Pathogens and Equity in the Pandemic Treaty - Key Takeaways for Negotiators - 28th July 2023

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Pathogens are essential ingredients to monitor the spread of disease, and for developing and producing the vaccines we use to fight infectious disease. Under international law, pathogens are not a resource freely available for use for the greater good. Instead, countries have sovereign rights over the pathogens isolated within their territories, and access can only be provided with the prior informed consent of the country of origin, subject to mutually agreed terms. Under this international system, access to pathogens should be accompanied by the sharing of benefits such as access to medical countermeasures. Such a system has been presented as a tool to counter global inequality in a pandemic.

In response to the widespread inequity witnessed during the COVID-19 pandemic, Member States of the World Health Organisation (WHO) are currently negotiating a new international legal instrument, intended to prevent pandemics and mitigate associated

inequalities – the Pandemic Accord or the Pandemic Treaty. Negotiations on this Treaty launched in March 2022 and are set to conclude by May 2024; a remarkably short time frame in international law terms.

The new instrument is intended to be grounded in equity, with equity positioned as both an objective and as an operational output. The Pandemic Treaty is intended to prevent future pandemics, improve pandemic response, mitigate associated inequalities (such as inequitable vaccine access), and improve compliance with international law during infectious disease emergencies. One option currently being explored in the negotiations for a Pandemic Treaty to operationalise equity is the establishment of a complex system of ABS for pathogens of pandemic potential, under the auspices of the WHO.

On 19th July 2023, and with the assistance of funding received from the **Royal Society of Edinburgh**, project leads **Dr Stephanie Switzer** (University of Strathclyde) and **Dr Mark Eccleston-Turner** (King's College, London), organised an event with the British Institute of International and Comparative Law on pathogen sharing and equity under the Pandemic Treaty, with a particular focus on vaccine inequity during the COVID-19 public health emergency.

This event was convened by Anthony Wenton, Research Fellow in Public International Law, British Institute of International and Comparative Law (BIICL), moderated by Dr Stephanie Switzer, with contributions from Professor Gian Luca Burci of the Graduate Institute Geneva, Prof Elisa Morgera, One Ocean Hub, University of Strathclyde, Dr Mark Eccleston-Turner, King's College London, Dr Michelle Rourke, Griffith University, Australia and Professor John Harrington, University of Cardiff. Harry Upton of King's College London acted as rapporteur for the event.

In the below briefing document, we provide an overview of discussions at the event,[1] accompanied by **key reflections, tools, and takeaways for negotiators to the Pandemic Treaty**. A video recording of the event can be found here.

[1] Please note that the reflections listed against each participant only reflect their views, and not necessarily the views of other participants.

Key Takeaways for the Pandemic Treaty Negotiators[2]

- Health security versus equity has been a central tension in the negotiations for a Pandemic Treaty, and there is a need for trust and concessions on both sides – these have been sorely lacking in the negotiations so far, but compromise is required to ensure a successful collaborative outcome.
- Pathogen sharing is fundamental to research and development but must be accompanied by equitable access to medical countermeasures such as vaccines. Pharmaceutical companies cannot expect to receive pathogen samples and genetic sequence data free of charge from the Global South and then sell products such as vaccines back to them at unaffordable prices.
- (Pathogen) access and benefit-sharing (ABS) has been offered as a potential solution to both the search for equity under the Pandemic Treaty as access to pathogen samples by the likes of pharmaceutical companies would be tied to the provision of medical countermeasures and other benefits.
- The WHO's *Pandemic Influenza Preparedness (PIP) Framework* has been offered as an example of a multilateral ABS instrument for pathogen sharing and the provision of medical countermeasures. While it has been successful in providing funds for the operation of the WHO's Global Influenza Surveillance and Response System, it is an - as yet - untried and untested benefit-sharing system for the provision of vaccines and antivirals. It is unclear how it will function to provide tangible benefits such as vaccines and other medical countermeasures when it matters; that is, during an influenza pandemic.
- It has been argued that ABS does not appear able to deliver the benefits it promises, and certainly not at the level demanded by global equity. Negotiators need to think beyond ABS.
- Fair and equitable sharing of benefits is a principle of international law which is distinct from ABS. Fair and equitable sharing of benefits cannot be achieved in the absence of trust, dialogue, and partnership with beneficiaries. A focus on defining fairness and equity in the context of an infectious disease emergency has both procedural and substantive dimensions.
- The legally binding human right to science (Article 15 ICESCR) is relevant for the Pandemic Treaty negotiations. It requires acknowledgement of the power dynamics in science, the obligation for States to regulate scientific endeavours to prioritize the needs of the vulnerable, as well as the need to affirm the agency of beneficiaries.

