Andrea de Guttry*

Is the International Community Ready for the Next Pandemic Wave? A Legal Analysis of the Preparedness Rules Codified in Universal Instruments and of their Impact in the Light of the COVID-19 Experience

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Abstract: The international community generally recognizes the importance of adopting adequate, timely and continuously updated prevention measures to reduce the risk of global health emergencies and pandemics. Nevertheless, as demonstrated by COVID-19, with its assumed mutation capacity, even the most sophisticated preventive measures cannot avoid the spread of new diseases. States are expected, therefore, to adopt specific preparedness measures to effectively anticipate, respond to, and recover from the impacts of likely pandemics. These measures have gained increasing interest in many treaties all over the world. The present article investigates the international obligations codified in universal instruments related to the adoption of preparedness measures for potential pandemics. Carefully examining relevant international treaties as well as emerging soft-law instruments, it will attempt to answer a pertinent question that has been raised time and again in the past and continues to be raised during the current COVID-19 crisis: are the existing preparedness measures still relevant and adequate or have they become obsolete or misleading? Since more COVID-19 viral waves are expected to arrive in the next months, the urgency of adopting adequate preparedness measures is even more evident. Moreover, the article analyses the current worldwide challenges related to the national implementation of preparedness measures. Considering the innovative drugs and diagnostics that are currently available, and that we can count on new technology platforms that significantly reduce the time needed to develop vaccines, it argues that inaction can no longer be justified, whether in legal, political or moral terms.

Keywords: pandemic, preparedness measures, international obligations, COVID-19, national implementation

*Corresponding author: Andrea de Guttry, Scuola Superiore Sant'Anna, Piazza Martiri della Libertà, 56127 Pisa, Italy, E-mail: deguttry@santannapisa.it

1 Introduction: Terminological Clarifications and Identification of the Legal Basis of the Preparedness Obligations

Infectious diseases and pandemics¹ have been an endemic part of human history. According to historians, the first recorded pandemic occurred during the Peloponnesian War around 430 BC.² Over the last 100 years, several pandemics have been registered: in 1918 the Spanish flu (with a death toll of about 40 million),³ in 1956–1958 the Asian Flu (with a death toll of about two million),⁴ in 1961 the Flu Pandemic (with a death toll of about one million),⁵ in 2005–2012 the HIV/AIDS Pandemic (with a death toll of about 36 million),⁶ and in 2009–2010 the H1N1 Pandemic (with a death toll of about 500,000).⁷ Furthermore,

1 So far, the WHO has never provided a clear definition of “pandemic” although reference is often made to the “pandemic phase” of infectious diseases. In the 2015 International Health Regulation (IHR) there is only a definition of public health risk which is “a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger” (Article 1 of the IHR) and of a “public health emergency of international concern” to be declared by the Director General of the WHO taking into consideration “(a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) scientific principles as well as the available scientific evidence and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic” (Article 12 of the IHR). For the purposes of this article, pandemic is “the worldwide spread of a new disease which has a significant impact on the affected societies.” On the problems related to the definition of pandemic, see more in Doshi (2011).

2 History.com (2020).

3 The 1918 influenza pandemic was the most severe pandemic in recent history. It was caused by an H1N1 virus with genes of avian origin: Center for Disease Control and Prevention (2019).

4 Asian Flu was a pandemic outbreak of Influenza A of the H2N2 subtype, that originated in China in 1956 and lasted until 1958. Estimates for the death toll of the Asian Flu vary depending on the source, but the World Health Organization places the final tally at approximately two million deaths.

5 The 1968 flu pandemic was caused by the H3N2 strain of the Influenza A virus. Although it has been characterized by a comparatively low mortality rate, it caused more than one million deaths, mostly in Hong-Kong.

6 First identified in Democratic Republic of the Congo in 1976, HIV/AIDS has truly proven itself as a global pandemic, killing more than 36 million people since 1981. Between 2005 and 2012, the annual global deaths from HIV/AIDS dropped from 2.2 to 1.6 million.

7 A (H1N1) was a new strain of influenza of swine origin. Severe consequences and deaths occurred in various groups of the population. In the first year of the pandemic between 151,000 and 475,000 deaths worldwide have been attributed to this influenza. “Healthcare services, particularly critical care units, were often stretched to their limits, and early recognition and treatment of severe disease could be life-saving”: European Centre for Disease Prevention and Control (2017).

according to the WHO, between 2008 and 2011 there were 1483 epidemic events in 172 countries.⁸ Notwithstanding strenuous efforts to prevent the outbreak of infectious diseases, such events, as confirmed by the COVID-19 case, will continue to affect the international community. A study carried out by the European Centre for Disease Prevention and Control, in close cooperation with the WHO regional office for Europe, states that a future influenza pandemic “is inevitable, although it cannot be predicted when it will happen nor how severe it will be.”⁹ According to the 2019 Annual Report on Global Preparedness for Health Emergencies, if it is true “to say ‘what’s past is prologue’, then there is a very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen killing 50 to 80 million people and wiping out nearly 5% of the world’s economy.”¹⁰ The World Bank has estimated that the annual global cost of a moderate to severe pandemic would be around US\$570 billion, or 0.7% of global income.¹¹ But if “the world were to face a fast-moving, airborne disease, such as the Spanish flu outbreak of 1918–1919, it would kill more than 33 million people in 250 days and erode 4.8% of global GDP – more than US\$3.6 trillion.”¹² There are many explanations for why pandemics will continue to happen. On the one hand, virologists candidly admit that despite enormous advances in virology and epidemiology, “many fundamental scientific questions concerning the origins, virulence, and diffusion of influenza remain unanswered.”¹³ On the other hand, the new features of the global economy (with incredible increases in the traffic of goods and the number of persons travelling worldwide), represent “a near-ideal condition to spread infections around the world.”¹⁴

8 Global Preparedness Monitoring Board (2019). The Report has been prepared by an independent monitoring and advocacy body, the Global Preparedness Monitoring Board, which urges political action to prepare for and mitigate the effects of global health emergencies.

9 European Centre for Disease Prevention and Control (2017).

10 Global Preparedness Monitoring Board (2019). According to a well-known scientist, “the likelihood of another influenza pandemic during the next 50 years is virtually 100%, but quantifying probabilities of mild, moderate, or severe events remains largely a matter of speculation because we simply do not know how pathogenic a new virus will be and what age categories it will preferentially attack. Assessing the most likely extent of morbidity and mortality is even more challenging”: Smil (2008).

11 World BankGroup (2016). A recent research by the Asian Development Bank estimates the global losses from COVID-19 “ranging from \$2.0 trillion to \$4.1 trillion, equal to 2.3–4.8% of global GD”: Asian Development Bank, (2020). <https://www.adb.org/sites/default/files/publication/575626/ado2020.pdf> (accessed February 26, 2020).

12 The World Bank (2015).

13 Smil (2008).

14 *Id.*

While prevention remains an essential tool, preparedness measures are becoming crucial to cope with future pandemics.¹⁵ According to the 2017 WHO document on “A Strategic Framework for Preparedness”,¹⁶ emergency preparedness is defined as “the knowledge and capacities and organizational systems developed by governments, response and recovery organizations, communities and individuals to effectively anticipate, respond to, and recover from the impacts of likely, imminent, emerging, or current emergencies.” In the 2015 WHO Framework for a Public Health Emergency Operations Centre,¹⁷ additional elements were provided to better understand the notion of preparedness which is “the product of a combination of planning, allocation of resources, training, exercising, and organizing to build, sustain, and improve operational capabilities based on risk assessments.”¹⁸

The same document describes differences between prevention and mitigation on the one hand and preparedness on the other as follows:

Prevention and mitigation involves the treatment of identified risks so as to prevent them or introduce measures to reduce their impact..... Preparedness involves assessment of capacities and capabilities, development of plans, development and maintenance of infrastructure, maintenance of stockpiles, design and implementation of procedures, and training of personnel. It also includes technical capacity building, planning, and training and exercising.¹⁹

These definitions, though not codified in binding instruments, are widely used and referred to by the international community.²⁰ This article draws on them as well. In

15 During the COVID-19 crisis, the lack of sufficient personal protective equipment even for the health staff, and the lack of coordination among the different actors involved in the response phase, originated serious problems in many countries and affected the quality of the medical response.

16 WHO, A Strategic Framework for Emergency Preparedness (2017). <https://apps.who.int/iris/bitstream/handle/10665/254883/9789241511827-eng.pdf;jsessionid=9C16566E3601A231C5B27AE39302E5C1?sequence=1> (accessed March 8, 2020). This framework identifies the principles and elements of effective emergency preparedness and lays out the planning process by which countries can determine their priorities and develop or strengthen their operational capacities. It also informs resource allocation, guiding decisions to ensure that financial investments support implementation.

17 WHO, Framework for a Public Health Emergency Operation centre (2015), https://apps.who.int/iris/bitstream/handle/10665/196135/9789241565134_eng.pdf;jsessionid=9DC8FF54B7459E790CAF2A489CE13936?sequence=1 (accessed March 8, 2020).

18 *Id.* at 42.

19 *Id.* at 15.

20 The importance of clear definitions on the various phases of a disaster has persuaded the United Nations General Assembly (UNGA) to create, in 2015, an open-ended intergovernmental expert working group with the task, amongst others, to update the terminology on Disaster Risk Reduction (G.A. Res. 69/284, U.N. Doc. A/RES/69/284 [June 3, 2015]). The definition proposed by

doing so, it carefully examines relevant international treaties and also pertinent UN documents. The treaties under investigation deal not only with health issues (first of all the WHO 1946 Constitution and the 2005 International Health Regulations),²¹ but also with more general questions related to managing disasters and especially those in which there is release of chemical, biological, radiological and nuclear substances, as long as they are applicable to pandemics.²² Moreover it

Working Group, is indeed very similar to the one of the WHO: “The knowledge and capacities developed by governments, response and recovery organizations, communities and individuals to effectively anticipate, respond to and recover from the impacts of likely, imminent or current disasters” (U.N. Doc. A/71/644 [Dec. 1, 2016]). In an Annotation to this definition, the WG clarifies further that Preparedness action is carried out within the context of disaster risk management and aims to build the capacities needed to efficiently manage all types of emergencies and achieve orderly transitions from response to sustained recovery.

Preparedness is based on a sound analysis of disaster risks and good linkages with early warning systems, and includes such activities as contingency planning, the stockpiling of equipment and supplies, the development of arrangements for coordination, evacuation and public information, and associated training and field exercises. These must be supported by formal institutional, legal and budgetary capacities. The related term “readiness” describes the ability to quickly and appropriately respond when required. A preparedness plan establishes arrangements in advance to enable timely, effective and appropriate responses to specific potential hazardous events or emerging disaster situations that might threaten society or the environment.

21 The First International Health Regulations were adopted by the World Health Assembly in 1969 and were amended in 1973 and 1981. Considering the growth in international travel and trade, and the emergence or re-emergence of international disease threats and other public health risks, a substantial revision of these Regulations took place. After a long and inclusive preparatory process, the fifty-eighth World Health Assembly approved the new and updated Regulations on 23 May 2005. They entered into force on 15 June 2007.

