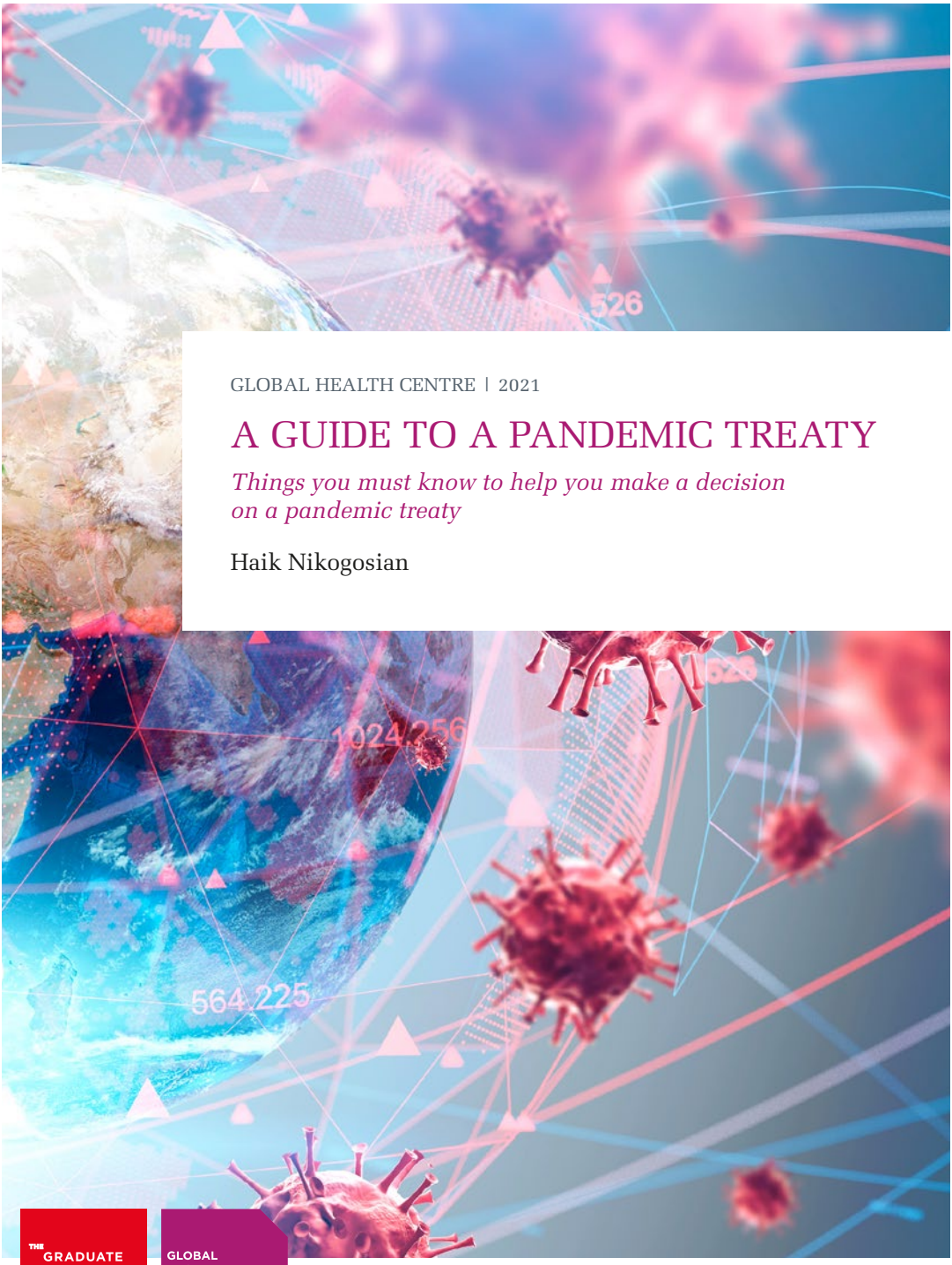

GLOBAL HEALTH CENTRE | 2021

A GUIDE TO A PANDEMIC TREATY

Things you must know to help you make a decision on a pandemic treaty

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INTRODUCTION

Why this guide?

The preparatory work towards the special session of the WHA in late November 2021 to consider a treaty or other international instrument for pandemic preparedness and response continues to trigger questions and debates on the subject matter. Many reviews, discussions and publications so far point to the need for synthesis and clarity on various aspects, important for countries as they engage in the process.

The WHO's only experience in negotiating and adopting an international convention (FCTC) dates back to the early 2000s, and the current generation of health diplomats and negotiators were largely not part of it. In addition, a future instrument on pandemics would be informed by international legal regimes existing in other fields, such as human rights, environment, trade and security, not sufficiently known in health circles. The presence of such a large body of international law relevant to health often also prompts questions on why the health domain itself is regulated by a handful legal instruments only, and why there is hesitation to international legal clarity even when it comes to confronting global health risks of this magnitude. Questions also arise on issues such as terms in use, types of instruments available, processes before and after adoption of a prospective treaty, and specific issues such as financial mechanisms, compliance and monitoring, science-policy interface, relations with the existing IHR (2005) etc.

This guide therefore represents an independent academic attempt to systematise and shed light on some of the most frequently asked questions or issues otherwise important in the run up of the special session of the WHA, and potentially beyond. It is part of a project located at the Global Health Centre at the Graduate Institute of International and Development Studies Geneva on options and benefits of a pandemic treaty, which includes also a series of policy briefs and articles by lead international figures and experts, a series of regional and stakeholder workshops, and a regularly updated one-stop shop website for various sources on governing pandemics in general and on a pandemic treaty in particular.

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Acronyms	
ABS	Access and benefit sharing
ACT–A	Access to COVID-19 Tools Accelerator
CBD	Convention on Biological Diversity
CEPI	Coalition for Epidemic Preparedness and Innovations
COP	Conference of the Parties
CRPD	UN Convention on the Rights of Persons with Disabilities
GAVI	The Vaccine Alliance
GPMB	Global Preparedness Monitoring Board
GSD	Genetic sequencing data
FAO	Food and Agricultural Organization of the United Nations
FCTC	WHO Framework Convention on Tobacco Control
HLIP	G20's High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IFI	International Financial Institutions
IHR (2005)	International Health Regulations (in their current revision of 2005)
IMF	International Monetary Fund
IOAC	Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme
IP	Intellectual property
IPCC	Intergovernmental Panel on Climate Change
IPPPR	Independent Panel on Pandemic Preparedness and Response
OIE	World Organization for Animal Health

Acronyms	
PPR	Pandemic preparedness and response
RCFIHR	Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response
UHC	Universal health coverage
UNFCCC	United Nations Framework Convention on Climate Change
UN	United Nations
UNEP	United Nations Environment Program
UNGA	United Nations General Assembly
WHA	World Health Assembly
WHO	World Health Organization
WHOC	Constitution of the World Health Organization
WTO	World Trade Organization

RATIONAL, MEMBERSHIP, INSTITUTIONS

1. Why is a treaty on pandemics under consideration?

The move for a pandemic treaty is driven by the scale and pressure of the pandemic challenge. COVID-19 revealed how badly the world is prepared to prevent and control pandemics. Several independent review committees and panels all pointed to the urgent need for a stronger international regime to confront pandemics, particularly as many issues requiring global solutions seem to be lying beyond the scope and mandate of the existing International Health Regulations—the only other type of legal instrument, other than conventions/agreements, available under the mandate of the WHO (more on different types of instruments can be found under Q7 and Q10). References are also made to the FCTC, the first convention adopted by the WHA in 2003 largely seen as having demonstrated the feasibility of negotiating and adopting a globally binding treaty (albeit the only one so far) on a major global health threat under the auspices of the WHO (more on this under Q12).

2. How does a treaty relate to recommendations of independent review committees?

Several review committees and panels have expressed support for a treaty or similar instrument to be developed to strengthen global pandemic preparedness and response following COVID-19.

The GPMB's Annual Report released in September 2020 called for convening a UN Summit on Global Health Security, with the intention on developing an international framework for health emergency preparedness and response. In a more recent statement, the Board reiterated its call to leaders to reach an agreement on a binding international framework.

The report of the IPPPR released in May 2021 included recommendations on transforming the international system responsible for PPR. The Panel specifically identified the need for a more focused and independent WHO, and the need for a pandemic treaty.

Two committees presented their reports to the 74th World Health Assembly in May 2021.The IOAC emphasised the importance of a new treaty in supporting Member States to comply with the IHR

(2005), particularly in the context of building resilience for pandemics, mobilizing financial resources collectively, and ensuring universal access to diagnostics, treatments and vaccines based on the principles of solidarity, equity, accountability, and transparency. The report of the RCFIHR underscored that a new treaty may cover topics that are not addressed by the IHR, such as for example the sharing of pathogens and genome sequence information, maintaining the global supply chain and equitable access to countermeasures, and prevention and management of zoonotic risks as part of the One Health approach.

