparedness (PIP) Framework, as set out in Resolution 60.28 of the World Health Assembly will need to be further considered.

and response, which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen; [...] (h) “pathogen with pandemic potential” means any pathogen that has been identified to infect humans and that is potentially highly transmissible, capable of wide, uncontrollable spread in human populations, and highly virulent, making it likely to cause significant morbidity and/or mortality in humans (j) “recipient” means receivers of WHO Pathogen Access and Benefit-Sharing (WHO PABS) Material from the WHO coordinated laboratory network, such as manufacturers of vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic prevention, preparedness and response, as well as biotechnology firms, research institutions and academic institutions. Any manufacturer that enters into any contracts or formal agreements with recipients or laboratories in the WHO coordinated network for the purpose of using WHO PABS Material on the manufacturer’s behalf for commercialization, public use or regulatory approval of that manufacturer’s vaccines, diagnostics or pharmaceuticals shall also be considered a recipient for purposes of this Agreement; [...] (l) “WHO coordinated laboratory network” means the international network of laboratories, coordinated by WHO, that conduct year-round surveillance of pathogens with pandemic potential, assessing the risk of an emerging pathogen with pandemic potential and assisting in pandemic preparedness measures; (m) “WHO PABS Material” means a pathogen with pandemic potential, as defined herein, and the genetic sequence data of such pathogens with pandemic potential.	contain the genetic information that determines the biological characteristics of an organism or a virus. ***(aa) “genetic sequence data” (GSD): means data or information generated through the application of sequencing technologies on genetic sequences, including all associated data and metadata.*** (f) “pandemic-related products” means products that are needed for pandemic prevention, preparedness and response, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen. ***All products used for addressing public health emergencies of international concern are presumed as pandemic-related products regardless of the pandemic potential of such emergencies****;* (h) “pathogen with pandemic potential” means any pathogen that has been identified to infect humans and that is potentially highly transmissible and capable of wide, uncontrollable spread in human populations and highly virulent, making it likely to cause significant morbidity and/or mortality in humans; (j) *“**R**ecipient **Entity**”* means receivers of PABS Material from the WHO coordinated laboratory network, ~~such as manufacturers of vaccines, diagnostics, pharmaceuticals and~~ ***that develop and/or produce diagnostics, vaccines, therapeutics and any*** other ***pandemic-related products*** ~~products relevant to pandemic prevention, preparedness and response~~,. ***The Recipient Entity may be a public or private entity including*** ~~as well as~~ ***government owned or government subsidized entities, non-profit organizations, commercial entities,*** biotechnology firms, research institutions and academic institutions ***that develop and/or produce pandemic-related products***. Any ***developer or*** manufacturer that enters into any contracts or formal agreements with ~~recipients~~ ***any Recipient Entity*** or laboratories in the WHO	characterised at the date of entry into operation of the PABS System pursuant to paragraph 7(f). Unknown pathogens encompasses pathogens with public health emergency of international concern potential, according to assessment under the decision instrument contained in Annex 2 of the International Health Regulation (2005), as amended. “Manufacturer” shall mean any entity that produces, including by means of licensing agreements, health products, namely vaccines, therapeutic or diagnostic products.

	coordinated network for the purpose of using WHO PABS Materials on ***developer/***manufacturer's behalf for commercialization, public use or regulatory approval of that ***developer/***manufacturer's vaccines, diagnostics**,** ***therapeutics or any other pandemic-related products*** ~~or pharmaceuticals~~ shall also be considered a ***R***ecipient ***Entity*** for purposes of this Agreement; (l) "WHO coordinated laboratory network" means the international network of laboratories, coordinated by WHO, that conduct year-round surveillance of pathogens with pandemic potential, assessing the risk of an emerging pathogen with pandemic potential, and assisting in preparedness measures; ***To be a part of the WHO Coordinated Laboratory Network, an authorized national laboratory must meet the criteria for designation and agree to comply with the provisions of SMTA 1 in Annex 1 and Terms of Reference in Annex 4.*** (m) "WHO PABS Material" means pathogen with pandemic potential, as defined herein*,* ***whether wild-type or modified, including their biological materials and parts thereof, clinical specimens,*** and the genetic sequence data of such pathogens with pandemic potential ***including associated data (meta and clinical data)***.	
Article 12. Access and Benefit Sharing		
1. The Parties hereby establish a multilateral system for access and benefit sharing, on an equal footing, the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to, pandemic-related products for pandemic prevention, preparedness and response.	1. The Parties hereby establish a ***transparent*** multilateral system for access and benefit sharing, on an equal footing, the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to pandemic-related products for pandemic prevention, preparedness and response.	1. The Parties recognize that enhanced prevention, including surveillance, preparedness and response will benefit from an effective multilateral system enabling equitable and rapid access to pathogens and their genetic sequences, as well as the sharing of benefits, including more rapid and equitable access to products that derive from the utilization of such pathogens and their genetic sequences. 2. For these purposes, the Pathogen Access and Benefit-Sharing System (the "PABS System") is hereby

