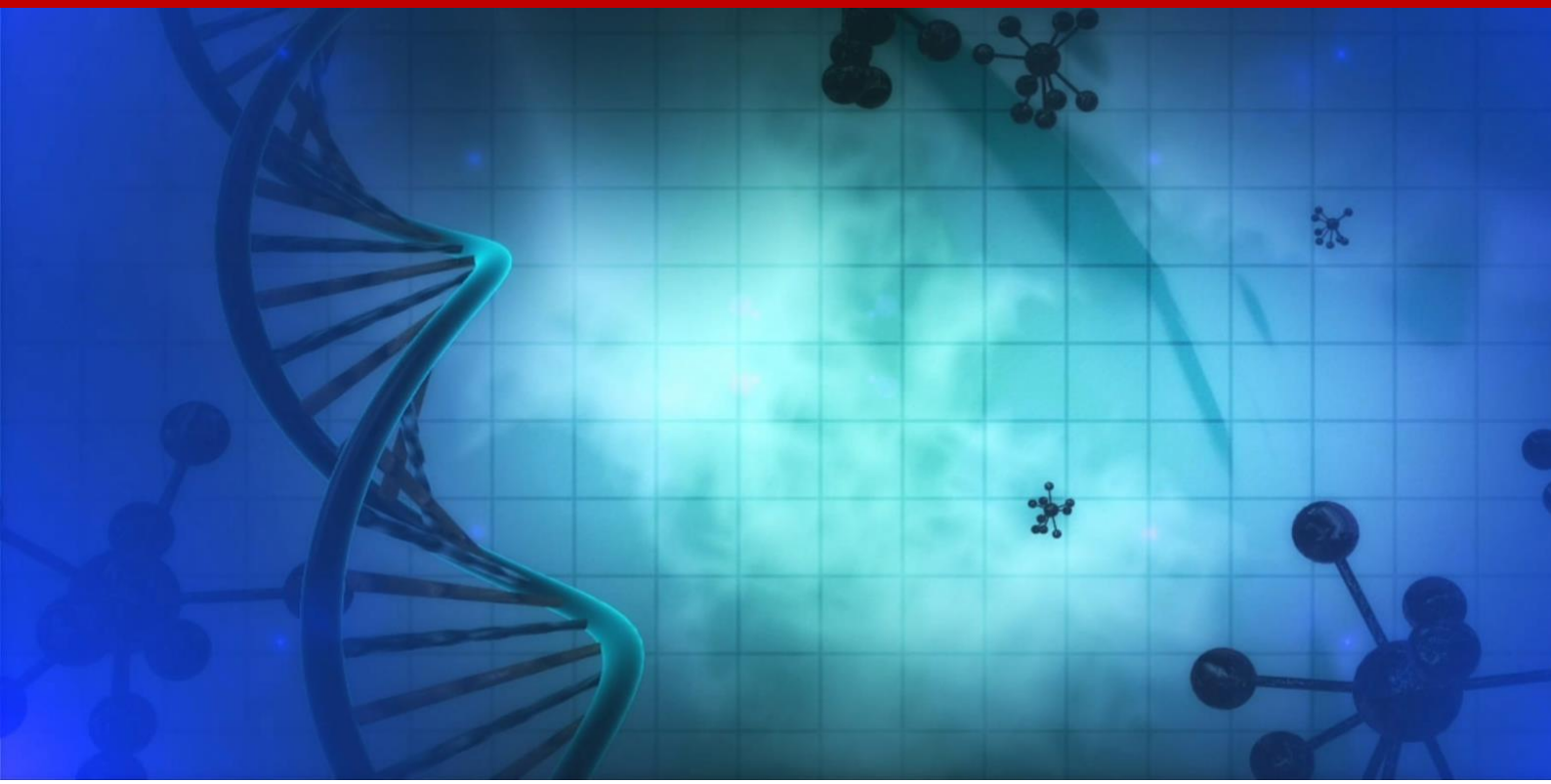
5th IGWG – 7-14th February 2026

Urgent Legal Notice



Draft Annex of Pathogen Access & Benefit Sharing (PABS) of the Highest International Concern

February 2026

GLOBAL HEALTH RESPONSIBILITY
GHR.AGENCY

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Draft Annex of
Pathogen Access & Benefit Sharing (PABS) of the Highest International Concern,
February 2026, The Global Health Responsibility Agency

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Layout: GHRA
Picture cover-page: Pixabay

Urgent Legal Notice - Draft Annex of PABS of the Highest International Concern

In light of the ongoing session of the Intergovernmental Working Group on the WHO Pandemic Agreement (IGWG), convened from 9–14 February 2026, Member States are respectfully urged to refrain from continued line-by-line consolidation on secondary or technical drafting points for as long as foundational legality questions remain unresolved. Divergences on drafting detail cannot be meaningfully narrowed unless and until delegations reach political agreement on the minimum legal validity conditions of the instrument and on the corresponding allocation of competences, safeguards, and accountability mechanisms.