The Report of the Pan European Commission on Health and Sustainable Development (September 2021) contained support for a new pandemic treaty. The Commission stated that such a treaty "should be truly global, enable compliance, have sufficient flexibility and include inventive mechanisms that encourage governments to pool sovereign decision-making in some policy-making areas".

The report by HLIP (July 2021) did not provide for direct linkages between the proposed global financial mechanism and a prospective treaty or other legal instrument. The report however did refer to the Global Environment Facility which is the financial mechanism for several multilateral treaties as "a useful reference in how countries have come together to finance the global commons".

3. Is this a good time to negotiate such a treaty?

The enormous challenge posed by COVID-19 created an unprecedented push for renewed global rules. In March 2021, a group of 26 heads of state and government and the President of the European Council, joined by the Director General of WHO, made a strong statement on the urgent need for a pandemic treaty. Countries later formed a Group of Friends of the treaty. Subsequently, the Seventy-fourth WHA (May 2021) decided to convene a special session in November 2021 to consider the matter.

There were views expressed that it may not be the right time to embark in potentially difficult negotiations on confronting future pandemics while still fighting the current one. Meanwhile, various reviews and expert opinions pointed to high probability of (and high level of unpredictability as to when) a new pathogen with human pandemic potential (or variants of it as the current pandemic shows) may emerge and spread. As Dr Tedros, WHO's Director General, put it, "the world cannot afford to wait until the pandemic is over to start planning for the next one". And as some of the recent reports highlighted, the cycle of panic, when a deadly outbreak strikes, and neglect, when it fades from memory, must end.

The world therefore may be facing a momentum and window of opportunity to act for stronger

global rules. The current situation differs notably from the WHO's first treaty-making experience. The idea of a tobacco treaty was brought up and advocated in expert and civil society circles long before reaching the WHO's political floor, while this time around a pandemic treaty is called for by influential political leaders, thus likely shortening the treaty path should countries decide to go down that route. It is also important to note the timeframes involved: negotiations for a treaty or other legal regime may take at least one year, with another 9–12 months minimally needed for its entry into force, as past experiences show. More on this can be found under Q31–32 and Q36.

4. What would the benefits of such a treaty be compared to revising the IHR (2005)?

A treaty on pandemics would be an expression of true political will to act collectively after the greatest global crisis of the past decades, something of key importance in fostering global coordination against global challenges posed by pandemics and beyond.

A treaty under Article 19 of the WHOC will not be limited—as is the case with the IHR (2005)—by boundaries of Article 21 of the WHOC, which is the legal base of the IHR. That means it can encompass much more than to only address the weaknesses and gaps in the IHR revealed during the COVID-19 response (see more on this under Q23). As a specialized instrument, it could also establish a clear set of principles for PPR.

A treaty under Article 19 of the WHOC can build on relevant experiences accumulated under various other multilateral treaties (see more under Q25 and Q28). This does not seem feasible under the IHR (2005) due to its different (somehow unique) status under international law. Further, such a treaty could enhance some of these experiences to match pandemic-specific needs, as for example by extending the scope of genetic resources encompassed by the Nagoya Protocol[1] to also cover genetic sequencing data, an issue of critical importance in pandemics (see more under Q27).

Countries will need to "opt-in" by ratifying the treaty, while amendments to IHR (2005) would take effect for all countries simultaneously, unless expressly opted-out (although not necessarily quicker than a treaty due to the mandatory lag between adoption and the entry into force which is two years in the current version of the IHR). Ratifications, meanwhile, generate high visibility and high-level political commitment around the accepted rules, something difficult to expect from amending the existing regulations which are viewed mostly from a technical perspective in countries.

1 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention in Biological Diversity

In most legal systems international treaties must be translated into national law following the ratification, thus binding all relevant sectors and the government as a whole to comply. This is not a set mechanism in the case of the IHR (2005), largely seen in the domain of the health sector to implement. As the IPPPR stated, "pandemic preparedness planning is a core function of government …, not a responsibility of the health sector alone". Insufficiencies in national legislation for emergency preparedness and response were also underscored in the report released by the RCFIHR.

A treaty would allow a dedicated governing body, a COP, to vigorously review and resolve evolving matters, negotiate protocols and guidelines, establish treaty bodies on matters of particular importance etc., something not readily available under the IHR (2005) which are governed by the WHA, a body of universal, not specialized, mandate.

Nevertheless, potential relations between a pandemic treaty and the existing IHR (2005) attract considerable attention and are important to resolve early on. This issue is covered under Q26.

5. Why in WHO?

As the lead authority in international health cooperation, WHO would be the most natural host of the treaty under consideration. The WHOC indeed provides the legal space for adopting conventions and agreements under its Article 19, already utilized in the past for negotiations and adoption of the FCTC. The statement issued by political leaders on 30 March 2021 explicitly referred to a treaty "rooted in the Constitution of the WHO, drawing in other relevant organizations key to this endeavour". Cooperation with other intergovernmental organizations is covered in Article 70 of the WHOC.

Therefore, discussions on whether "in WHO or elsewhere (with the UN particularly in mind)" seem to be driven not by constitutional considerations, but rather by the question on whether and how other relevant organizations could sufficiently support the prospective treaty, and the process for it, on various cross-cutting issues outside of health, such as trade, intellectual property, finance, environment and human rights. There may also be political considerations as in any health diplomacy process. An immediate mechanism for involving the UN system and other relevant organizations would therefore be paramount. Some of these mechanisms are discussed under Q34.

6. Who would be Parties to the treaty?

Any Member State of WHO can become a Party to a convention adopted by the WHA. In the case of the FCTC, eligibility has also been extended to States that are not members of WHO but are

members of the UN, and to regional economic integration organizations in line with growing practice in some other fields. This could also be important for a pandemic treaty. When both a regional economic integration organization and one or more of its Member States are Party to a convention (which is the case for example with the European Union and its Member States under several international conventions), the organization and its Members shall decide on their respective responsibilities, as well as voting terms, under the convention.

7. Are the terms treaty, convention and agreement used interchangeably?

Yes, they are generally used interchangeably internationally, although the interpretation might be more nuanced in some legal systems. The UN Charter, in its Article 102, refers to "treaties and international agreements". The WHO Constitution, in its Article 19, refers to "conventions and agreements". Neither statute however defines those terms. The Vienna Convention on the Law of Treaties (1969) defines treaty as "an international agreement concluded between States in written form and governed by international law ….". "Convention" in actual fact is the most common term used for multilateral treaties. In international practice, therefore, the terms treaty, convention and agreement are often used interchangeably.

In the case of WHO, this should be distinguished from "Regulations", a distinct type of legal instrument specified in—and limited to the scope of—a different article (Article 21) of the WHOC. This differentiation has historical origins as the innovative authority given to WHO to adopt regulations allowed to bring the pre-existing patchwork of international sanitary conventions under a single set of International Sanitary Regulations (the predecessor of the International Health Regulations) immediately applicable to all WHO Member States unless expressly opted out. More on this issue can be found under Q10 and Q11.

8. How do a regular and framework convention approaches differ?

The issue of a framework vs a "regular" convention captures considerable attention. The framework approach to treaty implies encompassing broad commitments for its parties, leaving specific details to subsequent protocols or other agreements. It therefore provides more space for consensus and compromise in treaty negotiations and adoption, but also creates legitimate expectation towards further protocols to provide the often-critical details. A framework—protocol approach can particularly be effective when protocols are expected to capture evolving science, technologies and evidence. It is also often used to increase the acceptability of the parent convention by deferring certain contentious issues (specific compliance mechanisms, for example) to protocols, negotiated in

parallel with the parent convention or at a later stage.

Protocols, meanwhile, generally take considerable time to negotiate, adopt and bring into force. The FCTC's first protocol, on illicit trade[2], was adopted and entered into force respectively 7 and 13 years after the parent convention came into force. The first protocols to the UNFCCC (the Kyoto Protocol) and the CBD (the Cartagena Protocol) required, respectively, 3 and 7 years to adopt and 10–11 years to enter into force once the parent conventions were in force.

Given the scale and urgency of the challenge, a framework convention approach to a pandemic treaty might be practical if states could agree to short definite timelines for negotiating further protocols, or to negotiating the most pressing one(s) in parallel with the parent convention (as for example in the case of the Optional Protocol to the CRPD which was adopted and entered into force at the same time as its parent convention). Should this be not deemed feasible, negotiating a "regular" convention, with possible protocols in future but critical details immediately in place, might be an option to consider.

9. Which purpose and legal status do Protocols carry?

Protocols build on general principles and objectives of their parent conventions but contain additional details and obligations not covered by them. As such they are not exclusive to a framework convention—protocol approach and can be adopted under any convention. Protocols should not be confused with other types of instruments such as guidelines. Protocols do establish new obligations, while guidelines assist with implementing the existing ones. Thus, a protocol, when adopted, becomes a new international treaty in its own right, requiring the usual procedures of signing, ratifications and entry into force. It is also generally governed by its own governing body (a Meeting of the Parties in most cases).

