Presentation for Global Health Law Committee Open Session for ILA Lisbon 2022

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1. The main order of business is to present and seek approval of the Committee Report. It is not the intention of the Committee to propose a resolution for adoption by the full ILA this meeting, unlike Kyoto where we did propose and see adoption of a resolution regarding addressing the COVID-19 pandemic.

2. I am going to discuss the elements of the report dealing with the potential reforms of international institutions that may be negotiated in response to the pandemic, and that would be adopted in contemplation of preparing for and addressing future pandemic outbreaks. As part of that I will be addressing the element of sharing biological materials and resources, including genetic resource data, that researchers need to respond to new outbreaks of disease. My Co-Chair, Brigit Toebes, will address elements of the negotiations involving potential amendments to the International Health Regulations adopted by members of the WHO, as well as the separate topic of the relationship between climate change and global health law, which forms the final part of our Committee Report.

3. It will be fresh in your mind that the events at the outset of the COVID-19 pandemic raised considerable controversy in regard to the behavior of national governments, and the role played by the World Health Organization (WHO) in addressing the outbreak. The principal question raised with respect to the WHO had to do with the process and speed at which it was decided by the Director General, Dr. Tedros, to declare a public health emergency of international concern, customarily abbreviated PHEIC. The Director-General is advised by an emergency committee composed of technical experts, but is not bound by the recommendation of those experts, and instead is solely responsible for the decision whether or not to declare a PHEIC. in the case of COVID-19, there was an initial meeting of the emergency committee (Jan. 22-23, 2020) that decided against making a recommendation to declare a PHEIC pending additional information and clarification, mainly in this case based on uncertainty regarding whether the SARS–CoV-2 virus was transmitting human to human, and was capable of airborne transmission. There was question regarding the mechanism of transmission. Although the period between meetings was not long, about one week (until Jan. 30), the decision by the Director-General not to declare a PHEIC at the initial meeting was widely and sharply criticized. Why was that? This is because the declaration would have informed WHO member governments regarding the urgency of measures they should take, including most specifically whether or not to impose travel restrictions. The theory, again, is that every day counts, and that if governments had acted sooner, the transmission of the virus across borders would have been limited or slowed. It should be noted that when the DG declared a PHEIC on January 30, 2022, he did not recommend the imposition of travel restrictions.

A second and related element was the transparency of the government of China with respect to providing timely and accurate information to the WHO and other members states about the virus, including information it may have had regarding human to human mechanism of transmission, the genetic make-up of the virus, and the source of the outbreak. In this particular case, the actions of an individual Chinese scientist who posted the genetic sequence on a publicly available database very shortly after it was identified is acknowledged to have largely mooted the question whether the government itself might have acted more expeditiously. In the meantime, however the government had taken down information regarding the laboratories that had been responsible for working on virus

identification and genetic sequencing, and particularly information on the database of the institution that had been conducting so-called gain-of-function research on related viruses. There was and remains a theory that the COVID-19 spread through an accident at that laboratory, and more problematically that the virus may have been artificially constructed at that laboratory. Another outstanding issue involving the WHO and its mechanisms is whether it had sufficient access to reliable information from the government of China, and whether the management of WHO should have been more forceful in demanding access to locally held data. We will revert to that as we consider potential areas of reform.

Another major question involving WHO is the inconsistent positions that were publicly taken as the outbreak progressed. First was the question of whether the WHO should have more quickly recommended that travel bans be imposed, particularly as it was becoming evident that travel between China and Italy at the early stages of the outbreak facilitated a more rapid transmission to Europe. A second had to do with recommendations regarding masks as WHO had initially hesitated to recommend mask wearing based on questions regarding whether they were effective in preventing the transmission of the virus. In retrospect, each of those decisions by WHO was poor. WHO has consistently hesitated to recommend travel bans on the theory that they are not likely to be effective in preventing the transmission of viral disease. That is, that viruses have a way of overcoming travel barriers, particularly as human beings have a tendency to act in disregard of health issues. With governments having routinely come to the conclusion that by reducing human interaction, including through travel, that the spread of a virus can be contained, the WHO operating theory has perhaps been discredited. Similarly, with mandatory facemask requirements imposed around the world - though not without pushback from the public in certain countries - backed by scientific evidence of the positive impact on reducing transmission, the WHO hesitation or delay in recommending facemasks again raises questions. At least some part of that hesitation resulted from a belief that an insufficient number of facemasks was available in the relevant time frame and recommending in favor would have created supply shortages for emergency personnel.

Depending on the length of one's memory, one may recall that WHO came under an extreme form of political attack during the COVID-19 outbreak as the then-President of the United States announced the withdrawal of the United States from the WHO following charges that the organization had been manipulated by the government of China. These charges were refuted by WHO, but that did not affect the calculus by the then-government of the United States. This naturally reduced the possibilities for ongoing cooperation at the political level, but probably should not be over-emphasized in the sense that scientific cooperation among countries remained fairly robust throughout the pandemic.