The PABS draft trajectory originates in the *Global Health Security* paradigm. A securitised, emergency-driven, product-centred approach to infectious-disease governance, as already criticized earlier with regard to the adoption of the Pandemic Agreement (PA)—one that normalises routine high-hazard access while externalising foreseeable harm—is institutionally and legally irresponsible.

It must be replaced with the concept of *Global Health Responsibility:* a rational, legally centered concept, reversing the current, securitized, emergency mode of pandemic preparedness, prevention and response (PPPR) with human dignity as its baseline grounded in binding duties of prevention and due diligence, enforceable human-rights adjudication and effective remedy, and accountability for foreseeable harm, including for internationally wrongful acts attributable to WHO, its Member States, and involved non-State actors.

These minimum drafting conditions—reflecting the *Global Health Responsibility* concept —include:

- enforceable biosecurity, biosafety, and dual-use constraints; verified access control, auditability, and traceability;
- an effective liability, remedy, and independent review architecture (including individual standing where harm and rights are directly affected);
- clear, reviewable limits on the exercise of discretion and on the invocation of immunity by the WHO Secretariat and, in particular, the Director-General.

As envisaged, the current draft Pathogen Access and Benefit-Sharing System (PABS) Annex would institutionalise a standing operational architecture for routine access to pathogens with pandemic potential (potential pandemic pathogens, PPP), including enabling digital sequence information and biological samples, for downstream development and manufacturing of pandemic-related medical countermeasures, conditional upon recognition as a "participating" entity pursuant to WHO-administered stipulations and contractual terms. In a highly digitalised, artificial-intelligence-enabled biotechnology environment, such an access infrastructure must be designed with default safeguards and legally enforceable constraint; otherwise, it risks becoming a biosecurity hazard in its own right. Yet the present draft remains largely referential, fragmented, and structurally under-specified on core biosecurity, institutional, and legal issues.

This notice is therefore concerned with biosecurity, institutional, and legality problems of fundamental nature: a system that institutionalises access to the highest-hazard pathogens (and their enabling information) cannot be lawfully constituted or operated—consistently with duties of prevention and due diligence; basic rule-of-law requirements (including legality in light of pre-existing obligations under the Biological Weapons Convention and related non-proliferation regimes, legal certainty, reason-giving, and effective review); and the intergovernmental character of treaty-making grounded in sovereign equality, consent, and good faith—on the basis of general references to "applicable" law without explicitly defined PABS standards, verification, auditability, enforceable constraints, and a functioning liability/remedy architecture in the event of release or misuse.

This approach aligns with the publicly recorded position and delegation mandate of the Slovak Republic for IGWG 5, regarding which calls for a substantial revision of the PABS Annex on grounds of legal certainty, sovereignty, enforceability of safeguards (including biosecurity/dual-use controls), and clear delimitation of WHO/DG powers.

Stakeholder Concern

We note with alarm that the negotiation of the PABS Annex is increasingly conducted as if it were a private-law access-and-market instrument, rather than an intergovernmental instrument intended to protect the public interest and global health. The PABS system will shape access to pathogens and related data and, by design, will determine the conditions under which medical countermeasures can be developed, validated, and placed on global markets. Actors with direct commercial, institutional, or portfolio interests in countermeasure pipelines therefore hold an intrinsic incentive to shape the legal architecture governing that access. Treating such actors as quasi-participants in the lawmaking process is not "inclusiveness"; it is conflict-of interest driven influence.

In September 2025 (IGWG2, 15–19 September), the IGWG agreed—subject to further consultation and confirmation at the opening of IGWG3—to invite "Relevant Stakeholders (Annexes A–E) to observe discussions of the IGWG3, as a pilot, in relation to the drafting and negotiation of the PABS Annex."

This is an extraordinary step taken by the Director-General: observers are not merely heard; they are institutionally positioned inside the live negotiating environment. In November 2025 (IGWG3, 3–7 November), the Bureau reported on this "pilot" decision. The record explicitly notes that "some delegations expressed a preference to maintain the modalities of engagement … as agreed at the first meeting," yet the "pilot" proceeded.

The Secretariat was requested to share the evolving on-screen draft text "with IGWG members and Relevant Stakeholders on a daily basis," effectively granting near-real-time access to the negotiating text and its trajectory. The scale of admitted influence is no longer marginal. The modalities now apply to the IGWG "open to all States and regional economic integration organizations as referred to in Article 32 of the WHO Pandemic Agreement," and they institutionalize extensive participation channels for multiple stakeholder categories, including attendance at IGWG subgroups—"with the exception of drafting groups unless otherwise agreed by the IGWG." As of 4 February 2026, Annex E alone enumerates 136 entities invited to provide inputs, on top of Annex A (20), B (26), C - Framework of Engagement with Non-State Actors (FENSA, 218) and D (44) categories.

This trajectory cannot be reconciled with WHO's own governance standards on engagement and conflicts of interest. The FENSA, adopted by the Health Assembly, requires that engagement "respect the intergovernmental nature of WHO and the decision-making authority of Member States," and "protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards."