Protocols are negotiated and adopted under the auspices of the respective parent convention, with only Parties to that convention eligible to negotiate and become a member. Parties to the parent convention that are not a party to a protocol remain bound by obligations in the subject area of the protocol that may for that subject area exist (usually in a more general form) in the parent convention. The number of protocols adopted under a convention is varying and can grow with time. For example, there is one protocol to the Vienna Convention for the Protection of the Ozone Layer, two to the UNFCCC and CBD, three to the UN Convention on the Rights of the Child, and five to the Convention on Certain Conventional Weapons.

2 Protocol to Eliminate Illicit Trade in Tobacco Products

10. What other types of international health instruments exist?

The WHOC provides for the following three types of international health instruments which the WHA can adopt: conventions and agreements (under Articles 19 of the WHOC); regulations (under Article 21) and recommendations (under Article 23). Conventions/ agreements and recommendations can be adopted on any matter within WHO's competence, regulations—on certain matters, as identified in Article 21, only.

Recommendations (usually in the form of codes, frameworks, strategies, plans of action and resolutions) are of a non-binding nature[3] thus often referred to as "soft law". They are generally quicker to agree on and they apply immediately as concluded, both aspects often seen as relative advantages of this category of instruments; nevertheless, despite the generally significant technical and political weight, they remain not mandatory for countries to follow and as such raised questions about potential efficacy to confront pandemics.

Conventions and regulations, in contrast, do give rise to binding international obligations thus often referred to as "hard law". In addition, conventions, unlike regulations (which enter into force for all Member States after an agreed period, unless expressly opted out) require ratification to become a Party, thus normally giving rise to considerable legal, political and whole-of-government effect while going to and through national parliaments.

Political Declarations often adopted at the UN on health matters (as also the one recommended by the IPPPR in relation to pandemics), represent another type of a non-binding instrument, this time outside the matrix of the WHO. Recent UN Political Declarations on noncommunicable diseases, antimicrobial resistance, tuberculosis and UHC fostered high-level political attention and commitment in these important areas of public and global health.

3 With a very few exceptions though, such as in the case of the compulsory requirement concerning standard material transfer agreements contained in the WHO's Pandemic Influenza Preparedness Framework

11. Treaties concerning international spread of diseases were adopted in the past. Why is it so different now?

The birth of the international legal regime in health dates back to the late 19th– first half of 20th centuries, when a series of international sanitary conventions and similar agreements were adopted to address the rising threat of infectious diseases. After the creation of WHO, 12 of these conventions and agreements, still in force by that time, were consolidated into the International Sanitary Regulations (1951), the predecessor of the International Health Regulations adopted in 1969 (themselves amended gradually and then revised into their current version of 2005). Why then does the idea of a new treaty to fight the spread of dangerous pathogens create so many questions? There are critical differences to take into account.

First, the "early" conventions addressed then well-known specific diseases (cholera, plague, yellow fever, typhus, smallpox and relapsing fever), while a pandemic treaty would largely address events of fast emerging and potentially unknown and unforeseen origin. Second, a predominant focus of the "early" conventions was the possible spread of infectious diseases from the East and the South westwards and northwards, through the international routes of trade and travel, something too narrow—and in fact obsolete—when applying to pandemic risks and geopolitical realities of the 21st century. Third, they were negotiated by much smaller number of countries and very different power constellations. Fourth, while the "early" conventions were the dominant, if not the sole, source of international law on infectious diseases, a pandemic treaty would need to be embedded in—and largely influenced by—existing international law relevant to health, particularly human rights law, trade law and environmental law, all products of the post-WW2 international order.

12. Can the experience of the FCTC, the WHO's only convention so far, help?

The WHO Framework Convention on Tobacco Control (FCTC) is the first—and only—global convention negotiated and adopted under the auspices of WHO; as such it is widely recognized as having opened a new legal dimension in international health cooperation. Some lessons from the FCTC

may indeed be noteworthy when considering a future health treaty.

Process-wise, the FCTC "unlocked" the WHO's treaty-making power embedded in its Constitution but never previously used, and showed a binding convention in global health was indeed feasible. It also became one of the most rapidly and widely embraced treaties in the UN system, with 40 ratifications (the threshold for entry force) achieved within 18 months after the adoption and with a total of 182 Parties to date.

Content-wise, the FCTC turned several key, but usually challenging public health features into legally binding obligations: a national coordination mechanism, a uniform reporting system, transfer of knowledge and technology, and protection from the undue interests of industry. It also showed the feasibility of working with non-health sectors within an international legal system, the feasibility of negotiating further protocols and guidelines promptly, and the power to safeguard the interests of health in the face of conflicting agendas and legal disputes in countries and internationally. These lessons may inform future legal frameworks in health, including in relation to pandemic preparedness and response. Tobacco use is, after all, often referred to as a pandemic.

13. The history of environmental treaties—can it inform a prospective pandemic treaty?

There is a wealth of experience in initiating, negotiating and implementing multilateral treaties in the area of environmental protection that might be of interest in the context of a possible pandemic treaty. Factors which triggered negotiating a treaty might be of particular relevance. The history shows that such triggers varied from compelling scientific data (common to most environmental treaties) to global catastrophic threats (such as in the case of the climate conventions) or other developments of potentially disastrous effect (such as in the case of the Stockholm Convention on Persistent Organic Pollutants and the Minamata Convention on Mercury). Agreement has been easier to achieve when the danger posed has been widely understood by experts and the public alike. In some cases, treaties succeeded non-binding instruments such as recommendations and guidelines which were deemed insufficient after some years in use (e.g., in the case of the Nagoya and Cartagena[4] Protocols to the CBD) or were adopted to address an urgent issue while commencing treaty negotiations at the same time (as for example in the case of the Basel Convention)[5]. Also of interest are the different modes of treaty initiation and negotiations, examples of leadership by individual or groups of countries, roles played by international organisations and expert bodies etc. More

4 Cartagena Protocol on Biosafety to the Convention on Biological Diversity

5 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

details of experiences from environmental treaty negotiations potentially valuable for a prospective pandemic treaty can be found in the policy brief[6] prepared in the frame of this project.

14. What is known about key factors influencing treaty effectiveness?

There is no standard formula in international practice and literature for determining whether a given multilateral instrument will be effective, and treaty effectiveness itself does not yet enjoy a widely-accepted definition. Nevertheless, given the large number of treaties and other international legal instruments already in existence, some judgments about factors that are conducive to success and issues that may detract from positive outcomes can be reached.

A policy brief[7] prepared in the frame of this project draws upon existing research in international law, international relations and regulatory theory to provide an overview of considerations that should be weighed in deliberations on such an instrument. The paper analyses a group of specific factors towards determining (and anticipating) treaty effectiveness.

The factors proposed and analysed relate to: political support, ratification, drafting and clarity, governance arrangements, regulatory design, synergies and compatibility, scientific data, financing globally and at national level, compliance mechanisms, strategic treaty management, indicators, evaluation, community of practice, global governance mobilisation, and justiciability. Such an analytical framework could potentially inform current and future discussions on a pandemic treaty. In the PPR context, lessons learned from implementation of and compliance to the IHR (2005) before and during COVID-19 would be of additional importance.

6 https://www.graduateinstitute.ch/sites/internet/files/2021-10/PolicyBrief1.pdf

7 https://www.graduateinstitute.ch/sites/internet/files/2021-10/GHC_PolicyBrief2.pdf

15. What is a typical structure of a treaty?

Many treaties have a similar structure, which can be outlined as follows:

- Introductory part: Preamble, objectives, definitions, scope of the treaty
- General provisions: Guiding principles, general obligations, elaboration of national plans and strategies
- Special provisions: Core substantive obligations
- Sharing of information, technology and resources: International cooperation, information exchange, technical assistance, technology transfer, capacity building, funding
- Institutional and legal provisions: Treaty bodies, financial mechanism, compliance, settlement of disputes, relationship with other treaties
- Procedural provisions: Adoption of protocols, amendments to the treaty, right to vote, signature/ratification/entry into force, reservations, withdrawal

Where a treaty is legally linked to another treaty (e.g., in the case of a protocol to the parent convention) the relevant features of the parent treaty, particularly those of institutional and procedural character, generally apply also to the linked treaty, with amendments and changes as dictated by the subject matter of the linked treaty.

16. What issues have been proposed for the pandemic treaty to cover?

Measures proposed so far in different forms and fora aim at addressing both the gaps and weaknesses in the current international normative framework for PPR. The proposals span a large spectrum of issues, from notification, information sharing and international travel and trade-related measures—areas already covered (but largely seen as inadequate) in the IHR (2005), to reducing the pandemic risk of zoonotic spill-over and reshaping global financing of PPR—areas where some forms of international cooperation, but not yet binding rules, exist.