22 The definition of disaster provided in the vast majority of relevant treaties permits to consider pandemics as events regulated by those treaties. This conclusion is perfectly aligned with the definition of disaster codified in the Draft articles on the protection of persons in the event of disasters, adopted by the International Law Commission at its sixty-eighth session, in 2016, and submitted to the General Assembly as a part of the Commission’s report covering the work of that session (U.N. Doc. A/71/10). The report is published in the Yearbook of the International Law Commission, 2016, vol. II, Part Two. According to Article 1.2 of the Resolution, “Disaster” means a

calamitous events which endanger life, health, physical integrity, or the right not to be subjected to cruel, inhuman or degrading treatment, or other fundamental human rights, or the essential needs of the population, whether of natural origin (such as earthquakes, volcanic eruptions, windstorms, torrential rains, floods, landslides, droughts, fires, famine, epidemics), or man-made disasters of technological origin (such as chemical disasters or nuclear explosions), or caused by armed conflicts or violence (such as international or internal armed conflicts, internal disturbances or violence, terrorist activities).

explores treaties devoted to the regulation of international assistance²³ which are an essential tool for increasing the effectiveness of future responses to pandemics.²⁴ Preparedness obligations can also be found in the frame of rules aimed at protecting fundamental human rights (such as the right to life, health, etc.).²⁵ The international monitoring bodies tasked to oversee the implementation of specific Human Rights Conventions, emphasized that

The duty to protect life also implies that States parties should take appropriate measures to address the general conditions in society that may eventually give rise to direct threats to life or prevent individuals from enjoying their right to life with dignity.....

Furthermore, States parties should also develop, when necessary, contingency plans and disaster management plans designed to increase preparedness and address natural and man-made disasters, which may adversely affect enjoyment of the right to life, such as hurricanes, tsunamis, earthquakes, radio-active accidents and massive cyber-attacks.²⁶

The International Law Commission (ILC) confirmed that every State has “the duty to ensure the protection of persons and provision of disaster relief assistance in its

This definition is similar to the one codified in the Resolution on Humanitarian Assistance adopted in 2003 by the Institute of International Law (<https://www.ifrc.org/Docs/idrl/I318EN.pdf> accessed March 5, 2020) and to that provided in the Report of the open-ended intergovernmental expert working group on indicators and terminology relating to disaster risk reduction (A/71/644, *supra* note 21). Section 5 of this Report contains “Recommendations of the open ended intergovernmental expert working group on terminology relating to disaster risk reduction”; in this frame the definition of disaster is the following: “A serious disruption of the functioning of a community or a society at any scale due to hazardous events interacting with conditions of exposure, vulnerability and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts.”

23 As authoritatively stated by the ILC, whenever a disaster manifestly exceeds its response capacity, “the affected State has the duty to seek assistance from, as appropriate, other States, the United Nations, and other potential assisting actors” (Article 11 of the Draft articles on the protection of persons in the event of disasters, *supra* note 22). The ILC further reinforced this obligation stating that consent to external assistance shall not be withheld arbitrarily by the affected State which is also requested to take the necessary measures to facilitate the prompt and effective provision of external assistance (*id.*, Article 13.2).

24 On the other hand, the effective use of the same treaties has to be included in the response phase (and will, therefore, not be examined in this article).

25 The Convention on the Rights of Persons with Disabilities explicitly requests States to take “in accordance with their obligations under international law, including international humanitarian law and international human rights law, all necessary measures to ensure the protection and safety of persons with disabilities in situations of risk, including situations of armed conflict, humanitarian emergencies and the occurrence of natural disasters.”

26 Human Rights Committee, General comment No. 36 on article 6 of the International Covenant on Civil and Political Rights, on the right to life, CCPR/C/GC/36, 3 September 2019, Para 30.

territory, or in territory under its jurisdiction or control.”²⁷ The jurisprudence of the International Human Rights Courts supports these conclusions. In a well-known case from 2008, the European Court of Human Rights (ECtHR), after clarifying that Article 2 (Right to life) of the 1950 European Convention on Human Rights (ECHR) “lays down a positive obligation on States to take appropriate steps to safeguard the lives of those within their jurisdiction,” concluded that this obligation entails “above all a primary duty on the State to put in place a legislative and administrative framework designed to provide effective deterrence against threats to the right to life.”²⁸ States also have the obligation of adopting preparedness measures to protect private property,²⁹ whenever regulated by an applicable treaty. The European Court stated, however, that in such a case “the authorities enjoy a wider margin of appreciation in deciding what measures to take in order to protect individuals’ possessions from weather hazards than in deciding on the measures needed to protect lives.”³⁰ The ECtHR confirmed that these conclusions are applicable to pandemics as well, as it pointed out that the respective obligation “must be construed as applying in the context of any activity, whether public or not, in which the right to life may be at stake.”³¹ Finally, it is important to note that there is also a thesis that preparedness obligations are codified in an autonomous rule. According to the ILC, “each State shall reduce the risk of disasters by taking appropriate measures, including through legislation and regulations, to prevent,

27 Article 10 of the Draft articles on the protection of persons in the event of disasters, *supra* note 22.

28 *Budayeva and Others v. Russia*, App. nos. 15339/02, 21166/02, 20058/02, 11673/02 and 15343/02, Judgment, March 11, 2013, paras. 128 and 129/. Even if this sentence might be interpreted as referring to borderline situations between preventive and preparedness measures, there are no doubts that the Court intended to refer also to the latter as confirmed by the wording used. In the same decision, namely it is stated that “all possible diligence in informing the civilians and making advance arrangements for the emergency evacuation” have to be taken (*id.* at para. 152). These arrangements envisaged by the Court represent typical examples of preparedness measures.

29 *Öneryildiz v. Turkey*, App. no. 48939/99, Judgment, Nov. 30, 2004, at least where there are international treaties protecting the right to the peaceful enjoyment of possession: in such a case, however, the European Court stated that “the authorities enjoy a wider margin of appreciation in deciding what measures to take in order to protect individuals’ possessions from weather hazards than in deciding on the measures needed to protect lives.”

30 *Id.* at para. 175.

31 *Kolyadenko and Others v. Russia*, App. nos. 17423/05, 20534/05, 20678/05, 23263/05, 24283/05 and 35673/05, Judgment, February 28, 2012, para. 158/. See also *Öneryildiz*, App. no. 48939/99 Judgment, November 30, 2004, at para. 89, in which the Court, making reference to the positive obligation to take all appropriate steps to safeguard life for the purposes of Article 2 of the ECHR, clarified that this obligation indisputably applies “in the particular context of dangerous activities, where, in addition, special emphasis must be placed on regulations geared to the special features of the activity in question, particularly with regard to the level of the potential risk to human lives.”

mitigate, and prepare for disasters.”³² Moreover, this autonomous rule draws “on principles emanating from international human rights law..... and from a number of international environmental law principles, including the “due diligence” principle,”³³ and is based on a “widespread practice of States reflecting their commitment to reduce the risk of disasters”³⁴ and on the recognition that this commitment has been incorporated by States into their national policies and legal frameworks.³⁵

2 Specific Preparedness Obligations Regulated in Universal Instruments

Prevention and response/recovery obligations in the field of pandemics have traditionally benefitted of a worldwide attention (as confirmed by the high number of international treaties devoted to these two aspects). By contrast, less attention has been dedicated to preparedness.³⁶ The likely reason for this deficit is that pandemics occurred infrequently and often did not gain widespread attention when they did happen. More recently, however, they have attracted increased interest, a point well reflected in the activities of various international organizations and in States’ increasing concern about future pandemics.³⁷

In the 1949 WHO Constitution, which is heavily focused on prevention obligations,³⁸ providing assistance³⁹ and promoting international cooperation,

32 Draft articles on the protection of persons in the event of disasters, *supra* note 23. In the Commentary to Article 9, at para. 9, the ILC further states that the word “shall” signifies “the existence of the international legal obligation to act in the manner described in the paragraph and is the most succinct way to convey the sense of that legal obligation.”

33 Paragraph 4 to the Commentary of the ILC to Article 9. On the “due diligence” principle, see more in Pisillo Mazzeschi (1989).

34 Paragraph 5 to the Commentary of the ILC to Article 9.

35 Paragraph 6 to the Commentary of the ILC to Article 9.

36 A good example in this regard is offered by the Constitution of the WHO, which focuses mainly on preventive measures.

37 See more in Sands (2016).

38 Article 2 of the Constitution lists, among the task assigned to the WHO, the following ones: “(g) to stimulate and advance work to eradicate epidemic, endemic and other diseases; ... (h) to promote, in co-operation with other specialized agencies where necessary, the prevention of accidental injuries.”

39 See the following tasks mentioned in Article 2: “(c) to assist Governments, upon request, in strengthening health services; (d) to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments”.

preparedness aspects were, basically,⁴⁰ not considered. Nevertheless, the WHO has been involved in supporting preparedness activities to manage pandemics. Initially it developed soft-law instruments such as Guidelines, Guides, Checklists, etc., which, as we will see shortly, contributed to increase the awareness on how to be better equipped for future pandemics.⁴¹ The WHO introduced preparedness obligations only at a later moment, mainly through the 2005 International Health Regulations (IHR).⁴² The general goal of the IHR is “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”⁴³ These regulations are binding. Specific preparedness obligations are codified in Article 13, which requests each State party to:

develop, strengthen and maintain as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as

40 Letter (k) of Article 2 of the WHO Constitution, which tasks the WHO “to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective,” might eventually be interpreted as including also preparedness measures.

41 There are several of these documents: see for example WHO, *Pandemic Influenza Risk Management*, - A WHO Guide to Inform & Harmonize National and International Preparedness and Response (2017). https://www.who.int/influenza/preparedness/pandemic/influenza_risk_management/en/ (accessed March 3, 2020); WHO, *Summary of Key Information Practical to Countries Experiencing Outbreaks of a (H5N1) and other Subtypes of Avian Influenza* (2016). https://www.who.int/influenza/resources/publications/avian_influenza_packagev1/en/ (accessed March 3, 2020); WHO, *Pandemic Influenza Preparedness and Response*, WHO Guidance Document (2009). https://www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/ (accessed March 3, 2020); WHO, *Checklist for Influenza Pandemic Preparedness Planning* (2005). https://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_4/en/ (accessed March 3, 2020).

42 In 1951, the Fourth World Health Assembly adopted International Sanitary Regulations which were amended by the first International Health Regulations adopted in 1969 and later amended in 1973 and 1981. The 2005 IHR entered into force in 2007 and were revised in the same year and later in 2014. The legal basis of the IHR is provided in Articles 21(a) and 22 of the WHO Constitution, which confer upon the World Health Assembly the authority to adopt regulations “designed to prevent the international spread of disease.” According to Article 59 of the IHR, they enter into force as a binding instrument for all WHO Member States that do not affirmatively opt out of them within 18 months from the date of the notification by the Director-General of the adoption of these Regulations.

