Organisation mondiale de la Santé

Soixante-Dix-Neuvième Assemblée mondiale de la Santé

Point 13.3 de l'ordre du jour provisoire A79/8

13 mai 2026

Groupe de travail intergouvernemental à composition non limitée sur l'Accord de l'OMS sur les pandémies

Rapport du Directeur général

1. Le Directeur général a l'honneur de transmettre à la Soixante-Dix-Neuvième Assemblée mondiale de la Santé les résultats des travaux du Groupe de travail intergouvernemental à composition non limitée (ci-après, le « Groupe de travail intergouvernemental ») en ce qui concerne la rédaction et la négociation de l'annexe décrite à l'article 12 de l'Accord de l'OMS sur les pandémies (voir l'annexe), conformément à la résolution WHA78.1 (2025). L'appendice, où figure le texte du projet d'annexe PABS tel que projeté à l'écran, est disponible en anglais seulement étant donné que le document est en cours de négociation.

Mesures à prendre par l'Assemblée de la Santé

2. L'Assemblée de la Santé est invitée à examiner le projet de décision recommandé par le Groupe de travail intergouvernemental à sa sixième réunion, qui figure en annexe au présent document, en vue de son adoption.

Annexe

Résultats des travaux du Groupe de travail intergouvernemental à composition non limitée sur l'Accord de l'OMS sur les pandémies en ce qui concerne la rédaction et la négociation de l'annexe décrite à l'article 12 de l'Accord de l'OMS sur les pandémies

1. Le Groupe de travail intergouvernemental à composition non limitée sur l'Accord de l'OMS sur les pandémies (ci-après, le « Groupe de travail intergouvernemental »), établi conformément à la résolution WHA78.1 (2025), s'est acquitté de son mandat tel que défini dans la résolution susmentionnée, et en particulier au paragraphe 9.1), selon lequel il est chargé, à titre prioritaire, de rédiger et de négocier l'annexe à l'Accord de l'OMS sur les pandémies décrite à l'article 12 de l'Accord (ci-après, l'« annexe PABS ») et de soumettre les résultats de ces travaux à l'examen de la Soixante-Dix-Neuvième Assemblée mondiale de la Santé.

2. Le Groupe de travail intergouvernemental a mené ses travaux sous la direction du Bureau, coprésidé par l'Ambassadeur Tovar da Silva Nunes (Brésil) et M. Matthew Harpur (Royaume-Uni de Grande-Bretagne et d'Irlande du Nord), avec comme Vice-Présidents et Vice-Présidente : M. l'Ambassadeur Vuyile Dlamini (Royaume d'Eswatini), le D^{r} Hanan Mohamed Al Kuwari (État du Qatar), le D^{r} Viroj Tangcharoensathien (Royaume de Thaïlande) et M^{me} Madeleine Heyward (Australie), et avec l'appui du Secrétariat.

3. Le Groupe de travail intergouvernemental a convoqué six réunions officielles, dont deux reprises, qui se sont tenues selon des modalités hybrides et structurées pour permettre des débats inclusifs entre les États Membres. Des réunions et des consultations informelles ainsi que des séances d'information ont eu lieu, avec la participation d'expertes, d'experts et de parties prenantes concernées. À ce jour, le Groupe de travail intergouvernemental a examiné des propositions de texte, effectué des examens section par section et progressé dans l'élaboration des principaux éléments du Système d'accès aux agents pathogènes et de partage des avantages découlant de leur utilisation.

4. Lors de la reprise de sa sixième réunion, le Groupe de travail intergouvernemental, après des négociations et conscient de son mandat, a reconnu l'importance de poursuivre les négociations pour finaliser ses travaux et a décidé de soumettre à la Soixante-Dix-Neuvième Assemblée mondiale de la Santé le texte de l'annexe PABS projeté à l'écran (voir l'appendice), qui n'est pas un texte final approuvé, en tenant compte de la mention qui y figure concernant le surlignage en couleurs dans le texte, pour refléter les progrès réalisés par le Groupe de travail à ce jour, et a recommandé à l'Assemblée de la Santé d'envisager d'adopter le projet de décision suivant :

> La Soixante-Dix-Neuvième Assemblée mondiale de la Santé,
>
> Rappelant la résolution WHA78.1 (2025), dans laquelle l'Assemblée de la Santé a adopté l'Accord de l'OMS sur les pandémies conformément à l'article 19 de la Constitution de l'Organisation mondiale de la Santé et a, entre autres, décidé d'instituer un groupe de travail intergouvernemental à composition non limitée (le Groupe de travail intergouvernemental), et prenant acte des progrès accomplis par le Groupe de travail intergouvernemental à ce jour,

A DÉCIDÉ que le Groupe de travail intergouvernemental devrait poursuivre ses travaux conformément au mandat défini au paragraphe 9.1) de la résolution WHA78.1 (2025), s'attacher, à titre prioritaire, à rédiger et négocier l'annexe décrite à l'article 12 de l'Accord de l'OMS sur les pandémies, notamment aux fins de l'établissement de contrats juridiquement contraignants devant être négociés et signés avec l'Organisation, et en soumettre le résultat à l'examen de la Quatre-Vingtième Assemblée mondiale de la Santé ou plus tôt s'il y a lieu, à l'occasion d'une session extraordinaire de l'Assemblée mondiale de la Santé organisée en 2026 comportant un seul point de l'ordre du jour consacré à ce résultat, puis faciliter, selon que de besoin, les activités liées à l'adoption de ladite annexe et à l'ouverture à la signature, à la ratification, à l'acceptation, à l'approbation, à l'adhésion ou à la confirmation formelle de l'Accord de l'OMS sur les pandémies.

Appendice

Draft PABS Annex text

(On-screen text as at 20:30 CEST – 30 April 2026)

Highlighting in the text indicates the following:

- Green highlighting: text for which initial agreement was reached
- Yellow highlighting: text for which initial convergence was reached
- Blue highlighting: IGWG Bureau text of 9 March 2026
- Grey highlighting: draft text from the Secretariat regarding additional details on WCLN- and WHO-recognized sequence databases

WHO Pathogen Access and Benefit-Sharing System ("PABS System")

I. Scope, objectives and use of terms

A. Scope and objectives

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "PABS Materials and Sequence Information") and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes, the Parties hereby operationalize the multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (hereinafter the "PABS System"). This Annex sets out the provisions governing the PABS System established in Article 12 of the WHO Pandemic Agreement. [NOTE: Pending consultation]

[1*bis*. In the event that the PABS System does not deliver equitable benefit-sharing as provided for in this Annex and fails to employ effective safeguards against diversion of resources for purposes beyond the scope of PABS system, Parties retain their full sovereign rights to apply national access and benefit-sharing Laws]

B. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) "**Pathogen with pandemic potential**" means any pathogen that has the potential for sustained transmission in humans and the potential to cause a pandemic emergency as defined in Article 1(c) of the WHO Pandemic Agreement. [*NOTE: Subject to further consultation – including on risk assessment, non-exhaustive list of pathogens, and exclusion of influenza viruses for the purpose of the PABS Annex*]

(b) "PABS Materials and Sequence Information" [includes] / [means] [respectively]: (i) [any] / [the] biological material (physical parts or components, including [but not limited to] DNA, RNA, and proteins [and metabolites] [when available]), [isolates of wild type pathogens, and modified pathogens for the purpose of the development of vaccines, therapeutics or diagnostics,] from pathogens with pandemic potential[, which has been transferred to a laboratory within the WHO-coordinated Laboratory Network in accordance with this Annex] ["PABS Materials")]; and (ii) [genomic] information from (i) generated through the application of biotechnology techniques[, which has been transferred to a WHO-recognised sequence database in accordance with this Annex] ["PABS Sequence Information")].