The issue of rapid and equitable sharing of pathogens and genetic sequencing data—not covered by the IHR (2005) but closely linked to the Nagoya Protocol—attracted considerable attention. Calls were also made for establishing a science-policy interface for PPR, by analogy with the IPCC. Independent reviews recommended to adopt a more practical formulation of travel measures currently in the IHR (2005), and to review the international coordination of travel and border restrictions in preparation for the next pandemics.

The need for enforceable compliance and accountability rules were mentioned in most reviews. Opinions also included the need for the treaty to define the term "pandemic", currently absent in the IHR (2005).

As of cross-cutting issues, points were raised concerning the human rights, intersectoral and development dimensions of a prospective treaty. Linkages to environment policies and One Health were consistently emphasised. Proposals concerning the supply of and equitable access to vaccines and other essential products and technologies underscored linkages to international trade and intellectual property rules. Proposals also referred to an overall strategy towards strengthening the WHO's capacity in relation to PPR.

Issues raised less often, but nevertheless attracting attention, include preparedness of health systems beyond public health capacities covered in the IHR (2005), and issues around social and economic response to support health action and outcomes. These aspects are covered under Q18 and Q19, respectively. A proposal was also made to rethink the paradigm of global health security to focus on "security of people not borders".

If eventually negotiated, the treaty would also address issues around international cooperation and assistance, as well as institutional and procedural matters (such as entry into force, treaty bodies, budget, reporting, amendments and dispute settlement) normally in the matrix of multilateral treaties (more on this under Q15).

17. How could the treaty address the One Health approach?

The One Health approach would bring a new, preventive dimension in confronting pandemics, not covered by the existing international system. Measures to better prevent, detect and respond to pathogen spillover from animals to humans stand high in current discussions. This would not be satisfactorily achieved through the interagency cooperation provisions of the IHR (Article 14), as it has been argued, nor would it reasonably fall under the scope of Article 21 of the WHOC. Interagency cooperation will require tools commensurate to the magnitude of the challenge. Legal re-

gimes linked to the work of FAO, OIE and UNEP, the WHO's One Health partners, in areas of wildlife trade[7], biodiversity[8] and land use[9] are important in a pandemic context but nevertheless lack a health purpose. A pandemic treaty could create the necessary bridges to those treaties to which all or a majority of WHO's Member States, are already parties to—an easier and coherent approach (and likely of interagency interest given the global multisectoral challenge), compared to amending the existing treaties to accommodate pandemic prevention (indeed under discussion in some expert circles). A treaty could also establish the needed legal umbrella for the closely linked issues of pandemic risk intelligence and assessments, as well as multisectoral action.

18. Would the treaty also address resilience of health systems beyond public health capacities?

Most national health systems, including those generally ranked as high-performing, came under extreme pressure during COVID-19. The shock caused to healthcare supplies, services and workforce shattered health outcomes in most countries, threating also the progress towards UHC. The IPPPR report concluded that "health systems and health workers were not prepared for a prolonged crisis". The IOAC report, in turn, emphasized that "ensuring delivery of an essential package of health services with sustainable funding is a key priority". The issue of resilience of health systems in PPR may therefore attract attention in future debates. After all, resilience is a core concept in disaster risk reduction that may also apply to the risk posed by pandemics.

From discussions so far it sounds likely that at least one element of health systems resilience—the availability of and access to essential vaccines, diagnostics, medicines and equipment would find its place in treaty negotiations should they eventually take place. However, critical challenges faced by health systems included also the other components of WHO's health systems framework, namely health services, and hospital capacity in particular; health workforce, including issues around capacity and protection; and governance and financing, including the coordination between primary and hospital services. Promoting resilient health systems to ensure pandemic preparedness, and ensuring the continuum and provision of essential health services in emergencies, including through international cooperation, are key provisions called upon by the watershed UN Political Declaration on Universal Health Coverage (2019)[10].

8 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITIES)

9 Convention on Biological Diversity (CBD)

10 United Nations Convention to Combat Desertification (UNCCD)

Going by experiences of other international legal frameworks, two groups of provisions might be given consideration. First, the treaty could establish minimal requirements for national healthcare service capacities as part of pandemic preparedness, by analogy with the core public health capacity requirements in the IHR (2005). Second, the treaty could contain provisions on mutual assistance, a frequent feature in international law, including in relation to emergencies; this would include, at a minimum, the right (by some legal opinions—even an obligation) of a Party to request assistance in times of crisis when the harm caused by a pandemic drastically exceeds its national capacity.

19. Would the treaty also address social and economic response?

This issue is underdiscussed in both expert and policy circles and it may be perceived as standing outside of the health mandate. Meanwhile, such measures (aimed at social and job protection, minimal income security, fiscal stimulus etc.) may be important in pandemics, for example to strengthen adherence to public health measures and to minimize the impact of social and economic disruptions on national health outcomes. It remains to be seen whether this peculiar aspect of pandemic response would eventually be discussed in the context of a pandemic treaty or other legal regime. Some international instruments, and particularly the Sendai Framework for Disaster Risk Reduction (2015) provide valuable examples in addressing both health and the livelihoods in emergencies. The UN framework for the immediate socio-economic response to COVID-19 (2020) is another important reference.

20. Which global financial mechanisms are being proposed and how they would relate to a pandemic treaty?

It is widely acknowledged that sustained, sizable and predictable financing will be critical to global PPR. Experts noted that the existing global mechanisms—WHO's Contingency Fund for Emergencies, the World Bank's Pandemic Emergency Financing Facility, and CEPI proved to be too small in the face of the unprecedented challenge of the current pandemic.

Several proposals for a stronger global financial mechanism are currently on table. The IPPPR recommended to create an International Pandemic Financing Facility, overseen by the proposed Global Health Threats Council. The Facility would raise USD 5–10 billion to support preparedness work globally, and issue USD 50–100 billion in bonds for response activities once a pandemic strikes. The UK-led Pandemic Preparedness Partnership's (PPP) proposal for the G7 Summit, too, contained a call to establish a new PPR facility.

The HLIP, an independent panel under the auspices of the G20, recommended to establish a Global Health Threats Fund, with a G20-centred Global Health Threats Board to provide financial oversight to it. The Fund would raise and manage USD 10 billion a year towards global public goods for PPR, with another USD 5 billion a year allocated directly towards strengthening the WHO and other existing institutions. The Panel also recommended, inter alia, making financing of global public goods and fast track funding for PPR part of the mandate of the World Bank, IMF and other IFIs; and allocating sizeable funding towards pandemic prevention in line with One Health, in addition to "traditional" PPR.

Generally, the HLIP's proposal appears to be accentuating preparedness (including prevention), while the PPP's proposal — response and the IPPPR's proposal — both. As for channelling the funds into day-to-day PPR, all three commissions seem to prefer utilizing the potential of existing implementing institutions (such as the Global Fund, GAVI, CEPI and the World Bank) rather than creating new ones or locating them with WHO. The support to WHO and its health emergencies program remains generally unclear.

How the proposed financial mechanisms would relate to the prospective pandemic treaty has not been discussed in length. From international practice, treaties can rely on an existing mechanism (for example, the Global Environment Facility (GEF) serving several environmental treaties), or create their "own" mechanism (for example, the "Ozone Fund" under the Montreal Protocol), or both (for example the UNFCCC with the "Green Climate Fund" as its main financial mechanism, complemented by climate change adaptation funds under the GEF). These and similar experiences could be useful to consider, along with the abovementioned and other possible proposals, when designing a global financial mechanism for PPR under, or linked to, a prospective treaty.

21. Which compliance and monitoring mechanisms in other international treaties could be looked at?

Issues around compliance, reporting, monitoring and accountability draw heightened interest in current discussions. A possible peer and/or expert review mechanism, by analogy with the human rights treaties, and taking into account the unfolding universal periodic reviews under the IHR (2005), captured special attention. Meanwhile, confronting pandemics would also require binding mechanisms for monitoring and verifications, due to the high level of unpredictability as to when and where pandemics may originate, the exceptional speed they spread, and the very high degree of inter-dependence between countries in preventing and responding to them. Periodic reviews, if made obligatory, would suite assessing preparedness, whereas assessing response would require more robust mechanisms. Expert also suggested that the prevention of pandemics would require agreed mechanisms to overcome obstacles of national sovereignty to monitor disease threats and

investigate novel pathogens independently.

This may lead countries to discuss additional mechanisms, such as external reviews, site visits and investigations. As international practices show, periodic external reviews can be a prime mechanism of monitoring (as for example in the case of the UNCCC and the ILO conventions) or can complement periodic peer-reviews (as in human rights treaties) to further independence and transparency. Site visits, to support compliance and investigate issues of concern, are usually defined in the treaty or a specialized protocol to it, with further refinements possible by the respective governing body; they can be designed to take place with (in most cases where such visits occur) or without (i.e., under the nuclear non-proliferation, chemical weapons and the prevention of torture conventions) a prior consent of the respective state. Monitoring committees, expert teams, special rapporteurs, inspectors, complaint procedures, conciliation commissions and special review meetings are some of the models used under different treaties. The above mechanisms could potentially inform discussions for compliance and monitoring mechanisms under a pandemic treaty.