		established. The PABS System shall act under the oversight of the [COP/governing body] and be authorised to enter into agreements, contracts or arrangements with Governments, organizations, institutions, firms or individuals and take other legal actions necessary to the performance of its functions for the purpose of carrying out its activities, in accordance with the rules, regulations and practice of the WHO. The PABS system shall be administered by the Partnership set out in article 13, bringing together the WHO, and the relevant organisations of the UN system, other relevant international organisations, regional organisations and stakeholders, including civil society and the private sector.[2]
2. The WHO PABS System shall ensure rapid, systematic and timely sharing of WHO PABS Material, as well as, on an equal footing, timely, effective, predictable and equitable access to pandemic related products, and other benefits, both monetary and non-monetary, based on public health risks and needs, to strengthen pandemic prevention, preparedness and response. 3. The Parties shall implement the WHO PABS System: (a) in a manner to strengthen, expedite and not impede research and innovation; (b) at all times, both during and between pandemics; (c) in a manner to ensure mutual complementarity with the Pandemic Influenza Preparedness Framework; and (d) with governance and review mechanisms, to be determined by the Conference of the Parties.	2. The ***objective of the*** WHO PABS System ***is to strengthen pandemic prevention, preparedness and response by the*** ~~shall ensure~~ rapid, systematic, and timely sharing of WHO PABS Material, as well as, on an equal footing, ***the rapid,*** timely, effective, predictable and equitable access to pandemic- related products, and other benefits, both monetary and non-monetary, ~~based on public health risks and needs~~, ~~to strengthen pandemic prevention, preparedness and response.~~ ***2bis. The PABS System shall also apply mutatis mutandis to pathogens that have the potential to cause a public health emergency of international concern within the scope of the IHR and to State Parties of the IHR. The provisions of SMTA and other benefit sharing obligations under this provision apply mutatis mutandis to such products and services that are used in prevention, preparedness and response to public health emergencies of international concern.*** 3. The ~~Parties~~ ***Director-General*** shall implement the WHO PABS System:	3. The PABS System shall cover access to previously unknown pathogens, as defined above in terms of use, their genetic sequence data and related available epidemiological and clinical information, their genetic sequence data, subject to applicable domestic and international safety and security, as well as data protection laws and regulations, as well as the sharing of benefits that arise from the utilization of such pathogens and data. The PABS System aims to provide clarity and legal certainty for providers and users of pathogens and data, as well as of benefits, and to strengthen, expedite, and not impede research and innovation. The WHO in cooperation with the other Quadripartite organisations shall monitor the progressive development of the parties' laboratory capacities, and shall issue guidance on the interpretation on what constitutes an unknown pathogen.

[2] Such Partnership should be established in article 13, without prejudice to the financing of each Partnership member, although the additional tasks assigned to the Partnership members will call for additional resources.

	(aa) take all measures necessary to apply, implement and operationalize all aspects of the WHO PABS System including the WHO Coordinated Laboratory Network, Standard Material Transfer Agreements (SMTAs), the PABS Sequence Database, monetary and non-monetary benefit sharing, and the PABS Advisory Committee simultaneously. (a) in a manner to strengthen, expedite and not impede research ~~and~~ **,** innovation ***and fair and equitable distribution of the benefits;*** (b) at all times, both during and between pandemics ***and take all measures necessary to ensure fair, transparent, equitable, effective and efficient implementation of the PABS System****;* (c) in a manner to ensure mutual complementarity with the PIP Framework ***the scope of which is limited to influenza virus of pandemic potential****;* and (d) ~~with governance and review mechanisms, to be determined by the Conference of the Parties~~. (e) ***in a manner that ensures application of the WHO PABS System in all situations involving WHO, where biological materials including genetic sequence data in relation to pathogen with pandemic potential and pathogens that have the potential to cause a public health emergency of international concern are shared.***	
Access to Pathogens and Genetic Sequence Data		
4. The WHO PABS System shall have the following components: (a) WHO PABS Materials sharing: I. Each Party, through its relevant public health authorities and authorized laboratories, shall, in a rapid, systematic and timely manner: (1) provide WHO PABS Material to a laboratory recognized or designated as part of an established WHO coordinated laboratory	4. The WHO PABS System shall have the following components: (aa) ***WHO Coordinated Laboratory Network(WCLN)*** I. ***The Director-General shall establish a WHO Coordinated Laboratory Network linking authorized national laboratories to achieve the objectives of PABS System. The Director-General may designate certain authorized national laboratories as***	5. Access to pathogens and genetic sequence data (a) Each Party, through its designated authorities, shall, in a safe, secure, rapid and systematic manner: (i) provide access to physical samples of pathogens within their control and available related epidemiological and clinical information useful for its utilisation (hereinafter the “samples”), to one or more

