NEGOTIATIONS FOR A WHO INTERNATIONAL INSTRUMENT FOR PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

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PARALLEL PROCESSES

Intergovernmental negotiating body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response

Working Group on Amendments to the International Health Regulations 2005 (WGIHR)

UN High Level Declaration on Pandemic Preparedness, Prevention and Response September 2023

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BACKGROUND

- Recognition of delayed action, failed coordination and gross inequity in providing health technologies during Covid-19

- Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) reviewed recommendations of:
  - Independent Panel for Pandemic Preparedness and Response
  - Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 Response
  - Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme

- March 2021, WHO DG and 15 Heads of State call for international pandemic treaty

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BACKGROUND

- World Health Assembly in December 2021 agrees to launch negotiations for a pandemic instrument, SSA/2/5

- January 2022, The United States proposes amendments to the International Health Regulations (2005)

- World Health Assembly in May 2022 agrees to establish process to arrive at a package of targeted amendments for consideration by the WHA 2024, in accordance with Article 55 of the IHR (2005), WHA75(9)

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INTERGOVERNMENTAL NEGOTIATING BODY

- Bureau members

  African Region – Ms Precious Matsoso (South Africa)
  Region of the Americas – Ambassador Tovar da Silva Nunes (Brazil)
  European Region – Mr Roland Driece (Kingdom of the Netherlands)
  Eastern Mediterranean Region – Mr Ahmed Salama Soliman (Egypt)
  Western Pacific Region – Mr Kazuho Taguchi (Japan)

- Resumed INB5 12-16 June 2023

- Plenary (open) and Drafting Group (closed)

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INTERGOVERNMENTAL NEGOTIATING BODY

- Drafting Group discussion focused on Bureau "conceptual zero draft" of the instrument WHO CA+ (A/INB/5/6) but Members can continue to refer to the compilation text (A/INB4/3 1 February 2023)
  - Chapter II: Articles 9 (Research and development), 10 (Liability risk management), 11 (Co-development and transfer of technology and know-how), 12 (Access and benefit-sharing), 13 (Supply chain and logistics), and 14 (Regulatory strengthening).

- Drafting Group informals: "trial" phase

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UPCOMING MEETINGS INB AND WGIHR

- Informals prior to INB6 17–21 July 2023
  - Article 9 - Research and development- 22 June; Article 12 - Access and benefit-sharing - 26 June; Article 13 - Supply chain and logistics - 30 June; 3 and 5 July
- INB6 plenary: remaining articles of Chapter II, then Chapters III and I
- Joint plenary session of the INB and the Working Group on Amendments to the International Health Regulations (WGIHR), 21 July and 24 July 2023
- WGIHR informals 29 and 30 June, WGIHR4 24 to 28 July 2023

