Response to proposals for 'protocols' of the Pandemic Agreement pursuant to Articles 19 and 21 of the WHO Constitution

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Following the adoption of the amendments to the International Health Regulations at the 77th session of the World Health Assembly (WHA), WHO member states are now focused on reaching consensus on the Pandemic Agreement. To facilitate consensus, one proposal that has been put forward is to promptly finalise the "greened text"[1] in much of its current form and take more time to develop further instruments to address the main outstanding, contentious issues under the Agreement, namely: pathogen access and benefit sharing (PABS) and One Health. This is in essence an attempt to create a framework convention, as originally proposed.

Proposals have considered these protocols either being adopted under Article 19 of the WHO Constitution, as a protocol to the Agreement, or under Article 21 in the form of Regulations. We would caution against any of the above and recommend that Member States negotiate the Pandemic Agreement on the basis of a single undertaking approach whereby nothing is agreed until everything is agreed. In this regard, Member States should continue to work towards a clear, detailed and self-contained text (including annexes), rather than leaving key aspects of the agreement to be negotiated at some later point in time as protocols. The latter approach risks delaying dealing with difficult issues, with the potential for agreement on these central issues of concern to never actually be reached. In addition, since One Health and PABS have been identified as pivotal to achieving equity within the Agreement, the legal landscape should support this by means of a unified, as opposed to fragmented approach, with a view to fostering legal certainty, solidarity and trust. A fragmented international legal system will cause

[1] As per A77/10, green highlighted text refers to text in respect of which initial agreement has been reached. This is in contrast to yellow highlighted text which indicates initial convergence was reached; and text with no highlighting where no convergence was reached.

confusion, delay and uncertainty regarding legal obligations of states both in preparation for, and in response to, the next pandemic.

Treaty protocols will create a fragmented legal landscape

Article 19 of the WHO Constitution provides the WHA the authority to adopt conventions or agreements on any matter within WHO's competence. Any convention or agreement adopted using this procedure would require agreement of at least two-thirds of the WHO Member States, prior to entry into force. Once this two-thirds threshold has been met, the relevant convention or agreement would only become binding upon those states which have acceded to the agreement and adopted it into their domestic legal systems via their national processes. The Pandemic Agreement would then need to specify a process for the development and adoption of subsequent Protocols.

The only Protocol adopted under a WHO treaty, the *Protocol to Eliminate Illicit Trade in Tobacco Products,* operates as a protocol to the WHO Framework Convention on Tobacco Control (WHO FCTC),[2] following a procedure directed by the terms of the FCTC Protocol (FCTC Art 33 (6)). Protocols are to be adopted by the Conference of the Parties (COP) of the FCTC, and "every effort shall be made to reach consensus" but may "as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session." Only Parties to the FCTC may be parties to a protocol (FCTC Art 33 (4)). Similar proposals are likely to be developed by the Pandemic Agreement for Protocols under that instrument.[3]

However, given how controversial PABS and One Health have been during these negotiations, it is clear that any Protocol, no matter how carefully designed, will not achieve universal adoption. Indeed, the FCTC Protocol entered into force following ratification from 40 Parties. Within the context of the Pandemic Agreement, the utility of Protocols with such small membership is questionable. This is because so much of the

[2] In the case of the Illicit Trade Protocol, entry into force was, 'ninetieth day following the date of deposit of the fortieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary' (Art 45 (1))

[3] At present, Art 31(2) of the Pandemic Agreement (in green highlighted text) says Protocols to the Agreement are adopted under the terms in Art 29(3) (also in green highlighted text) which says it requires a three-quarters majority vote of the parties present at COP.

Agreement has become centred around equity, and member states have come to associate equity with, among other things, the PABS system. Accordingly, should a member state become a party to the Agreement, but not to any subsequent protocol concerning how equity is intended to be operationalised would seem contrary to the object and purpose of the Agreement. It is possible for language to be inserted into the Agreement to the effect that a Member State can only be a party to the treaty if they *also* become a party to any subsequent protocol(s) in respect of pathogen access and benefit sharing (PABS), and One Health. However, even if Member States were willing to agree to such an obligation - and we are doubtful that any country would agree to be bound by unwritten, future obligations amounting to a 'blank cheque' - there would be significant difficulties in crafting Treaty language sufficiently strong to create a meaningful, clear legal obligation.[4] This will have four potential consequences: (1) creation of a fragmented, confusing legal landscape for pandemic prevention, preparedness and response, particularly if more than one protocol to the Pandemic Agreement is adopted and (2) offer opportunities for some Member States to escape key equity obligations, which are meant to be a central feature of the Agreement's design. Relatedly, this raises an additional potential concern; (3) that no additional Protocols are adopted, and the Agreement remains in essence an incomplete agreement, with comprehensive disciplines