43 Article 2 of the IHR. On the innovative nature of the IHR, see more Gostin and Katz (2016), Negri (2018) and Aronsson-Storrier (2019).

set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response capacities.⁴⁴

Annex 1 defines the core capacity requirements for surveillance and response and those for designated airports. In this frame, it provides a detailed list of preparedness obligations for the State to be properly equipped (both in terms of decision-making procedures and physical infrastructures) and to have staff duly trained to be ready (a) to detect and report diseases or deaths above expected levels for the particular time and place in all areas within its territory and (b) to manage the health emergency by providing support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g., equipment, supplies and transport). In 2011, the 64th World Health Assembly adopted, in accordance with Article 23 of the WHO Constitution, the Pandemic Influenza Preparedness (PIP) Framework for Sharing Influenza Viruses, Vaccines and other Benefits.⁴⁵ Although focused specifically on pandemic influenza, the framework contains several important recommendations for member States and for the WHO Secretary General. States are requested to introduce national preparedness measures to allow the fast sharing of H5N1 and other influenza viruses with human pandemic potential with the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State's choice.⁴⁶ National Influenza Centres and other authorized laboratories must make available, without charge, supplies of non-commercial diagnostic reagents and test kits for identifying and characterizing specimens of influenza.⁴⁷ Moreover, influenza vaccine manufacturers must be urged to set aside a portion of each production cycle of vaccines for H5N1 and other influenza viruses with human pandemic potential for stockpiling and/or use, as appropriate, by developing countries.⁴⁸ The WHO Secretary General has been tasked with seeking, in cooperation with several stakeholders, commitments for contributions to maintain and further develop a stockpile of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human

⁴⁴ On the basis of paragraph 1 of Article 13, States may demand an extension of the five years' deadline.

⁴⁵ WHO, Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits (2011). https://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf?sequence=1 (accessed March 12, 2020).

⁴⁶ Article 5.1.

⁴⁷ Article 6.4.1.

⁴⁸ Article 10.1.

pandemic potential⁴⁹ and to establish and keep a stockpile of vaccines and associated equipment, including syringes, needles and applicators.⁵⁰

Although apparently unrelated to the COVID-19 pandemic, unless the virus was produced in a laboratory (which has so far been denied by the interested States), the 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction plays an important role because its preparedness measures contribute to international capabilities for response, investigation and mitigation of outbreaks of any disease, and not only those provoked by an alleged use of biological or toxin weapons. Although in this treaty specific references to preparedness obligations are rare and limited to the international cooperation facet,⁵¹ during the regular meeting of the States Parties to the Convention, the review conferences (every five years), the inter-sessional meetings⁵² and other occasions, the importance of the need to identify preparedness measures has slowly surfaced and gained increasing attention. While many of the relevant documents are mere political commitments, a few can well be considered binding rules for the member States.⁵³ In the December

49 Article 6.8.1.

50 Article 6.9.1.

51 In general terms the only Article of the Convention which addresses, although in an ambiguous manner, the preparedness obligations is Article VII which reads as follows: “Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.”

52 The purpose of the intersessional programme is to discuss, and promote common understanding and effective action on those issues identified for inclusion by the Review Conference. At the Seventh Review Conference it has been decided to organize Annual Meetings of States Parties of one-week duration, commencing in 2012, to discuss, and promote common understanding and effective action on those issues identified for inclusion in the intersessional programme.

53 The BWC is very short, comprising only 15 Articles. Over the years, it has been supplemented by a series of additional understandings reached at subsequent Review Conferences, held every five years. The Sixth Review Conference (December 2014), taking into account the importance of providing administrative support to meetings agreed by the Review Conference, decided to establish an Implementation Support Unit (ISU) for the Convention within the Geneva Branch of the United Nations Office for Disarmament Affairs. The ISU prepared a useful list of “Additional agreements reached by previous Review Conferences relating to each article of the Convention” which shows the text for each Article of the Convention, followed by the additional agreements relating to that Article reached by the various Review Conferences. For the purposes of this document, an “additional agreement” is one which: “(a) interprets, defines or elaborates the meaning or scope of a provision of the Convention; or (b) provides instructions, guidelines or recommendations on how a provision should be implemented”. [https://unog.ch/80256EDD006B8954/\(httpAssets\)/81AF9E6BF8178CFDC1257D0F00312580/\\$file/BWC%20&%20Additional%20Agreements%20Post%207RC.pdf](https://unog.ch/80256EDD006B8954/(httpAssets)/81AF9E6BF8178CFDC1257D0F00312580/$file/BWC%20&%20Additional%20Agreements%20Post%207RC.pdf): accessed March 7, 2020.

2014 meeting of the States Parties to the Convention, a list of desired preparedness measures was approved. These measures include effective national capabilities, national plans and detection capabilities; appropriate command, control and coordination of cross-governmental planning and response; and regular training activities to strengthen national capacities.⁵⁴ The Eighth Review Conference, which took place in 2016, reaffirmed that “the international community should be prepared to face such situations well in advance and to dispatch emergency assistance in case of use of bacteriological (biological) or toxin weapons, and also to provide assistance, including humanitarian and other assistance to the requesting State Party.”⁵⁵ The Parties agreed that “national preparedness and capacities also contribute directly to international capabilities for response, investigation and mitigation of outbreaks of disease, including those due to alleged use of biological or toxin weapons.”⁵⁶ During the same conference, the parties furthermore stressed the urgent need for new procedures by which “timely emergency assistance can be provided, including to better identify accessible information on the types of assistance that might be available in order to ensure prompt response and timely emergency and humanitarian assistance by States Parties, if requested in the event of use of biological weapons.”⁵⁷ The increasing interest in preparedness measures is likewise testified by the decision to organize regular Meetings of Experts on

54 Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC), BWC/MSP/2014/5 (Dec. 15, 2014), para. 34 identifies the following tasks to be performed by States.

(a) Considering what might be done to deal with a threat or actual use of biological or toxin weapons, determining the sorts of assistance that might be required from other States Parties and international organizations and identifying who could provide it, as well as identifying any challenges to its provision; (b) Ensuring effective national capabilities, including through the use, as appropriate, of gap analyses and national plans; (c) Strong detection capabilities, including for disease surveillance, primed health communities, cost-effective rapid diagnostic tests, and accurate disease mapping, as well as appropriate countermeasures and recovery and decontamination options; (d) Appropriate command, control and coordination of cross-governmental planning and response as well as multi-agency assets during the life cycle of response efforts; and (e) Regular training activities to strengthen national capacities.

55 Eighth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, BWC/CONF.VIII/4 (Jan. 11, 2017), para. 33.

56 *Id.* at para. 40.

57 *Id.* at para. 38.

Assistance, Response and Preparedness⁵⁸ and by the relevant number of working papers devoted to this issue and submitted in the last years by States Parties.⁵⁹

The UN system has also played a role in this endeavour to reinforce national capacities to face a pandemic. In UN General Assembly Resolution 60/282 from 2006 approving the Political Declaration on HIV/AIDS,⁶⁰ the Heads of State and Government committed solemnly to

reinforce, adopt and implement, where needed, national plans and strategies, supported by international cooperation and partnership, to increase the capacity of human resources for health to meet the urgent need for the training and retention of a broad range of health workers, including community-based health workers; improve training and management and working conditions, including treatment for health workers; and effectively govern the recruitment, retention and deployment of new and existing health workers to mount a more effective HIV/AIDS response.

In the same year, in the Resolution on the United Nations Global Counter-Terrorism Strategy,⁶¹ the UNGA requested the UN system

to improve coordination in planning a response to a terrorist attack using nuclear, chemical, biological or radiological weapons or materials, in particular by reviewing and improving the effectiveness of the existing inter-agency coordination mechanisms for assistance delivery, relief operations and victim support, so that all States can receive adequate assistance. In this regard, we invite the General Assembly and the Security Council to develop guidelines for the necessary cooperation and assistance in the event of a terrorist attack using weapons of mass destruction.

Considering its content, the resolution is relevant for the purposes of this article for at least two reasons: a pandemic might be provoked by a terrorist attack releasing highly contagious viruses and, secondly, the preparedness activities implemented

58 The Eighth Review Conference and the 2017 Meeting of States Parties defined the working methods and the task of the meetings of Experts.

59 Implementation of Article VII – Submitted by South Africa, BWC/MSP/2015/MX/WP.10 (Aug. 6, 2015); Article VII: Analysis of existing resources and gaps and recommendations for future actions, submitted by Columbia, Greece, Italy, Lithuania, New Zealand, Norway, Republic of Korea, Slovenia, Switzerland, Turkey and the United States of America, BWC/MSP/2014/WP.1/ADD.1/Corr.1 (Dec. 8, 2014); Preparing for and Responding to Deliberate Events: Specific Proposals for Work Under Article VII Based on Examining Lessons Learned from the International Response to the Ebola Outbreak in West Africa – Submitted by the United States of America, BWC/CONF.VIII/WP.38 (Nov. 14, 2016); Strengthening Article VII: International Cooperation and Assistance in Preparing for and Responding to Biological Incidents - Submitted by the United States of America, BWC/MSP/2013/WP.2 (Dec. 3, 2013).

60 G.A. Res. 60/262, U.N. Doc. A/RES/60/262 (June 15, 2006).

61 G.A. Res. 60/288, U.N. Doc. A/RES/60/288 (Sept. 8, 2006).

to face potential terrorist attacks are usable in non-terrorist pandemic events as well.

On several occasions, the UNSC dealt with major health crises and consistently emphasized the importance of the preparedness measures to be adopted by member States with the support of relevant IOs. In its Resolution 2439 (2018) of 30 October 2018, devoted to the outbreak of the Ebola virus in the Democratic Republic of Congo, the SC requested all relevant parts of the United Nations System “to accelerate their response to the Ebola outbreak, within the overall coordination of WHO, including by supporting the development and implementation of preparedness and operational plans.”⁶² In a Statement by the President of the Security Council issued a few months later, he addressed a similar appeal to member States and civil society in affected and at-risk countries “to work urgently with relevant partners to improve their preparedness for preventing, detecting and responding to possible cases, as well as to implement optimal vaccine strategies that have maximum impact on curtailing the outbreak.”⁶³ Although these documents refer to an epidemic event, their relevance for a pandemic is self-evident.

To be effective, preparedness measures need to be highly contextualized and tailored to the specific cultural and socio-economic situation. The regional level seems optimal for addressing the issue in an effective manner because it allows for tactics to be calibrated to the peculiar features of a specific geo-political area. While this article focuses only on universal instruments, the activities promoted at the regional level need to be briefly introduced to paint a comprehensive picture of the overall preparedness measures. The European Union has been very active in this regards, adopting several pieces of sometimes very innovative legislation and political decisions such as the Action Plan to Enhance Preparedness against Chemical, Biological,

⁶² S.C. Res. 2439, U.N. Doc. S/RES/2439 (Oct. 30, 2018), para. 14. The SC already stressed the fundamental importance of preparedness measures in the previous S.C. Res. 2177, U.N. Doc. S/RES/2177 (Sept. 18, 2014) devoted to the first Ebola outbreak in Liberia and bordering States: at para. Nine of this Resolution the Council requested Member States “to implement relevant Temporary Recommendations issued under the International Health Regulations (2005) regarding the 2014 Ebola Outbreak in West Africa, and lead the organization, coordination and implementation of national preparedness and response activities.” Furthermore, at the following para. 11, the SC tasked the Secretary-General to ensure that all relevant United Nations System entities, including the WHO and UNHAS, accelerate their response to the Ebola outbreak, “including by supporting the development and implementation of preparedness and operational plans and liaison and collaboration with governments of the region and those providing assistance.”