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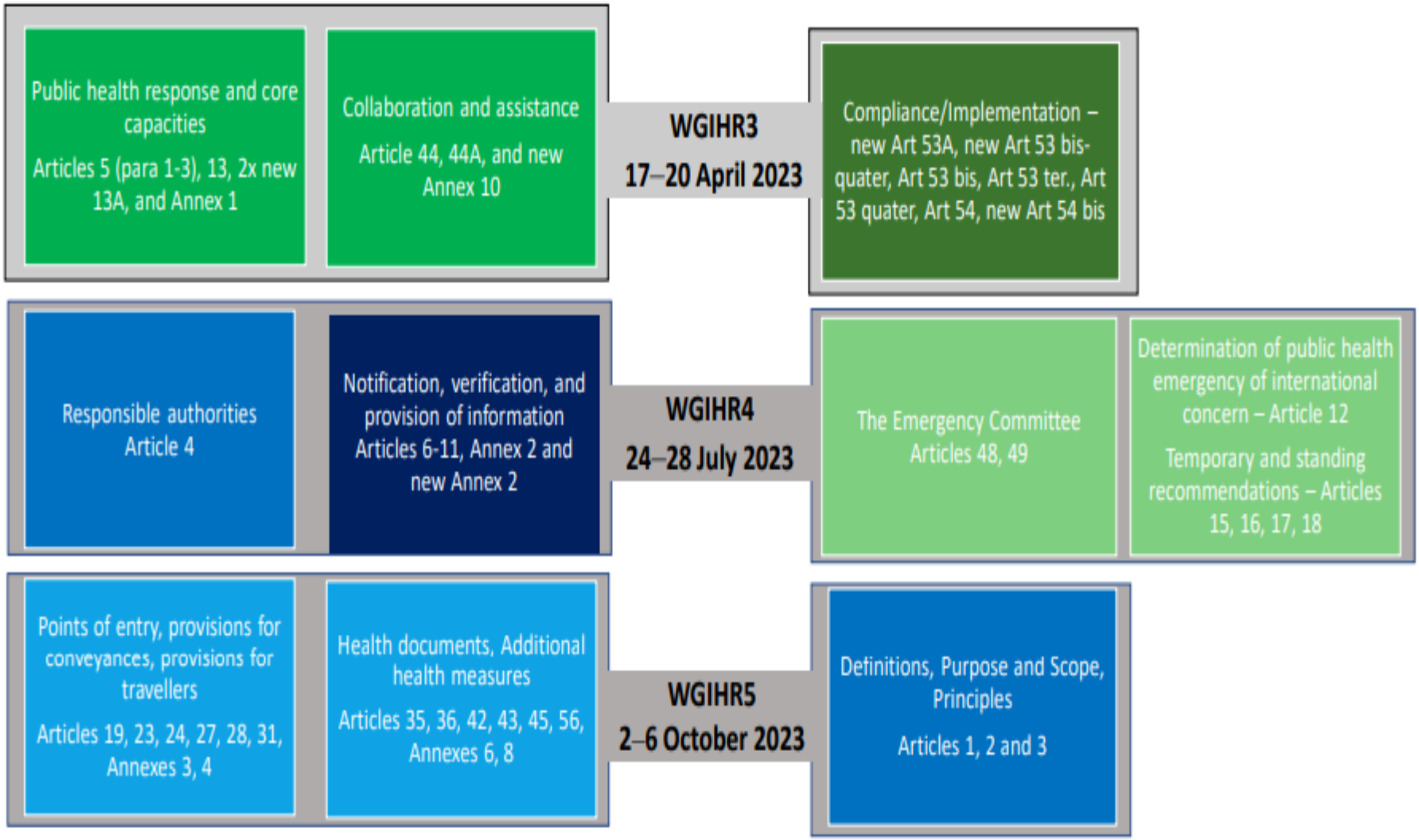
WGIHR: negotiation