[4] Indeed, such clauses are exceptionally rare in international law. The one notable exception to this is the Convention on Prohibitions or Restrictions on the Use of Certain Conventional Weapons which may be deemed to be Excessively Injurious or to have Indiscriminate Effects (1980) whereby each participant must consent to be bound by any two or more of the Protocols: Protocol on non-detectable fragments (Protocol I); Protocol on prohibitions or restrictions on the use of mines, booby-traps and other devices (Protocol II); Protocol on prohibitions or restrictions on the use of incendiary weapons (Protocol III). Protocol on Blinding Laser Weapons (Protocol IV) and the Protocol on the explosive Remnants of War (Protocol V). The most notable example of "single undertaking" in international law was provided for at the inception of the WTO, whereby all 'covered agreements' had to be agreed to as a condition of Membership, albeit plurilateral agreements were also provided for under WTO law (e.g. the Government Procurement Agreement). Applying the general principle of the single undertaking to the current context, States would have to accept all protocols of the pandemic agreement to be a party, although in contrast to the WTO example, States would be agreeing to be a party to protocols that have not yet been agreed. Until all elements of the text - including subsequent protocols - have been agreed, ratification at national level seems highly unlikely, and indeed, may be constitutionally prohibited due to the impossibility of scrutiny by national legislatures.

addressing key equity obligations not provided for.[5] A final consequence, (4) is that an empty shell of an Agreement with protocols to be defined at some point in the future will work as a disincentive to timeous ratification of the framework Pandemic Agreement; governments may instead wait for the protocols to be agreed and hence delay their ratification of the Pandemic Agreement itself.

The scope of Article 21 regulations are ill-suited for the pandemic treaty protocols envisaged

Article 21 of WHO Constitution allows for WHA to adopt regulations that concern sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease. In the first instance, the logic of using Article 21 of the WHO Constitution to create a range of subsequent protocols to the Pandemic Agreement may appear sound. There is hope that this will lead to wider adoption, as compared with adopting an Agreement under Article 19 of the Constitution, with the latter requiring acceptance by each Member in accordance with their own domestic processes to enter into force for that Member. Regulations under Article 21, on the other hand, operate on an 'opt-out' basis and come into force after due notice by the Director-General of their adoption – unless reservations or rejections are made within that time (Article 22, WHO Constitution), though they still require changes to domestic legislation to ensure implementation and ensure full compliance. Regulations, such as the IHR (2005) are widely adopted, and reservations are rare.[6] Indeed, it remains to be seen the extent to

[5] Of course, other areas of international law have grappled with how to manage the risk of an interim or incomplete agreement not being completed. The WTO Agreement on Fisheries Subsidies is one such example. This agreement was reached in 2022 but two areas of the negotiating mandate (subsidies on overfishing and subsidies on overcapacity) remained unaddressed within the text. A compromise was reached that negotiations would continue on subsidies liable to lead to overfishing and overcapacity but explicit within the text of the Agreement on Fisheries Subsidies (Article 12) is the direction that negotiations on these areas can't go on forever; "If comprehensive disciplines are not adopted within four years of the entry into force of this Agreement, and unless otherwise decided by the General Council, this Agreement shall stand immediately terminated." The inclusion of what has been referred to as an 'exploding' sunset clause therefore links completion of all areas of the negotiating mandate to the continued existence of the interim agreement.

[6] Historically, however, rejections are not as rare. The 1951 Sanitary Convention had several.

which rejections and/or reservations will be made to the recently adopted 2024 IHR amendments.

It is therefore thought (or hoped) that a system addressing PABS and One Health developed pursuant to Article 21 will be equally widely adopted. However, this cannot be assumed. In the first instance, the IHR (2005) are the result of more than 150 years of international cooperation to prevent the spread of infectious disease which began in 1851 at the first international sanitary conference in Paris. The IHR (2005) has significant normative value, and a shared understanding grounded in those 150 years of international cooperation[7] - which enabled Member States to work towards consensus on these issues, regardless of the manner and form the instrument took - be it Regulations or Treaty. This is not the case with the current negotiations around PABS, and One Health.