⁶³ S/PRST/2019/6 (Aug. 2, 2019). This appeal reflects the one contained in a Presidential Statement of 2014, referred to the first Ebola eruption, in which the Security Council restated “the importance of preparedness by all Member States to detect, prevent, respond to, isolate and mitigate suspected cases of Ebola within and across borders and of bolstering the preparedness of all countries in the region” (S/PRST/2014/24, November 21, 2014).

Radiological and Nuclear Security Risks, presented by the European Commission (EC) at the end of 2017,⁶⁴ the Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on Serious Cross-border Threats to Health,⁶⁵ which introduces an innovative joint procurement procedure to facilitate the advanced purchase of medical countermeasures for serious cross-border threats to health,⁶⁶ the creation of the European Centre for Disease

64 COM (2017) 610 final (Oct. 18, 2017), https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/european-agenda-security/20171018_action_plan_to_enhance_preparedness_against_chemical_biological_radiological_and_nuclear_security_risks_en.pdf (accessed March 13, 2020). The Action Plan is built on four main pillars, one of them being devoted to “Ensuring a more robust preparedness for and response to CBRN security incidents.” In this Pillar, given the inherently cross-border and transnational nature of the CBRN threats, the Commission encourages “capacity building activities in the EU, such as cross-border cooperation in training, exercises and response, facilitating mutual assistance, providing guidance, promoting minimum standards across the Union, and where needed, funding for trans-national projects in this area.” The Action Plan includes a specific set of priority actions to be taken in cooperation with Member States and other stakeholders: these include the further development and implementation of training courses and exercises, strengthening the existing institutions mandated to work in the management of CBRN events (European Emergency Response Capacity [EERC] of the UCPM, including the EU Medical Corps), strengthen preparedness of laboratories in the EU against serious cross-border threats to health, improving awareness, preparedness and response to bio-risks, including emerging threats.

65 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, Nov. 5, 2013, 2013 O. J (L 293) represents another fundamental piece of the EU architecture to deal with potential regional pandemics, including those provoked by terrorist activities. In the Preamble of this Decision it is stated very clearly that

Preparedness and response planning is an essential element for effective monitoring, early warning of and combating serious cross-border threats to health. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level.

66 The joint procurement procedure has, in any case, to comply with several stringent rules which are codified in paragraph 2 of Article 5. The usefulness and the relevance of the Joint Procurement Agreement has been tested during the COVID-19 emergency. Personal protective equipment – masks, gloves, goggles, face-shields, and overalls – as well as medical ventilators and testing kits are vital for hospitals, healthcare professionals, patients, field workers and civil protection authorities. The Commission has successfully launched in the first months of 2020 four different calls for tender for medical equipment and supplies on 28 February (gloves and surgical gowns), 17 March (personal protective equipment for eye and respiratory protection, as well as medical ventilators and respiratory equipment), and 19 March (laboratory equipment, including testing kits) – with participation of up to 25 Member States.

Prevention and Control (ECDC)⁶⁷ and the EU Civil protection Mechanism, which was updated in 2019.⁶⁸ Other European organisations (or regional organisations with mostly European member/participating States) that significantly contributed to honing preparedness obligations are the OSCE,⁶⁹ NATO,⁷⁰ the Euro-Arctic Region⁷¹ and the Black Sea Economic Cooperation

67 Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, Apr. 30, 2004, O.J. (L 142), 1–11. Among the activities carried out by the ECDC, one is extremely relevant for the purposes of this article: we are referring to ECDC, *supra* note 7.

68 Decision 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism, Mar. 20, 2019, O.J. (L 771), 1–15, which created the European reserve of additional capacities (the ‘rescEU reserve’). These include firefighting planes and helicopters, medical evacuation capacities and a medical team trained for setting up a field hospital and even stockpiling of medical equipment. On 19 March 2020, during the acute phase of the COVID-19 pandemic, the European Commission announced the decision to create a common European reserve of medical devices such as ventilators, personal protective equipment, reusable masks, vaccines and therapeutics and laboratory supplies. The cost of the stockpiling will be covered, up to 90%, by the Commission itself which will be responsible also for distributing the equipment to ensure it goes where it is needed most: https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health_en#ensuring-the-availability-of-supplies-and-equipment.

69 The OSCE aims to enhance national preparedness levels and capacities of its participating States. At its 13th Ministerial Council in 2005, the OSCE participating States adopted the OSCE Border Security and Management Concept (MC 2/05 [Dec., 6, 2005]). One of the contributions that the OSCE may make to assist its participating States to apply the Concept is the “facilitation of cross-border co-operation in the case of natural disasters or serious accidents in border zones.” In 2013, the OSCE issued a Self-assessment tool for nations to increase preparedness for cross-border implications of crises, which is intended to contribute to overall response preparedness by promoting existing tools and pointing national authorities to international and regional assistance frameworks: <https://www.osce.org/secretariat/104490?download=true> (accessed March 22, 2020).

70 A good example of preparedness measures within NATO is the decision to launch in 2003 the NATO Combined Joint CBRN Defence Task Force, which consists of the CBRN Joint Assessment Team (JAT) and the CBRN Defence Battalion. This is a NATO body specifically trained and equipped to deal with CBRN events and/or attacks against NATO populations, territory or forces. The Battalion and the JAT are trained and equipped to be deployed quickly in the full spectrum of NATO operations, including civilian crisis situations such as natural disasters. The Battalion is capable of conducting the following tasks: “CBRN reconnaissance and monitoring operations; Sampling and identification of biological, chemical, and radiological agents (SIB CRA); Biological detection and monitoring operations; Provision of CBRN assessments and advice to NATO commanders; CBRN hazard management operations, such as decontamination” (https://www.nato.int/cps/en/natohq/topics_49156.htm: accessed March 13, 2020).

71 See the 2008 Agreement between the Governments in the Barents Euro-Arctic Region on Cooperation within the Field of Emergency Prevention, Preparedness and Response, which represents an excellent example of a European sub-regional preparedness agreement. It covers cross-border cooperation within the field of emergency prevention, preparedness and response with the aim to render swift and effective assistance in emergency response operations. The Agreement was

(BSEC).⁷² Relevant rules have also been codified on the American continent (focusing mostly on modalities of requesting international assistance there),⁷³ in Africa,⁷⁴ in Asia⁷⁵ and even at the bilateral level.⁷⁶

signed in Moscow in December 2008. https://www.barentsinfo.fi/beac/docs/Agreement_Emergency_Prevention_Preparedness_and_Response_English.pdf (accessed March 23, 2020).

72 Protocol to the 1998 Agreement Among the Governments of the Participating States of the Black Sea Economic Cooperation on Collaboration in Emergency Assistance and Emergency Response to Natural and Man Made Disasters (2005). <http://www.bsec-organization.org/UploadedDocuments/StatutoryDocumentsAgreements/ADDPROTOCOL%20071120.pdf> (accessed March 23, 2020).

73 See, for example, the 2008 Agreement Establishing the Caribbean Disaster Emergency Management Agency, the 2006 Treaty on Security Assistance among CARICOM Member States, the 2003 New Constitutive Treaty of the Coordination Centre for the Prevention of Natural Disaster in Central America, the 2001 Inter-American Convention to Facilitate Disaster Assistance, and the 1991 Agreement Establishing the Caribbean Disaster Emergency Response Agency. Preparedness obligations have been codified also in the 2012 Social Charter of the Americas in which Member States declared their commitment to strengthen “their national, technical, and institutional capacity for disaster prevention, preparedness and response, rehabilitation, resilience, risk reduction, impact mitigation, and evaluation”: Social Charter of the Americas, adopted by the OAS General Assembly on June 4, 2012, OAS Doc. AG/doc.5242/12 rev. 2, Article 22.

74 See for example, the 1999 SADC Protocol on Health, aimed at coordinating regional efforts on epidemic preparedness, mapping prevention, control and where possible the eradication of communicable and non-communicable diseases. https://www.sadc.int/files/7413/5292/8365/Protocol_on_Health1999.pdf (accessed April 3, 2020).

75 See the ASEAN 2005 Agreement on Disaster Management and Emergency Response. The Heads of State/Government of the Member States of ASEAN adopted on 6 September 2016 in Vientiane, the Declaration on “One ASEAN One Response: ASEAN Responding to Disasters as One in the Region and Outside the Region” in which they further reinforced their commitment to increase the speed, scale and solidarity of ASEAN’s response. The signatories of the Declaration declared their willingness to earmark, as an additional preparedness tool, “both civilian and military assets, resources, capabilities and capacities, which may be available for the ASEAN Standby Arrangements that can be mobilized immediately to disaster-affected areas”: <https://asean.org/asean-declaration-on-one-asean-one-response-asean-responding-to-disasters-as-one-in-the-region-and-outside-the-region/> (accessed March 23, 2020). See also the 2005 Agreement on Disaster Relief Mutual Assistance between the Governments of the Member States of the Shanghai Cooperation Council. <http://eng.sectso.org/documents/20051026/207314.html> (accessed March 23, 2020).

76 In order to fulfil their obligation to protect the basic human rights of the affected population, to safeguard the environment and to fulfil other relevant international obligations, many States have concluded bilateral disaster-cooperation agreements which mostly regulate mutual assistance should a major disaster happen. Nowadays there are many bilateral treaties in this realm and many of them codify not only the international assistance but also additional preparedness obligations incumbent on States. For a list of these bilateral treaties see de Guttry, Venturini, and Paust (2012). See also the database prepared by the Scuola Sant’Anna: <http://disasterlaw.sssup.it/disasters-database/list-of-instruments-included-in-the-database/> (accessed March 25, 2020) and the ICRC Disaster Law Database. <https://www.ifrc.org/en/publications-and-reports/idrl-database/> (accessed March 25, 2020).

3 The Relevant Role of Soft-Law and Guidelines

Considering the specific nature of the preparedness measures and the continuous technological evolution that requires their quick adaptation and revision, more and more international and some national and non-governmental institutions have promoted non-binding documents (Guidelines, Resolutions, Actions Plans, etc.) with recommendations, definitions of standards and innovative tools to increase the level of preparedness of both IOs and States. The so-called soft-law instruments present, generally speaking, several advantages compared to international treaties. The modality of adoption of these documents is usually less time consuming and faster than a treaty and their update is quick and uncomplicated. These key features make soft-law instruments appealing tools even if they are not binding. Nevertheless, both the credibility of the organisation adopting these guidelines and the participatory preparation process that led to their approval contribute to increasing, *de facto*, their impact. The relevance of these documents is also proven by the fact that they (a) are often used to interpret the existing treaties; (b) are considered useful tools in the reconstruction of a possible customary law rule on a given topic; (c) often represent the starting point of a process that might lead in the future to a codification process and (d) allow for a better perception of new trends and priorities in the international community.

The list of soft-law instruments dealing with preparedness measures to face potential pandemics is very long and includes those adopted by universal and regional institutions as well as by individual States. Within the WHO, especially in the past, soft-law instruments such as Guidelines, Guides, Checklists, etc., have been very popular and contributed to raise awareness among the States about the need to be better prepared to face pandemics.⁷⁷ Given that they provide precious information to all the States, these instruments, which were regularly updated, also proved relevant as a capacity development tool.⁷⁸ In the more general area of

⁷⁷ There are several of these documents: see, for example, Pandemic Influenza Risk Management, *supra* note 41, and the other documents quoted at the same note.