FENSA further defines "institutional conflict of interest" as a situation where WHO's "primary interest as reflected in its Constitution may be unduly influenced" by a non-State actor, and stresses that such risk is highest where actors seek influence over governance and decision-making. WHA69.10 explicitly requests the Director-General to implement this framework coherently and consistently. Against that backdrop, it is institutionally indefensible that the Organization's leadership publicly frames the participation of "industry, research and academic institutions, laboratories, and other relevant partners" in PABS-related dialogues as a key contribution to "real-world perspectives" on what the system "needs."

The European Union's direct participation, as contemplated in Article 32 of the Pandemic Agreement, raises a distinct constitutional concern. A regional economic integration organization is structurally oriented toward internal-market and industrial policy objectives; it is not a sovereign public-health authority. EU primary law confirms that public health is a conferred, supportive competence**,** and—save narrow exceptions—harmonisation of Member States' health laws is prohibited**.** Any EU role in these negotiations must therefore be strictly confined to clearly identifiable conferred competences and must not be allowed to operate as a Member-State-equivalent negotiating posture. Granting an economic organization quasi-Party status in global health lawmaking sets a hazardous precedent: it displaces genuine public-health priorities with market-access and industrial considerations and degrades both the intergovernmental character and the substantive quality of the outcome.

The constitutional role of WHO is not to socialize draft legal architecture with structurally interested market actors inside a "pilot" drafting environment; it is to ensure that Member States set up legal rules that are capable to safeguard biosecurity and comply with their various international obligations.

We therefore call for an immediate restoration of intergovernmental governance boundaries: end all "pilot" modalities that embed stakeholders in drafting and negotiation; confine non-State actor engagement to transparent, time-bounded hearings after consolidated drafts exist; require comprehensive, public conflict-of-interest disclosures for any entity consulted as "expert" or "stakeholder"; and reaffirm that the PABS Annex must be negotiated by States—and not the industry.

Absent these corrections, WHO will be seen as abandoning institutional diligence, and the outcome will be epistemically and procedurally contaminated as a private, for-profit Annex —rules that cannot credibly claim to prioritize public health over stakeholder interests.

Biosecurity Concern

WHO's genuine constitutional function is to issue guidance and norms and standards setting, and its own WHO's *Global Guidance Framework for the Responsible Use of the Life Science* that, in the national and global interest, **essential standards must be in place**, with WHO expected to promote best practice by developing **norms and standards**.

While the draft imposes certain terms and conditions on laboratories in WHO-coordinated networks (including implementation of biosecurity/biosafety standards), it does not impose corresponding minimum biosecurity obligations on all downstream recipients and users of PPP-enabling sequence information that are genuinely embedded to the PABS System. Nor does it require baseline cybersecurity controls for WHO-recognised databases (robust authentication, tamper-evident access logging, incident response, and periodic independent audits).

Participating manufacturers are primarily regulated through benefit-sharing obligations and a "public health purposes" clause, rather than through a defined minimum safety governance package. In practice, PPP-enabling information is a high-leverage risk surface: once enabling sequence information is broadly accessible, restricting only physical samples cannot deliver meaningful risk reduction without enforceable governance of access, use, and traceability.

At this point, the reality of countermeasure proliferation and the origins of certain PPP should be recalled, particularly the worst catastrophe in history: the emergence of SARS Cov2.

According to credible official and independent assessments, the most plausible policy scenario that cannot be dismissed for purposes of future risk governance and responsible lawmaking, is that the SARS-CoV-2 virus emerged through a laboratory-associated pathway. A PPPR architecture that expands routine access and circulation of PPP materials/DSI must therefore be assessed against foreseeable laboratory accident and misuse pathways, not only against zoonotic spillover narratives.

Peer-reviewed literature has highlighted an unusual correlation between the SARS-CoV-2 S1/S2 junction (encompassing the furin cleavage site insertion at amino acid 681) and a 19-nucleotide sequence reported to match the reverse complement of a codon-optimised proprietary mRNA sequence appearing in a Moderna-assigned patent sequence listing (US 9,587,003; SEQ ID 11652), with the estimated probability for encountering an identical 19-nt reverse-complement match on the order of 3.21×10^{-11} by chance. Whether such correlations are ultimately explained by coincidence, artefact, or other mechanisms, they underscore a governance reality: industrial countermeasure development workstreams and proprietary sequence portfolios can intersect with (and shape incentives around) pathogen sequence information in ways that are not adequately addressed by open-science rhetoric or by generic "public health purpose" clauses.

The point is not to adjudicate origin claims within the PABS text. The point is that a global access architecture that explicitly includes "modified pathogens" and PPP-enabling sequence information must contain enforceable legal controls that make a recurrence of catastrophic laboratory-associated events materially less likely—and materially more accountable—than the pre-COVID status quo.