Taking all that into account, we have still not addressed what may have been the biggest institutional failure of the pandemic experience, which was the leadtime required to place vaccine supplies into production, noting that the actual scientific development of the vaccines was very rapid. And, just as important, the failure of the international community to assure some form of equitable distribution of vaccines particularly to health workers in countries lacking production capacity, a gap which persists today, though in a different form and for different reasons. While I do not consider the terminology particularly helpful, the vaccine response to pandemic outbreak is today referred to as "countermeasures", and prospects for development of improved capacity to develop, produce and distribute vaccines is now referred to as preparing countermeasures.

The development, production and distribution of vaccines is in many respects a complex subject matter that is in a separate category from WHO reform. Leading up to the COVID-19 pandemic, the scientific community was aware that we were collectively unprepared for an outbreak of a previously unknown

pandemic virus. First, there is always a lead time between identifying a new virus and creating a responsive vaccine. While today there is continued discussion of some type of universal vaccine against the SARS-type virus, this remains yet a work in progress. But, there are the additional significant problems of lack of production capacity worldwide, which includes decisions by the private pharmaceutical companies to largely exit the vaccine sector because of its lack of profitability. This then means that new facilities need to be built and/or upgraded to ramp up production. Also quite importantly, as we are all by now familiar, because vaccines are administered to large numbers of individuals and a defective vaccine might have extraordinarily negative consequences, there is a fairly extended period of testing that must go on before a vaccine is made available to a wide population.

There are numerous questions with respect to vaccines. One is whether we have made collectively the correct decision in leaving the development and distribution of vaccines very largely in the hands of private sector companies who act with motivations that do not necessarily reflect what we might refer to as the common good. Another has to do with the distribution of capacity, that is it is predominantly located in wealthier developed countries, though this is not to discount the role of India, for example in expanding capacity. But the question remains whether and how to expand capacity in geographies such as Africa. There is ongoing work being done, and I do not discount that, but whether and how this will be accomplished now that there is affectively a global over-supply of vaccine capacity remains to be addressed. And yet another problem or issue, which is existing today, is the problem of distributing vaccines that require specialized maintenance equipment and personnel in areas where resources are lacking, and where there is in fact resistance to taking the vaccines.

And as if all that we're not enough, countermeasures to pandemic outbreaks have become politicized in ways which we might not have foreseen or contemplated, though I suppose there are historical counterparts. This is a matter of human communications and psychology, as well as legal rules and science, a problem which we have scarcely tackled.

The problem set which I have just described most likely sounds overwhelming. And, up until now, the ability or willingness of the international community to seriously address preparing for and addressing pandemic outbreaks has been short term. When the outbreak fades, attention and commitment fades, and this tends to happen fairly quickly. Moreover, it has probably not escaped your attention that we are living in a very divided world from a political standpoint, and from many other standpoints. So, when we hypothesize regarding comprehensive responses to the COVID-19 pandemic in terms of preparing for the future, we have to take into account the very limited prospects for broad cooperation.

What does this mean from the standpoint of global health law and the future?

Not surprisingly, the WHO has appointed several high-level committees to investigate and make recommendations regarding various aspects of the problems, and in response to public demands has initiated a process of negotiation contemplating what is referred to as a Pandemic Treaty. But with that said, and as our report illustrates, once one goes beyond the surface, the details have been less than clear or the subject of any meaningful type of consensus. And, I should further make clear that some of the most important sets of proposals have not come from the WHO, but rather from the G20 and other groups that are concerned with addressing pandemics. A major reason for this, again, refreshing what you already know, is that the consequences of a pandemic outbreak such as COVID-19 go far beyond the individuals who die or are incapacitated, and their immediate families affected by it, but more broadly to the global economy which has seen tremendous economic losses that today are causing serious debt burden issues throughout the world. Therefore, international organizations such as the IMF and the

World Bank can hardly avoid being involved in addressing the problems and coming up with solutions, and there is a G20 high-level expert group house that has given perhaps the most detailed attention to that.

Should this whole business be situated within the WHO? From the outset I have thought this a too-limited option for a number of reasons, and suggested that an umbrella agreement needs to be negotiated within the framework of the United Nations. But, if one looks at the world around us today, one can easily question whether that is feasible at any level, and whether a much smaller group of like-minded countries like the G7 or G20 would be a good starting point. What is needed is political decisions at a high-level that can be directed towards finance ministries as well as health departments.
But if we can only reach decisions among smaller like-minded groups of countries, what will happen outside those countries? How do we address countries with far more limited resources?