network; and (2) upload the genetic sequence of such WHO PABS Material to one or more publicly accessible database(s) of its choice, provided that the database has put in place an appropriate arrangement in respect of WHO PABS Materials. II. The WHO PABS System shall be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote findable, accessible, interoperable and reusable data available to all Parties. III. The Parties shall develop and use a Standard Material Transfer Agreement (a PABS SMTA), which may be concluded through electronic means, and which shall include relevant biosafety and biosecurity rules, to be used with the transfer of WHO PABS Materials from a laboratory recognized or designated as part of an established WHO coordinated laboratory network to any Recipient. IV. Recipients of WHO PABS Material shall not seek to obtain any intellectual rights on WHO PABS Material.	***WHO Collaborating Centres for purposes of PABS System, provided it reflects adequate regional and sub-regional representation, as appropriate and balanced representation between developed countries and developing countries. The Director-General has the responsibility to ensure that each region and sub-region has sufficient capacity and facilities to undertake thorough risk assessment and response activities as set out in the Terms of Reference of the WHO Coordinated Laboratory Network including inter-laboratory sharing of outcomes arising from utilization of PABS Materials.*** ***II. The Director-General shall be responsible to facilitate the funds required to cover the costs related to shipment of PABS Material to and within WCLN by developing country Parties.*** (a) WHO PABS Materials sharing ***and Standard Material Transfer Agreements****:* ~~i. Each Party, through its relevant public health authorities and authorized laboratories, shall , in a rapid, systematic and timely manner: (1) provide WHO PABS Material to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (2) upload the genetic sequence of such WHO PABS Material one or more publicly accessible database(s) of its choice, provided that the database has put in place an appropriate arrangement with respect to WHO PABS material.~~ ~~ii. The WHO PABS System shall be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote findable,~~	laboratory or biorepositories participating in a network of laboratories coordinated by the WHO in cooperation with the other Quadripartite organisations, and, if it so decides, also to one or more laboratories recognised by the WHO or by any of the Party's designated authorities (hereinafter collectively referred to as "recognised laboratory"); and (ii) provide access to the genetic sequence data and relevant metadata of pathogens within their control (hereinafter "sequence data") by uploading it to one or more database(s), which is publicly accessible and recognised by the WHO or by any of the Party's designated authorities (hereinafter "recognised database"). (b) In providing access to samples or sequence data consent is given to the further transfer and use of such samples and sequence data subject to applicable safety and security and data protection rules and standards, as well as the provisions of this article. The Parties and the recognised laboratories and recognised databases shall ensure the expeditious further transfer and use in accordance with paragraph 5(e), and facilitate awareness of newly detected pathogens, as well as access to related samples and sequence data that may subsequently become available. (c) For purposes hereof, "rapid" provision shall mean provision no later than [...] hours from the time of acquisition and identification by a Party through its designated authorities of a pathogen or from the time the relevant sequence data have become available to a Party. Parties may seek the cooperation and support of other Parties with available laboratory capacities in order to identify and characterize

	~~accessible, interoperable and reusable data available to all Parties.~~ ***i. All transfers of PABS Material by an authorized national laboratory to a laboratory designated as part of the WHO Coordinated Laboratory Network and further transfers within the WHO Coordinated Laboratory Network shall be subject to agreement with the provisions of Standard Material Transfer Agreement 1 in Annex 1 (SMTA 1).*** ***ii. By providing PABS Materials to laboratories designated as part of the WHO Coordinated Laboratory Network, the provider Party provides their consent for the onward transfer and use of PABS Materials to Recipient Entities that have signed the Standard Material Transfer Agreement 2 in Annex 2 with WHO (SMTA 2).*** iii. The ~~Parties~~ ***Director-General*** shall ~~develop and~~ us***ing the*** ~~a~~ standard material transfer agreement (~~a PABS~~ SMTA ***2), in Annex 2, enter into agreement with Recipient Entities outside the WHO Coordinating Laboratory Network.*** ~~which may be concluded through electronic means, and which shall include relevant biosafety and biosecurity rules, to be used with the transfer of WHO PABS Material from a laboratory recognized or designated as part of an established WHO coordinated laboratory network to any Recipient~~. ***iv. Any sharing of genetic sequence data by laboratories within and by the WHO Coordinated Laboratory Network shall be through the WHO PABS Sequence Database, consistent with its requirements and subject to SMTA 1.*** ***v. Laboratories within the WHO Coordinated Laboratory Network*** and ***other*** ~~R~~recipients ***including Recipient Entities*** of WHO PABS	pathogens. (d) The WHO and the other Quadripartite organisations in consultation with existing recognised laboratories shall set out the guidelines for individual or networks of national or regional laboratories or biorepositories to be recognised as capable of receiving and transferring samples in a timely, safe and secure manner, make these conditions publicly available, and keep a publicly accessible list of recognised laboratories. The Parties in cooperation with WHO and the other Quadripartite organisations shall provide technical assistance to national or regional laboratories from developing countries in need for the purpose of obtaining such recognition. The WHO and the other Quadripartite organisations in consultation with existing databases shall also set out the guidelines for a database to be recognised as publicly accessible and as capable of receiving and transferring sequence data in a secure manner, make these conditions publicly available and keep a publicly accessible list of recognised databases. (e) In case that an institution, organisation or entity (hereinafter the "recipient") makes a request for access to samples or sequence data, such access shall be accorded on an expeditious basis as possible without conditions and with no discrimination by the recognized laboratory or recognised database as the case may be, to requesting recipients. For purposes hereof, "expeditious" provision shall mean provision no later than [...] hours from the time of the request for access samples or sequence data. In the event that a shortage of samples prevents a Party from fulfilling the obligations set out in this subparagraph, that Party shall inform the WHO and the PABS System of the situation and shall provide access as soon as it is practically possible. (f) Notwithstanding paragraph 5(e) any access shall