Neither the IGWG deliberations nor the draft provides a realistic, legally relevant account of how the medical countermeasure sector actually operates within the PPPR ecosystem. Pandemic product development is continuous and anticipatory. It relies on preparedness roadmaps, platform technologies, variant panels, assay surrogates, challenge systems, and iterative optimisation—designed to maintain regulatory readiness (including emergency-authorisation and rapid-deployment strategies) once a triggering event is framed within the emergency machinery.

This operational model is reinforced by the broader institutional architecture of WHO's PPPR ecosystem, including the WHO R&D Blueprint and partner preparedness programmes (including, inter alia, the Coalition for Epidemic Preparedness Innovations (CEPI)). For legal design purposes, these standing preparedness workstreams matter because they determine, *ex ante*, which PPP materials/DSI are developed, authorised and procured as medical countermeasures.

In practice, the WHO defined "priority pathogen" portfolios and preparedness roadmaps tend to converge on high-consequence pathogens such as: Lassa fever; Crimean-Congo haemorrhagic fever; Ebola virus disease (Zaire ebolavirus and Sudan ebolavirus) and Marburg virus disease; SARS-related coronaviruses (sarbecoviruses) and MERS-related coronaviruses (merbecoviruses); influenza A viruses with pandemic potential (including subtypes such as H5 and H7); Nipah; severe fever with thrombocytopenia syndrome (SFTS); dengue; Zika; mpox; and other high-consequence agents, depending on the programme and update cycle – upon which a global R&D environment is established, particularly through CEPI.

The legal design is therefore of highest relevance. By institutionalising routine access to PPP materials/DSI for countermeasure development and manufacturing, PABS will—unless expressly constrained—operate as a legitimization for laboratory workstreams that are functionally coextensive with DURC/ePPP enhancement pathways. The draft's silence on concrete prohibitions, oversight, and accountability mechanisms poses a biosecurity threat of international concern.

In the light of the plausible laboratory origin of SarsCoV2, as explained above, a legal architecture that predictably increases global exposure to DURC/ePPP pathways is not only irresponsible, but also incompatible with the WHO's constitutional object of "the attainment by all peoples of the highest possible level of health" and its coordinating mandate to protect—not endanger—global health. It also contradicts WHO's *Global Guidance Framework for the Responsible Use of the Life Sciences* (mitigating biorisks and governing dual-use research), which presupposes stringent governance of information hazards, access controls, and accountability for high-hazard research pathways.

Consequently, WHO and the Member States are under an international obligation to draft and implement PABS under *heightened* legal due-diligence standards, because "public health purpose" language is not, by itself, a compliance safeguard against diversion, prohibited assistance, or downstream misuse across jurisdictions.

Liability is an indispensable component of legality in a high-hazard access regime. A PABS architecture that expands routine access to PPP materials and PPP-enabling information must, at treaty/annex level, allocate responsibility and financial security ex ante (including strict-liability triggers, mandatory insurance or equivalent financial guarantees, and a standing compensation mechanism with accessible claims pathways). Absent such provisions, the system externalises foreseeable harm, defeats effective remedy, and undermines the duty of prevention that must govern the design and operation of high-risk biosecurity infrastructures.

This is also reinforced if biosecurity standards are analysed under the Biological Weapons Convention (BWC). Thus, States Parties must *never* permit activities inconsistent with Article I and must not "transfer" or "in any way assist, encourage or induce" any recipient to acquire prohibited agents, toxins, weapons, equipment, or means of delivery (Art. III), and must adopt all necessary domestic prohibitions and prevention measures (Art. IV). In parallel, UNSCR 1540 (2004) (Chapter VII) requires States to refrain from supporting non-State actors seeking biological weapons, to enact and enforce effective laws, and to maintain "domestic controls" over related materials—including accounting, securing and physical protection, plus border and export/trans-shipment controls. These obligations must be treated as controlling "relevant rules of international law" when interpreting and applying any newer instrument (systemic integration), and cannot be impaired by later arrangements on the same subject matter (*pacta sunt servanda*; successive-treaty rules). The PA itself enunciates this non-derogation logic by providing that it "shall not affect the rights and obligations" of Parties under other international agreements and legal instruments.

Particularly at the crossing of anticipated research and enhancement for vaccine modelling, dual use purposes often come under the pretext of ‚open science'. Open-science norms do not justify unconditional access to PPP-enabling information: the UNESCO Recommendation on Open Science (2021) explicitly recognises the need for measures to prevent or mitigate harmful consequences of open science infrastructures. Moreover, any PABS access architecture must be drafted and implemented consistently with Parties' pre-existing obligations (Art. 24 PA, under core non-proliferation and biosecurity instruments—most notably the BWC and UN Security Council Resolution 1540 (2004). A treaty-based access system that expands circulation of PPP materials and PPP-enabling DSI must therefore contain operative, enforceable controls that enable compliance with these obligations; generic references to "applicable law" are not sufficient.