⁷⁸ These tools offer, for example, a precious guide to States on how to elaborate a national pandemic influenza preparedness plan: see WHO, Essential Steps for Developing or Updating a National Pandemic Influenza Preparedness Plan (2018). https://www.who.int/influenza/preparedness/pandemic/essential_steps_influenza/en/ (accessed March 3, 2020). The aim of this document is to ensure that, when countries develop or update a plan, the objectives are clear and the essential steps and actions are taken. It should be used in conjunction with the checklist published in January 2018 and its applications, which aim to ensure that countries take into account all the essential capacities for pandemic response in the pandemic influenza preparedness planning: WHO, A Checklist for Pandemic Influenza Risk and Impact Management: Building Capacity for Pandemic Response (2018). <https://apps.who.int/iris/bitstream/handle/10665/259884/9789241513623-eng.pdf?sequence=1> (accessed March 28, 2020).

disaster management (including pandemics), the 1994 Yokohama Strategy and Plan of Action for a Safer World – Guidelines for Natural Disaster Prevention, Preparedness and Mitigation,⁷⁹ which was updated in 2005,⁸⁰ was one of the first soft-law instruments in this area. The original and revised versions provided detailed guidelines for natural disaster prevention, preparedness and mitigation with the goal of reinforcing national legislation and institutional arrangements. In the same vein, it is worth mentioning activities carried out within the framework of the United Nations International Strategy on Disaster Reduction (UNISDR), now United Nations Office for Disaster Risk Reduction (UNDRR): the Hyogo Framework for Action 2005–2015: Building the Resilience of Nations and Communities to Disasters⁸¹ and the Sendai Framework for Disaster Risk Reduction 2015–2030 (Sendai Framework).⁸² In 2004, the United Nations Interregional Crime and Justice Research Institute (UNICRI) launched the CBRN Risk Mitigation and Security Governance Programme⁸³ to encourage States to adopt a comprehensive CBRN approach to preparedness measures.⁸⁴

Other soft-law instruments address specific issues related to typologies of disasters, the nature of the risk, the location where such events occur or aspects aimed at facilitating international assistance.⁸⁵ The WHO adopted in 2013 the

79 World Conference on Natural Disaster Reduction, *Yokohama Strategy and Plan of Action for a Safer World. Guidelines for Natural Disaster Prevention, Preparedness and Mitigation* (May 23–27, 1994). <https://www.ifrc.org/Docs/idrl/I248EN.pdf> (accessed March 3, 2020).

80 World Conference on Disaster Reduction, *Review of the Yokohama Strategy and Plan of Action for a Safer World* (Jan. 18–22, 2005). <https://www.unisdr.org/2005/wcdr/intergover/official-doc/L-docs/Yokohama-Strategy-English.pdf> (accessed April 5, 2020).

81 The Hyogo Framework for Action was the first global instrument for implementing disaster risk reduction, adopted by the Member States of the United Nations. <https://www.ifrc.org/Global/hyogo-framework-federation-en.pdf> (accessed March 18, 2020).

82 The Sendai Framework for Disaster Risk Reduction 2015–2030 provides Member States with concrete actions to protect development gains from the risk of disaster. <https://www.undrr.org/publication/sendai-framework-disaster-risk-reduction-2015-2030>.

83 The programme was launched with the technical support of the International Atomic Energy Agency (IAEA), the Organisation for the Prohibition of Chemical Weapons (OPCW), the Implementing Support Unit of the Biological Weapons Convention (ISU BWC), the World Health Organization (WHO), Interpol, Europol and the World Customs Organisation (WCO): <http://www.unicri.it/topics/cbrn/> (accessed March 23, 2020).

84 At a later moment, UNICRI has further developed “CBRN Security Governance indicators” (http://www.unicri.it/topics/cbrn/security_governance/; accessed March 23, 2020) to support national leaders to check whether their preparedness measures are operating effectively.

85 See, for example, the Sendai Framework for Disaster Risk Reduction 2015–2030; the 2011 Resolution of the Customs Co-operation Council on the Role of Customs in Natural Disaster Relief (which encourages States to implement measures expediting and facilitating the customs clearance of relief consignments); International Telecommunication Union, Resolution on the Use of

Checklist and indicators for monitoring progress in the development of IHR core capacities in States Parties⁸⁶ It represents an important tool to monitor the development of core capacities at the national, intermediate and community/primary response levels, in accordance with the requirements for core capacity development in Annex 1 of the IHR (2005). A specific part of this Checklist is devoted to preparedness measures to be adopted, suggesting important indicators devoted, for example, to the surge capacity, i.e., the ability of the health system to expand beyond normal operations to meet a sudden increased demand.⁸⁷ Also the International Federation of the Red Cross has been very active in preparing various soft-law instruments related to the preparedness phase: one of the first was the 2011 “Introduction to the Guidelines for the Domestic Facilitation and Regulation of International Disaster Relief and Initial Recovery Assistance”,⁸⁸ aimed at strengthening legal preparedness at the national level for international disaster relief. Considering that most countries do not have special laws in place for facilitating and regulating international relief,⁸⁹ the guidelines offer them a wide spectrum of ideas and suggestions on how they can facilitate international assistance in case of a disaster.⁹⁰

Telecommunications/Information and Communication Technologies for Monitoring and Management in Emergency and Disaster Situations for Early Warning, Prevention, Mitigation and Relief (2006); the 2003 Resolution of the Institute of International Law – Humanitarian Assistance; the 1995 International Conference of the Red Cross and Red Crescent, Resolution 5 – Strengthening National Capacity to Provide Humanitarian and Development Assistance and Protection to the Most Vulnerable; the 1994 Yokohama Strategy and Plan of Action, *supra* note 79; the 1986 Red Cross Resolution on Disaster Relief in Case of Technical and other Disasters.

86 https://apps.who.int/iris/bitstream/handle/10665/84933/WHO_HSE_GCR_2013.2_eng.pdf;jsessionid=486C615C99A561F4D5F0157651D531F5?sequence=1 (accessed April 3, 2020).

87 According to the Checklist, “Surge capacity encompasses potential patient beds; available space in which patients may be triaged, managed, vaccinated, decontaminated, or simply located; available personnel of all types; necessary medications, supplies and equipment; and even the legal capacity to deliver health care under situations which exceed authorized capacity”.

88 IFRC, Introduction to the Guidelines for the Domestic Facilitation and Regulation of International Disaster Relief and Initial Recovery Assistance (2011). [https://www.ifrc.org/PageFiles/41203/1205600-IDRL%20Guidelines-EN-LR%20\(2\).pdf](https://www.ifrc.org/PageFiles/41203/1205600-IDRL%20Guidelines-EN-LR%20(2).pdf) (accessed March 30, 2020).

89 The lack of specific national law on international assistance originates a set of problems, including unnecessary red tape (such as restrictions and delays in customs clearance for relief goods and equipment, imposition of duties, tolls and other taxes on relief items and activities etc.) and in poor quality and coordination from some international providers.

90 The importance of these preparedness measures at national level to facilitate international assistance has been emphasized also during the 31st International Conference of the Red Cross and Red Crescent, which adopted a specific Resolution on Strengthening Normative Frameworks and Addressing Regulatory Barriers Concerning Disaster Mitigation, Response and Recovery, Res. 31IC/11/R7 (Nov. 28–Dec. 1, 2011). https://www.ifrc.org/PageFiles/93534/31IC_R7_disaster%20laws_adopted_12Dec_clean_EN.pdf (accessed March 17, 2020).

In major disasters, such as pandemics, the possibility of using not only civilian but also military assets has become crucial. During the COVID-19 lock down, the role of the armed forces has been very visible in many States. The army has been used to support the local police in patrolling the streets and protecting specific targets, provide logistical support to the health system and produce medicine and personal safety equipment in their laboratories. The involvement of military personnel and equipment during a disaster raises several issues, both political and legal in nature. Therefore, the need arose to address and regulate them well ahead of a disaster. Although the use of the army might be considered more an issue to be discussed in the response stage, it has significant repercussions for the preparedness phase because it implies that significant preliminary work needs to be carried out. Issues such as the legal framework of the participation of military staff and assets on the occasion of a pandemic event, coordination between civil and military authorities, a clear definition of the chain of command and the training of military staff, inevitably need to be well organized in advance. For this reason, they are mentioned here as emerging issues to be dealt with in the preparedness phase. The Oslo Guidelines on the use of Foreign Military and Civil Defence Assets (MCDA) in Disaster Relief (Oslo Guidelines), the preparation of which involved all interested stakeholders,⁹¹ represent an innovative answer to this challenge.⁹² They regulate the use of MCDA “following natural, technological and environmental emergencies in times of peace”⁹³ with the aim “to establish the basic framework for formalizing and improving the effectiveness and efficiency of the use of foreign military and civil defence assets in international disaster relief operations.”⁹⁴ Although these guidelines are primarily intended for use by UN humanitarian agencies and their implementing and operational partners, they can also be used “by decision-makers in Member States and regional organizations when considering the use of

91 They were the result of a collaborative effort that culminated in an international conference in Oslo, Norway, in January 1994 and were released in May 1994. The following States and Organizations were involved in the preparation of the “Oslo Guidelines”: Argentina, Austria, Belgium, Germany, Indonesia, Italy, Japan, Kenya, the Netherlands, Norway, Russian Federation, Switzerland, United Kingdom of Great Britain and Northern Ireland, United States of America, AFDRU, Brown University’s Watson Institute, DHA, European Union/ECHO, ICDO, ICRC, IFRC, INSARAG, NATO, Steering Committee for Humanitarian Response, UNHCR, UN Legal Liaison Office, University of Naples, University of Ruhr, WHO and Western European Union.

92 The first version of the Guidelines is dated 1994 but the unprecedented deployment of military forces and assets in support of humanitarian response to natural disasters confirmed the need to update and to revise them in 2006 and in 2007: Guidelines on the Use of Foreign Military and Civil Defence Assets in Disaster Relief – “Oslo Guidelines”, updated Nov. 2006 (Revision 1.1 Nov. 2007).

93 *Id.* para. 10.

94 *Id.* para. 9.

military and civil defence assets to provide assistance to civilian populations in natural disasters and technological or environmental emergencies in times of peace.”⁹⁵

Even at the regional level there are numerous soft-law instruments that typically deal with specific issues. NATO has been very prolific in this regard, issuing several Guidance documents such as the 2009 Checklist and Non-Binding Guidelines for the Request, Reception and Provision of International Assistance in the Event of a CBRN Incident or Natural Disaster.⁹⁶ These Checklist and Non-Binding Guidelines are provided “for national preparedness in requesting and receiving international assistance and should be used by emergency planners and managers at operational level.”⁹⁷

The “Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSED III): Advancing implementation of the International Health Regulations” is another relevant tool for that part of the world.⁹⁸ Finally, between 2014 and 2018, G7 member States made 55 commitments relating to health emergencies specifically, including preparedness.⁹⁹ In the recent Declaration adopted in Paris in May 2019, the G7 Health Ministers confirmed their commitment to “continue to offer assistance to 76 partner countries and regions, building on countries’ expertise and existing partnership, for this implementation, in particular to strengthen and maintain core capacities required; and therefore, to help reduce the vulnerability of countries to public health emergencies.”¹⁰⁰

In sum, one can well conclude that there are plenty of soft-law instruments, at both the universal and the regional level,¹⁰¹ containing precious suggestions and recommendations on how States can best prepare for a potential pandemic. These instruments, which stimulate awareness among States of the importance of preparedness and contribute to minimizing the consequences of pandemics, are all non-binding. However, considering that in a few cases special mechanisms to monitor the

⁹⁵ *Id.* para. 14.