A recent review of relevant international practices by the United Nations University concluded with a proposal for key design principles for review and investigation mechanisms potentially applicable to pandemics. They include, inter alia: ensuring political and financial independence; aiming at prompt access to sites and information; triggering high-level state — not health ministry alone — response in cases of concern; and motivating states to conduct reviews and grant access to investigations. Overall, they would aim at identifying — and helping to remedy — domestic shortcomings in the face of a common global challenge.

22. Would the treaty establish a science-policy platform?

A science-policy platform may indeed be important given the complexity of issues involved in PPR and to ensure that that constantly evolving science and evidence can inform policy solutions.

Two existing models could be taken into consideration. In a first model, the relevant bodies exist outside the treaty machinery for full independence, informing, nevertheless, the development of international law in the respective areas. Two prominent examples include the IPCC, established by WMO[11] and the UNEP in 1988 (before the adoption of the UNFCCC), and the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), established by the UNEP in 2012. In a second model, a subsidiary body is established by the treaty itself, as for example the

11 Political Declaration of the United Nations High-level Meeting on Universal Health Coverage: "Universal health coverage: moving together to build a healthier world" (2019)

Subsidiary Body for Scientific and Technological Advice under the UNFCCC, which informs and advises the COP on science and technology matters relating to the Convention, including, importantly, those drawn from the IPCC reports.

In the case of a pandemic treaty, it may also be important to consider processes already in place, in view of synergy and non-fragmentation. WHO's Secretariat is establishing its International Scientific Advisory Group for Origins of Novel Pathogens (SAGO). Other relevant initiatives include the WHO Hub for Pandemic and Epidemic Intelligence, the WHO's pilot BioHub, and the Global Pandemic Radar, with the support of Germany, Switzerland and the UK, respectively. Calls were also made for an independent panel on pandemic preparedness and response modeled on the IPCC.

A science-policy body under the prospective treaty might be the interface linking the treaty to these and future similar mechanisms, to ensure the Parties and the COP are advised on science and technology advancements relevant to the development and implementation of international rules and guidelines under the treaty.

23. What are the issues that a treaty could resolve beyond the IHR?

Issues of political, legal, institutional and multisectoral nature that a treaty under Article 19 of the WHOC could resolve beyond the scope of the IHR (2005) are mentioned under Q4. This section therefore focuses on "subject-based" matters of transboundary impact highlighted by independent committees and experts as requiring solution.

Such issues might be those not reasonably falling under the scope of Article 21 of the WHOC for Regulations, the only other type of legally binding instrument in the possession of WHO; and/or those partly regulated by other multilateral treaties to which synergy with, and a treaty-format adaptation to, would be necessary.

Drawn from the above considerations, subject-based matters that a new treaty could resolve beyond the scope of the IHR (2005) could be the following: reducing the risk of zoonotic spillover in line with One Health; access and benefit sharing in relation to pathogens and genetic sequencing data; supply of and access to vaccines and other essential products; travel regulations specific to peculiar conditions of pandemics and above those contained in the IHR(2005); legal backup to global financing; preparedness of health services beyond public health capacities; mechanisms of treaty compliance, including monitoring, verifications and investigations; and declaring public health emergency of pandemic potential. Social and economic countermeasures could be another such area should countries decide, in principle, to address this peculiar aspect of pandemic re-

sponse. The first three of the above issues indeed stand high in current discussions for a treaty or other instrument on pandemics, while others attracted lesser, in some cases marginal, attention. More on some of these issues can be found under Q17–21, Q24 and Q27.

The treaty may also cover other substantive issues depending on whether the IHR(2005) are revised in parallel. Countries may consider a treaty to target issues specific to pandemic threats, not to international spread of disease in general.

24. What would trigger the response measures under the treaty to unfold?

The treaty should define the term "pandemic" (also possible via amending the IHR (2005), and to establish a mode for declaring a public health emergency of pandemic potential (PHEPP). The latter would be impractical via an amendment to the IHR (2005) as it needs to come into force simultaneously with the other response provisions of the treaty, and in addition it would create a two-layer emergency declaration mechanism under the same instrument given that the IHR (2005) already contains provisions for Public Health Emergency of International Concern (PHEIC).

In the same time, independent committees pointed to the insufficiency of the PHEIC mechanism, particularly in the context of pandemics. The RCFIHR emphasized the need of differentiation between the declaration of a PHEIC and the characterization of a pandemic, and the need for clarity about actions required after a PHEIC is actually declared. On a similar note, the IOAC noted that "the broad binary nature of the PHEIC mechanism does not provide a sufficient or actionable indication to Member States of the nature or severity of epidemic and pandemic risks", and that the temporary recommendations that follow "must be tied to a set of concrete actions and response measures …". The treaty could entrust declaring PHEPP to the WHO Director General through a mechanism established in a treaty. In turn, declaring PHEPP would automatically unlock the response measures under the treaty.

25. Which features from other international treaties could potentially be utilized?

The UN-system treaties contain valuable features that could be consulted/utilized. Examples include provisions on: cross-sectoral measures when responding to large scale global risks (e.g. the UNFCC); notifications on incidents potentially affecting other states (e.g. the Cartagena Protocol, the Conven-

tion on nuclear accidents[12] and the Basel Convention); cooperation in legal proceedings and law enforcement (e.g. the Convention on Transnational Organized Crime, the Protocol on illicit trade in tobacco products[13], and the Convention Against Torture[14]); mutual assistance (many treaties), including assistance on accidents response (e.g. the convention on assistance in nuclear emergency[15]); technology transfer (e.g. the UNFCCC); financial mechanisms (see examples under Q20), and mechanisms for reporting and monitoring, including universal periodic reviews (human rights treaties) and special review meetings of the treaty's governing body (e.g. the Convention on Nuclear Safety).

There is also wealth of experience accumulated in relation to various compliance mechanisms, including compliance bodies (e.g., most environmental treaties), investigations (e.g., the CRPD) and inspections and verifications (e.g., treaties in areas of arms control, nuclear safety and torture prevention). In some cases (e.g., conventions on disability and torture) specific compliance measures are agreed through optional protocols, negotiated either in parallel to[16] or after[17] the completion of the parent convention. Experiences around compliance and monitoring are also described under Q21.

Linkages to other international treaties are also explained in various other parts of this Guide, in their respective contexts.

12 World Meteorological Organization

13 Convention on Early Notification of a Nuclear Accident

14 Protocol to Eliminate Illicit Trade in Tobacco Products (to the WHO Framework Convention on Tobacco Control)

15 Convention against Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment

16 Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

17 Optional Protocol to the UN Convention on the Rights of Persons with Disabilities

RELATIONS WITH OTHER INTERNATIONAL INSTRUMENTS

26. How would a pandemic treaty relate to the existing IHR (2005)?

From a legal perspective, and as of common practice in international law, the treaty may include a provision on its relationship with other international instruments, including clarifying that the treaty would be interpreted and applied to be compatible with, and complementary to, the IHR (2005). A reciprocal provision concerning compatibility with other relevant international agreements is already contained in the IHR (2005), in its Article 57.

From the perspective of application on the ground, the "all hazards" approach of the IHR (2005) seems well suited for most causes and events of international spread of disease, such as outbreaks of various intensity and coverage, natural disasters, chemical and nuclear accidents etc. Pandemics however are special in their speed and magnitude of spread, the scale and scope of disruptions caused, and often their origin, hence the ongoing discussion for a dedicated instrument, potentially a treaty, focused on pandemics.

A pandemic treaty could follow on from the IHR once the international spread of disease reaches pandemic potential and is formally declared as such by modalities agreed in the treaty; it would then trigger measures to prevent the event reaching pandemic proportion, and to respond should prevention and containment fail. The treaty and the IHR could therefore be complementary, not competing, to follow a principle "one instrument at a time" during a particular outbreak. Overlaps may also be avoidable in the pre-response stages, as the treaty's proposed prevention component is absent or marginal in the IHR (2005), and its preparedness component could only aim at areas not covered by the Regulations (such as health service capacities beyond surveillance and public health, a pre-negotiated platform for development and supply of vaccines and other essential products, and access to agreed financial mechanisms and resources "both for investmemt in preparedness and to be able to inject funds immediately at the onset of a potential pandemic" as recommended by the IPPPR).

The IHR thus would maintain their central role in preventing and controlling the international spread of disease in various types of health emergencies. They would then "hand" this role to the prospective treaty once such spread is formally declared as having reached a pandemic potential.

27. How would the treaty relate to the Nagoya Protocol[18] and the PIP Framework[19] on issues of access and benefit sharing?

