

Exploring the Role of Non-Parties' Participation in the WHO Pandemic Agreement Negotiation from the Perspective of Transparency

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2024 International Conference on WHO Pandemic Treaty Negotiation

National Chengchi University, Taipei

2024/11/20

Outline



Pandemic Agreement

- Background
- Principles
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Transparency


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- Functions
- Provisions

Non-Parties' Participation

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Background: Timeline

2021/12: WHA 2nd Special Session,
Decision SSA2(5)



2022/2/24: INB 1~2024/5/24: INB 9



2023/5: 76th WHA progress report
submitted



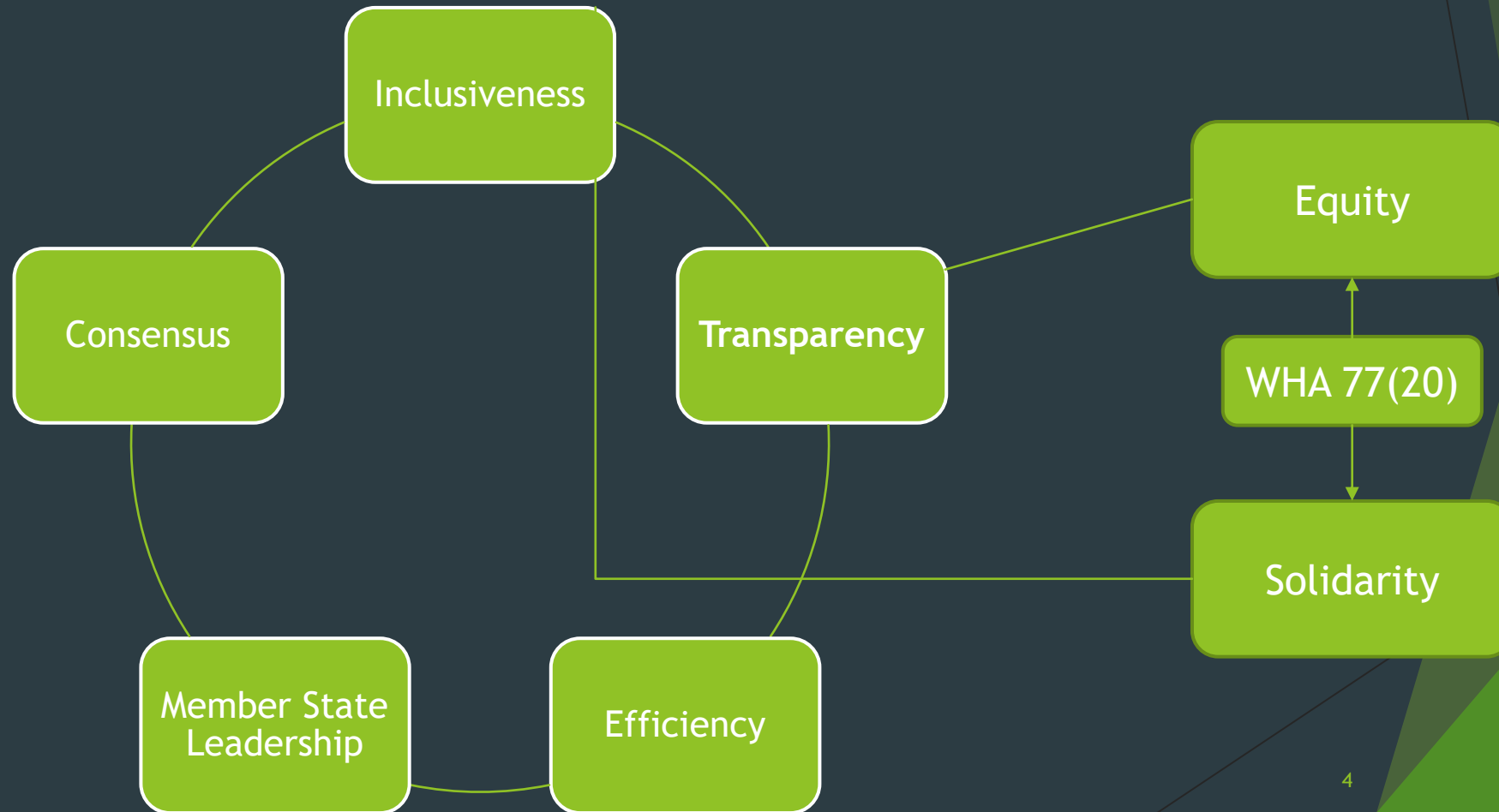
2024/5: 77th WHO final outcome failed



2024/6~:WHA77(20) mandate extended:
INB 10-11-12

Guiding Principles: SSA2(5)

The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response



Who are “Non-Parties”?