⁹⁶ NATO, Checklist and Non-Binding Guidelines for the Request, Reception and Provision of International Assistance in the Event of a CBRN Incident or Natural Disaster. https://www.nato.int/eadrcc/docs/checklist_eng.pdf (accessed May 17, 2020).

⁹⁷ *Id.* Chapter 1, para. 2.

⁹⁸ WHO, Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSED III): Advancing implementation of the International Health Regulations (2005a). <https://iris.wpro.who.int/handle/10665.1/13654> (accessed May 3, 2020).

⁹⁹ All the documents adopted by the G7, G8 and G20 are available at <http://www.g7g20.utoronto.ca> (accessed May 23, 2020).

¹⁰⁰ G7 Health Ministers Declaration: For an Inclusive, Evidence-Based and Sustainable G7 Action in Global Health (Paris, May 17, 2019). <http://www.g7.utoronto.ca/healthmins/2019-health.html> (accessed May 13, 2020).

¹⁰¹ See, for example, the Asia Pacific Strategy for Emerging Diseases, *supra* note 98.

effective implementation of these documents have been introduced¹⁰² and that in many cases the institutions that prepared them declared their availability and readiness to support, both technically and financially, States wishing to implement them in their national system, the conclusion has to be reached that these guidelines and recommendations are playing a very important role which cannot be neglected.

4 Current Challenges to the Implementation of Preparedness Measures at National Level

A careful examination of the rules codified so far in treaties (including those specifically devoted to deal with pandemics and other disasters insofar as they are applicable to pandemics) and soft-law instruments allows one to conclude that pandemic preparedness measures to be implemented by States and, where relevant, IOs are numerous, diverse and multifold. The investigation of relevant international sources carried out in the previous paragraphs permit the following summary of preparedness activities States are requested/suggested to implement (the relevant sources are indicated in the respective footnotes)¹⁰³:

- professional and regularly updated planning of pandemic emergencies;¹⁰⁴
- establishment of legal and operational frameworks to allow both first responders and law enforcement officers (if needed) to intervene quickly and safely;¹⁰⁵

102 The already commented G.A. Res. 60/288 adopting the United Nations Global Counter-Terrorism Strategy specifically foresees that every two years there will be an assessment of the progress made in the implementation of the Strategy to evaluate the need to update it to respond to changes. The Resolutions in which the UNGA carries out this assessments are based on comprehensive Reports of the UNSG which include a detailed account on the efforts carried out by IOs and by Member States to implement the four pillars of the Strategy: see, for example, the paragraphs 21 and 22 of the Report of the Secretary General, Activities of the United Nations system in implementing the United Nations Global Counter Terrorism Strategy, A/70/826 (Apr. 12, 2016). The Sixth Review of the Strategy took place on 26 June 2018. The Assembly adopted the resolution (A/RES/72/284) on the Review of the Strategy by consensus, as it had done with all other previous five resolutions on the Review of the Strategy. These regular assessments contributed, undoubtedly, to stimulate States and IOs to do their best to implement the UNGA recommendation. This kind of moral suasion exerted by the key UN institutions proved to be quite effective.

103 See also Aronsson-Storrier (2019).

104 Annex 1 to the IHR; Meeting of the States Parties to the BWC (Dec. 15, 2014), *supra* note 54; WHO, Regional Office for Europe (2012).

105 Article 44, letter d) of the IHR; Annex 1 to the IHR; WHO (2018).

- maintaining effective disease surveillance and laboratory systems with enough capacity to analyse samples (domestically or through collaborating centres);¹⁰⁶
- a system in place that allows immediate reporting of newly emerging diseases that could spread internationally;¹⁰⁷
- a scheme that encourages rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories;¹⁰⁸
- ensure that the capacities set forth for designated points of entry are developed;¹⁰⁹
- adoption of clear provisions on the chain of command during a pandemic event;¹¹⁰
- availability, when needed, of enough support from specialized staff and logistical assistance to be activated through a proper emergency organisation and through the establishment of a more extensive global, public health reserve work force;¹¹¹
- delivery of adequate training and exercises to prepare and test relevant staff;¹¹²
- maintaining the necessary infrastructure to respond to health emergencies;¹¹³
- laboratories ready to be activated and equipped to detect and report diseases or deaths above expected levels in all areas within the territory of a State;¹¹⁴
- availability of adequate and updated equipment, including, where appropriate, Personal Protective Clothing, decontamination-lorry, etc.;¹¹⁵

106 Article 13, para. One of the IHR; Annex 1 to the IHR.

107 Article 13, para. 1, and Article 19, letter (c) of the IHR; Annex 1 to the IHR.

108 World Health Assembly, Resolution WHA 60.28 (May 23, 2007); WHO; Pandemic Influenza Preparedness Framework, *supra* note 45.

109 Article 19, letter (a), and Articles 20-26 of the IHR; Annex 1 to the IHR.

110 Meeting of the States Parties to the BWC (Dec. 15, 2014), *supra* note 54; WHO, Emergency Response Framework- II Edition (2017). <https://apps.who.int/iris/bitstream/handle/10665/258604/9789241512299-eng.pdf?sequence=1> (accessed May 28, 2020).

111 Article 13 IHR, Review Committee on the Functioning of the IHR (2005) in relation to Pandemic (H1N1) 2009.

112 G.A. Res. 60/282; Meeting of the States Parties to the BWC (Dec. 15, 2014), *supra* note 54.

113 Article 13, para. 1, of the IHR; Annex 1 to the IHR.

114 Article 13, para. 1, of the IHR; Annex 1 to the IHR.

115 Article 13, para. 1, of the IHR; Annex 1 to the IHR.

- maintaining the necessary infrastructure to respond to health emergencies¹¹⁶ and ability of the health system to expand beyond normal operations to meet a sudden increased demand;¹¹⁷
- implementation of all preparedness rules foreseen in the WHO 2011 Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines;¹¹⁸
- measures in place to share, in the case of an influenza pandemic, Pandemic Influenza Preparedness biological materials to ensure ongoing global monitoring and risk assessment and the development of safe and effective influenza vaccines in conformity with the Standard Material Transfer Agreement;¹¹⁹
- mobilization of financial resources to facilitate implementation of the obligations under the IHR and, possibly, the creation of a contingency fund for public health emergencies;¹²⁰
- specific internal rules for the use of military assets during the crisis;¹²¹
- the organisation of information flows well planned in advance with a clear indication of who is entitled to issue official updates about the event and its consequences;¹²²
- ensure that designated National IHR Focal Points have the authority, resources, procedures, knowledge and training to communicate with all levels of their government and on behalf of their governments as necessary;¹²³

116 Annex 1 to the IHR; Statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19) (Apr. 30, 2020). [https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)) (accessed June 4, 2020).

117 WHO, 2013 Checklist and indicators for monitoring progress in the development of IHR core capacities in States Parties, cit, *supra* note 86.

118 WHO, Pandemic Influenza Preparedness Framework, *supra* note 45.

119 WHO, Pandemic Influenza Preparedness Framework, *supra* note 45. The Standard Material Transfer Agreement establishes the rights and obligations of Global Influenza Surveillance and Response System (GISRS) 2 laboratories when transferring PIP biological materials within GISRS and to parties outside GISRS.

120 Article 44, letter c) of the IHR; Annex 1 to the IHR; Review Committee on the Functioning of the IHR (2005) in relation to Pandemic (H1N1) 2009.

121 Oslo Guidelines, *supra* notes 91 and 92.

122 WHO, WHO Outbreak Communication Planning Guide (2008). <https://www.who.int/ihr/elibrary/WHOOutbreakCommsPlanngGuide.pdf> (accessed May 25, 2020); WHO Pandemic Influenza Preparedness & Response Guidance, *supra* note 41.

123 WHO Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation (2014); Annex 1 to the IHR.

- provide coordination and capabilities at the national and regional levels;¹²⁴
- the definition of a general legal and political framework that allows States to quickly activate, whenever deemed opportune, an international assistance request and to allow this assistance to be carried out in a pre-defined legal framework;¹²⁵
- collecting and disseminating information on S&T developments, including new research in areas relevant to the Convention, exchanging information about databases and networks and ensuring access to such databases and networks;¹²⁶
- guarantee that all preparedness measures are consistent with International Human Rights Law and that they take into special account the specific need of persons with disabilities.¹²⁷

Examining all these measures in light of the COVID-19 pandemic, one can well argue that preparedness measures emerging from international instruments (both hard and soft-law) continue to be relevant, have been continuously updated and integrated¹²⁸ and cover almost all the different fields of action. The real problem concerning their effectiveness is, therefore, related to their implementation at national level. To ensure that all these rules are respected, several monitoring schemes have been introduced in the IHR and in other relevant documents. States Parties and the Director-General were requested to regularly report to the Health

124 Article 13, para. Five and Article 44 of the IHR; Annex 1 to the IHR; WHO (2018); Statement on the third meeting of the International Health Regulations (2005), *supra* note 116.

125 Articles 13 and 44 of the IHR; Annex 1 to the IHR; Article 11 of the Draft articles on the protection of persons in the event of disasters, *supra* note 22; Meeting of the States Parties to the BWC, *supra* note 56; IFRC, Introduction to the Guidelines for Domestic Facilitation., *supra* note 88.

126 Proposals for the Final Document of the Eighth Review Conference of the Biological and Toxin Weapon Convention, Submitted by the Bolivarian Republic of Venezuela on behalf of the Group of the Non-Aligned Movement and Other States, [https://www.unog.ch/80256EDD006B8954/\(httpAssets\)/A6E0EA72D8D9F2BFC1258061007885AE/\\$file/NAM+GROUP-BWC+-+WORKING+PAPER+VIII+REV+CONF-ISP-ISU-S&T+-FINAL+VERSION.pdf](https://www.unog.ch/80256EDD006B8954/(httpAssets)/A6E0EA72D8D9F2BFC1258061007885AE/$file/NAM+GROUP-BWC+-+WORKING+PAPER+VIII+REV+CONF-ISP-ISU-S&T+-FINAL+VERSION.pdf) (accessed June 5, 2020).

127 Convention on the Rights of Persons with Disabilities; G.A. Res. 74/270.

128 In the Statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), which met in Geneva on 30 April 2020, there is a specific paragraph devoted to preparedness measures in which States are invited “to strengthen preparedness for health emergencies, and build resilient health systems, incorporating lessons learned during different stages of the pandemic, and sharing experiences” ([https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news-room/detail/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19))): accessed May 28, 2020).