Access and benefit sharing (ABS) is one of the highly discussed topics within the context of a pandemic treaty. The IHR(2005) only remotely encompass the issue. Their Article 6 (notification), Article 44 (collaboration and assistance) and Article 46 (transport and handling of substances and materials) seem only loosely linked to, and not used in practice, in relation to access and benefit sharing. Member States of WHO later adopted a dedicated instrument in this area, the PIP Framework (2011). The Framework is not a legal instrument but it comprises a valuable compulsory mode for virus and benefit sharing that applies to both public and private actors (albeit covering pandemic influenza viruses only).

The Nagoya Protocol (NP) on access and benefit sharing, which entered into force in 2014, broadened the legal base of the subject area, but appeared to be creating challenges when applied to public health, not least due to uncertainties of applicability to human pathogens, bilateral rather than global/multilateral approaches in ABS, and the resulting patchwork of national laws not always consistent across countries due to significant flexibilities provided by the NP.

A prospective pandemic treaty could potentially resolve those issues by specifying and streamlining ABS measures pertinent to pandemics, and by extending the scope employed in the NP to cover also GSD in addition to pathogens. Incorporating ABS measures in the prospective treaty would be in the spirit of Article 4.4 of the NP stating that the Protocol will not apply to genetic resources covered by specialized international ABS instruments; this would likely prevent conflict between the NP and a pandemic treaty should the latter embrace ABS as part of PPR.

Extending the scope of the PIP Framework to cover all types of pandemic pathogens through a new annex in the IHR (2005) is an alternative proposed in some expert circles. Such scenario might need to be weighted against potential difficulties to achieve synergy between the different instruments, due to the very loose connection of the IHR(2005) to ABS, different approaches to ABS in the NP and the PIPF, and the uncertainty whether such annex would qualify as a specialized international instrument in the context of the NP. In a related case, the PIP Framework (2011) was negotiated as a stand-alone instrument, not in the frame of (and not stemming from) the IHR (2005).

The pandemic treaty may nevertheless benefit from the global and public-private sector coopera-

18 Optional Protocol to the Convention against Torture and Other Cruel, Inhuman and Degrading Treatment or Punishment

19 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

tion approaches in the PIP Framework. Whether it might also replace the PIP Framework, through for example a specialized Protocol establishing universal ABS procedures for all pathogens of pandemic potential, can possibly be discussed in parallel with negotiations of the parent treaty or once the treaty is in force.

28. Which other international treaties to look at for synergy?

The negotiations on a future pandemic treaty would have to take into consideration the existing scope of applicable international law. Relations with and applicability of legal regimes in health, environment, security, disaster response and other areas are discussed under Q12–14; Q17, Q21, Q25, Q27. Calls have also been made to harmonize the proposed treaty with relevant legal regimes in trade, intellectual property, human rights and related areas.

In the area of trade, discussions have taken place on the degree of flexibility available to states under the TRIPS Agreement[20] and the Doha Declaration[21]. The TRIPS Agreement provides for the protection of Intellectual Property (IP) by members of the WTO. The 2001 Doha Declaration has reaffirmed a degree of flexibility available to WTO members in granting compulsory licenses, including but not limited to situations of public health crises. The COVID-19 pandemic has resulted in calls to suspend certain provisions of the TRIPS Agreement by means of a temporary IP waiver, to clarify the scope of flexibilities available in relation to medicines, vaccines, diagnostics and other related technologies and materials. A pandemic treaty would need to address the issue of financing innovation and access to technologies in the peculiar supply and demand conditions of pandemics in light of the existing international trade and IP law. Issues related to application of certain provisions in health emergencies, such as import/export bans and restrictions, may also arise in the context of the TBD and SPS agreements of the WTO[22].

In the area of International Human Rights Law, the relevant legal frameworks include the ICCPR, as well as domain-specific conventions.[23] Under Article 4 of the ICCPR, any derogation to human rights obligations found in the Covenant must be founded upon the existence of a "public emergency which threatens the life of the nation". The Siracusa Principles,[24] which provide an authoritative

20 Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

21 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) in particular Arts. 30 & 31

22 Declaration on the TRIPS agreement and public health (2001)

23 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Articles 2-3; and Agreement on Technical Barriers to Trade (TBT Agreement), Articles 2 & 5

24 International Convention on the Elimination of All Forms of Racial Discrimination (ICERD; Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); Convention on the Rights of the Child (CRC); Convention on the Rights of

statement of standards applicable in the event of emergency, further clarify that measures which restrict enjoyment of human rights must be prescribed by law to respond to a "pressing public or social need" while conforming to the principles of necessity and proportionality. Finally, the workers' rights are also human rights. The prescription of emergency measures limiting the enjoyment of social, economic and cultural rights would have to accord with the conditions set by the Art. 4 of the ICESCR and with the applicable ILO Standards.[25]

Persons with Disabilities (CRPD)

25 UN Commission on Human Rights: The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights, 28 September 1984, E/CN.4/1985/4, available at: https://www.refworld.org/docid/4672bc122.html

BEFORE THE SPECIAL SESSION OF WHA

29. What is the work expected until the special session of WHA in November 2021?

The principal preparatory work lies with the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies. The 74th World Health Assembly held in May 2021 requested the Working Group to prioritize the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response and to provide a report to be considered at the special session of the WHA in November. The Working Group, led by a geographically representative Bureau (Botswana, France, Indonesia, Iraq, Singapore and the United States) met in July and September 2021 and will convene further meetings to prepare its report. The WHO Secretariat provides the necessary support to the WG.

Several mechanisms and events, linked to or otherwise important in view of the special session, are unfolding in parallel. A high-level discussion has taken place at the UN General Assembly in New York on 22 September 2021. At the G20 level, health ministers met under the Italian Presidency in early September, with important discussions expected in Rome also in October, first at the joint meeting of finance and health ministers (expected to review, inter alia, the report of the HLIP, the independent panel on financing), followed by discussions at the G20 summit. The Group of Friends of a pandemic treaty, comprised of countries from all WHO regions, continues its work in Geneva. Also active is the Group of Friends of Solidarity for Global Health Security in New York.

The GPMB, the first of international bodies that called for a UN summit and a new international framework for PPR in Sep 2000, has recently reaffirmed its support for a new legal framework. The IPPPR, which delivered its main report in May 2021, has briefed a UN General Assembly informal meeting in July on its recommendations and envisages further discussions at various political fora in autumn.

Work is also in progress in expert and academic circles. The Global Health Centre at the Graduate Institute Geneva is convening a project on options and benefits of a pandemic treaty, aimed at assisting countries with knowledge and analysis ahead of the special session of the WHA and poten-

tially beyond (see more under the Introduction). A project on legal tools for pandemic preparedness is in progress in the O`Neill Institute for National and Global Health Law at Georgetown University, USA. The Panel for a Global Public Health Convention, a coalition of global leaders and experts, has been reaching out high-level figures and senior decision makers across the world for a treaty and lasting positive change in global PPR. Discussions on a pandemic treaty/instrument are scheduled at the European Health Forum in Gastein in late September and at the World Health Summit in Berlin in late October 2021

30. What concerns were raised so far?

From a **political** perspective, concerns were raised that embarking in negotiations to confront future pandemics may detract attention and resources from fighting the current one. Some authors noted that a treaty process is usually slow while strengthening mechanisms for PPR is urgent. Concerns were raised that various proposals on a treaty content do not touch sufficiently issues around social and economic countermeasures and issues of equity, and more generally that the proposed treaty should not be perceived as primarily a high-income countries initiative and needs to be appealing to countries in different levels of development. Some civil society groups raised a concern that a treaty on preparedness and response would mark a political shift to health security and this should not be done without at the same time strengthening UHC. Another issue often raised by civil society is, that so far, the discussions were primarily driven by Member States and academia, however, not by the broader society and civil society, as e.g. the climate change treaties (see also Q3 and Q35 on related issues).

From **institutional** perspective, questions were asked whether a WHO treaty would be able to sufficiently address issues outside the health domain such as trade, supplies, transport, finance, social protection, law enforcement etc, or instead a treaty under broader UN auspices should be the answer. Concerns were also raised that a treaty under Article 19 of the WHOC, with countries joining the treaty individually over time (and some perhaps not at all), would bring to a two-track situation when all Member States of WHO are parties to the IHR but only part of them to the new treaty. Possible difficulties with ratification in countries, and whether the prerequisite number of ratifications required for the treaty's entry into force can be achieved speedily enough are another issues capturing attention. A related concern is that a treaty governed by a body separate from the WHA (a COP by most international practices) would weaken WHO's authority in health emergencies. It has been noted that the international system on health emergencies is already fragmented (various committees, boards, networks and partnerships, most with membership of or even co-chaired by WHO but actually independent in their operations), thus new proposals, including the one for a pandemic treaty, need to be looked at for their consolidation potential.