Concretely, PABS therefore needs explicit, operational safeguards at least equivalent to: binding risk-assessment gates; licensing/authorization and purpose limitation backed by end-use/end-user due diligence and refusal duties where misuse risk is non-negligible; chain-of-custody, traceability and auditability for transfers and access; mandatory biorisk management systems with biosafety *and* laboratory biosecurity (including inventory/accountability for "valuable biological materials," security/access control, transport procedures, emergency response, accident/incident investigation, competency-based training, and reporting/whistleblowing mechanisms).

Duplication & Fragmentation Concern

A concerning defect arises under the draft's own "non-duplication" instruction (Section I.A.2(h)) with regard to the Pandemic Influenza Preparedness (PIP) Framework and the Convention on Biological Diversity (CBD) and the Nagoya Protocol that constitutes an access and benefit sharing (ABS) mechanism.

The clause is normatively empty unless operationalised through a binding conflict rule and sequencing clause that prevents parallel ABS channels for the same pathogen category. The PIP Framework is not an exclusive influenza ABS regime: functionally it applies only to those influenza viruses with human pandemic potential that States choose to route through Global Influenza Surveillance and Response System (GISRS) and thereby constitute "PIP biological materials"; influenza samples outside GISRS fall under domestic ABS measures adopted pursuant to the CBD and the Nagoya Protocol, and—absent formal recognition as a "specialized instrument" under Nagoya Protocol Article 4(4)—even influenza within PIP's scope remains covered by CBD/Nagoya as the default regime. This legal reality already enables bilateralism and forum selection that can sideline the WHO or PABS/PA networks; it also demonstrates that "universality" is structurally unattainable because ABS operates across fragmented treaty membership (CBD-only, CBD+Nagoya, and non-parties to PA).

Nagoya Protocol Article 8(b) preserves nationally determined emergency flexibilities and expressly contemplates expeditious ABS measures in "present or imminent emergencies," thereby sustaining parallel bilateral pathways even where WHO schemes exist. Moreover, Nagoya Protocol Article 4(4) conditions any displacement of the Protocol on the existence and applicability of a "specialized international access and benefit-sharing instrument" that is consistent with, and does not run counter to, the objectives of the CBD and the Nagoya Protocol—an inherently limited conflict rule that cannot be presumed to yield comprehensive, universal disapplication for PIP or PABS.

Finally, the WHO PA enters into force only after the deposit of the sixtieth instrument of ratification (Article 33) and will realistically never become a universal legal instrument; PA/PABS therefore cannot cure pre-existing CBD/Nagoya fragmentation and will instead layer additional, non-congruent obligations onto it. In other words, the PA/PABS layer will therefore be non-universal by design, duplicating influenza ABS for some actors while leaving others outside the treaty architecture, and amplifying legal uncertainty rather than resolving it.

The same structural failure mode is visible for sequence data: WHO's own governance analysis records that genetic sequence data (GSD) is not included in the definition of PIP Biological Materials; similar or identical data are commonly accessible via open databases and cannot be reliably tracked or traced, undermining enforceability and legitimate expectations.

These constraints force a binary institutional decision: Member States must either (i) expressly integrate or terminate the PIP Framework at WHA level and consolidate influenza ABS into a single coherent regime with clear legal effect, or (ii) adopt an explicit carve-out excluding influenza within the PIP/GISRS scope from PABS, with a *lex specialis* sequencing rule and an anti-circumvention clause barring Secretariat-driven parallel custody, storage, characterisation, redistribution, or access infrastructures (including any PABS laboratory network with new contractual requirements or BioHub-type arrangements) for that covered influenza category. Proceeding with technical negotiations while preserving parallel, bypassable architectures is not "complementarity"; it is institutional duplication and an irresponsible approach with global implications that needs to be solved until further negotiations take place.

Institutional Concerns

The PA/PABS operates through WHO-administered procedures and provides the DG exceptional powers. Under the IHR (2005), as amended in 2024, the DG determines whether an event constitutes a Public Health Emergency of International Concern (PHEIC) and, where applicable, whether it also constitutes a "pandemic emergency" (Article 12); convenes and composes the Emergency Committee through selection from expert rosters (Articles 48–49); and issues and modifies Temporary Recommendations once a PHEIC/pandemic emergency is determined (Article 15), as well as Standing Recommendations for ongoing risks (Article 16). The PHEIC/PE determination has direct implications

for the PA and activates the PABS System. In the broader PPPR ecosystem, several other regulatory, procurement, and allocation workstreams are also activated through the PHEIC/PE determination.

However, the extensive unilateral decision-making powers of the DG within the PPPR framework are of general legal concern, because they trigger (a) quasi emergency legal effect, (b) sets the operative normative frame through recommendations and guidance (quasi-legislative), and (c) determines or effectively closes dispute avenues through internal final-instance decision structures (quasi-judicial). At the same time, the PA/PABS System has no oversight or control function versus the Director-General. In detail, these powers by the DG are:

Executive function (trigger and activation power): The DG's determination and termination of a PHEIC/pandemic emergency under Article 12 IHR, coupled with the procedural control over Emergency Committee constitution (Articles 48–49), operates as the primary gatekeeper for escalation, acceleration, and de-escalation of the global emergency machinery. Where PABS is designed to operate "downstream" of this machinery—by channelling PPP materials/DSI into accelerated countermeasure development and manufacturing—this executive trigger power becomes co-extensive with the activation of high-hazard access and high-value industrial pathways.