Assembly on the implementation of the regulations.¹²⁹ To support and facilitate the work of Member States in preparing their national reports, the WHO developed a monitoring framework¹³⁰ through which States Parties can monitor and evaluate their own implementation of IHR capacities in accordance with the requirements for capacity development outlined in Annex 1 of the IHR.¹³¹ These national reports are examined by a Review Committee appointed by the WHO Director-General. In its 2014 Report, the Review Committee indicated that at the end of 2014 “64 States Parties had indicated that they met the minimum core capacity standards; 81 States Parties had requested an additional two-year extension of the implementation deadline; and 48 had not communicated their intentions to WHO.”¹³² The IHR Review Committee presented also additional recommendations with the aim “to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts.”¹³³ These recommendations led, in 2015, to the development of the Joint External Evaluation (JEE), which was updated in 2017.¹³⁴ The JEE allows Member States “to request as needed to evaluate country capacity to prevent, detect and rapidly respond to public health threats independently of whether they are naturally occurring, deliberate or accidental.”¹³⁵ So far, more

129 Article 54 of the IHR.

130 WHO, International Health Regulations (2005), IHR Monitoring and Evaluation Framework (2018). <https://apps.who.int/iris/bitstream/handle/10665/276651/WHO-WHE-CPI-2018.51-eng.pdf?sequence=1> (accessed May 28, 2020). The Framework is the result of a wider consensus among technical experts from WHO Member States, technical institutions, partners and WHO.

131 To facilitate the data collection, an Electronic State Parties Self-Assessment Annual Reporting Tool (e-SPAR) has been created. The e-SPAR is a web-based platform proposed to support State Parties of the International Health Regulations to fulfil their obligation to report annually to the World Health Assembly on the implementation of capacity requirements under these Regulations and to encourage the transparency and mutual accountability between States Parties towards global public health security, under the WHO IHR Monitoring and Evaluation Framework. <https://extranet.who.int/e-spar/> (accessed May 23, 2020).

132 WHO, Report to the Director-General of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation (Nov. 13–14, 2014). https://www.who.int/ihr/B136_22Add1-en_IHR_RC_Second_extensions.pdf?ua=1 (accessed April 28, 2020).

133 These additional approaches “should consider, amongst other things, strategic and operational aspects of the IHR, such as the need for high-level political commitment, and whole of government/multisector engagement” (*id.*).

134 WHO, Joint External Evaluation Tool: International Health Regulations 2005, Second Edition (2018). <https://apps.who.int/iris/bitstream/handle/10665/259961/9789241550222-eng.pdf?sequence=1> (accessed April 18, 2020).

135 *Id.* at 8.

than 100 States¹³⁶ have undertaken a JEE, resulting in the detection of more than 6000 critical capacity gaps.¹³⁷ Beside this system, which aims at monitoring States' compliance with international rules, a new instrument is surfacing. It is based on the opposite approach, namely to convince States to respect the rules by using incentivating measures. The WHO "Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits" is a good example of this new approach.¹³⁸ As reflected already in its title, the framework offers several incentives (such as facilitated access to antivirals stockpiles and to vaccines in the inter-pandemic period, tiered pricing, technology transfer¹³⁹ and sustainable and innovative financing opportunities) to those States that fulfil their preparedness obligations. This new modality of encouraging good practices deserves the highest attention.¹⁴⁰ It will be interesting to see whether, in the near future, it actually increases compliance. The introduction of an increasingly sophisticated monitoring system represents a fundamental step forward in increasing the effectiveness of the preparedness exercise insofar as it stimulates States to act consistently with their international obligations. The ongoing discussion within the WHO on how to continue to improve the IHR's existing monitoring system¹⁴¹ is an important evidence of the increasing attention devoted to this crucial aspect.

In light of the variety of the preparedness measures and considering that in almost all States their implementation is left to a plurality of institutions, both at national and at regional/local level, innovative tools have to be introduced within the national legal systems to carry out in a smooth and timely manner the various activities. In order to be more effective, these envisaged reinforced national

136 All the JEE mission reports are available at <https://www.who.int/ihr/procedures/mission-reports/en/> (accessed March 23, 2020).

137 Glassman, Datema, and McClelland (2018).

138 The Framework document introduced also an additional oversight mechanism which includes the World Health Assembly, the Director-General and the independent "Advisory Group", is expected to provide evidence-based reporting, assessment and recommendations regarding the functioning of the Framework (Article 27).

139 Article 6.13.3 of the Framework states that technology transfer "should be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time, on mutually agreed terms, and be suitable to the capacity of recipient Member States, to empower developing countries to study and manufacture influenza vaccines, diagnostics and pharmaceuticals."

140 According to a recent study of the WHO, currently there are "too few incentives to encourage countries to invest in preparedness, and there has been limited progress in developing innovative financial motivators (e.g. matched funding from donors)": WHO (2019).

141 See, for example, WHO, Meeting Report: WHO Technical Review Meeting of the Joint External Evaluation (JEE) Tool and Process (2017). <https://apps.who.int/iris/bitstream/handle/10665/259206/WHO-WHE-CPI-2017.53-eng.pdf?sequence=1> (accessed May 22, 2020).

coordination tools should be based on a commonly agreed set of principles (rule of law, precautionary approach, sound and effective administration, transparency, accountability). Divergent, fragmented, partial national implementation measures might negatively affect their success, imply a significant increase in their costs and they might even involve the international responsibility of the State for breaches of its international obligations.

The analysis carried out in the preceding paragraphs allows one to conclude that at least some of the previously mentioned measures have attracted a high level of interest in the international community (and, therefore, numerous rules have been codified), while others have received less attention. The rules concerning the implementation of the preparedness obligation to be equipped to call for international assistance are, for sure, among the most popular. During the COVID-19 crisis, the relevance of international cooperation emerged in clear terms: although the virus affected almost all States, international cooperation to face the pandemic has been strongly encouraged¹⁴² and amplified.¹⁴³ There are dozens of universal, regional, sub-regional and even bilateral treaties devoted to regulating the activation of the international assistance mechanism. The plurality of options available to States should a disaster happen is related to the consideration that, as solemnly stated by the ILC, the affected State has discretionary power “to choose from other States, the United Nations, and other potential assisting actors the assistance that is most appropriate to its specific needs.”¹⁴⁴ The high number of treaties at the universal, regional and even bilateral levels to regulate all aspects of future incoming or outgoing international assistance operations can well be explained by way of the changing nature of pandemics and the consequences thereof which make it imperative to count on international assistance.¹⁴⁵ Given that so far no duty to cooperate in providing disaster relief has emerged within customary international law,¹⁴⁶ these treaties are even more important. Moreover, the obligation to train the first responders (through training courses and full-fledged exercises) has received much attention, and hundreds of

142 The UNGA, in its Res. 74/270, U.N. Doc. A/RES/74/270 (Apr. 2, 2020), underlined that “the COVID-19 pandemic requires a global response based on unity, solidarity and renewed multilateral cooperation.”

143 The cooperation included the sharing of info, health material, financial assistance, exchange of health personnel, etc. Many States and regional organizations have been very active in promoting international cooperation during the COVID-19 crises: for the role played by the EU, see more at https://ec.europa.eu/international-partnerships/topics/eu-global-response-covid-19_en; for the international cooperation activities undertaken by the PRC, see more at the section devoted to the COVID-19 emergency on the official web site of the Chinese MFA. https://www.fmprc.gov.cn/mfa_eng/topics_665678/kjgzbdffyq/ (accessed May 3, 2020).

144 Article 11 of the ILC Report, *supra* note 22.

145 Nalbandyan (2015).

146 Fouad (2020).

specific training initiatives and complex simulation exercises, including pandemic elements, are organized every year worldwide at all levels.¹⁴⁷ Another preparedness measures which is attracting increasing attention in the international community refers to the disputed and sensitive issue of the use of military personnel and staff to face the consequences of a pandemic. The large-scale use of armed forces during the COVID-19 emergency is clear evidence of this need.

On the other hand, lesser attention has been given to the preparation of well-planned information flows that clearly identify who is entitled to issue official updates about the event and its consequences. Preparation on how to communicate risks during a pandemic is of utmost importance because it increases public and professional confidence and trust.¹⁴⁸ Lessons learned during the 2009 H1N1 pandemic highlight difficulties that public health authorities faced in communicating scientific uncertainty. Risk communication is targeted to the public but also to key stakeholders and responders such as health workers to continuously update them about the evolving situation and about interventions, in particular the pandemic vaccine. In the recent Fukushima incident, which is unrelated to a pandemic event but raises similar problems, “conflicting information soon after the onset of the Fukushima Daiichi accident because of the lack of preparedness led to distrust in the national and local governments among the public and increased fear of damage caused by radiation.”¹⁴⁹ Finally, the COVID-19 crisis has made clear that more attention needs to be devoted to preparedness measures in densely inhabited urban areas, which demand specific approaches to enable the management of future health emergencies.

5 A Sensitive Issue Raised in the Implementation Phase: The (High) Costs of Preparedness Measures

The implementation of all the above-mentioned activities requires significant investment. The question of costs has become dramatic, especially in light of the poor financial situation of most of the States. In countries with a reasonably comprehensive

¹⁴⁷ According to Global Preparedness Monitoring Board (2019), at p. 23, “As part of IHR (2005) monitoring, 103 simulation exercises and 50 after action reviews have been conducted”.

¹⁴⁸ The WHO has been very active in producing relevant Guides and Handbooks on this specific issue: see, for example, the 2008 WHO Outbreak Communication Planning Guide, *supra* note 122; and WHO (2005b).

¹⁴⁹ Japanese Red Cross, Nuclear Disaster Guidelines for Preparedness, Response and Recovery (issued on Mar. 30 2015, and updated in Mar. 2016 and Nov. 2018. <http://ndrc.jrc.or.jp/infolib/cont/mst/G0000001nrcarchive/000/072/000072662.pdf> (accessed March 23, 2020).

and well-functioning underlying health system, it has been calculated that “financing improved preparedness might cost less than \$1 per person per year, not a huge sum compared to the scale of the risks to human lives and livelihoods.”¹⁵⁰ In any case, the benefits that derive from adequate investment in preparedness measures are remarkably clear¹⁵¹ and no one can ignore their positive side-effect of reinforcing the fight against endemic diseases, improving general health services and increasing the capacity to deal with other typologies of future disasters (both natural and man-made). Participating in the 2017 Munich Security Conference, Bill Gates underlined the irony “that the cost of ensuring adequate pandemic preparedness worldwide is estimated at \$3.4 billion a year—yet the projected annual loss from a pandemic could run as high as \$570 billion.”¹⁵² In most of the countries that have a well-functioning health system, there is still an urgent need for parliaments and public opinion to stimulate and lobby their governments to increase investment in preparedness measures. In low- to medium-income countries, the priority is to have access to specific funds, in the form of both subventions and affordable long-term credits. In both cases, there are at least three main issues that deserve to be briefly addressed: how to reduce the costs of these preparedness measures to make them affordable to most States, how to facilitate access to international financial instruments to support investments in pandemic preparedness and how to define the limits of States’ discretionary powers to set priorities in the preparedness measures to be financed.

Several initiatives aimed at identifying sustainable financing mechanisms and ways to increase and improve the efficiency of domestic and global financing for health security have been carried out within the WHO.¹⁵³ The urgency to ensure “*fair, transparent, equitable, efficient and timely access to and distribution of preventive tools, laboratory testing, reagents and supporting materials, essential medical supplies, new diagnostics, drugs and future COVID-19 vaccines*” has been

150 International Working Group on Financing Preparedness (2017).

151 As stated in a recent report, these acts of preparedness “are a global public Investing in health emergency preparedness will improve health outcomes, build community trust and reduce poverty, thereby also contributing to efforts to achieve the United Nations Sustainable Development Goals”: Global Preparedness Monitoring Board (2019) at p. 6.