- ▶ Recognized by WHA SSA(2)5
 - ▶ Representatives of organizations of the United Nations system
 - ▶ Representatives of organizations of other intergovernmental organizations with which WHO has established effective relations
 - ▶ Observers
 - ▶ Representatives of non-State actors in official relations with WHO
 - ▶ Representatives of other relevant stakeholders as decided by the INB
 - ▶ Experts as decided by the INB
- ▶ Not clearly recognized non-Parties?
 - ▶ Individuals?
 - ▶ Non-WHO Member?

Why Non-Parties' Participation Matters?

Effectiveness: a virus respects no borders

Efficiency & Equity: Health as a public goods & distribution of public goods

Justice: Health as a fundamental human right

Transparency Principle: Concept & Functions

Narrower view: Procedural tools

- Access to information; notifications

Broader view: Substantive norms

- Participation in rule-making
- Engagement in deliberation of norms
- Assurance of accountability
- Effectiveness of implementation

Transparency related provisions: Preamble (I)

- ▶ [1bis. Recognizing that individuals, having duties to other individuals and to the community to which they belong, and that the relevant stakeholders, are under responsibility to strive for the observance of the objective of the present Agreement,]
- ▶ 2. Recognizing that differences in the levels of development of Parties engender different capacities and capabilities in pandemic prevention, preparedness and response and acknowledging that unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger that requires support through international cooperation, including the support of countries with greater capacities and resources, as well as predictable, sustainable and sufficient financial, human, logistical, technological, technical and digital health resources,

Transparency related provisions: Preamble (II)

- ▶ 6. Recognizing that the international spread of disease is a global threat with serious consequences for lives, livelihoods, societies and economies that calls for the widest possible international and regional collaboration, cooperation and solidarity with all people and countries, especially developing countries, and notably least developed countries and small island developing States, in order to ensure an effective, coordinated, appropriate, comprehensive and equitable international response, while reaffirming the principle of the sovereignty of States in addressing public health matters,
- ▶ 8. Recognizing the critical role of whole-of-government and whole-of-society approaches at national and community levels, through broad social participation, and further recognizing the value and diversity of the culture and traditional knowledge of Indigenous Peoples as well as local communities [, including science and evidence-based traditional medicine,] in strengthening pandemic prevention, preparedness, response and health systems recovery,

Transparency related provisions: Preamble (III)

- ▶ 9. Recognizing the importance of ensuring political commitment, resourcing and action through multisectoral collaborations for pandemic prevention, preparedness, response and health systems recovery,
- ▶ 10. Reaffirming the importance of multisectoral collaboration at national, regional and international levels to safeguard human health, ...
- ▶ 12. Reiterating the need to work towards building and strengthening resilient health systems, with adequate numbers of skilled, trained and protected health and care workers to respond to pandemics, to advance the achievement of universal health coverage, particularly through a primary health care approach [and equitable access to health products]; and to adopt an equitable approach to mitigate the risk that pandemics exacerbate existing inequities in access to health care services,
- ▶ 13. Recognizing the importance of building trust and ensuring the timely sharing of information to prevent misinformation, disinformation and stigmatization,

Transparency related provisions: Preamble (IV)

- ▶ 15. [Recalling 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 timely, safe, transparent, accountable and rapid sharing of materials and information on pathogens with pandemic potential for public health purposes, and, on an equal footing, the timely, fair and equitable sharing of benefits [arising therefrom (DEL)], taking into account relevant national, domestic, and international laws, (DEL / RETAIN)] NOTE: Upon finalization of Art 12.1
- ▶ 16. Stressing that adequate pandemic prevention, preparedness, response and health systems recovery is part of a continuum to combat other health emergencies and achieve greater health equity through resolute action on the social, environmental, cultural, political and economic determinants of health,,

Transparency related provisions:

Chapter I: Introduction

- ▶ Art. 1 (Use of terms) : (b) One health approach: ... in an equitable manner; (c) PABS material and information; (g) people in vulnerable situations; Foot note: to be inserted with the first mention of the term “relevant stakeholders”. The term “relevant stakeholders” is understood in the context of article 2(b) of the WHO Constitution, as well as the WHO Framework of Engagement with Non-State Actors. (new j) transfer of technology; (new k) the sharing of know-how
- ▶ Art. 2 (Objective): guided by equity and the principles ...
- ▶ Art. 3 (Principles): sovereignty, human rights, freedoms of all persons
 - ▶ 4. Equity as a goal [, principle] and outcome of pandemic prevention, preparedness and response, striving for the absence of unfair, avoidable or remediable differences among and between individuals, communities and countries
 - ▶ 5. Solidarity with all people and countries in the context of health emergencies, inclusivity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics, recognizing different levels of capacities and capabilities

Transparency related provisions:

Chapter II: The world together equitably: achieving equity in, for and through pandemic prevention, preparedness and response

- ▶ Art. 4 (Pandemic prevention and surveillance) : international collaboration
- ▶ Art. 5 (One health approach): interconnection b/t ... that is coherent, integrated, coordinated and collaborative among all relevant organizations, sectors and actors ...
- ▶ Art. 6 (Preparedness, readiness and health system resilience): the need for equity; equitable access to clinical care; transparency, cost-effective procurement practices; maintain national health information systems; international data standards for interoperability
- ▶ Art. 7 (Health and care workforce): eliminating all forms of inequalities and discriminations and other disparities, such as unequal remuneration and barriers faced by women; in coordination with other relevant international and regional organization
- ▶ Art. 9 (Research and Development): rapid sharing of information and result; equitable access to evidence synthesis; transparent and public sharing of research result; rapid and transparent publication of clinical results; timely and equitable global access to pandemic-related health products
- ▶ Art. 10 (Sustainable and geographically diversified local production): equitable geographical distribution; sustainable, timely and equitable access to products; public-private partnerships
- ▶ Art. 11 (Transfer of technology and know-how) : voluntary and mutually agreed terms; global technology transfer hubs coordinated by ... other mechanism or networks;

Transparency related provisions:

Chapter II: The world together equitably: achieving equity in, for and through pandemic prevention, preparedness and response

- ▶ Art. 12 (Pathogen access and benefit-sharing system): sovereign right of States; collective action to mitigate public health risks; sharing of materials and sequence information ; fair and equitable sharing of benefits; a multilateral system for safe, transparent, and accountable access and benefit sharing for pathogens; robust [inclusive], transparent, and evidence-based governance, review, and accountability ;
- ▶ Art. 13 (Supply chain and logistics): equitable access; in partnership with relevant stakeholders; equitable allocation based on public health risk and need; accountability, transparency, and inclusiveness in the governance of the GSCL Network; promotion of transparency across the value chain
- ▶ Art. 13 bis (Procurement and distribution): publish relevant terms of its purchase agreements with manufacturers; exclude confidential provisions;
- ▶ Art. 14 (Regulatory systems strengthening): technical assistance; cooperation with other int'l org.
- ▶ Art. 17 (Whole-of-government and whole-of-society approach): effective and meaningful engagement of communities, stakeholders through social participation in planning, decision-making, implementation, monitoring and evaluation of policies ...
- ▶ Art. 18 (Communication and public awareness): risk communication, effective community-level engagement
- ▶ Art. 19 (International cooperation and support for implementation): promotion of transfer of technology and know-how and sharing of expertise and financial assistance ...
- ▶ Art. 20 (Sustainable financing): predictable financing in an inclusive and transparent manner; transparent financial reprogramming plans; inclusive and accountable governance and operating models; improved efficiency and coherence at scale, enhance transparency and be responsive to the needs ...

Transparency related provisions:

Chapter III: Institutional arrangement and final provisions

- ▶ Art. 21 (Conference of the Parties): adopted by consensus; subsidiary bodies
- ▶ Art. 22 (Right to vote)
- ▶ Art. 23 (Report to the COP): reporting and exchange of information subjects to confidentiality and privacy; report be made publically available online
- ▶ Art. 24 (Secretariat)
- ▶ Art. 25 (Settlement of disputes)
- ▶ Art. 26 (Relationship with other international agreements and instruments)
- ▶ Art. 27 (Reservations)
- ▶ Art. 28 (Declarations and statements)
- ▶ Art. 29 (Amendments)
- ▶ Art. 30 (Annexes)
- ▶ Art. 31 (Protocols)
- ▶ Art. 32 (Withdrawal)
- ▶ Art. 33 (Signature)
- ▶ Art. 34 (Ratification, acceptance, approval, formal confirmation or accession)
- ▶ Art. 35 (Entry into force)
- ▶ Art. 36 (Depositary)
- ▶ Art. 37 (Authentic texts)