(b) "**PABS Materials and Sequence Information**" means respectively: (i) any biological material from a pathogen with pandemic potential, including but not limited to DNA, RNA, proteins [and metabolites derived from pathogens with pandemic potential] [including modified pathogens] [and shared by a Party]; and (ii) any nucleotide sequence data including genomic [and other multi-omic] information generated directly from a pathogen with pandemic potential [and shared by a Party].

(c) "**Participating Manufacturer**" means an entity, including a developer, that manufactures [or develops] vaccines, therapeutics and/or diagnostics, including by means of licensing agreements, and that has entered into a legally binding WHO PABS Contract [and whose access of the PABS System entails the obligation to enter into a WHO PABS Contract with WHO] / [in order to access] the PABS System. [This definition includes entities that may manufacture and/or hold intellectual property rights over the manufacturing of vaccines, therapeutics and/or diagnostics.]

New proposed terms:

(d) ["**Real-time production**" refers to the total amount of safe, quality and effective vaccines, therapeutics and diagnostics for a pathogen with pandemic potential produced by a participating manufacturer, to be calculated from the time a pandemic emergency is determined by the WHO DG to when the DG determines the pandemic emergency has ended.]

(e) ["**Safe, quality and effective vaccines, therapeutics and diagnostics**" refers to vaccines, therapeutics and diagnostics for the purposes of preventing, treating or diagnosing the disease that has given rise to a PHEIC or pandemic emergency that have received regulatory approval from a national or regional regulatory authority, [**and**]/[or] WHO Listed Authority, or WHO Prequalification, or WHO Emergency Use Listing, or a future equivalent WHO specified status.]

(f) "**Affordable prices to the World Health Organization**" refers to the lowest price of vaccines, therapeutics or diagnostics, negotiated by WHO with a Participating Manufacturer. Such price shall not be higher than those offered through global or regional procurement mechanisms. Pricing shall be negotiated and implemented in a transparent manner. *[NOTE: GAVI formula may be considered]*

(g) ["**Public health purposes**" refers to the use of PABS Materials and Sequence Information, solely for the purpose of pandemic prevention, preparedness, and response, including research and development.]

II. Implementation of the PABS System

A. Operation of the PABS System

1. The operation of the PABS System rests on two [core] pillars: the rapid and timely sharing of PABS Materials and Sequence Information and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits, both monetary and non-monetary, including annual monetary contributions, vaccines, therapeutics and diagnostics arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes. *[NOTE: subject to further discussions on the relevant provisions]*

1bis. To support the operationalization of the rapid and timely sharing of PABS Materials, the WHO Coordinated Laboratory Network (hereinafter, the WCLN) is hereby established.

2. All elements of the PABS System shall come into operation simultaneously[, in accordance with this Annex] [, including the availability of enforceable WHO PABS contracts, a functional PABS tracking mechanism and operational benefit sharing modalities].

[3. [Implementation of the PABS System shall] / [In the implementation of the PABS System…] [recognize and] [respect][the rights of Indigenous Peoples [and] / [as well as] local communities and their] traditional knowledge [of Indigenous Peoples as well as local communities] including traditional medicine with regard to PABS Materials and Sequence Information and the PABS System]. / [Implementation of the PABS System shall [recognize and] respect the rights of Indigenous Peoples and local communities over traditional knowledge associated with PABS Materials and Sequence Information. Access to such traditional knowledge shall be subject to prior informed consent and benefit-sharing in accordance with applicable national legislation and international obligations, including the Nagoya Protocol [as applicable and without creating obligations for States not Party to such instruments.]

3. In the implementation of the PABS System, the Parties shall recognize and respect the traditional knowledge of Indigenous Peoples and of local communities, including traditional medicine, with regard to PABS Materials and Sequence Information.

4. Each Party, in the implementation of the PABS System, shall respect and comply with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection [, including traceability, related to sharing, transportation, handling and safe and secure storage of pathogens with pandemic potential].

[5. The terms and conditions applicable to all participants in the PABS System shall require those participants to:

[5*alt.* All participants of the PABS System shall as a condition of participation, be subject to respective standardized legally binding contractual instruments. The terms and conditions applicable to the participants of the PABS system shall require the participants to:]

(a) [share and/or utilize] / [use of] PABS Materials and Sequence Information [solely] for public health purposes/ [the purposes of pandemic prevention, preparedness and response] [, which include risk assessment, surveillance activities, diagnostic applications, and research and development for pandemic prevention, preparedness and response];

(a*bis*) comply with applicable [access and] benefit-sharing obligations as described in Section [II.B and] II.C;

(a*ter*) comply with applicable provisions regarding onward transfer of PABS Materials and the sharing of PABS Sequence Information. [NOTE: Add specification for applicable provisions]

(b) handle PABS Materials and Sequence Information in accordance with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection;

(c) [appropriately] acknowledge the use of PABS Materials and Sequence Information in presentations and publications and the contributions of collaborators, including laboratories, in particular from developing countries, providing PABS Materials and Sequence Information; and

(d) [not claim any intellectual property or other rights that limit the facilitated access to or use of PABS Materials and Sequence Information, or their genetic parts or components, [in the form received from the PABS System.]]

(d) not claim any intellectual property rights over PABS Materials and Sequence Information, or their genetic parts or components, in the form received from the PABS System.

(e) [have the necessary certified laboratory facilities, equipment, personnel, and have the appropriate national licenses and permits to carry out research work with the received pathogenic materials of the corresponding pathogenicity group.]

(e) [NOTE: 9 March version moves para 5(e) to Section B(2)(a)]

6. The participants of the PABS System include [, *inter alia*]:

(a) laboratories that have agreed to the terms and conditions of the ~~WHO Coordinated Laboratory Network (hereinafter~~ WCLN~~)~~ for [access to,] sharing of [and utilization of] PABS Materials and Sequence Information, consisting of laboratories that have agreed to [contracts] / [[legally binding] terms and conditions] [in a contract with WHO] as described in section B;

(b) WHO [PABS sequence database and] recognized sequence databases for sharing of PABS Sequence information, consisting of databases that have agreed to operate under [contracts] / [[legally binding] terms and conditions] [in a contract with WHO] as described in section B;

(b) databases that have agreed to terms and conditions for WHO-recognized sequence databases for sharing of PABS Sequence Information;

[b*bis*. all users/participants should abide by common terms and conditions.]

