Challenges and Prospects for the Intergovernmental Negotiations to Develop a New Instrument on Pandemic Prevention, Preparedness, and Response

Global Health Law

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Abstract: As Member States of the World Health Organization (WHO) meet in an International Negotiating Body (INB) to negotiate a legally binding agreement on pandemic prevention, preparedness, and response for submission to the 77th World Health Assembly in May 2024, this column reflects on creative but pragmatic and complementary means that could be employed in the short timeframe allotted for this important global health law negotiation.

On June 24, 1948, only a few years after World War II, Dr Andrija Štampar of Croatia, a key architect of the founding document establishing the World Health Organization (WHO), stood before the first ever World Health Assembly. He had just been elected its President by acclamation, a recognition of his extraordinary achievements in health care, and he addressed the assembled diplomats and health ministers gathered in Geneva from countries around the globe.

He began his remarks by saying that the preamble of that founding document, the 1946 Constitution of the World Health Organization, expressed the "quintessence of all that has occupied the greatest minds working during the last two hundred years in the field of health."

For a "quintessential" document, the preamble of the WHO Constitution is surprisingly brief. It is composed of only nine one-sentence paragraphs, the first two of which form the cornerstone of contemporary global public health: first, that "[h]ealth is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"; and second that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[1]

At that first World Health Assembly, Dr Štampar shared his feelings on the occasion of this culmination of his life's work. "Science," he said,

> has taught us how to secure health for everyone, but the results of this scientific research cannot become reality and materialize before the existing economic, social and other relations among peoples have been further improved. During my numerous journeys all over the world I have realized that we can learn so much from one another ... Each country has its own peculiarities, and what may be good for one may not be so good for another. But one basic truth applies to all of them and that is that every individual has a fundamental right to health.

About This Column

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In language which echoed Dr Štampar's words to the 1st World Health Assembly, all 194 WHO Member States committed in 2021 to develop a new pandemic instrument guided by "the principle of solidarity with all people and countries," "prioritizing the need for equity" and "with a view to achieving universal health coverage."

This historic 2021 "special" session of the World Health Assembly was convened to consider what has been aptly described as "the glaring limitations of the public health response" to the COVID-19 pandemic.[2] There, the 194 Member States of WHO decided on a path aimed at reshaping global health architecture to strengthen pandemic prevention, preparedness, and response by developing a new convention, agreement, or other international instrument.[3]

An Ambitious Deadline

WHO Member States set a deadline for the project, committing to submit a convention or agreement to the World Health Assembly's 77th session in May 2024, a timeframe of some two and half years. This extraordinary international effort to negotiate what is sometimes referred to as the "pandemic treaty" is well underway — and it is running on an extraordinarily tight schedule.

There is a view that the schedule for developing the pandemic convention or agreement cannot be met. With only seventeen months from the date of this writing, it is unclear whether the international community can operate with the same determination and speed today, in the wake of the most severe health crisis of the new millennium, as it did more than 75 years ago, in the wake of the gravest political-military crisis of modern times.

International treaty making processes are notoriously complex, and often lengthy, endeavors. Within the arena of global health law, past reforms have taken years for countries to forge consensus on normative instruments. Both the 2003 WHO Framework Convention on Tobacco Control, currently WHO's only binding international convention, and the 2005 revision of the International Health Regulations, a wholesale revision of existing regulations to prevent the international spread of disease, took years to prepare and negotiate.[4] Even non-binding global health instruments have required extensive time, as evidenced by the 2011 Pandemic Influenza Preparedness Framework, a landmark effort to secure equitable access to vaccines in the event of an influenza pandemic, which took four years of contentious negotiations to develop.[5]

The Intergovernmental Negotiating Body (INB) that is currently developing the pandemic treaty, however, is operating in a uniquely historic context that may help to bring its ambitious "delivery date" within the reach of negotiators.

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A Unique Negotiation

For several decades, countries have increasingly shown both ingenuity and practicality in their approaches to international instrument-building efforts. Such diplomatic approaches could, potentially, help produce a pandemic instrument that is delivered on time, while also being substantive, effective, and inclusive.[6] The current process encompasses numerous practices and modalities developed by countries across a range of international fields, including the international environmental arena, that are being considered by the INB.

These approaches include the possibility of using different forms or structures for the agreement. One approach is a "framework," or iterative process, to establish substantive and evidence-based international rules, building ambition over time. As recommended by the Independent Panel on Pandemic Preparedness and Response, tasked by WHO with identifying the factors that led to COVID-19 pandemic, such a "Pandemic Framework Convention" could involve countries agreeing to work in a stepwise manner, prioritizing agreement on concrete key objectives, like ensuring equitable access to medical countermeasures such as vaccines, therapeutics and diagnostics, while setting future target dates for other measures.[7] Among the most compelling examples of this approach is the successful, evidence-based development of the Vienna Convention for the Protection of the Ozone Layer, which serves as the foundational instrument of the Montreal Protocol on Substances that Deplete the Ozone Layer of 1987. Another approach is to focus on specific core obligations and implementing measures in the foundation instrument itself. These options are not necessarily mutually exclusive, a point which may lead to the possibility of a hybrid form or structure.