[2] Please note that not all takeaways for negotiators necessarily reflect the views of all participants. This section on key takeaways has therefore been written in accordance with the Chatham House rule.

- The sharing of the benefits of scientific research and development does not need to occur in the form of ABS, and indeed, there are only limited circumstances where ABS would be applicable in scientific R&D.

Summaries of discussions

Professor Gian Luca Burci

Professor Burci used his talk to contextualise the concurrent negotiations of the Pandemic Treaty, as well as the process for revising the *International Health Regulations* (IHR 2005), the latter being the current set of international rules governing international preparedness and response to public health emergencies of international concern and other health risks. Professor Burci argued that throughout the COVID-19 pandemic, fundamental questions have been raised regarding global health governance and leadership. These questions include the distribution of power and control; the level, sources, and sustainability of funding; public versus private authority; respect for human rights obligations and strengthening these where possible and; the need for clearer, stronger, legal obligations in respect of pandemic preparedness and response.

Professor Burci explained that the proposal for a 'Pandemic Treaty' began with the European Union, and a group of so-called 'Friends of the Treaty' from all WHO regions. He explained that there was suspicion early on about the EU's motivation for pursuing a treaty, and several states raised several important questions in this regard, i.e., what was wrong with the IHR and other international instruments that addressed both prevention and response? And more importantly, what could/would/should the content of a treaty be? Furthermore, questions have been raised as whether the WHO was the appropriate forum for such an instrument, rather than the UN for example, given the broad substantive content that was being discussed – from intellectual property rights, animal welfare standards, the human/animal interface – all of which appeared to be more appropriately housed in other UN (as well as non-UN) fora.

Professor Burci stressed that it is **more accurate at this stage to speak of a 'pandemic instrument' than a treaty.** States wish to keep their options open about the status of the

instrument until the last minute, partly as a negotiation tactic, and partly in recognition of the need to appease skeptical states like the United States, who have been reluctant to fully engage with the idea of a treaty since the initial proposal from the EU. Indeed, the United States jump started the process on IHR amendment and reform, partly in response to the Pandemic Treaty negotiations. To this end, several African states, as well as key Asian states such as India, Bangladesh and Indonesia have focused their efforts on IHR reform and proposed sweeping amendments, largely because they were lacked confidence that the US will adopt a new Treaty.

Professor Burci emphasised how **challenging the timelines for negotiating the Pandemic Treaty and IHR amendments are**. There is a sense that the pressure to complete both negotiations by May 2024 stems from a concern that the end of the COVID-19 pandemic may lead to a loss of momentum. There could also be some urgency to wrap up negotiations before the US presidential election in late 2024, where a shift to a Republican presidency could see the US withdraw from the entire negotiation process. Professor Burci noted that the US is taking Pandemic Treaty negotiations seriously, which is giving some states confidence that it could be concluded in time.