(c) [[individuals or] entities] / [users/participants of the PABS System…] using [accessing] [PABS Materials and Sequence Information] / [the PABS System] for commercial purposes [as a condition of access or use] which [[have]/[shall] agree[d] to] [contracts] / [[legally binding] terms and conditions], and] sign WHO PABS Contracts [prior to access] setting out[,

inter alia,] their obligations [for benefit-sharing] / [with respect to their use of the PABS System] as described in section[s B and] C; and

(c) entities utilizing PABS Materials and Sequence Information for commercial purposes that have entered into legally binding WHO PABS Contracts; and

(d) [individuals or] entities / [users/[participants of] the PABS System…] [using PABS Materials and Sequence Information] for non-commercial purposes which [[have] agree[d] to] / [are bound by] [contracts] / [[legally binding] terms and conditions] as described in section[s B and] C [and contained in a contract with WHO].

(d) individuals or entities utilizing PABS Materials and Sequence Information for non-commercial purposes that have agreed to terms and conditions.

[ALT to replace both (c) and (d) above: Entities concluding contracts or entering into cooperation agreements with WHO, pursuant to section C. 1, C. 2 and/or C. 3.]

[(d)*bis* [*add reference to PABS tracking mechanism*]

7. [Participating Manufacturers and other entities that have signed [and complied with] WHO PABS Contracts [, or agreed to [and complied with] [legally binding] terms and conditions,] shall not be subject to additional benefit sharing measures with respect to use of the PABS system that is covered by such contracts [, and shall not be subject to access and benefit sharing measures and obligations that duplicate those of the Pandemic Influenza Preparedness Framework, to ensure that the PABS System is implemented in a manner complementary to, and not duplicative of, the Pandemic Influenza Preparedness Framework]. [In accordance with Article 12.5 [(d)(ii)]], each Party shall review and, as it deems appropriate, align its national and/or regional access and benefit sharing measures applicable to PABS Materials and Sequence Information within the scope of this Annex, so that measures that are contrary to, or inconsistent with, or duplicative of, this Annex will not be applied upon entry into operation of all elements of the PABS System. Use of the PABS System beyond its scope will be subject to applicable law on access and benefit-sharing.]

7. In accordance with Article 12, each Party shall review and, as it deems appropriate, align its national and/or regional access and benefit-sharing measures applicable to PABS Materials and Sequence Information within the scope of this Annex, so that measures that are contrary to, inconsistent with or duplicative of, this Annex will not be applied upon entry into operation of all elements of the PABS System. Participating Manufacturers and other entities that comply with WHO PABS Contracts shall not be subject to additional benefit-sharing measures with respect to matters covered by such contracts. Entities using PABS Materials and Sequence Information for purposes beyond the scope of the PABS System shall be subject to applicable law on access and benefit-sharing.

B. Access to PABS Materials and Sequence Information

1. [In the case of a health event [within the meaning of IHR (2005)],] Each Party, [upon confirmation] / [identification] of a pathogen with pandemic potential, [and] / [after] initial national risk assessment [and in a manner consistent with applicable international law] [, CBD [& Nagoya Protocol,] [and with the IHR (2005)] [shall] / [may], [where applicable], and with] [without prejudice to] applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity [and export control] of pathogens, and data protection:

(a) through a [registered] laboratory or laboratories authorized under relevant national or domestic procedures:

(i) [transfer,] / [provide access to] [and notify WHO through National Focal Points of the relevant characteristics and, upon request,] [share [the characteristics of] PABS Materials, as [soon as] [available]/[possible]] [stored in national laboratories or in another state or at regional level, as deemed appropriate], [on a priority basis] with [a] / [one or more] WCLN laboratories of the Party's choice [which have agreed to contractual obligations] [Materials, which is under a Party's control and contain a pathogen with pandemic potential, including a pathogen contained in the list referred to in section III.A.(e)ii, as soon as possible and within [X] days of identification of such pathogen] [, [in compliance with] / [following] biosafety and biosecurity practices] [, subject to availability of financial resources];

(i*alt*) share PABS Materials, as soon as available, on a priority basis, with one or more WCLN laboratories of the Party's choice, and notify WHO thereof;

(ii) [upload] / [provide access to] PABS Sequence Information, as soon as [available]/[possible], on a priority basis to one or more WHO recognized sequence databases of the Party's choice [Sequence Information, which is under a Party's control, of a pathogen with pandemic potential, including a pathogen contained in the list referred to in section III.A.(e)ii., within [X] days of sequencing such pathogens];

(ii)*bis* In case a notification to the WHO is required pursuant to articles 6 and 7 of the IHR (2005) the notifying Party shall make available upon request of the WHO the material, and sequence information if available, related to the notification in accordance with the provisions of this Annex.

(iii) [assign and attach] / [facilitate the use of] / [ensure that] a [unique persistent] identifier [is assigned and attached] to each PABS Material and Sequence Information [that is fully compatible and interoperable with identifiers used in other international databases] [, and in a manner that such identifiers are permanently linked to each other and identifies the originating laboratory] [and in a manner that:

(1) permanently links identifiers to the originating laboratory and provider country;

(2) maintains traceability through all stages of research, development, and commercialisation, including derivatives and modifications;

(3) enables provider countries to track all downstream uses and applications of materials originating from their territory;

(4) automatically triggers benefit-sharing obligations when commercial value is generated from identified materials;

(5) prevents circumvention through sequence modifications, synthetic biology, or other technological alterations that maintain functional similarity to the original material";

(iii*alt*) ensure that a unique persistent identifier is assigned and attached to each PABS Material and Sequence Information;

(b) [provide metadata required for risk assessment, where applicable;]

(b*alt*) [provide, as soon as available, in accordance with national legislation and, where applicable, international obligations, accurate and if possible detailed public health information, including non-confidential clinical and epidemiological information, needed for the assessment of the pathogen with pandemic potential, and continue to share the aforesaid in the event additional information becomes available;]

(c) [take [appropriate] measures, in accordance with national legislation and [applicable] international obligations, to ensure that traditional knowledge associated with genetic resources [and other derivatives] that is held by Indigenous Peoples [and] / [as well as] / [of] local communities regarding PABS Materials and Sequence Information [including traditional medicine] shall be accessed with the prior and informed consent[,] [and] / or approval and involvement of [these] / [the concerned] Indigenous Peoples [as well as] / [of] local communities, and under mutually agreed terms; and]

(d) agree to onward transfer and use of PABS Material and Sequence Information, [[in line with the]/[subject to the recipient agreeing to [applicable]] [legally binding] terms and condition] / [in accordance with the provisions set out in section C.4].

(d) agree to onward transfer and use of PABS Materials and Sequence Information, in line with the applicable terms and conditions;

1*bis* The WCLN shall comprise laboratories, authorized by their national government and operating under national or domestic laws, that demonstrate the capacities to perform technical functions required to support the PABS system, and agree to the Terms and Conditions and the core Terms of Reference set out below. In addition:

(a) For *WCLN National laboratories*, each Party shall select, in consultation with the WHO Secretariat, and WHO shall recognize, one or more national laboratories to serve as WCLN national laboratory (hereby referred to as a "WCLN National Laboratory"). In the event there is more than one WCLN National Laboratory within a Party, the Party shall designate one of the laboratories as the focal point for communication with WHO.