From **legal and technical** perspective, views were expressed, inter alia, that proposals towards using precautionary principle in ordering strict public health measures and those concerning "digitalized surveillance" and "infodemic management" to be examined for their compatibility with human rights law. Questions were asked whether countries will be able to agree on strict compliance and accountability measures without compromising on other substantive obligations, something crucial for a treaty to be potent and to stipulate global adherence in the same time. Some authors are of the view that deficiencies of the current system could be easier addressed by amending and/or interpreting the IHR (2005), and that even if negotiating a new instrument is the path chosen it then should take place under Article 21 (regulations) rather than Article 19 (conventions and agreements) of the WHOC.

AT AND AFTER THE SPECIAL SESSION OF WHA

31. What does a typical multilateral treaty process consist of?

A process for a multilateral treaty typically involves preparatory work, negotiations, adoption, signature, ratifications and entry into force. A formal decision of the respective governing body (the WHA in this case) to embark into negotiations would kick off such process. The decision would normally involve establishing an intergovernmental negotiating body open to all Member States to draft and negotiate the intended treaty. Preparatory work to precede negotiations frequently includes an expert level intergovernmental process to review available information and evidence and develop draft elements of the intended treaty which the subsequent negotiations would build on.

Intergovernmental negotiating bodies frequently require several sessions to meet to agree on a text to be submitted for adoption. There were for example five negotiating sessions over approx. 1–1,5 years in the case of the UNFCCC, the Basel Convention and the UNCCD[26] and six negotiating sessions over approx. 2,5 years in the case of the FCTC and the CRPD[27]. Remarkably, it took less than 5 months for countries to negotiate and adopt the two interrelated conventions[28] on notification and assistance in nuclear emergencies in the aftermath of the Chernobyl tragedy in 1986.

Adoption of a treaty takes place by, or under the auspices of, the governing body under whose authority the negotiations have taken place. The UNFCCC and FCTC were adopted by the UNGA

26 Examples include the Nursing Personnel Convention and Recommendation (1977); Social Protection Floors Recommendation (2012); Employment and Decent Work for Peace and Resilience Recommendation (2017)

27 UN Convention to Combat Desertification

28 Convention on the Rights of Persons with Disabilities

and the WHA, respectively. Some other treaties in the UN system were agreed by diplomatic or other high-level conferences under the auspices of the UNGA.

Details with respect to further stages of a treaty process, namely signature, ratifications and entry into force, are presented under Q36.

32. Which process could the special session of WHA initiate should a treaty option be chosen?

The resolution of the 74th WHA requests the Director General "to convene a special session of the WHA in November 2021 … with an agenda … dedicated to considering the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response *with a view towards the establishment of an intergovernmental process* to draft and negotiate such convention, agreement or other international instrument …". This may provide space for the special session to not only prioritize a particular type of international instrument, but to also initiate an intergovernmental process towards the chosen instrument without delay, taking into account the urgency of the problem.

Should the special session choose a convention or agreement under Article 19 of the WHOC as the desired type of instrument, it could then also establish an intergovernmental negotiating body to draft and negotiate such a convention, along with a short preparatory mechanism to support the negotiating body in commencing its work as soon as possible (by analogy with other international treaty processes). Such a decision by the Special Session would save approx. 6 months in the treaty process compared to waiting for the next regular session of the WHA to establish a negotiating body and mechanism. The time saved could even be 12 months should the preparatory mechanism (often a technical intergovernmental working group to prepare draft elements of the convention) be requested to report to the following WHA (as in the case of the FCTC) before the actual negotiations start.

33. Who would negotiate the treaty?

For a WHO treaty the negotiating power lies with its Member States. It is common for governments to form multisectoral delegations, led by senior health and/or foreign affairs representatives, to participate in negotiations. Lower-resource countries, particularly those with small or no permanent missions in Geneva, are generally constrained in the number of delegates, but this may be different in the case of "hybrid" negotiations.

Because of the cross-sectoral nature of most health matters, front-line negotiators are often under pressure to reconcile the views—often conflicting ones—of different sectors. Governments therefore frequently set up national multisectoral (often also multi-stakeholder) coordination mechanisms to support the country's participation to multilateral negotiations. Policy coherence achieved at home frequently proves critical in actual negotiations at the multilateral stage.

It is also frequent for groups of countries to negotiate with a common position and voice, thus combining resources and knowledge in negotiating the often-complex issues for which not every country, particularly the smaller ones, may have the specialized expertise. The detailed preparatory work for different topics may be undertaken by a country that has particular knowledge in the issue, with the other members benefiting from that work thanks to the relationship of mutual trust within the group. It is customary for regional and other group consultations to take place both during and between the negotiating sessions.

34. How could the UN- and wider international system support the treaty negotiations?

The proposed treaty would inevitably touch cross-cutting issues related to, inter alia, trade, intellectual property, finance, technologies, One Health, environment, transport, migration and human rights. The unprecedented challenge posed by pandemics will require broad international and multisectoral consolidation worldwide. It will therefore be important that relevant international organizations and the wider UN-system are involved. Past experiences and some of the current activities and proposals point to various mechanisms that could be utilized.

Going back to the experience of the FCTC, a UN ad-hoc interagency task force on tobacco control was established in the same year as the WHO's process for the framework convention was launched, and in addition, an influential report by the World Bank made an important contribution to negotiations by providing compelling economic arguments for tobacco control. In a later experience, the UNODC[29] and WCO[30] were invited and made important contributions to the negotiations of the FCTC's Protocol to Eliminate Illicit Trade in Tobacco Products.

WHO's current partnerships with the WTO and WIPO[31] on trade, intellectual property and innova-

29 Convention on Early Notification of a Nuclear Accidend; and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency

30 UN Office on Drugs and Crime

31 World Customs Organization

tion aspects of public health, with the World Bank for the Global Preparedness Monitoring Board, with FAO, OIE and UNEP on One Health, and with a number of global health actors involved in the ACT-A, would bring important insights to negotiations. There have been proposals for the World Bank to set lending and performance targets for PPR, and for the IMF to include pandemic preparedness assessment into its existing mechanism of consultations with Member States—measures potentially relevant to a monitoring and preparedness framework under a prospective treaty. The ongoing considerations at G7 and G20 level provide additional political momentum.

Various recent committees and panels, along with supporting the proposal for a pandemic treaty, called also for a UN special session or summit and a Political Declaration to commit transforming PPR. Such mechanism could indeed provide strong political back up to a prospective treaty should states decide to negotiate one. In the past, UN high level conferences on environment, human rights, women, population and climate, among others, elevated the public and political profile of these global issues and prompted sustained international action, including through subsequent or existing treaties.

35. Who else would contribute to negotiations?

It is customary for not only intergovernmental but also non-state organizations in official relations with the host organization to be invited as observers to negotiations. In the case of the WHO, such organizations may include nongovernmental organizations, international business associations and philanthropic organizations. Their participation would be regulated by the WHO's Framework for Engagement with non-State Actors (FENSA).

Nongovernmental organizations (NGOs), including professional networks, played an active role in processes leading to, in particular, environmental and human rights treaties. The role of NGOs was significant also in the process for the FCTC, when they formed a Framework Convention Alliance to support negotiations. Views of relevant private sector bodies are often requested, provided there is no actual or perceived conflict of interest. In the case of a pandemic treaty, a range of industries, from pharmaceutical to international transport, may have important insights to share. The host organization can also, as in some cases in the past, organize hearings before and/or during the process of negotiations, where the interested entities present their evidence, views and positions (without however entering into a debate).

Non-state actors, including NGOs, the private sector and academia, also contribute frequently at the domestic scene, through national multi-stakeholder consultative mechanisms often set up by governments in parallel with and in support of particular multilateral negotiations.

36. What is the process after a treaty's adoption?

The first step is signing the treaty, followed by ratification and the entry into force.
Multilateral treaties are normally opened for signature for a certain period of time (one year in the case of the FCTC, for example). Signature itself doesn't make the state legally bound by a multilateral treaty. It's rather an act expressing the state's willingness to continue the process towards ratification (or other acts as explained below) and it commits the state to refrain, in good faith, from acts that would defeat the object and purpose of the treaty.

Ratification, formally deposited, does constitute consent to be legally bound by a treaty. Multilateral treaties usually designate an international organization and most commonly the Secretary General of the United Nations as depositary. There are also other acts in international practice with the same legal effect as ratification: *accession*, in cases when the treaty is already in force, including when the state didn't previously sign it; *acceptance* and *approval* in some legal systems; and *formal confirmation* in the case of international organizations—all with same legal effect as ratification.

Multilateral treaties enter into force following ratification or acceptance/approval by a requisite number of states, to be specified in the treaty and varying considerably. For example, only 20 ratifications were required for the Basel Convention and CRPD to enter into force, while the number was 40 for the FCTC, 50 for the UNFCCC and the Minamata Convention[32], and 55 for the Paris Agreement. Given the purpose of a pandemic treaty and the high level of interdependence between states in achieving the intended outcomes globally, negotiators might incline towards the higher rather than the lower end of that range.

