Annex 1: Summary of Overall Comments and Recommendations

The INB zero draft presents the first step towards a legally binding accord that would govern PPR among WHO member states. It includes some positive provisions and principles, setting the process in the right direction in general. However, several outstanding issues need to be addressed as the negotiation progresses.

On definitions (Article 1, 18)

- The definition of "pandemic" should exclude subjective aspects that could cause delay in qualification and should not lead to limiting the use of mechanisms that need to be undertaken as a matter of routine.
- The division of "inter-pandemic" and "pandemic" needs to be revisited as it may not be entirely appropriate to support measures that need to be undertaken at all times for PPR.
- There should be greater clarity under both Article 1 and Article 15.2 on the procedures of declaration of both the beginning and the end of a pandemic, especially to avoid arbitrary claims by stakeholders.
- The definition of "pandemic-related products" should include components, materials, parts, cell-and-gene therapies, antibiotics, data and know-how needed for production; it should also cover existing products tackling potential new outbreaks of existing pathogens and new variants.
- Whether AMR is indeed a "pandemic" as defined by the draft should be clarified.

On scope (Article 5)

- Whether the accord addresses only future pandemics or present inequities also is unclear from the zero draft. For ongoing outbreaks/known pathogens, there are existing challenges related to equitable access to technologies and medical tools needed to tackle them. The zero draft does not clarify how these challenges would be addressed by the accord.

On transparency (Article 4.6 and several other provisions, see Annex 2 for more details)

- The guiding principle of transparency should be revised to include requirements from the WHA 72.8 transparency resolution and beyond
- The transparency-related obligations included in the zero draft need to be strengthened as outlined in detail in Annex 2.
- There are a number of transparency provisions that are entirely missing from the zero draft and need to be added. These include provisions to address:

  Confidentiality and trade secrets:

  - A positive obligation for states to review national laws and practices concerning trade secrets and confidentiality should be introduced to establish a stronger public interest doctrine and expand exceptions for the purpose of protecting public health.
  - Confidentiality clauses should be restricted, and prohibited during pandemics, especially on pricing, cost, manufacturing capacity and supply schedules, IP and technology licensing terms, in public procurement and supply contracts, IP licensing and technology transfer agreements.

Freedom of information/Right to information:

  - A positive obligation for states to review national laws and practices should be introduced to establish stronger requirements for governments and other public entities to actively disclose relevant information including on procurement, supply, distribution, cost and pricing, in a public health emergency, and to improve procedures for disclosure of information requested by the public.
- Transparency requirements for all R&D funders and funding recipients, particularly those receiving public funding, including private and public foundations, product development partnerships and other philanthropic organisations.
- To address issues identified above and ensure greater consistency, transparency should be established as a separate Chapter or Article altogether.

On principle of common but differentiated responsibilities and capabilities (CBDR) to address inequity (Article 4.8)

- While the zero draft includes the important guiding principle of CBDR to address inequity among states, this principle needs to be more explicitly reflected. Substantive provisions under Chapter III, V, VI should include explicit language to differentiate responsibilities between developed countries and developing countries on issues of transfer of technology, removing IP barriers, increasing R&D capacities, increasing local and regional manufacturing capacities, supporting national action plans on AMR and financing for PPR.

On global supply, strategic stockpiling and equitable allocation (Article 6)

- There should be measures to reject hoarding. Binding commitments to reserve a portion of domestic supplies for global stockpiles, akin to the SVES model, in emergency circumstances are one potential consideration.
- Article 6.3 (a) needs to be revised with the following considerations:
  - Strategic stockpiling at the global level needs to address present access challenges to existing products that tackle possible new outbreaks and new variants
  - It should specify that states shall coordinate with each other and with the WHO Network to plan stockpiling at the national and regional levels, to ensure proportionality in national and regional stockpiling and to prioritise sufficient global stockpiles dedicated to supplying resource-limited settings, countries most affected, vulnerable and at-risk people and communities, and humanitarian contexts
  - Clearer synergy is needed between global strategic stockpiling under this provision and increasing supply options addressed under Article 9 and 10
  - Developing countries, particularly those most affected, should be included in the design of any mechanism to manage strategic stockpiles at the global level
- Article 6.3(b) should be revised to incorporate transparency requirements beyond the context of the WHO Network, and to encompass an expanded scope of information.
- Article 6.3(c) needs to specify what is being allocated, who is setting priorities, and how the needs of vulnerable people and communities, particularly those living in humanitarian contexts, will be accommodated within the “equitable allocation mechanism”.

On access to technologies, transfer of technology and know-how (Article 7)

Article 7 should be improved by:

- Introducing new provisions to specify transparency requirements for IP information, including but not limited to patent status, landscaping analysis, non-patent IP information, IP licensing and technology transfer agreements.
- Introducing a positive obligation for states to review and revise national laws and regulations to fully incorporate public health flexibilities.
- Introducing a new provision to specify that states should refrain from introducing TRIPS-plus provisions and requirements through unilateral actions, or bilateral and regional trade and investment agreements.
- Introducing measures to ensure maintenance of manufacturing and supplying capacity, once established, for both existing medicines and future pipeline products.
- Removing the division of "inter-pandemic" and "pandemic" periods in Article 7.3 and 7.4, particularly for measures that need to be available for use at all times.
- Removing the exhaustive list of flexibilities allowed under Article 7.4 to keep an open-ended construction enabling states to use all flexibilities they need for protecting access to medical products.
- Clarifying the strategic connection between Article 7 and Article 9 so that technology transfer requirements under public funding agreements, as articulated under Article 9, can be supportive of, and facilitate access to, technology under Article 7.