(b) For *WCLN Reference laboratories*:

(i) WCLN Reference Laboratories shall be designated by WHO in consultation with relevant host country and the laboratory concerned, may be a WCLN National Laboratory; and shall: a) have the capacity, *inter alia,* to receive, store, identify, characterize, culture, curate as relevant, and share pathogens with pandemic potential, taking into account capacities and specialization and; b) have full and unrestricted access to at least biosafety level 3 laboratory facilities that meet recognized international and national standards; c) rely on financial support provided only by governmental and/or non-commercial sources;

(ii) A laboratory may serve as both a WCLN National Laboratory and a WCLN Reference Laboratory;

(iii) with a view to ensuring equitable representation of the WHO regions there shall be at least one WCLN Reference Laboratory in each WHO region, reflecting a balanced representation of reference laboratories in developing countries.

(c) WHO and WCLN Reference Laboratories shall, subject to available resources, provide support, capacity-building and training of personnel in laboratories in developing countries to promote their participation in the WCLN, in line with normative functions of WHO.

2. The [legally binding] [terms and conditions] / [contracts with WHO] applicable to laboratories [which have agreed to such terms and conditions] [in concurrence with the State Parties] within the WCLN shall require those laboratories to, inter alia:

(a*bis*.) have the necessary [national licences,] facilities, equipment and personnel, and [ensure the safe handling and shipment of any PMSI including through compliance with the] [meet required] relevant international and national biosafety and biosecurity levels and standards necessary to safely handle pathogens with pandemic potential;

(a) ensure that a unique persistent identifier is retained for each PABS Material, [and where applicable] each PABS Sequence Information, including for purposes of onward transfers [to track the movement of pathogens];

[(*ALT* a) ensure that PABS Materials are recorded and managed using relevant information management systems, including unique persistent identifiers, that conform to internationally recognized, evidence-based standards and guidance and that enable reliable identification over time;]

(b) share [all]/[relevant] results and analyses [promptly and in a standardized format]/] [*NOTE: specify timely*] [with WHO and [the]/[all] Party/[Parties] provid[ing] PABS Materials and Sequence Information [in a timely manner];

(c) use PABS Material and Sequence Information [solely] for public health purposes *[NOTE: define]*;

(d) [upon request], [mandatory requirement to] / [seek to] [engage [with] scientists from originating laboratories, especially those from developing countries, in scientific projects associated with research on PABS Material and Sequence Information, and [seek]/[ensure]/[shall guarantee]/ [encourage]/[offer] their co-authorship in the preparation of manuscripts for presentation and publication] [according to best practices for scientific publications]; [and]

(e) [acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing PABS Material and Sequence Information, in line with internationally recognized scientific guidelines]; and

(f) [[agree not to claim intellectual property rights on PABS Material and Sequence Information] [or parts thereof in any form, including any modified form or for any use] *[ADD/EXEMPTION: synthesized or modified sequences, derived products like vaccines diagnostics, manufacturing processes, data analysis tools and algorithms*].]

(g) ensure that, through the relevant material transfer agreement and/or notice of shipment, onward transfers of PABS Materials outside the WCLN are subject to the requirements in Section II.A.6 and the recipient's commitment to enter into a WHO PABS Contract or agree to terms and conditions as described in Sections II.C.1, C.2 and C.3, as applicable;

(g) *[Point on recording all transfers in PABS Tracking Mechanism]*

(h) notify WHO of onward transfers of PABS Materials, both within and outside the WCLN;

(i) comply with the WCLN Terms of Reference applicable to the laboratory.

2*bis.* In order to satisfy the criterial for participation in the WCLN, laboratories shall comply with the terms and conditions set out in paragraph (2) above, and shall agree to Terms of Reference that shall include, inter alia, the following:

(a) For *WCLN National Laboratories*:

(i) Follow WHO recommended guidance to detect pathogens with pandemic potential.

(ii) Conduct testing and relevant analyses of clinical specimens for the purpose of identifying and characterizing pathogens, which may be of pandemic potential.

(iii) Alert WHO immediately when a pathogen is detected that cannot be readily identified and/or characterised.

(iv) Receive PABS Material from other laboratories in the country.

(v) Assign, attach and/or ensure that a unique persistent identifier or equivalent mechanism enabling reliable identification over time is retained for each PABS Material shared, and where applicable, each PABS Sequence Information uploaded, including for purposes of onward transfers.

(vi) Generate and upload PABS Sequence Information, as relevant and subject to existing capacity, to WHO recognized sequence databases.

(vii) Share PABS Materials, as appropriate, upon request, at the recipient's cost, with WCLN Reference laboratories, on the same terms and conditions as those provided in II.A.6 and II.B.2 of the PABS Annex to the WHO Pandemic Agreement.

(viii) Share relevant results and analysis of PABS Materials with WHO, in a timely manner.

(ix) In the event of de-recognition/designation, destroy or return any PABS Material.

(b) *WCLN Reference laboratories:*

(i) Conduct advanced analysis, as appropriate, including confirmatory testing, pathogen characterization and novel diagnostic methods in relation to detecting pathogens with pandemic potential.

(ii) Share relevant results and analyses of PABS Materials in a timely manner with the originating country and with WHO.

(iii) Receive, propagate, and store, as appropriate, PABS Materials, and retain the assigned unique persistent identifier for each PABS Material in its possession, including for purposes of onward transfer.

(iv) Share PABS Materials upon request with other WCLN laboratories, on the same terms and conditions as those provided in II.A.6 and II.B.2 of the PABS Annex to the WHO Pandemic Agreement.

(v) Upload PABS Sequence Information to WHO recognized sequence databases, ensuring that the uploaded PABS Sequence Information retains the relevant unique persistent identifier.

(vi) Support national laboratories, including capacity building, in the international laboratory's own country as well as in other countries, to enable them to fulfil their functions, including as set out in these terms of reference.

(vii) In the event of de-recognition/designation, destroy or return any PABS Material.

2*ter*. For the purposes of implementation of this Annex, a WHO recognised sequence database is a database that has been recognized by WHO that has agreed to, and demonstrates capacity to comply with, the Terms and Conditions and core Terms of Reference for WHO-recognised databases set out below, subject to applicable data protection and privacy laws.