Professor Burci went on to discuss the substantive content of the Pandemic Treaty and argued that there is significant concern within the Geneva diplomatic community about the content of the current draft of the instrument. He noted reports that the interests of many states, particularly those from the Global South, are not well reflected. He emphasised that there was **concern about the lack of civil society engagement in the process**, which may explain a **lack of human rights focused language within the current draft text**. Professor Burci discussed that the proposed content from the most recent draft covers a broad range of areas, alongside the themes of prevention, preparedness, response, including capacity building, access and benefit sharing, wide raging compliance and accountability systems, funding mechanisms and pooled procurement of drugs. Professor Burci argued that much of this is still up for negotiation,

and we are likely to see shifting positions and language within future drafts, as we get closer to the culmination of the negotiation process. Professor Burci also noted that there are overlapping proposals in the Pandemic Treaty draft and the proposed IHR amendments, in particular regarding access and benefit sharing, access to medical countermeasures and assistance to developing countries. Member States are currently discussing ways and means to both ensure complementarity between the two instruments and avoid gaps and inconsistencies.

Professor Burci concluded by noting that **equity has been central to the negotiations, and indeed was part of the justification for the Pandemic Treaty being created in the first place**: many questions remain, however, particularly about the appropriateness of 'common but differentiated responsibilities' in health emergencies, how to build on the experience of COVAX and ACT-A, IP management, and the financing of WHO and equitable access to medical countermeasures. Professor Burci argued that health security versus equity was the central tension in the negotiations, and there is a need for trust and concessions on both sides – these have been sorely lacking in the negotiations so far, but **in terms of key takeaways for the Pandemic Treaty Negotiations**, both sides must take meaningful steps to ensure a successful collaborative outcome.

Dr Michelle Rourke

Dr Rourke commenced her presentation by explaining how pathogens are disease-causing microorganisms. Pathogen sharing usually - though not always - revolves around a sample taken from a human or animal, which is then shared within the scientific community for research purposes. Pathogen sharing is integral to scientific research, and the development of vaccines and other medical countermeasures.

The value of these pathogens is not just in the physical sample, but also in the genetic sequence data of the pathogen. However, physical samples are still important and valuable because of the variations in the genetic make-up of pathogen populations in different hosts or different locations at different times. Pathogens such as RNA-based viruses have no 'proofreading' mechanism so can change/mutate more quickly than DNA-based viruses such as smallpox. COVID-19 is caused by an RNA virus and can change significantly over a relatively short period of time.

Influenza – and the threat of an influenza pandemic – has long been a concern of public health professionals. Since the early 1950s, a global network of WHO-affiliated labs has emerged to monitor changes in influenza viruses, now called the WHO's Global Influenza Surveillance and Response System (GISRS). The GISRS operates via WHO Collaborating Centres which receive influenza viruses from National Influenza Centres. The Collaborating Centres then contribute information towards vaccine recommendations to be provided by the WHO for seasonal and pandemic influenza vaccines. The operation of GISRS was disrupted in 2006/2007 by Indonesia's refusal to share influenza samples with the WHO on the basis that Indonesia had 'viral sovereignty' over their samples under the Convention on Biological Diversity (CBD). This came after Indonesia discovered that the WHO had been sharing their sovereign genetic resources with a pharmaceutical company without any guarantee that products developed from these samples would be available to Indonesia.

"Disease affected countries, which are usually developing countries, provide information and share biological specimens/virus with the WHO system; then pharmaceutical industries of developed countries obtain free access to this information and specimens, produce and patent the products (diagnostics, vaccines, therapeutics or other technologies), and sell them back to the developing countries at unaffordable prices."

Sedyaningsih *et al.,* (2008)

Significant tension was created by this refusal to share. While some criticised the notion of viral sovereignty, others felt that Indonesia's position was both justified under international law – the CBD – as well as on moral grounds related to notions of commutative justice. Dr Rourke outlined that **developing countries in general wanted equitable access to vaccines as well as transparency, whereas the Global North was heavily in favour of free and unencumbered sharing of pathogens for research and development purposes.**

The 'solution' to the tension provoked by the Indonesian refusal to share was the adoption, by the World Health Assembly in 2011, of the *Pandemic Influenza Preparedness (PIP) Framework*. This is a soft law mechanism established by the WHO which recognises state sovereignty over biological resources, and requests that States share samples of influenza with human pandemic potential with GISRS. Companies such as vaccine manufacturers which receive samples from GISRS must agree to sign a standard material transfer agreement (or SMTA) – a private law contract – through which they agree to provide a range of benefits such as vaccines in the event of an influenza pandemic.