Quasi-legislative function (normative steering by recommendation): Although IHR recommendations are formally "non-binding", Temporary Recommendations (Article 15) and Standing Recommendations (Article 16) produce strong de facto normative effects: they shape national measures, procurement decisions, regulatory de-risking, and private-sector compliance expectations under time pressure. Where the same institutional actor that triggers the emergency also frames the applicable "appropriate measures", the system departs from minimum expectations of norm-setting discipline, transparency, and controllability that are required in high-hazard governance.

Quasi-judicial concentration (internal finality; deficit of independent review): The IHR dispute clause permits States Parties, where negotiations fail, to refer unresolved inter-State disputes to the Director-General for settlement efforts (IHR Art. 56(2)), while the Director-General simultaneously holds the emergency-activation competence under the IHR (including the determination of a PHEIC / pandemic emergency). Separately, WHO's Emergency Use Listing (EUL) contractual architecture provides that disputes may be referred to the Director-General for a decision that is "final and binding" on the parties. The draft PABS Annex amplifies this concentration by assigning alleged non-compliance—and breaches of WHO PABS contracts—to the Director-General, who "will review the circumstances" and "determine" or "take the necessary action," with only consultative involvement of an Advisory Group and reporting to the COP. When emergency framing, normative steering, and compliance/dispute closure converge in the same institutional office, the arrangement conflicts with core rule-of-law requirements recognised as general principles of law: legality and non-arbitrariness; transparency and reason-giving; an impartial and independent decision structure where eligibility, access, and high-value participation are determined; and the availability of effective review and remedy—captured by *nemo judex in causa sua*.

These competences are incompatible with the law of international organisations. A treaty regime that is generically embedded into the WHO Secretariat, i.e. the leadership of the DG, and centralises (i) emergency triggers, (ii) operational access control, (iii) normative "public health purposes" framing, and (iv) final-instance dispute closure—while simultaneously operating through commercializing contracts and immunity-shielded structures—creates an accountability vacuum that is incompatible with minimum requirements of due process and justiciability. In such conditions, the PABS Annex cannot be defended as a conventional intergovernmental instrument under the purview of international law.

Commercialization Concern

PA/PABS converts access to laboratory materials and DSI to manufacturers commitments for the purpose of commercialization and pandemic product manufacturing and proliferation.

Art. 12 PA requires that participating manufacturers provide WHO, pursuant to legally binding contracts signed with WHO, rapid access targeting 20% of real-time production, including a minimum 10% donation and the remainder "reserved at affordable prices," with distribution "on the basis of public health risk and need," and further "additional benefit-sharing provisions" to be set out in those contracts. At the Annex level, alleged non-compliance or breach of WHO PABS contracts is channelled to the Director-General, who "will review the circumstances" and "take the necessary action," with only consultative input and ex post reporting.

The structural consequence is that the DG is mandated as a centralised commercial pipeline administrator: WHO is not merely coordinating intergovernmental cooperation; it becomes a global contractual power for access, eligibility, and allocation decisions.

This centralisation is aggravated by the draft's handling of both in-kind and monetary benefits. Article 12.6 mandates that a minimum threshold of 10% of each participating manufacturer's real-time production be made available to WHO "as a donation," with the remaining portion "reserved at affordable prices," and provides that distribution shall be based on public-health risk and need and that the Global Supply Chain and Logistics (GSCL) Network "may be used to this end"; the GSCL Network is, in turn, to be developed, coordinated and convened by WHO, under COP oversight, with its structure and modalities only to be defined later. In parallel, the Agreement requires the PABS Instrument to address "benefits, both monetary and non-monetary, including annual monetary contributions," yet it does not specify how this financial architecture should be run and who should administer it, define the 10% monetary contribution - from which baseline, etc. Therefore, standard contracts have been again proposed by 80 countries, representing the global South, which were sidelined earlier.

Eventually, it will be the DG who will be positioned to operationalise the product-share obligations and key financial parameters through WHO-administered contracts, while the COP is envisaged to develop modalities ex post; this allocates immediate executive discretion to the Secretariat and leaves concrete financial governance questions unresolved. In particular, the draft does not define—at the level of binding rules—the amount and valuation basis, triggering conditions, payer and beneficiary identification, permissible purposes and ring-fencing, governance and fiduciary controls, independent audit rights, transparency and publication duties, nor the remedies for non-payment or misuse. In effect, both the allocation of the 10% in-kind donation (and the remainder reserved to WHO) and manufacturers' monetary obligations—together with the terms on which they are credited as compliant—are left to discretionary contract design and Secretariat-coordinated allocation mechanisms rather than to predetermined intergovernmental constraints.