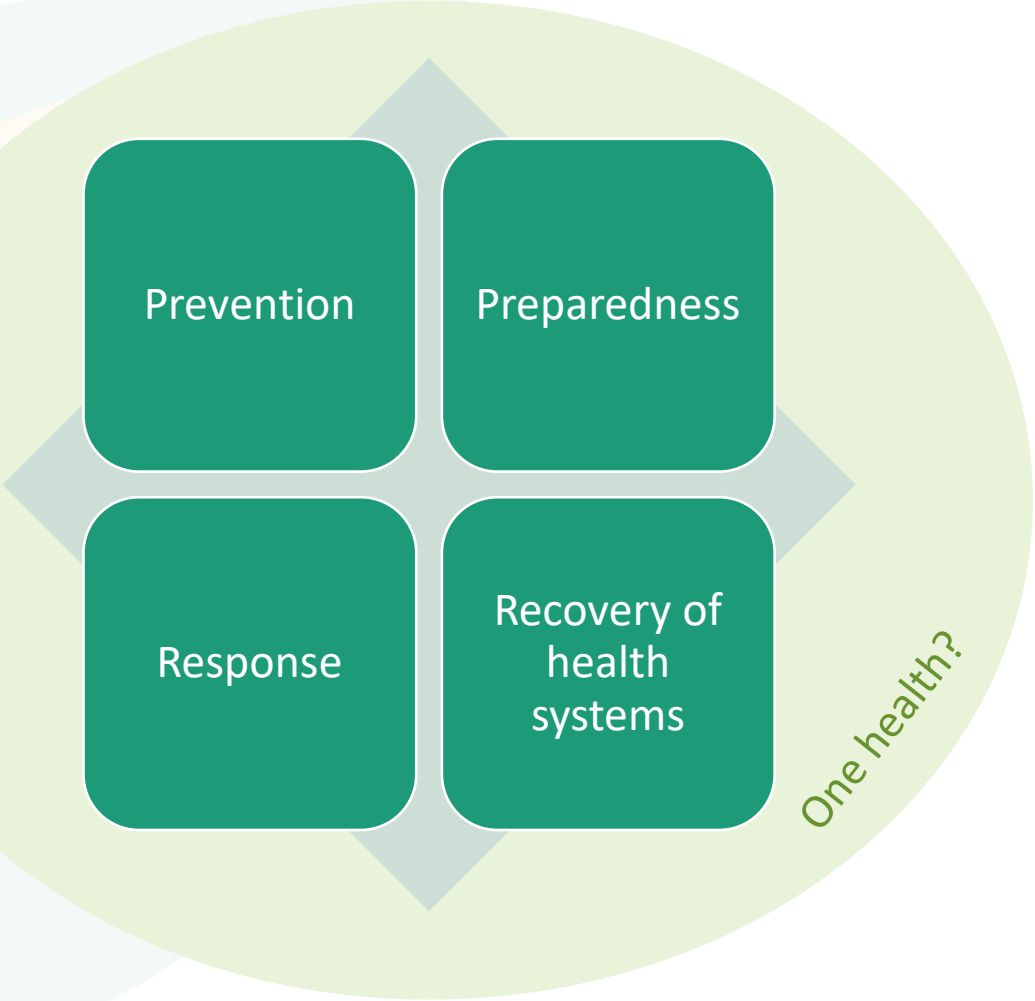


Instrument (and legal basis)	Process for establishment / entry into force	Material scope	Legally binding or non-binding character	Amendments	Example(s)
Conventions or agreements (Articles 19, 20)	Adopted by the Health Assembly through a two-thirds vote (though adoption by consensus is possible); Come into force for each Member State when accepted by it in accordance with its constitutional processes	Any matter within the competence of the Organization	Legally binding on States Parties	Formal amendment process	WHO Framework Convention on Tobacco Control
Regulations (Articles 21, 22)	Adopted by the Health Assembly through a simple majority (though adoption by consensus is possible); Come into force for all Member States after due notice has been given of their adoption by the Health Assembly, except for such Member States as may notify the Director-General of rejection or reservations within the period stated in the notice.	(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.	Legally binding on States Parties	Formal amendment process	International Health Regulations (2005) WHO Nomenclature Regulations
Recommendations (Article 23)	Adopted by the Health Assembly through a simple majority (but well-established practice is adoption by consensus)	Any matter within the competence of the Organization	Not legally binding on Member States, however political effects of expected implementation and compliance; binding on the WHO Secretariat	Adoption of a new resolution or decision	Pandemic Influenza Preparedness (PIP) Framework (resolution WHA64.5) Global Code of Practice on the International Recruitment of Health Personnel (resolution WHA63.16) International Code of Marketing of Breast-milk Substitutes (resolution WHA34.22)

SCOPE OF THE PANDEMIC INSTRUMENT

Pathogens causing outbreaks and pandemics

Include:
- of zoonotic origin?
- resistant to antimicrobial agents?



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INB BUREAU TEXT

- Selective in suggesting non-binding elements vs legal obligations

- Draft fails to present an adequate balance of legal rights and obligations of countries at different levels of development

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PRINCIPLES

- Equity
- Common but differentiated responsibilities and respective capabilities
- Respect for human rights
- International solidarity
- PPPR as a global public good
- Transparency

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EQUITABLE ACCESS TO MEDICAL PRODUCTS

- Binding Rules

  vs

  Voluntary Cooperation

- Investment - financing

- Governance – institutional arrangements

Multilateral system for access to pathogen samples-data and sharing of benefits that arise

INB/5/6 Art 9, Art 11, Art 13, art 12?