Further, countries have increasingly shown a common commitment to transparency, inclusiveness, and participation in their normative development processes. In the context of the INB, its mandate prescribes a

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"whole-of-government and whole-of-society approach." This reflects both the "impact-on-everything" nature of the COVID-19 pandemic, as well as the increasingly influential role of stakeholders across all sectors of society, including civil society, indigenous groups, the private sector, and (especially in the age of social media) the global general public. In a historic first for such intergovernmental negotiations, through two separate rounds of public hearings, the global public was invited to submit views to WHO directly to help inform the work of the INB. In the second round, over 400 video submittals were received and remain available for viewing on the WHO website. These contributions reflect the diversity of viewpoints from a variety of actors, including private citizens and organizations from every region of the world. In addition, four informal focused consultations (IFCs) with experts were convened to provide in depth discussion on key topics. These were broadcast publicly, and the outcomes of both the IFCs and public hearings will be considered in the drafting of the instrument.

Such broad engagement can strengthen the legitimacy and acceptability of the instrument and the process by which it is developed — and ultimately ensure its effectiveness.[8]

A Binding Obligation

To promote inclusiveness across states, the INB decided in July 2022 that "the instrument should be legally binding and contain both legally binding as well as non-legally binding elements," thus setting the stage for a pandemic instrument that could be "calibrated" in terms of legal "bindingness,"[9] including "soft law" elements within a larger "hard law" package. The INB decision to permit sequenced consideration of both hard and soft law speaks to the openness of WHO Member States to consider the use of the full range of normative "tools" that the WHO Constitution provides in reshaping global health architecture in the post COVID-19 pandemic world.[10] The decision has also raised the question whether the two different arrangements — conventions/agreements and regulations — could be used in combination, in a mutually reinforcing way.

The INB decided that in working towards a binding convention or agreement under Article 19 of the WHO Constitution, which enables the World Health Assembly to adopt conventions or agreements on any matter within WHO's competence, the INB will do so "without prejudice to also considering, as work progresses, the suitability of Article 21."[11] This reference to "Article 21" means that the negotiators can also consider, in addition to a traditional international "convention/agreement" as a vehicle for pandemic safeguards, a different and normatively rare WHO vehicle of a binding "regulation" for pandemic preparedness and response. This particular normative tool is set out in Article 21 of the WHO Constitution.

Although both instruments, a convention/agreement and a regulation, would be binding under international law, they would come into force (i.e., they would become legally effective) in different ways. With a convention or agreement, as seen in the WHO Framework Convention on Tobacco Control (the FCTC), a country "opts into" the instrument, accepting it by informing the depositary, if and when it decides to do so. If a country takes no action, the convention does not bind it. With a WHO regulation, a country is bound as the default, unless it explicitly "opts out" of the instrument. Thus, if it takes no action, it is bound by the regulations.[12] Thus, all 194 WHO Member States are party to the 2005 IHR because no country "opted out." Also, under the WHO Constitution, regulations come into force for all Member States on an agreed date. Thus, the 2005 IHR came into force for all 194 WHO Member States on precisely the same day (June 15, 2007), because this entry into force date is set out as a term of the regulation itself.

A Flexible Approach

Yet another approach that countries have employed to promote inclusiveness is showing flexibility with respect to treaty ratification itself, for example permitting countries to select among protocols, as in the case of the Convention on Conventional Weapons, or even opening protocols of a treaty to countries that are not party to the main instrument itself. This is the case, for example, with the Optional Protocol on the involvement of children in armed conflict, which is open to all countries, irrespective of whether a country is party to its overlying parent convention, the Convention on the Rights of the Child.

Many treaties also include elements which, although they lie within a legally-binding instrument, are not themselves obligatory. The WHO Framework Convention on Tobacco Control (FCTC), by way of example, has provisions which recognize certain technical health realities, such as "tax measures are an effective and important means of reducing tobacco consumption," but do not require mandatory related steps beyond providing related reporting.

An Equitable World

In order to ensure the effectiveness of the pandemic treaty, particularly in meeting the priority set out in its mandate on equitable access to medical countermeasures, the INB will be considering how to operationalize this fundamental equitable principle to ensure access and benefit sharing.

It is here that science and diplomacy can converge to guarantee equitable access to medical countermeasures, such as vaccines, therapeutics, and diagnostics. Recent developments in the field of synthetic biology mean that it is today possible to produce both vaccines and diagnostics based on the genetic sequence of viral pathogens, i.e., the genetic code of DNA "letters" that makes up a virus's genetic material. This sequence can be transmitted like any other information file – even as an attachment to an email. The implications of this for promoting near instant sharing of information will be crucial to quickly begin production of diagnostics and vaccines. At the same time, the importance of ensuring equitable

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access to those pandemic products, especially for countries in greatest need, is critical.[13]

Whether the INB can develop concrete mechanisms to help ensure that pathogenic samples and information, and countermeasure products, are both reliably and equitably shared is a key question going forward. Lessons from other evidence-based negotiating processes suggest that a multi-stakeholder approach to finding solutions, as well as building upon existing structures and agreements, can well serve negotiators.

Conclusion

These different but complementary approaches to developing international agreements share the common aim of creating pathways for compromise and consensus in areas where, in the words of Dr Štampar, "… each country has its own peculiarities, and what may be good for one may not be so good for another" — but where all have accepted the fundamental principle that "every individual has a fundamental right to health."

Note

The author has no conflict to disclose.

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