Treaties can also be revised or amended to reflect unfolding advances in scientific information and technology, and some treaties even comprise built-one provisions to allow Parties to respond quickly to such advances. The Montreal Protocol[33], for example, has undergone seven adjustments and amendments after its entry into force in 1989. Amendments may also concern other aspects, as for example the two amendments adopted to the Rotterdam Convention[34] concerning procedures and mechanism on settlement of disputes and compliance.

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32 World Intellectual Property Organization

33 Minamata Convention on Mercury

34 Montreal Protocol on Substances that Deplete the Ozone Layer (1987)

37. Would the treaty process itself have an impact?

Treaties' principal impact is expected after their entry into force. However, treaties also have anticipatory effect and the treaty process itself is often capable to induce policy change. In the case of the FCTC, for example, many countries started strengthening their tobacco control policies already during the treaty negotiations, often noted as "power of the process".

Policy effects can also be expected in the period between the adoption and entry force. First, many countries do formally sign treaties before considering ratification which is largely seen as expression of interest to comply with the treaty (although not yet legally bound). Second, the process of ratification normally triggers considerable political and multisectoral mobilization in the subject area. Third, for a treaty not yet in force, a state can notify that it would give effect to the legal obligations specified in that treaty provisionally, or can implement certain provisions through pre-existing national law. Fourth, researchers showed that in some cases states start making changes in domestic policies in the period between adoption and ratification to signal their genuine commitment and trustworthiness towards implementing the treaty, thus potentially increasing chances of ratification by neighbouring and other states.

The above mechanisms underline the multidimensional character of treaty effects, including through interim commitments or prior actions, although of course the principal effect would follow the ratification and entry into force.

38. What governance mechanisms must be established should a treaty be adopted?

A Conference of the Parties (COP) is the common type of governing body in most multilateral treaties. The COP meets in its first session as soon as practicable, but normally not later than one year after the entry into force of the treaty. Matters commonly considered at an early stage are, inter alia: adoption of the Rules and Procedure and the financial rules of the COP; decision on budget cycle and adoption of the first budget; outlining areas and timelines of potential protocols, guidelines and similar instruments, particularly in the case of a framework convention; establishing a system of national implementation reports; criteria and arrangement for the participation of observers. One other matter requiring early attention is establishing arrangements for synergy between the COP and the governing body of the host organization (WHA in this case), through, for example, reciprocal decisions of the two bodies.

As a matter of priority, the COP will also a establish a permanent secretariat, to succeed an interim

secretariat usually entrusted to the host organization before the permanent one can be in place. More on this can be found under Q39.

39. What are options for a Secretariat?

There are various models to look at, from integrated to fully autonomous or even as a full-fledged international organization in some cases. One frequent model, used also for the FCTC, is a quasi-autonomous secretariat established within the host organization (WHO in this case), with reporting lines to the head of the host organization on administrative matters and to the COP on treaty matters.

In the spirit of the current attitude towards strengthening the role of WHO in health emergencies, entrusting the permanent Secretariat to WHO (to its health emergencies program, more specifically, which would likely be requested to be the interim secretariat anyway), might be an alternative to consider. Although not common in international treaty practice, this might be justified by the special nature of the treaty's subject area and the close linkages to WHO's overall mandate in health emergencies, including linkages between the prospective treaty and the IHR. In other words, while the governing body of the prospective treaty will need to be separate from the WHA, in view of different membership and governing distinct legal regimes, the secretariat may (as in most practices), but may also not necessarily need to, follow that same logic.

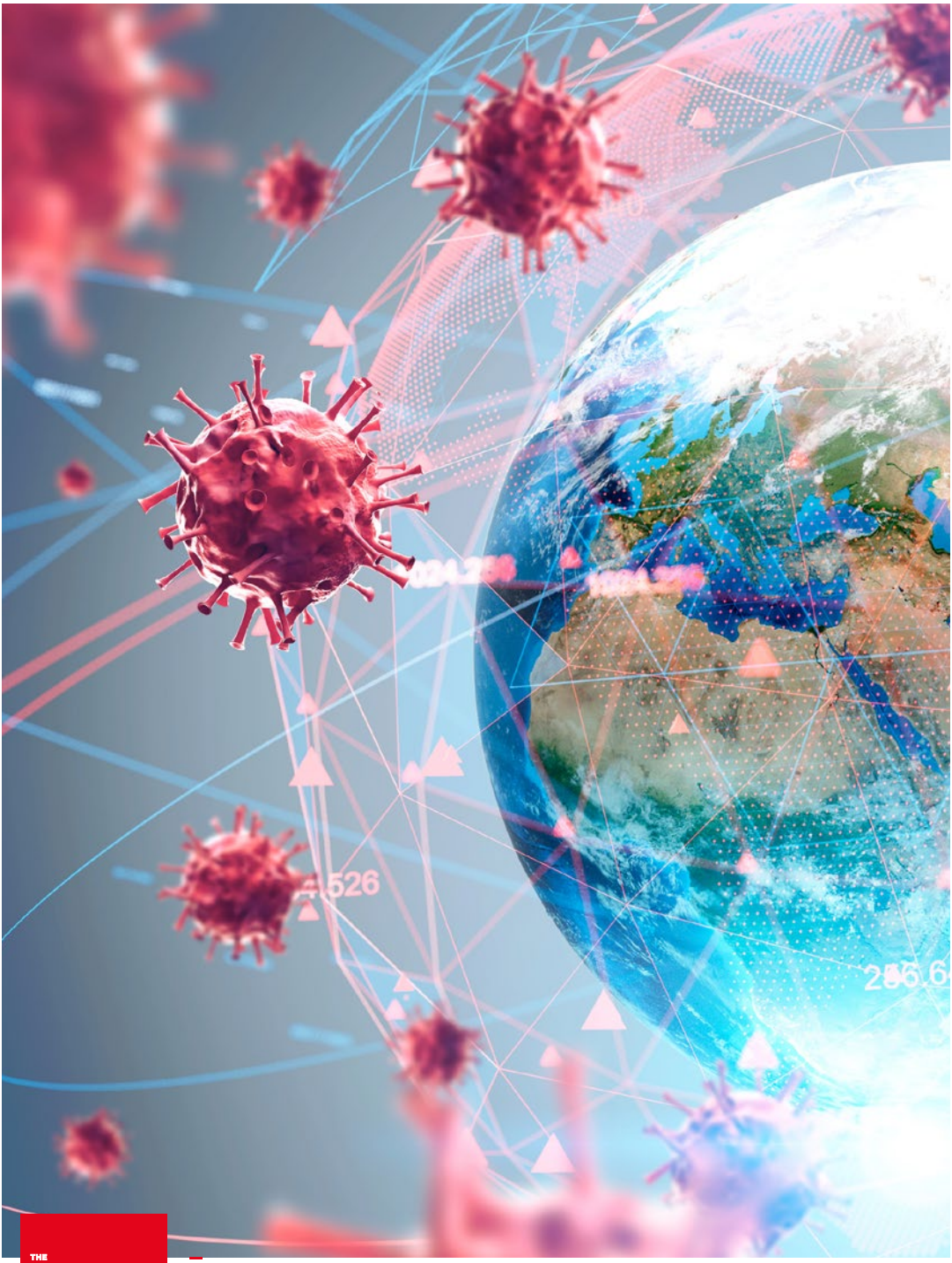
Some existing practices might be useful to look at. One case of the WHO providing services of a treaty secretariat is the Protocol on Water and Health[35], to which the WHO's Regional Office for Europe and the UN Economic Commission for Europe jointly serve as Secretariat. Examples of secretariats serving more than one governing body with different membership (although not exactly a COP along with the governing body of the parent organization), include, among others, the joint Secretariat of the Basel, Rotterdam and Stockholm Conventions, serving the three respective COPs engaged in closely related environmental matters; and joint treaty secretariats, including the one of the FCTC, serving governing bodies of the parent convention and the protocol(s) to it.

35 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (1998)

40. How can states that are not a Party participate, contribute to and benefit from a treaty?

It is customary in multilateral treaties that states which are not a party to a convention may attend the public sessions of the COP (often also meetings of its subsidiary bodies) as observers. In the case of the FCTC for example, this provision applies to member states and associate members of WHO, members of the UN or its specialized agencies and regional economic integration organizations which are not a party to the Convention.

Such arrangements provide the opportunity for non-parties to participate in deliberations without right to vote, thus contributing to discussions on matters of global importance that may concern all countries irrespective of party-status. The observer status is also often seen as a valuable avenue of keeping in touch with members, bodies and work of the treaty which a state may be on its way of accession. It has also been shown that a state non-party may well legislate and act in conformity with provisions of a treaty, thus utilizing benefits of the internationally agreed standards without being legally bound to them. This is the case for example with the United States in relation with the CBD and some other international treaties.



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