The PIP Framework is an access and benefit-sharing (ABS) instrument under which access to sovereign genetic resources is exchanged for benefits associated with their use in scientific research and development. It is a multilateral ABS agreement, with WHO acting as the mediator of the ABS transactions. The origins of ABS are traceable to the CBD, which directs that users of genetic resources must obtain the prior informed consent of the country of origin and come to mutually agreed terms about how the genetic resources will be used, as well as what associated benefits will be shared with the country of origin. The central provisions of the CBD on ABS have been fleshed out via the 2010 *Nagoya Protocol*. The PIP Framework's interaction with the CBD (and indeed Nagoya Protocol) are still to be determined.

Dr Rourke reminded the audience that **the PIP Framework has not yet been tested in a pandemic: it only applies during an influenza pandemic, and we have not had such a pandemic since the establishment of the PIP Framework. I*n terms of a key takeaway for negotiators, it is not clear that the SMTAs will function effectively to provide access to 'benefits' such as vaccines and other medical countermeasures when it matters.*** While the PIP Framework has worked to enhance trust, it is not clear how long this will last in the context of a health emergency, and these issues need to be thought through in the context of the ongoing Pandemic Treaty negotiations. A 'copy and paste' from the untried and untested PIP Framework leaves the world at risk in the next pandemic.

Dr Mark Eccleston-Turner

Dr Eccleston-Turner began by explaining that ABS, which is short for access to genetic resources and the sharing of benefits associated with their use in research and development, is based on the notion that States have sovereign rights over their genetic resources and that use of sovereign genetic resources in research and development should occur with the prior informed consent of the country of origin, and on mutually agreed terms with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the country of origin.

He used his talk to argue that pathogen ABS is a transaction; the exchange of a pathogen for a 'benefit' which requires use of sovereign resources to access key benefits, and that these transactional approaches encourage developing countries to use their pathogenic genetic resources as bargaining chips to secure enhanced access to diagnostics, medicines and vaccines developed with those samples.

He set out that it was important to note that ABS, despite originating in the UN's biodiversity regime, was never just about biodiversity conservation. It was also supposed to deliver fairness and equity and redress some historic injustices, especially in post-colonial settings, set against a backdrop of a long history of colonial resource extraction. These exploitative practices continue to this day and when it comes to pathogens, there are very clear recent examples of exploitation in the field of public health from H5N1, Ebola in West Africa, Zika and MERS.

ABS has done little to achieve the goals of biodiversity conservation, sustainable use and fair and equitable benefit sharing in the environmental law space. Clearly, while the CBD has been in operation for 30 years, the ABS premise has yet to live up to its promises. The ABS transaction in the CBD was a compromise that was supposed to ensure that access to genetic resources occurred using the favoured market mechanism of the time; trading sovereign genetic resources for benefits that could be used for environmental conservation and sustainable use initiatives. The ABS transaction has not solved these problems in the environmental space, with Dr Eccleston-Turner expressing alarm at the continued push towards using the ABS policy mechanism in the public health space where the incentives and goals are very different from those of environmental conservation.

Bilateral pathogen ABS means that benefits only accrue to those best placed to negotiate access to benefits; this means that it is not always those with the greatest need that get access to benefits in exchange for providing access to sovereign goods. Whereas multilateral ABS (via WHO) cannot provide equity either – it breaks the link between States providing samples to the WHO and benefits being accrued (i.e., WHO cannot guarantee benefits to States providing samples under the system), and the whole system is therefore vulnerable to freeriding. However, even if a multilateral pathogen ABS system could deliver benefits, it cannot do so equitably, and does not break the status quo of the

existing publicly subsidised market system whereby wealthy States dominate supply and leave too little for the Global South. For example, the obligations in the PIP Framework – which was meant to require pharmaceutical users of the GISRS system to agree to at least 10% of their real-time production being donated to WHO, and an additional 10% reserved for purchase by WHO at affordable prices – some pharmaceutical users of the GISRS have agreed to as little as 2.5% of their production capacity.