	Material shall not seek ***or assert*** ~~to obtain~~ any intellectual rights on WHO PABS Material ***or parts thereof, in any form including any modified form or for any use***. ***vi. Access to and use of genetic sequence data shall be subject to standard terms and conditions contained in a click-wrap Data Access Agreement or Database Access Agreement, as applicable.*** (ab) ***WHO PABS Sequence Database*** ***(i) WHO PABS Sequence Database shall provide access to registered users with verifiable institutional accounts. For the purpose of WHO PABS Sequence Database, registered users with verifiable institutional account are users supported by an institution that has registered with WHO, whose credentials are verified by WHO*** ***(ii) Registered users with a verified institutional account shall have access to genetic sequence data from WHO PABS Sequence Database, subject to agreement inter alia to the following terms and conditions that will be contained in a click-wrap Data Access Agreement annexed as Annex 3:*** ***1. Data shall be used solely for individual purpose and shall not be distributed to any third party who is not a registered user of the WHO PABS Sequence Database;*** ***2. Data shall not be used in any activity that may lead to development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;*** ***3. User shall not seek or assert intellectual property rights over any genetic sequence data accessed or parts thereof, in any form including any modified forms or for any use;***	be subject to applicable safety, security and data protection rules and standards, as well as the provisions of this article including paragraph (h). Access to samples shall be free of charge, or, when a fee is charged, it shall be limited in amount to the approximate cost of services rendered. (g) The PABS System shall be consistent with and mutually supportive of relevant international rules and guidelines, notably those for collection of patient specimens, material and data, as well as with open access and open science principles, and shall promote effective, standardized, global and regional databases that make findable, accessible, interoperable and reusable data available to all Parties and recipients. (h) As an access condition under the PABS system, no entity shall claim any intellectual property rights on the unmodified sample or the unmodified sequence data as received pursuant to paragraph 5. Samples or sequence data may otherwise be the subject of intellectual property rights, provided that the criteria relating to such rights are met. A recognised laboratory may have used technology protected by IPRs for the preparation of the sample. Any recipient of such sample acknowledges that such IPRs shall be respected.

	4. ***User is aware of the requirements of the PABS System including the WHO PABS Sequence Database, its benefit sharing requirements: monetary contribution and other benefit sharing contained in SMTA2;*** 5. ***The User agrees to pay the required monetary contributions in a timely manner, as set out in [...], for using or benefitting from the PABS System;*** 6. ***The User is aware that a Recipient Entity as defined by the PABS System has to commit to terms and conditions contained in SMTA2. In the event, the User is a Recipient Entity as defined by the PABS System, the User agrees to be bound by terms and conditions contained in SMTA2.*** 7. ***The User shall actively seek the participation of scientists to the fullest extent possible from originating laboratory, especially those from developing countries, in their scientific projects associated with research on the genetic sequence data and actively engage them in preparation of manuscripts for presentation and publication.*** 8. ***The User shall appropriately acknowledge in presentations and publications, the contributions of collaborators, in particular the laboratories/countries providing PABS Materials, using existing scientific guidelines.*** 9. ***Any User engaged in "Gain-of-function" research, or in any other research that genetically alters an organism in a way that may enhance its biological characteristics or functions, shall inform and regularly update the Director-General on the outcomes of the research. The User also agrees to comply with any conditions that may be imposed by the Director-General, to safeguard public health.***	

	(iii) Other Databases may link with WHO PABS Sequence Database subject to agreement inter alia to the following terms and conditions that will be contained in a Database Access Agreement between WHO and other databases: ***1. Access shall only be provided to registered users with verifiable institutional accounts.*** ***2. Agrees to regularly provide WHO the list of registered users and their contact details.*** ***3. Agrees to inform its users that access to genetic sequence data obtained from the WHO PABS Sequence Database is subject to inter alia to terms and conditions mentioned in paragraph (...) and by accessing the genetic sequence data the user agrees to the terms and conditions contained in the Data Access Agreement of WHO.*** ***4. Agrees to monetary contribution as required by the WHO PABS System for any commercialization of genetic sequence data obtained from the WHO PABS Sequence Database.***	
Benefit Sharing		
4. (b) PABS multilateral benefit sharing: I. Benefits, both monetary and non-monetary, arising from access to WHO PABS Materials, shall be shared fairly and equitably, pursuant to a PABS SMTA, which may be concluded through electronic means. II. The PABS SMTAs shall include, but not be limited to, the following monetary and non-monetary benefit-sharing obligations: A. in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices to WHO) of the	4. (b) PABS multilateral benefit-sharing ***consists of monetary and non-monetary benefit sharing****:* ~~(i) Benefits, both monetary and non-monetary, arising from access to WHO PABS Materials, shall be shared fairly and equitably, pursuant to a PABS SMTA, which may be concluded through electronic means.~~	6. Multilateral benefit-sharing The Parties recognize that effective multilateral benefit sharing requires contributions from Parties as well as from stakeholders, and in particular from manufacturers of health products and pandemic-related health products. To this end, this paragraph sets out benefit sharing provisions applicable to Parties in A) pandemic situations and B) at all times. These provisions shall also form the basis for the benefit sharing commitments of manufacturers of health products and pandemic-related health products to be set out in the Standardised Benefit Sharing contracts between such