3. [The [legally binding] terms and conditions applicable to] [WHO recognized sequence databases [that have agreed to contractual obligations [for the purposes of the PABS System] shall operate under the following legally binding terms and conditions, inter alia:] / [for sharing of PABS Sequence Information shall require those databases to, inter alia:]

(a) ensure that a unique persistent identifier [containing information from the laboratory of origin as well as the country of origin] is [assigned, attached and] retained for [usage for] each PABS Sequence Information;

[(a)*alt* ensure that PABS Sequence Information are recorded and managed using relevant [national] information management systems that conform to internationally [and regionally] recognised evidence based standards and guidance, and that enable reliable identification over time;]

[(a)*bis* agree to implement user registration and verification system, data access agreement and any other requirement of the PABS System;]

(b) apply [appropriate] /[relevant] [national] information security policies and practices, and quality standards (sequence data and information curation), with relevant [sustainable] interoperability [provided that such interoperability shall preserve UPIs and ensure full traceability of PABS Sequence Information and its derivatives] requirements [including to enable reliable identification of PABS Sequence Information over time and to support interoperability];

(c) [inform users] / [require users, as a condition of access, to agree to legally binding terms] / [inform entities receiving PABS Sequence Information] about the WHO Pandemic Agreement and the PABS System, including that [access to and] use of PABS Sequence

Information [may]/[shall] trigger obligations to share/expectations of sharing of benefits arising from such [access and/or] use;

(c) notify users of the requirements in Section II.A.6, and that utilization of PABS Sequence Information entails commitment to enter into a WHO PABS Contract or agree to terms and conditions as described in Sections II.C.1, C.2 and C.3, as applicable;

[(c) ALT Provide access to PABS Sequence Information, without discrimination, to registered and verified users that have accepted the data access agreement, requiring compliance with requirements of the PABS System including benefit sharing obligations].

(d) [require] / [encourage and support] users of PABS Sequence Information, [to commit through a data access agreement…] in line with internationally recognized scientific guidelines, to appropriately acknowledge: i) use of the PABS Sequence Information in presentations and publications; and ii) where known, the contributions of collaborators, including laboratories/countries providing PMSI; and

(d) enable the reporting of, and preserve information on, data provenance, including the country of origin and laboratory which generated the PABS Sequence Information;

(e) [agree not to claim intellectual property rights over PABS Material and Sequence Information.]

[(e) *bis*. notify users that failure to comply with the applicable terms and conditions and/or WHO PABS Contract [including benefit sharing obligations] may/[shall] result in denial, suspension or termination of access to PABS Sequence Information, where applicable

[(e) *ter*. [support the rapid upload [transferring, receiving]/ [and availability] of PABS Sequence Information , [and to make available to all Parties and recipients data which are findable, accessible, interoperable and reusable], and provide access thereto free of charge]

[(e) *quater*. only share PABS Sequence Information if the prospective recipient is registered with the WHO PABS sequence database or WHO recognised sequence database and the prospective recipient has accepted the data access agreement.]

(e) *quater.* comply with their own policies regarding onward sharing of PABS Sequence Information;

(e) *quinquies*. ensure their governance practices and terms of use are transparent and publicly accessible, including for the participants of the PABS System;

(f) comply with the WHO recognized sequence database Terms of Reference

[3*alt*. WHO recognized sequence databases hosting PABS Sequence Information shall enter into a binding agreement with WHO and operate under terms and conditions that ensure conditional access, respect for national sovereignty over genetic resources and associated sequence information, and enforcement of mandatory benefit-sharing obligations. These terms and conditions shall require WHO recognized sequence databases to, inter alia:

(a) ensure that a unique persistent identifier is retained for each PABS Sequence Information;

(b) apply relevant information security policies and practices, and quality standards (sequence data and information curation), with relevant interoperability requirements, including support for regional databases with full computational functionality to ensure equitable access to analytical capabilities.

(c) inform users that access to and use of PABS Sequence Information triggers mandatory obligations under the WHO Pandemic Agreement and the PABS System to share benefits arising from such use, and require users to commit to a legally binding Data Access Agreement before downloading or accessing PABS Sequence Information.

(d) require users of PABS Sequence Information to commit through a Data Access Agreement, prior to access, to: (i) appropriately acknowledge use in presentations and publications; (ii) acknowledge contributions of collaborators, including laboratories/countries providing PMSI; (iii) fulfil all benefit-sharing obligations; and (iv) not claim intellectual property rights over PABS Material and Sequence Information, including derivatives and modifications thereof.

(e) agree not to claim intellectual property rights over PABS Material and Sequence Information.

(f) WHO recognized sequence databases shall sign a binding agreement with WHO committing to:

(i) implement and enforce all requirements;

(ii) respect sovereignty of provider countries, including compliance with any access conditions specified;

(iii) maintain transparent records of all data access, with such records available to provider countries upon request;

(iv) immediately suspend access for violators; and

(v) report annually to the PABS Coordinating Body.

(g) failure by a database to fulfil these obligations shall result in:

(i) suspension of WHO recognition status;

(ii) notification to all Parties;

(iii) potential liability for damages to provider countries; and

(iv) prohibition on hosting new PABS Sequence Information until compliance is restored.

[3*bis*. The terms and conditions applicable to the participants of the PABS System using PABS Materials and Sequence Information for commercial and/or non-commercial purposes shall require those participants to, inter alia:

(a) register legal name and institutional affiliation, country of residence/incorporation and intended use category (commercial, non-commercial) before accessing PABS Sequence Information from a WHO recognized sequence databases;

(b) use PABS Material and Sequence Information [solely] for public health purposes;

(c) agree with benefit sharing expectations/obligations arising from the use of PABS Materials and Sequence Information, as described in Section C;

(d) apply the relevant standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection;

(e) comply with the relevant rules regarding onward transfer of PABS Materials and the sharing of PABS Sequence Information;

Information

(f) appropriately acknowledge, in line with internationally recognized scientific guidelines:

(i) use of the PABS Sequence Information in presentations and publications; and

(ii) where known, the contributions of collaborators, including laboratories/countries providing PMSI; and

(g) agree not to claim intellectual property rights over PABS Material and Sequence.

[3*ter*. The WHO shall establish and maintain up to date registry of PABS Materials and Sequence Information that will allow participants in the PABS System to search and identify PABS Materials and Sequence Information stored in national and regional databases as relevant.]

3 quater. WHO recognized sequence databases shall, subject to appliable data protection and privacy laws, comply with the terms and conditions set out in paragraph (3) above, and shall agree to the Terms of Reference that shall include, inter alia:

(1) Support the timely submission and availability of PABS Sequence Information to facilitate public health surveillance, risk assessment and response. PABS Sequence Information should be made available in a manner that enables timely discovery and use by the global public health community, consistent with the governance and access frameworks of the participating database.

(2) Maintain transparent governance practices and publicly accessible terms of use, clearly communicate applicable access conditions and user responsibilities, including as set out in the PABS Annex, and support appropriate acknowledgment of contributors in accordance with internationally recognized scientific practice.

(3) Collect, preserve, and display information on the originating laboratory, registered submitting entity, and contributors associated with each sequence record and provide clear attribution and citation information associated with sequence records including persistent identifiers and contributor details to support appropriate acknowledgment in accordance with internationally recognized scientific practice.

(4) Maintain a minimum set of core metadata necessary to support public health use, traceability, and attribution and support the updating of such metadata as additional information becomes available.

(5) Assign, attach, and retain a unique persistent identifier for each PABS Sequence Information record, ensuring identifiers remain stable, valid, and resolvable over time, and are retained and propagated during data exchange and integration.

(6) Preserve and display identifiers assigned by originating laboratories or upstream systems, support cross-referencing where multiple identifiers exist, and maintain linkage between sequence records, associated metadata, related information, and support version control and maintain linkage between record versions.

(7) Support interoperability through structured, machine-readable data and metadata, and enable sequence records to be cross-referenced and discovered across databases and systems.