To illustrate the problem in real time, we recently saw the completion of the World Health Assembly which mainly dealt with improving the budgetary process of WHO, without a firm commitment by the funding governments. And, agreement on a potential amendment of the International Health Regulations that would set a time period for governments to accept or reject the amendment. This is not agreement about amendment, but agreement about the period of acceptance. Otherwise, the main decision of the WHA seems to be to continue talking in the future.

Our Committee Report lays out the basic issues on the agenda of addressing pandemic-related reform to the international institutional structure. As a Committee, we did not attempt at this stage to express a preferred mechanism of negotiation or a specific outcome. This reflects in substantial measure our collective recognition of the difficulties currently facing the international community in terms of cooperative exercises. We have a pretty good idea about what would be done in ideal circumstances, but how we will go about negotiating and concluding agreements in the current environment is a difficult problem to address. There seems to be general agreement that from a WHO standpoint there is room for modification of the International Health Regulations given that they contain their own in-built process for amendment by action of the members states, with acceptance at the option of each member. But whether agreement can be reached regarding some type of more intrusive process that could somehow guarantee access to country data is another question entirely. Perhaps not so strangely, there is recognition that in our New World of virtually universal access to social media and posting of information that each individual government today is not in complete control of how access to information and materials are provided. Of course, there are more open and closed systems, but as the COVID-19 pandemic illustrated, information does appear to flow fairly expeditiously, almost regardless of governmental intent. Beyond that, there appears to be agreement that any new pandemic treaty will be negotiated as a self-standing instrument open for the typical treaty approval process. Much reference has been made to the model of the Framework Agreement on Tobacco Control that provided for incremental addition of protocols. In other words, start with the low hanging fruit, and leave negotiation on more difficult subjects for later. But, it has been pointed out that the Framework Agreement protocol process has not itself yielded substantial benefits in terms of finding new commitments, so whether that is the best option is uncertain.

I want to turn briefly before Brigit commences to a subject matter that is subject to negotiation at WHO, and that involves extending commitments in regard to sharing of pathogenic materials, and particularly adding the subject of genetic resource data, beyond the commitments already made in the Framework on Pandemic Influenza Preparedness or PIP. Some of you are too young to recall when in the context of an outbreak of avian flu in about 2005, a major controversy arose when Indonesia in 2007 refused to

supply biologic samples of infected tissue to foreign researchers on grounds that materials would be used to create treatments and/or vaccines that would be patented in the high income countries, and then sold prices which countries like Indonesia would find unable to afford. Before agreeing to supply samples, Indonesia demanded that arrangement be made that would provide it and similarly situated countries with the results of research for the local population. This triggered a debate regarding whether biological materials such as viruses were global public goods, the common heritage of mankind, etc., or were instead materials under the sovereign control of the country in which they were situated. It was brought to the attention of officials at WHO, who initially seemed unaware of the legal situation, that the Convention on Biological Diversity and international law generally situated biological materials within the territory of a country as under its sovereign control, so that from a legal standpoint Indonesia seemed to be on solid ground in demanding equitable access to the results of any biological materials research before allowing access.

Several years of negotiation followed, before agreement on the PIP Framework. These negotiations were highly contentious, centering around the question of whether the high income country private sector companies would commit to transferring intellectual property and resources for production to lower income countries within the Framework. While ultimately there was agreement that the WHO research centers themselves would not be able to take intellectual property rights such as patents in the results of research on the biological materials, this restriction did not extend to private sector entities who ultimately received those materials. Instead, the recipient entities agreed to enter into access agreements under which they had the option either to provide technology or to provide WHO with a stockpile of products for use in the addressing of an outbreak. These so-called material transfer agreements have so far not resulted in transfer of technology and/or production capacity, though there have been contributions to a WHO stockpile.

Committee member contributors to our report focused on the fact that the Framework achieved a certain type of equity by the agreement to provide certain benefits to WHO in exchange for access to the biological materials. The suggestion is made that this provides a type of model for further modification of the Framework, or a new agreement, in terms of achieving equity. Because I was fairly closely involved in the preparatory work on the PIP Framework then as a consultant for WHO, I thought it important to point out that the demands for equity made by the lower income countries were not exactly met in the PIP Framework negotiations. The principal demand was for technology and the capacity to produce vaccines and treatments. That demand was not met. Had it been met, we may have been in a better situation when the COVID-19 pandemic outbreak occured. We might have had better access to vaccines in lower income countries. The idea of some type of WHO stockpile as an alternative did not help during the COVID-19 pandemic, if for no other reason than this was not a pandemic flu outbreak. But, the main point is that when will you look to the PIP Framework negotiations as a model, we should keep in mind that it was a limited success, in the first place. And, in the second place, demands for access to technology have continued to represent a struggle at the multilateral level, including as manifest by the weak result of the TRIPS Agreement waiver negotiations. These matters are no less contentious today than they were during the PIP Framework negotiations.