production of safe, efficacious and effective pandemic-related products for distribution based on public health risks and needs, with the understanding that each Party that has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and manufacturers; and B. on an annual basis, contributions from Recipients, based on their nature and capacity, to the capacity development fund of the sustainable funding mechanism established in Article 20 herein. (c) The Parties shall also consider additional benefit-sharing options, including: I. encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries through WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic related products; II. tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products, that consider the income level of countries; and III. encouraging of laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.	~~(ii) The PABS SMTAs shall include, but not be limited to, the following monetary and non-monetary benefit-sharing obligations:~~ ~~1. in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related products for distribution based on public health risk and need, with the understanding that each Party which has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and manufacturers; and~~ ***i. Recipient Entities shall comply with benefit-sharing obligations set out in SMTA 2.*** ***ii. Any entity, including manufacturers of diagnostics, vaccines, therapeutics and other pandemic-related products, using or benefitting from the PABS System, shall make*** on an annual basis, ***monetary*** contributions ~~from Recipients, based on their nature and capacity~~, to the capacity development fund of the sustainable funding mechanism established in Article 20. ***It is decided that the sum of annual contribution shall be x% of total 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.*** ***For the purposes of this paragraph, product or service includes any technology, outcome, diagnostics, vaccines, therapeutics and any service provided supporting the development of products for commercialization.***	manufacturers and the PABS System pursuant to paragraph 7(e). *A. Specifically during a pandemic situation* In the case of a pandemic situation as declared pursuant to art …, the Parties shall cooperate and take appropriate measures with the aim to ensure the following elements are set out in standardised benefit sharing contracts between the PABS System and manufactures pursuant to paragraph 7(e) or otherwise adhered to: Manufacturers of pandemic-related health products shall make available to the Partnership for equitable distribution on the basis of public health risk, need and demand, […%] percent of their production of safe and effective pandemic-related health products, as defined in paragraph 7(b), on a quarterly basis ([…%] free of charge and […%] at not-for-profit prices), while a pandemic situation persists. Such products shall be made available and delivered only upon request of the Partnership in accordance with the provisions set out in the contracts concluded pursuant paragraph 7(e). *B. At all times* The Parties shall cooperate and take appropriate measures with the aim to ensure the following elements are set out in standardised benefit sharing contracts between the PABS System and manufactures pursuant to paragraph 7(e) or otherwise adhered to: i. Manufacturers of health products commit to engage in capacity-building and scientific and research collaboration on mutually agreed terms with scientists and researchers from developing countries, which are Parties to this Agreement, in the research, development or production phase of products related to the pathogen sample they acquired through the PABS System, with the aim to build technical skills and

	[Placeholder: The percentage has to be determined. It is currently being examined, further proposals on this will be made in the upcoming meetings.] ~~(c) The Parties shall also consider additional benefit-sharing options, including:~~ ~~i. encouragement of manufacturers from developed countries to collaborate with manufacturers from developing countries through WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products;~~ ~~ii. tiered-pricing or other cost-related arrangements such as no-loss/no-profit arrangements, for purchase of pandemic-related products, that consider the income level of countries; and~~ ~~iii. encouragement of laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.~~ **(c)** ***Traceability and reporting mechanisms*** ***The Director-General shall put in place in a timely manner a transparent traceability mechanism that uses an electronic system in order to track in real time the movement of PABS Materials into, within and out of the WHO Coordinated Laboratory Network.*** ***Extract from Annex 2, Standard Material Transfer Agreement 2 (SMTA 2)*** *(full version available under Annexes, p. 17)*	capacities. Such collaboration shall be facilitated by the PABS System and set out in the contracts concluded pursuant paragraph 7(e); ii. Manufacturers of health products will contribute to support the WHO coordinated laboratory network, as well as capacity building activities, including to facilitate the participation of laboratories and biorepositories from developing countries in the network and their ability to rapidly detect and characterise pathogens and analyse genetic materials. Annual contributions for this purpose shall be set in the contracts pursuant paragraph 7(e) and shall take into account the need to facilitate participation in the PABS System by manufacturers, which are medium and small size enterprises, as well as by manufacturers whose use of PABS System is limited to specific pathogen classes. iii. In case a public health emergency of international concern is declared pursuant to article 12 of the IHR, and unless a pandemic situation is declared [pursuant to article … of the IHR as amended] and the provisions in paragraph 6.A.(b) apply, the manufactures of relevant health products, as defined in paragraph 7(b), shall make available at not-for-profit prices to the Partnership, […%] percent of safe and effective health products on a quarterly basis, while the public health emergency of international concern persists. Such products shall be made available for use on the basis of public health risk, need and demand, with particular attention to the needs of developing countries, and shall be delivered only upon request of the Partnership in accordance with the provisions set out in the contracts concluded pursuant paragraph 7(e).