(8) Cooperate with WHO-supported catalogues, registries, or other relevant visibility mechanisms.

(9) Apply appropriate information security and data stewardship practices, maintain data quality and integrity and ensure reliability and persistence of sequence records and associated metadata.

C. PABS System benefit-sharing

1. WHO PABS Contracts with Participating Manufacturers shall include, inter alia, the following obligations:

(a) In accordance with Article 12.5 and 12.8, each Participating Manufacturer shall:

(i) [In accordance with Article 12.5,] provide monetary benefits, including annual monetary contributions [by commercial users] based on objective, transparent and measurable criteria [related to the operational costs associated with the functioning of the PABS system], and taking into account their [use of PABS Materials and Sequence Information as well as their] nature and capacity / [based on a percentage of revenues generated from pandemic-related health products developed using PMSI]; and

[(i)*alt.* provide monetary benefits, including annual monetary contributions [based on objective, transparent and measurable criteria,] calculated as a percentage of annual net sales revenue derived from products utilizing PABS Materials and Sequence Information, at a rate to be determined by the Conference of the Parties but not less than [0.1%] of such revenue, or a minimum fixed annual contribution of [xx], and taking into account their use of PABS Materials and Sequence Information as well as their nature and capacity;]

[(i)*bis.* Participating manufacturers shall make milestone payments to the PABS Fund upon: (i) filing patent applications for PABS-derived inventions; (ii) initiating Phase

III clinical trials; (iii) receiving regulatory approval; and (iv) reaching sales thresholds determined by the COP.]

[(i)*ter.* Manufacturers shall pay royalties of [X]% of net sales from PABS-derived products, with differentiated rates determined by the COP considering product type, pandemic vs. inter-pandemic use, and manufacturer capacity.]

[(i)*quater*. Provide access to safe, quality and effective vaccines, therapeutics, and diagnostics at affordable prices and on a priority basis for WHO, supporting its coordinated response to public health risks and events pursuant to Article 13.3 of the International Health Regulations (2005).]

(ii) commit to at least [x] / [two] / [three] of the following options: [NOTE: for discussion on "nature and capacity"]

(1) capacity-building and technical assistance, for the benefit of developing countries, based on their needs and as jointly agreed;

(2) research and development cooperation [[on mutually agreed terms] with [the relevant Party and] scientists and researchers especially from developing countries];

(3) facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005); [NOTE: Additional proposal]

(4) [Production partnership with other manufacturers, including through] the granting of non-exclusive licenses [aimed to increase the availability] [to manufacturers in developing countries for the effective production and delivery] of vaccines, therapeutics and diagnostics[, especially of the Parties most affected by a Pandemic Emergency or a Public Health Emergency of International Concern [under mutually agreed terms]; and

(5) other forms of transfer of technology as mutually agreed,[1] including transfer of relevant knowledge, skills and technical expertise[, especially for the production of vaccines, therapeutics and diagnostics;]

[(6) contribution to [regional and/or] international stockpiles.]

(b) In the event of a public health emergency of international concern, in accordance with Article 12.7, Participating Manufacturers shall implement benefit-sharing provisions, including options regarding access to safe, quality and effective vaccines, therapeutics and diagnostics for the pathogen causing the public health emergency of international concern, such as:

[1] For the purposes of the WHO Pandemic Agreement, "as mutually agreed" means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.

(i) agreeing to provide, where available, promptly and on a priority basis to WHO on its request, such products [as a donation or] at affordable prices, based on needs assessed by WHO.

(ii) [To allocate and deliver upon request to]/[Reserve for] WHO at least 20% of real-time production of safe, quality and effective vaccines, therapeutics and diagnostics for the pathogen causing PHEIC (or of the stocks in the inventory, in case of no real-time production) and make available to WHO, on its request, at least 8% [10%] of real-time production free of charge and the remaining 12% [10%] at not-for-profit prices.]:

(iii) [options regarding] access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern[, such as contributions to global or regional stockpiles and/or sustaining buffers to maintain readiness] [to the extent consistent with the manufacturer's production capacity];

[(iii)*alt*. Agree to provide promptly and on a priority basis to WHO on its request, adequate supplies of vaccines, therapeutics and diagnostics for the pathogens causing PHEICs at affordable prices based on needs assessed by the IHR Emergency Committee.]

(iv) granting of non-exclusive licenses for vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern [mainly for] / [prioritizing] manufacturers in developing countries]; and

(v) [access to [relevant health products as determined in the International Health Regulations] / [other pandemic-related health products.]

(vi) [identify an experienced partner facility that has the requisite capacity and capability, in the affected region, for technology transfer that would be triggered when a PHEIC is determined.]

[(b *alt. 1*) In the event of a public health emergency of international concern, in accordance with Article 12.7, Participating Manufacturers shall provide the following benefit-sharing provisions:

(i) Provide promptly and on a priority basis to WHO on its request, adequate supplies of vaccines, therapeutics and diagnostics for the pathogens causing PHEICs, free of charge and at affordable prices, based on needs assessed by the WHO. Participating manufacturers shall reserve at least 20% of real-time production (or of the stocks in the inventory, in case of no real-time production) for WHO to ensure its needs are met promptly and on a priority basis, of which at least 8%(10%) of real-time production shall be provided free; **AND**

(ii) Grant to WHO, upon signing the WHO PABS Contract, non-exclusive, royalty-free, worldwide licenses that can be sublicensed, in the event of a PHEIC, to manufacturers in developing countries on standard terms and conditions, ensuring equitable geographic distribution and in accordance with sound public health principles, for the development, production and supply of vaccines, therapeutics, or diagnostics relevant to the public health emergency of

international concern. This paragraph and licenses granted shall also apply in the event a pandemic emergency is declared. Sub-licensing shall be triggered where the Participating Manufacturer is unable to meet all the needs of WHO and affected countries in a timely manner or on the recommendation of the IHR Emergency Committee.

(b)*bis* In addition to above benefits, Participating manufacturers may choose to provide other benefits from the following options:

(i) provide contributions to WHO coordinated global or regional stockpiles and/or sustaining buffers to maintain readiness of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern;

(ii) Provide WHO free access to other pandemic-related health products.]

[(b *alt*. 2) In the event of a public health emergency of international concern, in accordance with Article 12.7, Participating Manufacturers shall provide the following benefits:

(i) agrees to provide promptly and on a priority basis to WHO, on its request, adequate supplies of vaccines, therapeutics and diagnostics for the pathogen causing public health emergency of international concern, at affordable prices, based on needs assessed by the IHR emergency committee.

(ii) granting of non-exclusive licenses for vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern; and

In addition to above benefits, Participating manufacturers may choose to provide other benefits from the following option i.]

[(b *alt.* 3) In the event of a public health emergency of international concern as determined by the WHO DG pursuant to IHR art. 12, [is caused by a pathogen identified to have pandemic potential in accordance with section 1 B… and …,] a participating manufacturer shall [provide a time-bound offer to WHO to sell at an affordable price and/or] make available to WHO[,] as a donation [of] / [and/or reserved at affordable prices,] no less than 10 per cent of its real time production of safe, quality and effective vaccines, therapeutics and diagnostics [that have received regulatory approval or authorization for the purpose of preventing, treating or diagnosing the disease that has given rise to such] / [for the pathogen of pandemic potential causing the] PHEIC.