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ACCESS TO PATHOGEN SAMPLES/GENETIC SEQUENCE DATA / INFORMATION AND EQUITABLE SHARING OF BENEFITS

Country define terms and conditions for access. Bilateral contract: require prior informed consent, set mutually agreed terms for sharing benefits that arise from utilization

Regulation under Convention of Biological Diversity / Nagoya Protocol

Or establish a Multilateral system for access and sharing with benefits?

CBD/Nagoya rules not applicable (specialised ABS instrument)

Art 12, option B

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WEAK EU / US PROPOSALS FOR RAPID ACCESS TO PATHOGEN SAMPLES/GENETIC SEQUENCE DATA / INFORMATION

- Propose de-linking multilateral access and multilateral benefit sharing
- Benefit sharing proposed as voluntary measures to promote access to medical products
- US/EU propose to make **best efforts** to request medical product manufacturers to **reserve** part of their production to LICs/MICs (pharma has proposed to voluntarily agreed to do so) when the product is in scarce supply. No legally binding commitment.
- EU support affordability by **efforts to promote** tiered pricing. Propose a Countermeasures Expert Committee

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ELEMENTS OF POTENTIAL MULTILATERAL PABS SYSTEM

- Unified system: access and benefit sharing.
- Potential trade-off for facilitated access should be concrete benefits that are **additional** to other provisions on equitable access to medical products that are part of effective PPPR
- Parties through authorized laboratories provide rapid/timely access to samples/GSD through designated database(s) as part of an established WHO coordinated laboratory network
- Terms and conditions defined in standard agreements, i.e. SMTAs entered with the WHO
- SMTA2 for onward transfer and use outside the WHO Coordinated laboratory network

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ELEMENTS OF POTENTIAL MULTILATERAL PABS SYSTEM

- Production of any pandemic related products implies utilization of pathogens with pandemic potential

- Recipients of materials shall not claim IPRs on the pathogens with pandemic potential or their genomic sequences or their components or diital sequence information

- Benefit sharing:
  - Monetary (annual contributions/access fee). X% of annual revenue of product
  - Real time access of minimum 20% of the production of pandemic-related products to support their equitable distribution through the WHO Allocation Mechanism
  - Collaborate with manufacturers from developing countries and WHO initiative to transfer technology and know-how and strengthen capacities for the timely scale up of pandemic-related products
  - Sharing of R&D results
  - Collaboration and contribution in scientific R&D, education and training

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South Centre related publications

- SC Statement to Resumed INB5, 12 June 2023
- Opening Statement of the South Centre to the Seventy-Sixth World Health Assembly, 22 May 2023
- Summary of the intervention by Carlos Correa, Executive Director of the South Centre, at the UN General Assembly – Pandemic Prevention, Preparedness and Response Multi-Stakeholder Hearing, New York, May 9th, 2023
- Statement to WHO INB4, 27 February 2023
- Statement on extension of TRIPS waiver for COVID-19 diagnostics & therapeutics, 9 January 2023
- Statement on WHO proposed instrument on pandemics, 9 December 2022
- Can WHO Negotiations Lead to a Just Framework for Prevention, Preparedeness and Response to Pandemics as Global Public Goods? Research Paper 147, 28 February 2022?, Munoz V
- Mainstreaming Equity in the International Health Regulations, Policy Brief 108, March 2022, Syam N
- A New Treaty on Pandemics: Some Key Issues from a Global South Perspective, Working Paper, November 2021, Bustamante et al
- A New WHO International Treaty on Pandemic Preparedness and Response: Can It Address the Needs of the Global South? Policy Brief 93, July 2021, Nyam N, Velasquez G

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Thank you!

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