In addition to these practicalities, Dr Eccleston-Turner argued that the ABS transaction creates a framing or a norm that a State is entitled to receive vaccines because it has provided sovereign genetic resources. However, paradoxically, ABS detracts from the achievement of norms such as the human rights to health and science, and access to medicines under the human right to health. There is a concern that framing these issues such as access to vaccines as an operational output of an ABS transaction detracts from key norms such as the right to health and the right to science. These norms have legal, political and moral value, even if they may be said to lack strong enforcement mechanisms within international law.

In terms of the implications of this for the Pandemic Treaty negotiations, Dr Eccleston-Turner emphasized that transactional approaches during a health emergency are unfair and inefficient, and that this inefficiency is apparent in both sides of the transaction that pathogen ABS seeks to facilitate. ABS transactions slow down the rapid sharing of pathogens with the wider international research community, potentially hampering the response to an unfolding health emergency, and ABS (whether bilateral or multilateral) cannot ensure equitable access to vaccines during a pandemic. Indeed, it is not even clear that it can secure any medical countermeasures at all in an emergency.

Dr Eccleston-Turner concluded that we need to look beyond the market mechanisms of ABS that have perpetuated unfair dealings to the continued detriment of developing nations. **Developing countries should not be made to feel that ABS policies are their**

only opportunity to get access to vaccines and antivirals during an infectious disease emergency. We should be looking to address the issue of access to pathogens in parallel with the fair and equitable provision of medical countermeasures in a pandemic. Linking the two issues with a mechanism designed to address the market failure of biodiversity conservation guarantees that neither access to pathogens nor the sharing of the benefits associated with their use will occur in a fair and equitable manner.

Professor Elisa Morgera

Professor Morgera provided her reflections on fair and equitable benefit-sharing in the context of the WHO negotiations for a Pandemic Treaty. She emphasised that ABS (the mechanism under the CBD and Nagoya Protocol, which has been predominantly interpreted in a bilateral way) should be considered as separate from fair and equitable benefit-sharing, with the latter concept argued to be a general principle of international law.

Professor Morgera emphasised that there may be an opportunity to ***learn lessons from existing multilateral systems to inform how fair and equitable benefit-sharing may be achieved.*** In other multilateral systems, fair and equitable benefit-sharing has **procedural (voice and predictability) and substantive (wellbeing and capabilities) dimensions.** In that regard, consideration of an '**active role for beneficiaries**' and the establishment of a **dialogue** with beneficiaries regarding the identification of benefits is required. She emphasised that **not just any benefit will do.** Dialogue is **different from a 'mere logic of exchange'** and the passive receipt of benefits by the recipient. This requires due regard be given to the importance of **trust and the establishment of effective and meaningful partnerships.** It is to be noted that the recently concluded international agreement on marine biodiversity beyond national jurisdiction (BBNJ Agreement (sometimes referred to as the High Seas Treaty) envisages the establishment

of a Benefits Sharing Committee to do such a thing, though its exact terms of operation are still to be determined.

In terms of the implications of the above for the Pandemic Treaty negotiations, fair and equitable sharing of benefits cannot be achieved in the absence of trust, dialogue and partnership with beneficiaries. A focus on what is fair and equitable has both **procedural and substantive dimensions**.