It should be remembered the scope of Article 21 Regulations is far more limited than a Treaty adopted under Article 19, with the former providing the Health Assembly the authority to adopt regulations concerning only a limited, prescribed list of topic areas.[8] It is unclear how the proposed protocols fit into the narrow scope prescribed at Article 21(a)-(e). Simply put, not all areas of health concern will 'fit' within the scope of Article 21. To give an example, while the recent 2024 IHR amendments have added a Coordinating

[7] Of course, it might be possible to direct that only Parties to the Agreement can be Parties to any subsequent Protocol, though Article 31 (4) of the recent draft text (A77/10) on this specific issue is in brackets and not yet greened. In addition, while such a direction seems straightforward from a legal perspective, it becomes more complicated if Article 21 procedures are utilised. This is because it would presumably not be the COP to the Agreement adopting the protocol but rather it would be the WHA authorised to adopt a protocol as Regulations under Article 21 of the WHO Constitution. In this regard, however, it is notable that the recent draft text (A77/10) does not specifically mention the possibility of protocols being adopted pursuant to Article 21, instead directing that in adopting protocols, the decision-making terms for amendments under the Agreement shall apply (see discussion at n 3 above). However, and notably, while the possibility of Article 21 regulations is not explicitly addressed in A77/10, such a possibility *was* provided for in an April 2024 draft (A/INB/9/3 Rev.1), Article 31 (2), which directs that the decision-making terms for amendments (as above) would apply to the adoption of protocols, but where the protocol was adopted under Article 21, 'it shall further be presented to the World Health Assembly for consideration for adoption.'

[8] Article 21 (*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.

Financial Mechanism, it is also the case that financing in itself wouldn't *necessarily* fit within the scope of Article 21(a).[9] This is because the new Coordinating Financial Mechanism is part of a suite of reforms to the IHR, whereby the overall purpose of the IHR fits into Article 21(*a*) "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease." Outside of this context, financing, in and of itself, would not fit into Article 21(a) as clearly as a finance mechanism when taken as one component of the entire IHR.

On One Health, while this is relevant to the prevention of the international spread of disease, such activities come within Article 21 only so far as the contours of One Health seek to address issues such as antimicrobial resistance (AMR), mid-stream and upstream prevention of zoonotic spillover events[10], and do not extend to the full range of sectors encompassed by 'One Health'.[11]

In respect of PABS, it is far more difficult to envisage a PABS system falling within the scope of "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease." Moving PABS from Article 19 to Article 21 will not change or alter the significant differences of opinion that member states have regarding the purpose, content and functioning of any future PABS mechanism. Accordingly, utilising the legal form of Article 21 cannot, on its own, ensure universal adoption of these subsequent Regulations – Member States can send reservations to the text or opt-out of the Regulations entirely. This is important for two reasons; firstly, fragmentation of the international system during the next pandemic will cause confusion, delay and uncertainty regarding legal obligations of states. As a result, during the next health emergency any one of (or a combination of) the Pandemic Agreement, IHR, Pandemic Influenza Preparedness (PIP) Framework, PABS or Convention on Biological Diversity (CBD)/Nagoya Protocol (and we should not forget the potential implications of

[9] As far as finance has relevance to enable Parties to "equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities".
[10] On mid-stream and upstream prevention, see discussion in Ginevra Le Moli, 'The Containment Bias of the WHO International Health Regulations', British Yearbook of International Law (2023); https://doi.org/10.1093/bybil/brad001.
[11] E.g., see Mettenleiter, T.C., Markotter, W., Charron, D.F. et al. The One Health High-Level Expert Panel (OHHLEP). One Health Outlook 5, 18 (2023). https://doi.org/10.1186/s42522-023-00085-2.

CBD COP Decision 15/9 on Digital Sequence Information)[12] will be followed by different countries with respect to sharing information, data, and physical samples with human pandemic potential. Finally, adopting the Pandemic Agreement under Article 19, and Protocols under Article 21 causes a clear problem with jurisdiction, in that a state not party to the Pandemic Agreement, could be a party to its implementing instrument (and would be expected to be, given the opt-out nature of instruments adopted under Article 21). This causes a clear problem with responsibility for implementation and supervision/compliance, and where responsibility for this lies between the COP to the Agreement, and the WHA for the Regulation Protocol.

Recommendation

In light of the above we do not recommend that member states opt to create subsequent protocols, either by means of a COP decision[13] - whatever that might look like -, under Article 19 or under Article 21. Instead, we recommend that states negotiate the Pandemic Agreement on the basis of a single undertaking approach whereby nothing is agreed until everything is agreed. Indeed, that has been the approach taken in negotiations - at least until recently -and it is unclear why there has been a change in orthodoxy, other than a desire to delay difficult issues for discussion at another time.

Our recommendation is that negotiations should continue on the basis of a single undertaking is particularly important given the connections of PABS and One Health to notions of equity and solidarity that members view as being central to the Agreement.

[12] Fifteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Decision 15/9: Digital Sequence Information on Genetic Resources. (19 December 2022) CBD/COP/DEC/15/9. Parties to the Convention on Biological Diversity (CBD) have decided to establish a multilateral mechanism for the fair and equitable sharing of benefits arising from the utilisation of Digital Sequence Information (DSI) on genetic resources as part of the Kunming-Montreal Global Biodiversity Framework. This multilateral mechanism is to include a global fund and will encompass DSI on any genetic resources within the scope of the CBD, including pathogens.

[13] See discussion above at (n 7).