On increasing R&D capacity (Article 9)

- There should be a new provision that strengthens WHO's role in coordinating the priority setting of R&D based on public health needs, providing guidance for funding priorities accordingly, and supporting international clinical trials. Developing countries and regional bodies should be supported to play a leading role in this process.
- Articles 9.2 and 9.3 should go beyond requiring states to "encourage" and "endeavour" to include "appropriate" access conditions to publicly funded R&D. Instead, states should require a set of minimum binding and publicly available access conditions to be adopted by all funders. This should include, in particular:
    - Affordable and transparent pricing requirement of end products (a cost of goods plus reasonable margin or no profit-no loss during a public health emergency can serve as models)
    - Non-exclusive licensing/technology transfer requirement to ensure diversity of manufacturing and supplying
    - Funders' retention of rights linked to the research funded, including those that would mandate them to license technology, IP and know-how if the manufacturer's supply doesn't meet demand in a timely manner or is not reasonably priced (taking reference to the so called "march-in rights")
    - Transparency requirements, including publication of full R&D costs, clinical trial costs, clinical trial protocols and disaggregated preclinical and clinical trial results data, subsequent IP licensing, sub-licensing and technology transfer agreements, prices and costs of production, and information on supply capacities and delivery schedules.

Critically, the full contractual terms of the R&D funding agreement itself should be published in their entirety.
    - Access plans and transparent indicators which encompass registering and making available the drugs, vaccines or diagnostics, particularly where the clinical trials have been hosted
    - Timely access to comparator drugs, tests, assays or vaccines needed for comparison studies, regulatory approvals and/or R&D
- On transparency:
    - Transparency should be the norm when public funds are involved and not limited to "the extent of the public funding received". This should be mandatory and should be applied at all times, regardless of the source of funding.
    - Confidentiality provisions should not be included in key agreements that govern R&D and access to health technologies, particularly when public funds are involved and when the technologies are for tackling pandemics. States should prohibit the inclusion of confidentiality provisions in public supply and procurement contracts, IP licensing and technology transfer agreements
    - A sub-section to mandate disclosure of clinical trial costs should be added to Article 9.10.
    - Governance documents of global health institutions and other relevant bodies involved in PPR, including R&D, should be published in full
- The obligations in Article 9 towards access conditions and transparency as mentioned above should be applied to R&D carried out by NSAs, the private sector, funding agencies, product development partnerships and other global health actors.
- States that fund and/or host such organisations and clinical trials/research activities in their territories should mandate and oversee the implementation of needed governance changes, access conditions, transparency principles and participation of LMICs, including CSO representatives, for greater accountability.
- Access conditions for technologies already developed through public funds for known pathogens of pandemic potential need to be renegotiated/reviewed and new terms publicised, including when carried out through Product Development Partnerships, private sector and other international organisations.

On WHO Pathogen Access and Benefit Sharing Mechanism (Article 10)

- Article 10 should go beyond pathogens and their genomic sequences to expand the scope of materials covered under the PABS mechanism to include biological samples/patient specimens.
- Instead of an arbitrary and insufficient ceiling of 20% of pandemic-related products for WHO, a more open-ended approach to benefit sharing based on a rolling assessment of needs should be explored.
- A core package of benefit sharing obligations should be established and should include training, technology transfer for local production, priority access to end products, affordable prices, joint research, non-exclusive IP licensing, capacity building and other knowledge sharing options.
- Key elements of ethics in health research such as obtaining consent, benefit sharing and post-trial access and registration of health technologies included in the "Guidelines for Health-related Research Involving Humans" of CIOMS should be incorporated in the accord and made mandatory.

- States should review or establish material transfer agreements incorporating the core package of benefit sharing obligations to address challenges of access to existing and pipeline health products tackling existing pathogens with pandemic potential and their new variants.
- States should review and strengthen national and regional legislative, regulatory and policy mechanisms on ABS.
- States should establish requirement of disclosure of origin of pathogens, genomic sequences and other biological materials in patent applications to ensure traceability and accountability.
- States should use IP flexibilities to ensure the full implementation of benefit sharing requirements under PABS.

On provisions addressing AMR (Article 18, 11)

- The accord should incorporate the 2015 Global Action Plan on AMR, establishing explicit and measurable obligations for states to implement, particularly to address financial and technical gaps to develop and implement national action plans on AMR.
- Binding obligations to coordinate AMR R&D financing and priority setting and conditions to ensure stewardship and access are needed across the accord, particularly under Article 18, 7, 9.
- AMR consumption, use and access to antimicrobials should be included in surveillance and monitoring. Instead of being treated separately, laboratory capacity for AMR surveillance and diagnostics should be an integral part of the overall laboratory capacity strengthening.
- Pathogen data sharing should follow the principles and mechanisms concerning access and benefit sharing, promoting transfer of technology and know-how and equitable supply and allocation.