Assessment & Suggestions: Participation in rule-making & implementation

- ▶ Establishment of subsidiary bodies (art. 21.7) should insure the inclusiveness of relevant stakeholders or non-state actors.
- ▶ Add art. 21.2 bis: The Conference of the Parties shall [, at its first meeting,] consider establishing an inclusive, transparent and effective [voluntary] [monitoring [and evaluation DEL] DEL] [assessment and support] system for the implementation of the WHO Pandemic Agreement [, complementing existing mechanisms, DEL] with the aim of promoting and supporting learning among parties, best practices, [accountability DEL] and coordination of resources, in a manner that is consistent with the IHR.]
- ▶ Derived from previous draft: (e) invite ... the services and cooperation of, and information provided by, ... other international and regional intergovernmental organizations and nongovernmental organizations and **bodies**; (f) promote, including by establishing appropriate processes, cooperation and coordination with and among relevant legal instruments and frameworks and relevant global, regional, sub-regional and sectoral **bodies**...

Assessment & Suggestions: Deliberation & review of norms

- ▶ Previous draft Art. 8 regarding preparedness monitoring and function reviews is deleted. No more global peer review mechanism to assess the gaps. Move to Art. 6 and up for the Party to decide.
- ▶ Delete Art. 16 and move to Art. 19 regarding international cooperation. Should clarify whether “relevant organizations” includes NGOs, stakeholders; and should not subject to the request of the Party.
- ▶ No more explicitly mention an “Implementation and Compliance Committee”, “a panel of experts to provide scientific advice” and a “WHO PABS System Expert Advisory Group” to serve deliberation or review function.

Assessment & Suggestions: Assurance of accountability

- ▶ No definition prescribed in Art. 3 regarding the general principles such as “equity”, “inclusiveness” and “accountability” which had been defined in previous draft.
- ▶ Original definition of accountability is limited to States, whereas the regional economic organization is eligible to be a Party to the Agreement, the term should be used as the Party instead of States being subject to accountability
- ▶ The draft should consider requiring “international organization” such as WHO or its subsidiary bodies to subject to the principle of accountability.
- ▶ The scope of accountability should cover the decision be made on the based of scientific evidence.

Assessment & Suggestions: Access to information

- ▶ Lack of definition of “transparency” principle in Art. 3.
- ▶ Art. 14 require Party making publically available and keep updated information on regulatory process and dossiers. Art. 13 bis require Party provide relevant information when sharing health products. Art. 18 (communication) and Art. 20 (sustainable financing) provides relevant information sharing obligations.
- ▶ The scope of information to be shared should be extended to international organizations, subsidiary bodies or other intermediate bodies holding pandemic-related information.
- ▶ The beneficiary of those information seems to be Parties to the Agreement; and does not extend to individuals or NGOs to make a claim for access to such information.

Selected issues (I)

- ▶ Art 6 requires Parties monitoring health system functions and infrastructure; It is unclear whether current operational mechanism or practices such as IHR Monitoring and Evaluation Framework & Joint External Evaluation will be maintained as usual to welcome non-members' voluntary participation?
- ▶ In zero draft, art. 9.4 (R&D) provides “each Party should encourage non-State actors to participate in and accelerate innovative R&D for addressing novel pathogens ...”; Is there any particular reason to remove this paragraph from the Bureau's text? Or is art 9.2(c) encouraging the participation of “relevant stakeholders” intended to cover “non-State actors”?
- ▶ Art. 10 encourages to arrange long-term contract with manufacturers. During COVID-19, exclusive licenses agreements between manufacturers and agents/distributors hinder the effective and prompt access to vaccines due to the status of monopoly or oligopoly in certain regions. It is suggested that a non-exclusive arrangement should not be limited to manufacturers in different countries but extend to cover the relation between manufacturers and their agents or distributors in different regions.

Selected issues (II)

- ▶ Art. 12 (PABS), it is unclear whether the recipients of PBAS Material are limited to manufacturers or biotechnology firms of the Parties? What if those from non-Parties willing to participate the PABS system, will they be able to receive PABS Material?
- ▶ Art. 19: The Parties shall cooperate to assist in building implementation capacities for developing Parties subject to “mutually agreed” terms and “within the means and resources at their disposal”; However, if a Party lacks the necessary capacity, the Parties shall be facilitated by relevant “organizations”. It is not clear the exact meaning or scope of “organizations”. Does it refer to “other NGOs” or include non-Parties?

Thank you for listening!

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