	Article 5: Benefit Sharing Obligations of the Recipient Entity 5.1. The Recipient Entity commits to keep WHO informed of all uses PABS Materials and to make the required monetary contributions in a timely manner, for using the PABS System. 5.2. In the event of a public health emergency of international concern or a pandemic the Recipient Entity agrees to: (a) Donate at least 20% of its real-time production of each pandemic-related product manufactured, to WHO for distribution based on public health risk and need. The Recipient Entity shall comply with its commitment based on products and timetable determined by the WHO in consultation with the PABS Advisory Committee; (b) Supply vaccines, therapeutics, diagnostics and other pandemic-related products at affordable prices to developing countries, and to comply with WHO's allocation plan, if such a plan is recommended by WHO. For the purpose of this paragraph "Affordable pricing" for developing countries means 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". (c) 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 product development and manufacturing, for the production and supply of	iv. If a public health emergency develops into a pandemic situation and the provisions of 6.A. become applicable, the amount of health products made available pursuant to paragraph 6.B.iii shall be counted against the amount due pursuant to paragraph 6.A.

	pandemic-related products, needed in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions in accordance with sound public health principles with the aim to diversify production and expand supply options to facilitate prompt equitable access in developing countries. For the purposes of this paragraph, the Recipient Entity shall on request by WHO share the complete regulatory dossier including the full technical know-how as well as any materials needed for the development and production such as cell-lines, hybridomas, plasmids, yeast, or mammalian cells, with the sublicensees of WHO. 5.3 Prior to the declaration of a PHEIC, with the aim to prepare for an early response, at the recommendation of the Director-General, the Recipient Entity shall donate a part of its real-time production, not exceeding 20% of its real-time production, to address access needs in developing countries including for purposes of WHO stockpile. Any affected country may also request the Director-General to operationalize this paragraph. The Director-General shall make the recommendation to this effect, in consultation with the affected countries and the Emergency Committee.	

General provisions and entry into operations of the PABS System		
5. In the event that pandemic-related products are produced by a manufacturer that does not have a PABS SMTA under the WHO PABS System, it shall be understood that the production of pandemic-related products requiring the use of WHO PABS Materials, implies the use of the WHO PABS System. Accordingly, each Party, in respect of such a manufacturer operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to require such a manufacturer to provide benefits in accordance with paragraph 4(b)(ii) of this Article. 6. The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic related products, based on public health risks and needs. 7. The Parties shall ensure that all components of the WHO PABS System are operational no later than 31 May 2025. The Parties shall review the operation and functioning of the WHO PABS System every five years.	5. In the event that pandemic-related products are produced by a manufacturer that does not have a PABS SMTA under the WHO PABS System, it shall be understood that the production of pandemic-related products ***typically*** requiring the use of WHO PABS Materials, implies the use of the WHO PABS System. Accordingly, each Party, with respect to such a manufacturer operating within its jurisdiction, shall take all appropriate steps, ~~in accordance with its relevant laws and circumstances~~, to require such a manufacturer to provide benefits ***required by the PABS System including as set out in SMTA 2*** ~~in accordance with paragraph 4(b)(ii) of this Article~~. ***5bis Governance of the PABS system*** ***(a) The implementation of the PABS System will be overseen by the World Health Assembly. An independent, free of conflict of interests, oversight "PABS Advisory Committee" is established to monitor and provide guidance on the functioning of the PABS System and to undertake assessments of the trust-based system needed to protect public health. The composition of the PABS Advisory Committee shall be based on equitable representation of the WHO regions, taking into account the importance of balanced representation between developed and developing countries. The PABS Advisory Committee shall be composed of xx members possessing appropriate qualifications in related fields, with a skill mix of internationally recognized policy makers, public health experts and technical experts so as to ensure the effective exercise of the functions of the committee.*** ***(b) The PABS Advisory Committee in accordance with its terms of reference will function in monitoring the implementation of the PABS system. The terms of reference and modalities for***	7. (a) Recipients which are non-for-profit institutions, organisations and entities, including academic or research institutions, and are not engaged in the commercial use of samples or data shall be exempted from any sharing of benefits pursuant to paragraph 6, but are encouraged to make voluntary contributions to support the management and implementation of the PABS System, including through scientific collaborations, training and capacity building activities. (b) The health products, including pandemic-related products, covered by the provisions of this article are limited to vaccines, therapeutic and diagnostic products that are prequalified by the WHO or have received a positive WHO Emergency Use Listing assessment or an authorisation from a national regulatory authority for treatment, diagnosis/detection or prevention of the disease which has given rise to the declaration of a pandemic situation, or of a public health emergency of international concern. (c) Parties shall take all necessary steps to facilitate the export of pandemic-related products, in accordance with applicable international law. (d) The [COP/governing body], shall review the operationalization, including the fulfilment of the criteria set out in paragraph 7(f), and functioning of the PABS System every four years. Any modification to the provisions set out in this article shall be adopted by means of amendments to this Agreement. (e) The Parties shall cooperate and take appropriate measures with the aim to encourage and facilitate the manufacturers of pandemic-related health products, including small and medium-sized enterprises which are active in the research and development of new health products, to commit to the relevant provisions of this Article, in particular the elements set out in paragraph 6.A. and 6.B., as early as possible and