Where a public health emergency of international concern develops into a pandemic emergency, the commitment in this paragraph shall no longer be applicable to a participating manufacturer during the pandemic emergency, and the commitments pursuant to paragraph (c) shall apply to such Participating Manufacturer.]

[(b)*bis.* Parties shall ensure that pandemic-related health products committed under WHO PABS Contracts, including quantities allocated or reserved for WHO pursuant to this Section, are not subject to export prohibitions, restrictions, licensing requirements or other measures having equivalent effect during a public health emergency of international concern or a pandemic emergency. Where a Party adopts measures affecting the export of pandemic-

related health products, such measures shall not apply to quantities committed to or allocated through the PABS System, which shall be granted priority clearance and shipment.]

(c) In the event of a pandemic emergency, in accordance with Article 12.6, each Participating Manufacturer shall make available to WHO rapid access targeting twenty per cent (20%) of its real-time production of safe, quality and effective vaccines, therapeutics and diagnostics for the pathogen causing the pandemic emergency, provided that:

(i) a minimum threshold of ten per cent (10%) of its real-time production is made available to WHO as a donation; and

(ii) the remaining percentage, with flexibility based on the nature and capacity of each Participating Manufacturer, is reserved at affordable prices to WHO. *[NOTE: Subject to further consultations]*

2. WHO PABS Contracts with other entities [accessing and/or] utilizing PABS Materials and Sequence Information for commercial purposes, including developers that do not manufacture vaccines, therapeutics or diagnostics, shall, in accordance with Articles 12.5[(a)] and 12.8, include, inter alia, obligations for such entities to:

(a) provide monetary benefits, including annual monetary contributions [[which could be graduated] / [calculated as a defined percentage of revenues [derived]/[arising] from [pandemic related health] products] / [health products] [and services] using PABS Material or Sequence Information]] / [based on objective, transparent and measurable criteria, and taking into account their use of PABS Materials and Sequence Information, as well as their nature and capacity]; and

(a) *ALT* provide monetary benefits, including annual monetary contributions [based on objective, transparent and measurable criteria] / [related to the operational costs associated with the functioning of the PABS system], and taking into account their [use of PABS Materials and Sequence Information as well as their] nature and capacity / [based on a percentage of revenues generated from [pandemic-related] health products [and services] developed using PMSI]; and

[(a)*bis*. make available products and services at fair and reasonable prices for developing countries;]

(b) [based on their nature and capacity, [provide]/[commit] to [and fulfil] at least two of the following options]/[commit to all of the following mandatory obligations, adapted to their nature and capacity]:

(i) capacity-building and technical assistance [where applicable];

(ii) research and development cooperation [where applicable];

(iii) granting of non-exclusive licenses to manufacturers in developing countries for the effective production and delivery of vaccines, therapeutics and diagnostics; and[/or]

(iv) other forms of technology transfer as mutually agreed, [FN8] including the transfer of relevant knowledge, skills and technical expertise.

(iv) other forms of technology transfer as mutually agreed,[2] including the transfer of relevant knowledge, skills and technical expertise.

(v) facilitation of rapid access to available [pandemic-related] health products [and services], with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);

[2*bis*. In case the entity mentioned in para 2 is a developer of vaccines, therapeutics and diagnostics for pathogens with pandemic potential, it shall, in addition to benefits provided under Paragraph 2, grant to WHO non-exclusive, royalty-free, worldwide licenses, taking into account licenses that can be sublicensed to manufacturers in developing countries on standard terms and conditions, ensuring equitable geographic distribution and in accordance with sound public health principles, for the development, production and supply of vaccines, therapeutics, or diagnostics relevant to a public health emergency of international concern or a pandemic emergency, and during the inter-pandemic period in developing countries. These licenses shall continue to apply in the event that a pandemic emergency is declared.]

3. [Applicable] [WHO legally binding] [terms and conditions for] entities [accessing]/[sharing and/or utilizing] PABS Materials and Sequence Information for non-commercial purposes [[following biosafety and biosecurity [practices]/[standards] [and traceability mechanism], where appropriate],] shall [include], inter alia, [require each entity to] / [require such entities to] /[obligations to]:

(a) acknowledge in presentations and publications, the contributions of collaborators, including [originating] laboratories/countries providing PABS Material and Sequence Information, [in line with internationally recognized scientific guidelines] [and referencing the unique persistent identifier of the said PABS Material and Sequence Information];

(b) [seek to] engage scientists from originating laboratories, [in line with internationally recognized scientific guidelines] [in accordance with national and/or domestic law,] especially those from developing countries, in scientific projects associated with research [and development] on [PABS Material and Sequence Information]/[pandemic prevention, preparedness and response], and [seek]/[engage and consider options for]/[seek to ensure]/[offer] [early, meaningful engagement of] their co-authorship in preparation of manuscripts for presentation and publication, [subject to applicable rules for co-authorship attribution,] promoting broad and free access;

(c) based on their nature and capacity, [upon request of the State Party, in accordance with national and/or domestic law,] [consider options for][…]:

(i) capacity-building and technical assistance, [such as] [supporting]/[conducting [of]] risk [analysis and] assessment and outbreak forecasting; [and/or]

(ii) research and development cooperation; and

(iii) monetary benefits.

[2] For the purposes of the WHO Pandemic Agreement, “as mutually agreed” means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.

[(d)*bis*. make available all outcomes from the non-commercial use of PABS Materials and Sequence Information freely available and accessible in the public domain;]

(d) inform WHO, and enter into a WHO PABS Contract [as appropriate], in the event they intend to utilize PABS Materials and Sequence Information for commercial purposes.

III. Governance and review of the PABS System

A. Governance

1. The Conference of the Parties shall oversee and promote implementation of the PABS System. In support of this function, a subsidiary body to be known as the PABS Advisory Group is hereby established [and shall operate in a manner consistent with the WHO Regulations for Expert Advisory Panels and Committees]. The Conference of the Parties shall approve at its first session terms of reference for the PABS Advisory Group and modalities for its operationalization and governance. [NOTE: Subject to further consultation on text in brackets]

New 2. The PABS Advisory Group shall:

(i) be comprised of independent experts, free of conflict of interest, with competence in fields relevant to this Annex, paying particular attention to the need to ensure equitable geographic representation, gender balance and balanced representation between developed and developing countries;

(ii) provide technical guidance and evidence-based recommendations to facilitate the implementation and operation of the PABS System and report to the Conference of Parties, [through the Director-General,] on operational and technical matters related to the PABS Annex; [NOTE: Subject to further consultation on text in brackets]

(iii) as necessary and no later than every five years, review, update and provide to the Conference of the Parties [for its consideration][, through the Director-General,][a non-exhaustive] / [an indicative] list of pathogens with pandemic potential [, as developed by the Secretariat];
[for the purposes of facilitating the operation of the PABS system, [compile] / [develop based on a proposal by the Secretariat] a non-exhaustive list of pathogens with pandemic potential, based on scientific evidence, and report thereon to the Conference of Parties [for its consideration] at its first session[, through the Director-General]

[(iv) advise the Director-General on matters of conflict resolution with participants of the PABS system;]

[(v) provide technical and advisory input, including legal input, in relation to allegations of non-compliance or material breach of the PABS System, including, as appropriate, to inform the consideration of possible actions to be taken].