In a system where WHO simultaneously (i) determines contractual participation conditions, (ii) allocates pandemic products, and (iii) polices alleged breaches, the absence of a defined financial architecture for "annual monetary contributions" (purpose limitation, ring-fencing, conflict-of-interest controls, independent audit, public reporting, and enforceable remedies) is not a technical gap; it is a rule-of-law deficit that predictably invites disputes over fairness, diversion, equal treatment, and integrity—especially where allocations and payments translate into commercially exploitable advantages.

On constitutional and accountability grounds, positioning the Director-General/Secretariat as a concentrated allocator and enforcer of highly profitable contractual entitlements raises a serious *ultra*

vires / improper-delegation risk vis-à-vis WHO's intergovernmental structure: under the WHO Constitution the Director-General is the chief technical and administrative officer subject to the authority of the Executive Board and the Health Assembly, not an autonomous market operator.

In parallel, immunity cannot be treated as a blanket shield for commercialization of the access to genetic material and sequences : there is no general "commercial activity" exception written into the UN General Convention or the Specialized Agencies Convention; the primary safety-valves are waiver and the obligation to provide appropriate dispute settlement (such as arbitration) for private-law disputes. In the United States, after Jam v. International Finance Corporation (2019), immunity under the International Organizations Immunities Act tracks the Foreign Sovereign Immunities Act and may be denied for commercial activity with a United States connection.

Finally, a Secretariat-centred contracting/allocation monopoly creates foreseeable competition-law exposure at least indirectly: discriminatory access to an essential input channel (potential pandemic pathogen (PPP) materials and digital sequence information (DSI), as well as emergency product placement), de facto exclusivity effects, foreclosure of non-favoured suppliers, and coordinated behaviour risks among "participating manufacturers" under a single contractual template can crystallise into anticompetitive outcomes—while opaque monetary flows and benefit allocations also create predictable audit, procurement-integrity, and tax and anti-money laundering compliance risks for participants and intermediaries.

Call for Action & Mandatory Drafting Requirements

For the avoidance of doubt, the present Bureau text is not merely "unfinished". It is already structured to institutionalise routine access to PPP materials and PPP-enabling digital sequence information while leaving controlling legality questions unresolved. In a high-hazard governance context, delegations cannot lawfully proceed on the premise that missing elements may be deferred to future "guidance", discretionary implementation, or opaque processes.

The Slovak Republic has publicly recorded this core point as a matter of legal mandate for IGWG 5: its delegation is instructed to demand a substantial revision of the PABS Annex, stressing legal certainty, State sovereignty, compliance with basic principles of international law, and the insertion of explicit, legally binding and enforceable safeguards directly into the Annex text (including biosecurity/bioprotection mechanisms addressing dual-use and enhancement-type risks), together with clear delimitation of WHO powers (including the Director-General), checks and balances, independent dispute settlement, and an express liability/compensation regime.

Against that benchmark—and to render any further drafting legally defensible—the following are mandatory minimum drafting requirements (i.e., legal validity conditions) that must be agreed politically and fixed in treaty/annex text before the process can credibly proceed:

(1) Biosecurity and biosafety governance as operative law (not aspirational policy): Insert explicit, legally binding and enforceable norms governing access, handling, storage, cross-border transfer, and downstream use of PPP materials and PPP-enabling digital sequence information, including: verified identity and authorisation; robust traceability; baseline cybersecurity for databases and analytical pipelines; mandatory incident reporting; and concrete dual-use and enhancement controls (including prior authorisation and sanctions). These safeguards must be drafted as operative obligations in the Annex, not deferred to recommendations or left to discretionary implementation.

(2) Clear delimitation and separation of WHO functions; prevention of concentrated discretion: Define with legal precision the powers and limits of the WHO Secretariat and the Director-General within PABS operations; prevent undue concentration of executive, normative, and control functions without

brakes, counterweights, and Party oversight; and separate PABS operational activities (designation, recognition, contracting, access decisions) from WHO's general constitutional functions to avoid institutional conflation, conflicts of role, and unreviewable discretion. Member States must be able to exercise effective, ex ante control over high-hazard operational discretion; the present design does not provide that control.

(3) Institutional overlap, interface rules, and non-universal accession: Adopt conflict-of-laws and interface provisions that make PABS coherent with existing WHO infrastructures (e.g., Pandemic Influenza Preparedness Framework / Global Influenza Surveillance and Response System, BioHub, emergency-use processes) and that govern Party/non-Party interaction. Parallel, already existent WHO infrastructures, networks, and custody/redistribution initiatives risk being undermined and fragmented through a non-universal Pandemic Agreement treaty regime.

(4) Private-law contracting, legality of quasi-commercial operations, and enforceability: Because PABS will operate through WHO designation decisions and private-law contracts with participating manufacturers and other users, the Annex must codify procurement-grade legality: transparent eligibility criteria; equal treatment; reason-giving duties; audit/compliance clauses; and effective review/appeal pathways. Standard-form clauses that exclude rights or remedies or deny standing are not suitable for a standing, high-value allocation regime.