	the operation of the PABS System shall be adopted by the World Health Assembly. ~~6. The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic- related products, based on public health risks and needs.~~ ***6bis Parties shall ensure the fair, transparent, equitable, effective and efficient operationalization and functioning of the PABS System including its various components, and take measures to ensure the compliance of non-state actors with the PABS System such as the WHO PABS Sequence Database terms and conditions, monetary contributions, standard material transfer agreements.*** ***6ter Parties agree to facilitate the immediate shipment to WHO of products that Recipient Entities have committed to supply under SMTA2.*** 7. The Parties shall ensure that all components of the WHO PABS System are operational no later than 31 May 2025 ***and all parts of the PABS System shall become operational simultaneously***. The Parties shall review the operation and functioning of the WHO PABS System every five years.	before a pandemic situation is declared with the aim of improving planning and preparedness. Such commitments shall be set out in legally binding, standardised benefit sharing contracts between relevant manufacturers of health products and the PABS System, who will keep their implementation under review and make them public, while respecting commercial confidentiality. The Director General shall report regularly to the Parties on the conclusions of such contracts. (f) With the aim to ensure that the legally binding provisions related to both access to pathogens and genetic sequence data and multilateral benefit sharing take effect at the same time and actual benefits accrue the PABS System shall start to operate when the Director General of the WHO determines in consultation with the Panel of Experts for Scientific Advise and the Partnership members that: I. the System is ready to do so, in particular with regard to the capacities of the networks of national and regional laboratories and repositories coordinated by the WHO, giving priorities to their capacity to handle pathogens with public health emergency of international concern potential, according to assessment under the decision instrument contained in Annex 2 of the IHR, and II. a sufficient number of manufacturers have concluded standardised benefit sharing contracts pursuant to paragraph 7(e). Such sufficient number shall include (1) manufacturers accounting for at least […]% of sales of vaccines, […]% of sales of therapeutics, and […]% of sales of diagnostics, all measured on the basis of worldwide turn-over related to products for communicable diseases; and (2) at least the majority of the [10] largest vaccines manufacturers, the majority of the [15] largest therapeutics manufacturers, and the majority of the [15] largest diagnostics manufacturers,

		all measured by worldwide sales turn-over related to products for communicable diseases. (g) The PABS System shall report yearly to the Parties on its operation, including on the use of the annual contributions provided for in article 6.B.ii.
8. The Parties shall ensure that the WHO PABS System is consistent with, supportive of and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization thereto. The WHO PABS System will provide certainty and legal clarity to the providers and users of WHO PABS Materials. The WHO PABS System shall be recognized as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol.	8. The Parties shall ensure that such system is consistent with, supportive of, and does not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol thereto. The WHO PABS System will provide certainty and legal clarity to the providers and users of WHO PABS Materials. ***Parties shall consider measures for recognition of the*** ~~The~~ WHO PABS System ~~shall be recognized~~ as a specialized international access and benefit sharing instrument within the meaning of Article 4(4) of the Nagoya Protocol ***five years after the PABS System including its WHO PABS Sequence Database and benefit sharing becomes operational***.	7. (h) The Parties agree and affirm that the PABS System constitutes a specialised access and benefit-sharing instrument within the meaning of Article 4.4 of the Nagoya Protocol. The Parties further agree that relevant domestic and regional access and benefit sharing rules and legislation shall not apply to the sharing of pathogen samples or sequence data as well as benefits, which is carried out pursuant to the PABS System.
Annexes		
-	***ANNEX 1: STANDARD MATERIAL TRANSFER AGREEMENT 1 (WITHIN THE WHO COORDINATED LABORATORY NETWORK)*** ***Article 1: Parties to the Agreement*** *1.1 Parties to SMTA 1 are limited to laboratories that have been designated by WHO and have accepted to work under agreed WHO Coordinated Laboratory Network terms of reference.* *The Provider is the laboratory sending PABS Materials, and The Recipient is the laboratory receiving PABS Materials,*	-

	1.2 Provider and Recipient are hereafter collectively referred to as "Parties". ***Article 2: Subject Matter of the Agreement*** *[Placeholder for PABS Material: To be added once the definition is agreed]* ***Article 3: Definitions*** *[Placeholder: To be added once the definitions are agreed]* ***Article 4: Right and Obligations of the Provider*** *3.1 The Provider undertakes to comply with the terms of reference of the WHO Coordinated Laboratory Network.* *3.2. The Provider agrees to the onward transfer and use of the PABS Materials, to any members of the WHO Coordinated Laboratory Network, on the same terms and conditions as those provided in Standard Material Transfer Agreement within the WHO Coordinated Laboratory Network (SMTA 1).* *3.3 The Provider consents to the onward transfer and use of the PABS Materials to Recipient Entities outside the WHO coordinated laboratory network on the condition that the Recipient Entity has concluded and signed a Standard Material Transfer Agreement outside the WHO coordinated laboratory network (SMTA 2) with the WHO.* *3.4 The Provider shall inform the WHO of shipments or transfer of PABS Materials to entities inside/outside the WHO coordinated laboratory network by recording in the PABS Tracking Mechanism.*	