Professor Morgera also underlined the importance of the **legally binding human right to benefit from scientific progress and its applications (the right to science, set out in Article 15 ICESCR)** for the Pandemic Treaty negotiations. The normative content of the right to science is such that there must be an opportunity for all to contribute to scientific research and fairly share in the benefits of scientific advancements, as well as an obligation to protect against the negative consequences of scientific progress e.g. negative implications on health, food security as well as the physical environment. The human right to science also directs that priorities for scientific research should focus on issues of relevance to the most vulnerable and where there is greatest need.

In terms of the implications of this for the Pandemic Treaty negotiations, a focus on the right to science requires acknowledgement of the power dynamics in science, as well as the need to affirm the agency of beneficiaries. This requires, among other things, a focus on mutual capacity building between the Global North and South, as well as technology co-development. **Perhaps more fundamentally, harnessing equity requires the building of trust, which in turn requires attention to be given to 'what went wrong' in the past to erode trust**.

Professor Morgera then reflected on her experiences of equity under her directorship of the One Ocean Hub, a global inter-disciplinary research collaboration across the UK, Africa, South Pacific and the Caribbean, as well as UN agencies and other international

partners which is pioneering research on human rights and the marine environment, to support fair and inclusive decision-making for a healthy ocean whereby people and planet flourish. She stressed how fair research partnerships have become key across the *entire* One Ocean Hub. Her experiences are ***relevant to the Pandemic Treaty negotiations*** as they underline how it is crucial to recognise the importance of genuine collaboration and fair research partnerships in ensuring that there can genuinely be 'transformative change.' In a related sense, it is important to understand how the 'chain of knowledge production' influences governance – this requires transparent bodies that are eager and equipped to engage with all sectors and the entire 'chain.' **In terms of takeaways for the Pandemic Treaty negotiations,** there is a need to be cognisant of how knowledge production influences governance. There is also a need to support synergies between different areas of research and governance, as well as to promote iterative learning across different regimes.

In terms of key takeaways for the Pandemic Treaty Negotiations, Professor Morgera concluded by noting the need to promote different conceptions and perspectives of equity, including the promotion of Global South perspectives. She also recommended a focus on what went wrong not just during COVID-19 but also during previous pandemics and indeed, during intra-pandemic times. Finally, she emphasised the importance of knowledge production – for equity but also more generally – across different scales and levels. The fair and equitable sharing of the benefits of scientific research and development does not need to occur in the form of an ABS transaction, and attention needs to be focused on how to maximize global benefits.

Professor John Harrington (discussant)

Professor Harrington commenced his discussion by noting how COVID-19 has been a crisis for global health governance, prompting the desire for change. The Pandemic Treaty offers the opportunity for profound changes to this system, if, and only if, negotiators are willing to be bold. The events of the COVID-19 pandemic have demonstrated that the State is a key actor in global health governance but, importantly, that not all States are equal. Colonialism is a key theme in these negotiations – it has historic routes (in the 'discipline' of Global South states by the Global North as part of the new international economic order) but is still central today and manifested itself in the COVID-19 pandemic as, *inter alia*, vaccine nationalism, unequal border restrictions and vaccine passports.

The agency and assertiveness of Global South actors is an important feature of the Pandemic Treaty negotiations. ***Three key values may be useful to underpin negotiations going forward: solidarity, equity and sovereignty***. However, for these values to be effective, a number of points must be taken into account;

- An impoverished view of equity is encapsulated by a focus upon the transactional element of ABS. Much may be learned from looking at how other international systems provide for fair and equitable benefit-sharing which, as noted by Professor Morgera, is separate from ABS, in terms of its operation as a general principle of international law.

- The principle of solidarity needs to be integrated at a higher level, including in research and governance.

- Sovereignty has limits (demonstrated by inability to prevent the transmission of pathogens beyond State borders) but it is also powerful and cannot be ignored in the Pandemic Treaty negotiations.

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Any comments or questions on this briefing document should be addressed in the first instance to the project leads; **Dr Stephanie Switzer** stephanie.switzer@strath.ac.uk and **Dr Mark Eccleston-Turner** mark.eccleston-turner@kcl.ac.uk