(5) Immunity cannot defeat remedies in a high-hazard access-and-contracting regime: Where WHO (or WHO-designated operators) enters private-law arrangements with manufacturers and other non-State actors, effective enforceability requires express, limited waivers of immunity for PABS-related contractual, compliance, and compensation claims and/or an equivalent binding claims forum with enforceable outcomes. Otherwise, the system produces an immunity-based accountability vacuum incompatible with minimum rule-of-law requirements in high-hazard governance.

(6) Independent dispute settlement and review outside exclusive internal WHO structures: Create an independent dispute settlement and review mechanism for designation, access, contracting, suspension, and incident-response decisions. A system that concentrates operational discretion internally while denying independent review is neither credible nor legally sustainable.

(7) Liability and compensation as a component of legality: Insert an express liability and compensation regime (strict liability, mandatory financial security, and a standing compensation mechanism), with individual standing and effective remedies. PABS cannot be operated as a high-hazard regime without enforceable allocation of responsibility and financial securities analogous to other high-risk sectors.

(8) Integrity, anti-corruption, and limits on stakeholder integration (including safeguards for regional economic integration organisations): Codify binding conflict-of-interest disclosure, recusal, exclusion, and transparency rules. Stakeholders may submit information, but they must not be integrated as de facto co-drafters of operative eligibility, access, or contracting rules. The participation of the European Union as a regional economic integration organisation further requires ring-fencing against industrial-policy capture, including enforceable transparency and review safeguards.

(9) Competition and non-discrimination safeguards against exclusionary allocation: Any alignment logic that pre-empts national or regional access-and-benefit-sharing measures upon PABS entry into operation must be tightly constrained so it cannot—through WHO designation/recognition decisions and Secretariat implementation under the Director-General's authority—function as an exclusionary market-allocation mechanism that confers privileged access to PPP-enabling information and materials on a limited set of actors. Non-discrimination, transparent participation criteria, and reviewability are mandatory, including an express pacta tertiis / non-pre-emption safeguard.

(10) Non-proliferation and counter-terrorism compatibility (Biological Weapons Convention / United Nations Security Council Resolution 1540) as operative treaty law: The Annex must contain explicit compliance clauses and operative controls ensuring that PABS access, transfer, and digital-sequence sharing are structured to enable Parties' full compliance with pre-existing obligations under the Biological Weapons Convention and United Nations Security Council Resolution 1540 (2004). This requires more than a generic "consistent with applicable law" reference. At minimum, the Annex must: preserve and affirm Parties' powers and duties to apply effective controls (including export controls and controls over intangible technology transfer); require verified end-user/end-use conditions and denial/suspension powers where proliferation risks arise; require criminalisation and enforceable sanctions for prohibited conduct by participating entities; and clarify that "public health purposes" and any alignment logic cannot be construed to pre-empt or dilute non-proliferation and counter-terrorism controls.

In addition, and as a condition of institutional legality, the IGWG must rescind the "pilot" modalities embedding Relevant Stakeholders in live negotiations, including modalities applied to entities assessed under the FENS, and restore a strict separation between intergovernmental drafting and non-State actor consultation.

Global Health Responsibility instead of Global Health Security

For the avoidance of doubt, the present PABS design is institutionally and legally indefensible. It operationalises a securitised, emergency-driven and product-centred model that normalises routine high-hazard access and contract-based allocation while externalising foreseeable harm and insulating decisive Secretariat functions from effective intergovernmental control. This trajectory must be replaced—not refined—by Global Health Responsibility: human dignity as the baseline; legally bounded prevention and due diligence; verifiable safeguards, traceability and auditability; independent review and enforceable remedies; and accountability for foreseeable harm.

Absent the mandatory drafting conditions set out above, the PABS Annex would institutionalise a foreseeable risk of catastrophic and irreversible transboundary harm and could not be implemented consistently with its own requirement of conformity with applicable international law and applicable biosafety, biosecurity and export-control standards (Section I.A.2(c)). In such circumstances, adoption and implementation would be incompatible with the WHO Constitution and entail a serious ultra vires risk; the World Health Assembly could not validly adopt the Annex, in its present form, under Article 19 of the WHO Constitution.

Formal notice is hereby given that any attempt to finalise and operationalise PABS in its present configuration—i.e., while institutionalising routine access to PPP materials and PPP-enabling information without operative safeguards, liability, independent review and effective remedy, and without reviewable limits on Secretariat discretion—would foreseeably engage responsibility and contestation under public international law. Where harm materialises, the design and operation of such a high-hazard governance architecture would be susceptible to attribution and legal challenge, including under the International Law Commission Articles on the Responsibility of International Organizations and, where applicable, under the law of State responsibility, for internationally wrongful acts and failures of due diligence. Global Health Responsibility is therefore not an optional policy preference; it is the minimum legally defensible replacement framework for any PABS instrument.