	Article 5: Rights and Obligation of the Recipient *4.1 The Recipient undertakes the following with respect to the PABS Materials:* *(a) To comply with the terms of reference of WHO coordinated laboratory network and to use the PABS Material solely for purposes listed in the Terms of Reference.* *(b) To inform WHO of shipments of PABS Materials to entities inside/outside the WHO coordinated laboratory network by recording in the PABS Tracking Mechanism.* *(d) In the event of further transfers within the WHO coordinated laboratory network, to do so in accordance with SMTA 1.* *4.2 The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens or PABS Material from their countries and actively engage them in preparation of manuscripts for presentation and publication.* *4.3 The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or PABS Material, using existing scientific guidelines.* *4.4 The Recipient shall share the outcomes of their utilization of PABS Materials with other authorized national laboratories.*	

	Article 6: Intellectual property rights *5.1 Neither the Provider nor the Recipient shall seek or assert any intellectual property rights over any PABS Materials or parts thereof, in any form including any modified form or for any use.* ***Article 7: Genetic Sequence Data*** *6.1 With respect to genetic sequence data, the Recipient agrees to comply with the terms and conditions as applicable to the users of the WHO PABS Sequence Database.* *[Placeholder for standard provisions such as on dispute resolution, warranty, duration of agreement, acceptance and applicability and signature]* ***ANNEX 2: STANDARD MATERIAL TRANSFER AGREEMENT 2 (SMTA 2)*** ***Article 1. Parties to the Agreement*** *WHO and* ***Recipient Entity*** ***Article 2: Subject matter of the Agreement*** *[Placeholder for PABS Material: To be added once the definition is agreed]* ***Article 3: Definitions*** *[Placeholder: To be added once the definitions are agreed]* ***Article 4: Intellectual Property*** *The Recipient Entity shall not seek or assert any intellectual property rights over any PABS Materials or parts thereof, in any form including any modified forms or for any use.*	

	Article 5: Benefit Sharing Obligations of the Recipient Entity *5.1. The Recipient Entity commits to keep WHO informed of all uses PABS Materials and to make the required monetary contributions in a timely manner, for using the PABS System.* *5.2. In the event of a public health emergency of international concern or a pandemic the Recipient Entity agrees to:* *(a) Donate at least 20% of its real-time production of each pandemic-related product manufactured, to WHO for distribution based on public health risk and need. The Recipient Entity shall comply with its commitment based on products and timetable determined by the WHO in consultation with the PABS Advisory Committee;* *(b) Supply vaccines, therapeutics, diagnostics and other pandemic-related products at affordable prices to developing countries, and to comply with WHO's allocation plan, if such a plan is recommended by WHO.* *For the purpose of this paragraph "Affordable pricing" for developing countries means 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".* *(c) 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 product development and*	

	manufacturing, for the production and supply of pandemic-related products, needed in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions in accordance with sound public health principles with the aim to diversify production and expand supply options to facilitate prompt equitable access in developing countries. *For the purposes of this paragraph, the Recipient Entity shall on request by WHO share the complete regulatory dossier including the full technical know-how as well as any materials needed for the development and production such as cell-lines, hybridomas, plasmids, yeast, or mammalian cells, with the sublicensees of WHO.* *5.3 Prior to the declaration of a PHEIC, with the aim to prepare for an early response, at the recommendation of the Director-General, the Recipient Entity shall donate a part of its real-time production, not exceeding 20% of its real-time production, to address access needs in developing countries including for purposes of WHO stockpile. Any affected country may also request the Director-General to operationalize this paragraph. The Director-General shall make the recommendation to this effect, in consultation with the affected countries and the Emergency Committee.* ***Article 6: Genetic Sequence Data*** *6.1 With respect to genetic sequence data, the Recipient Entity agrees to comply with the terms and conditions applicable to the users of the WHO PABS Sequence Database.*	

	Article 7: Third Parties and Service Providers *7.1 The Recipient Entity shall only further transfer the PABS Materials if the prospective recipient has concluded a SMTA with WHO. Any such transfer shall be reported to the WHO.* *7.2 The Recipient Entity shall remain fully responsible for the compliance of all obligations with respect to PABS Material in the event of transfer of PABS Materials to any third parties under contract with the Recipient Entity. The Recipient Entity shall ensure that PABS Materials shall not be utilized by such third parties for research, development or production other than as directed by the Recipient Entity and that the PABS Materials are returned to the Recipient Entity or destroyed, in accordance with appropriate bio-safety standards, at the end of utilization.* *[Placeholder for standard provisions on: Dispute resolution, Liability and indemnity Privileges and Immunity, Name and Emblem, Warranties, Duration of Agreement Termination, Governing Law, Signature and Acceptance.]* ***Annex 3 Click-Wrap Data Access Agreement to be developed reflecting terms and conditions as provided in paragraph (X)]*** ***Annex 4: Terms of Reference of WHO Coordinated Laboratory Network***	