Note: include reference to the list non-exhaustive list of pathogens with pandemic potential in the pathogen with pandemic potential definition.

**NOTE: WHA79 Resolution adopting the Annex to request the DG to establish a technical advisory body to "compile a non-exhaustive list of pathogens with pandemic potential, based on scientific evidence" for consideration of the COP at its first meeting – based on WHA78.1 paras 12 and 15(4).*

3. For the purposes of coordination, implementation and operation of this PABS Annex, the Secretariat of the World Health Organization, as Secretariat of the WHO Pandemic Agreement pursuant to Article 22 thereof, shall, inter alia:

(a) in accordance with relevant provisions of the WHO Pandemic Agreement, administer and coordinate the PABS System under the guidance of the Conference of the Parties, and regularly report to the Conference of the Parties;

(b) collaborate with relevant international organizations*, and relevant stakeholders, and, as appropriate, relevant regional institutions;

[*ADD Footnote: from Article 12 – In the context of collaboration with the World Health Organization, "relevant international organizations" is understood in accordance with the Constitution of the World Health Organization.]

(c) develop [for approval by the IGWG or World Health Assembly] terms of reference for [, and coordination of,] laboratories in WHO Coordinated Laboratory Networks, as well as WHO recognized sequence databases [which are in accordance with the terms and conditions set out in sections [II.A.6,] II.B.2 and II.B.3], [for approval by the Conference of the Parties, [pursuant to Section III.A.1] and operationalize the WCLN and the recognition of databases for sharing PABS sequence information in accordance with requirements set out in Section II.B. of this Annex and the Terms of Reference approved by the Conference of the Parties] [so that they are available when the PABS System [comes into operation] / [operations commence]]; [*NOTE: pending Secretariat's presentation of a consolidated textual proposal on the WCLN and recognized sequence databases.*]

(d) operationalize / administer the WCLN and the recognition of databases for sharing PABS Sequence Information according to the requirements set out in Section II.B of this Annex; [*NOTE: pending Secretariat's presentation of a consolidated textual proposal on the WCLN and recognized sequence databases, as well as the outcomes of discussions on Section II.B.*]

(e) make publicly available, inter alia, lists of laboratories authorized under relevant national or domestic procedures that are part of the WCLN; WHO-recognized databases for sharing PABS Sequence Information; concluded WHO PABS Contracts [including term sheets,] while protecting [proprietary]/[confidential] information; and full information on the amount and use of monetary contributions and measures pertaining to non-monetary benefit-sharing; [NOTE: *pending consultation on bracketed text, including the Secretariat's presentation of a consolidated textual proposal on the WCLN and recognized sequence databases]*

[(e)*bis*. establish a PABS tracking mechanism in accordance with Section II.B;]

[(e)*ter*. establish and maintain an up-to-date PABS catalogue as a searchable index of PABS materials and sequence information available through the PABS system;]

(g) [establish [rules and] criteria [and procedures] for assessing the nature and capacity of PABS users and [participating manufacturers] [, as appropriate,]] [enter into WHO PABS Contracts] / [sign PABS Contracts on behalf of the WHO] and agree terms and conditions according to the requirements set out in Section II.C of this Annex [and in so doing, aim to maximize the impact on public health and PPR of the commitments entered into by participating manufacturers and other entities];

(h) mobilize and facilitate technical assistance to Parties, [for the purpose of the implementation of this Annex,] upon request, and collaborate to strengthen required capacities [for this purpose], especially in developing countries.

(i) finalize specific Terms of Reference for WCLN laboratories and WHO recognized sequence databases, as necessary;

(j) recognize/designate WCLN laboratories and WHO recognized sequence databases, in accordance with the Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration, current as of entry of force of the WHO Pandemic Agreement, and periodically review the status of the WCLN and WHO recognized databases, including recognitions/designations;

(k) publish the list of laboratories that have been recognized/designated as laboratories of the WCLN and provide that list to the first session of the Conference of the Parties. As necessary, the Secretariat shall submit to subsequent sessions of the Conference of the Parties new designations/recognitions of laboratories, and bring to the attention of the Conference of the Parties the withdrawal or removal of laboratories from the WCLN;

(l) coordinate the WCLN in accordance with the principles set out in Article 3 of the WHO Pandemic Agreement;

(m) provide the list of WHO recognized databases to the first session of the Conference of the Parties. As necessary, the Secretariat shall submit to subsequent sessions of the Conference of the Parties new recognitions of databases, and bring to the attention of the Conference of the Parties the withdrawal or removal of databases;

(n) provide support, capacity-building and training of personnel in laboratories in developing countries to promote their participation in the WCLN;

(o) periodically review, in consultation with the PABS Advisory group, the Terms of Reference for WCLN laboratories and for WHO recognized sequence databases, and may propose amendments to promote the effective implementation of this Annex, as necessary, and report thereon to the Conference of the Parties; and

3bis The Conference of the Parties may consider possible establishment of a WHO PABS Sequence Database, with, as appropriate, support of the WHO Secretariat.

4. Any Party may address any allegation(s) of non-compliance with the terms of the PABS System as follows:

(a) any allegation(s) of non-compliance by an institution or laboratory in a WHO Coordinated Laboratory Network and WHO recognized sequence databases with its terms of reference may be brought to the attention of the WHO Director-General, who will review the circumstances and may discuss the matter with the PABS Advisory Group to determine appropriate action(s) to be taken. Where there has been a material breach by an entity in a WHO Coordinated Laboratory Network and/or WHO recognized sequence databases, the Director-General may consider suspending or revoking the WHO designation/recognition of that entity; and

(b) any allegation(s) of non-compliance or breach of WHO PABS Contracts may be brought to the attention of the WHO Director-General, who will review the circumstances and take the necessary action in consultation with the Advisory Group, and report thereon, as appropriate, to the Conference of the Parties.

4. Any Party may bring any allegation of non-compliance by an institution or laboratory in the WCLN or a WHO-recognized sequence database with the applicable terms and conditions to the attention of the WHO Director-General, who will review the circumstances and may discuss the matter with the PABS Advisory Group to determine appropriate action(s) to be taken, including, where appropriate, the consideration of suspending or revoking the WHO designation/recognition

of that entity. Any allegation of non-compliance with, or breach of, WHO PABS Contracts shall be addressed in accordance with the relevant terms of those contracts, and the Director-General shall report to the Conference of the Parties regarding any such allegations.

B. Review of the PABS System

The Conference of the Parties shall review the PABS System, with a view to ensuring its effective implementation, operations and functioning, no later than five years after entry into force of the WHO Pandemic Agreement and thereafter every five years. In addition, the Conference of the Parties may also conduct extra-ordinary reviews of the PABS System, as it deems appropriate.