152 The text of the speech of Bill Gates is available at <https://www.gatesfoundation.org/Media-Center/Speeches/2017/05/Bill-Gates-Munich-Security-Conference> (accessed May 29, 2020). According to another studies the figures are different: “whereas the cost of response and economic loss from a pandemic is estimated to be as much as \$60 billion per year, it is estimated that \$4.6 billion per year, or 0.65 cents per person, would be enough to address current capacity gaps in epidemic readiness”: Glassman, Datema, and McClelland (2018).

153 The WHO and the Government of the Republic of Korea convened a meeting in Seoul on 26–27 July 2017, to identify new tool for sustainable financing mechanisms to improve the efficiency of domestic and global financing for health security. The report of the meeting is available at <https://apps.who.int/iris/bitstream/handle/10665/274158/WHO-WHE-CPI-2018.38-eng.pdf?ua=1> (accessed May 28, 2020).

emphasized by the UNGA as well in its Resolution 272 of 20 April 2020¹⁵⁴ and in the Ministerial Declaration adopted on 27 September 2018 by the Group of 77 and China.¹⁵⁵ At the regional level, the Joint Procurement mechanism regulated in the 2013 Decision 1082/2013/EU of the European Parliament and of the Council as well as the initiatives undertaken by the Asian Development Bank¹⁵⁶ are good examples in this regard.

On the second issue, the World Bank's Pandemic Emergency Financing Facility¹⁵⁷ and Health Security Financing Assessment Tool (HSFAT) offer additional opportunities to national Governments to prioritize national preparedness plans.¹⁵⁸ Other financial opportunities to support preparedness measures include the Regional Disease Surveillance Systems Enhancement Program of the World Bank,¹⁵⁹ the International Bank for Reconstruction and Development (IBRD) Catastrophe Deferred Drawdown Option CAT-DDO,¹⁶⁰ the Global Crisis Response

154 G.A. Res. 74/274, U.N. Doc. A/RES/74/274 (Apr. 20, 2020). Emphasis added.

155 At para. 135, the Ministers emphasized “the need to promote access to affordable, safe, effective and quality medicines, diagnostics and other technologies. In this regard, Ministers have recognized that generic drugs have played a key role in ensuring access to medicines in the developing world.”

156 On Jan. 29–30, 2018 in Bangkok, a conference took place on “Building Sustainable Financing and Resilient Systems for Health Security”. It was co-hosted by the Australian Department of Foreign Affairs and Trade (DFAT), Asian Development Bank, US Government's Centers for Disease Control and Prevention, World Health Organization, and the World Bank. The meeting was organized for stakeholders in East Asia and Pacific countries to share their experiences in building sustainable financing, resilient health systems, and pandemic preparedness. <https://www.worldbank.org/en/news/feature/2018/02/28/making-pandemic-preparedness-financially-sustainable-in-east-asia-and-the-pacific> (accessed May 18, 2020).

157 The PEF is a facility established for the purpose of providing financial support to Eligible Countries and Responding Agencies to help prevent a high-severity infectious disease outbreak from becoming a pandemic: The International Bank for Reconstruction and Development, the International Development Bank and the World Health Organization, Pandemic Emergency Financing Facility Framework (June 27, 2017). <http://pubdocs.worldbank.org/en/670191509025137260/PEF-Framework.pdf> (accessed June 5, 2020).

158 See more at Osewe (2017).

159 One of the specific aims of this program is to strengthen national and regional cross-sectoral capacity for collaborative disease surveillance and epidemic preparedness in West Africa. <https://projects.worldbank.org/en/projects-operations/project-detail/P154807> (accessed May 23, 2020).

160 The Development Policy Loan with a Catastrophe Deferred Drawdown Option (Cat DDO) is a contingent financing line that provides immediate liquidity to address shocks related to natural disasters and/or health-related events. It serves as early financing while funds from other sources such as bilateral aid or reconstruction loans are being mobilized. Cat DDOs can also be used to “enhance countries’ capacity to plan for and manage crises by securing access to financing before disaster strikes”: <http://pubdocs.worldbank.org/en/526461507314946994/product-note-cat-ddo-ibrd-2018.pdf> (accessed June 3, 2020).

Platform launched by the World Bank Group,¹⁶¹ the new initiatives offered by International Development Association¹⁶² and the increasing disbursement of bilateral donors for preparedness activities.¹⁶³ Although various recent studies have demonstrated that the funds available for preparedness measures are insufficient,¹⁶⁴ too fragmented and often neither well known nor easy to access by interested States,¹⁶⁵ it seems that there is at least an increasing awareness of the importance of identifying new instruments to financially support national efforts to reinforce

161 The Global Crisis Response Platform (GCRP) has been launched in response to calls from the Development Committee, the G-20 Finance Ministers and Central Bank Governors to bring together its crisis-related mechanisms, instruments and products under the same umbrella. The GCRP should provide scaled up, systematic and better coordinated support for managing and mitigating current and future crises, across the spectrum of risks and vulnerabilities: World Bank Group (2016), at para. 10.

162 In 2016, IDA expressed its commitment “to support at least 25 IDA countries in developing pandemic preparedness plans” and to support “25 countries in developing frameworks for governance and institutional arrangements for multi-sectoral health emergency preparedness, response and recovery.” To achieve these goals a CRW allocation of SDR2.1 billion has been approved to support IDA countries’ response and preparedness against severe natural disasters, economic crises, and health emergencies: IDA, *Towards 2030: Investing in Growth, Resilience and Opportunity*, approved by the Executive Directors of IDA on January 12, 2017 (modified on January 31, 2017). <http://documents.worldbank.org/curated/en/348661486654455091/pdf/112728correctfilePUBLICRptfromEDsAdditions-to-IDA-Resources-2-9-17-For-Disclosure.pdf> (accessed June 8, 2020).

163 “Data for 2015 from OECD’s Creditor Reporting Survey show that the top nine donors—United States, United Kingdom, Germany, Canada, Japan, Australia, Korea, Norway and the Bill and Melinda Gates Foundation—contributed over \$4 billion to preparedness activities in 2015 alone. This funded seven major preparedness functions: capacity strengthening, response, treatment and case management, governance and stewardship, education and behaviour change, activities in the veterinary sector, and Research and Development (R&D)” (International Working Group on Financing Preparedness 2017), at p. 48.

164 Recommendation no. Six of Global Preparedness Monitoring Board (2019) at p. 9, requests development assistance funders to

create incentives and increase funding for preparedness. Donors, international financing institutions, global funds and philanthropies must increase funding for the poorest and most vulnerable countries through development assistance for health and greater/earlier access to the United Nations Central Emergency Response Fund to close financing gaps for their national actions plans for health security as a joint responsibility and a global public good. Member states need to agree to an increase in WHO contributions for the financing of preparedness and response activities and must sustainably fund the WHO Contingency Fund for Emergencies, including the establishment of a replenishment scheme using funding from the revised World Bank Pandemic Emergency Financing Facility.

165 Sands (2017a), Glassman, Datema, and McClelland (2018).

preparedness measures.¹⁶⁶ Recent initiatives such as the Global Health Security Agenda,¹⁶⁷ the Global Alliance for Vaccines and Immunisation (GAVI),¹⁶⁸ the creation, in November 2016, of the International Working Group on Financing Pandemic Preparedness,¹⁶⁹ which presented in December 2017 a landmark report with several relevant recommendations and suggestions¹⁷⁰ and the launch, in 2017, of the Coalition for Epidemic Preparedness Innovation's (CEPI's), a global partnership between public, private, philanthropic, and civil society organisations,¹⁷¹ further testify to the ongoing worldwide efforts to increase the availability of international financial resources for preparedness measures. Even in the 2016 Ise-Shima Declaration, the G7 leaders underlined the importance of mobilizing the financial resources of relevant international organisations for “strengthening preparedness for and prevention of pandemics.”¹⁷² These efforts are of utmost importance considering that for many countries, especially the poorest and most fragile, “there is clearly a role for international development assistance in reinforcing pandemic preparedness. Here, the challenge is to ensure such contributions are effectively coordinated

166 New ideas on how to face the financial constraints have been presented also in the Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation.

167 The Global Health Security Agenda (GHSa) brings together a group of countries, international organisations, NGOs and private sector companies in order to advance a world safe and secure from infectious disease threats. More info at <https://ghsagenda.org/> (accessed June 3, 2020).

168 GAVI was launched in 2000 by the Bill and Melinda Gates Foundation and a group of founding partners with the goal to encourage manufacturers to lower vaccine prices for the poorest countries in return for long-term, high-volume and predictable demand from those countries.

169 This Group brings together experts and leaders from multilateral organizations, academia, philanthropic institutions and businesses with the aim to “propose ways in which national governments and development partners can ensure adequate and sustainable financing for actions to strengthen pandemic preparedness and thus enable effective compliance with the International Health Regulations”: Sands (2017b). The secretariat of the Group is provided by the World Bank.

170 International Working Group on Financing Preparedness (2017).

171 CEPI was founded in Davos by the Governments of Norway and India, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the World Economic Forum. Its mission is to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. CEPI has secured financial investment from several Governments, as well as from the Bill & Melinda Gates Foundation, and Wellcome. The European Commission provides substantial financial contributions to support relevant projects through its mechanisms. CEPI has also received donations from the private sector (Citadel, LuluLemon, WePlay and Ndemica) and individuals: <https://cepi.net/about/whowere/> (accessed May 3, 2020).

172 G7 Ise-Shima Leaders' Declaration – G7 Ise-Shima Summit, 26–27 May 2016, 11, <http://www.g7.utoronto.ca/summit/2016shima/ise-shima-declaration-en.pdf> (accessed May 20, 2020). For an analysis of the real implementation of these commitments by the G7 States, see G7 Research Group (2016).

and prioritized, and that we transition to a sustainable funding arrangement, rather than something that withers when donor priorities change.”¹⁷³

In terms of the third issue, it should be underlined, once more, that dedicating available domestic resources and recurrent spending for preparedness is an essential part of “national and global security, universal health coverage and the Sustainable Development Goals (SDG).”¹⁷⁴ Having said this, it has to be noticed that many countries (with the above-mentioned exception of those with a very low-level income) could self-finance pandemic preparedness measures through the national budget and, where possible, through direct financing from the private sector. Nevertheless, it cannot be denied that guaranteeing sustained commitment to financing pandemic preparedness measures often proves to be extremely difficult “since the mark of success is that nothing happens, and there will always be multiple competing priorities.”¹⁷⁵ In a well-known case, the European Court of Human Rights made clear that “an impossible or disproportionate burden must not be imposed on the authorities without consideration being given, in particular, to the operational choices which they must make in terms of priorities and resources.”¹⁷⁶ Borrowing a concept widely used in the jurisprudence of the international human rights courts, States enjoy, therefore, a “margin of appreciation” in determining which preparedness measures must go first and which will have to be implemented later.¹⁷⁷ The exercise of this discretionary power is, however, always subject to the control of the relevant Courts, should there be a dispute over whether a State respected its preparedness obligation.¹⁷⁸

The lack of available financial resources, however, does not always justify the delays in the adoption of national preparedness measures that do not require additional financial burdens. While important improvements have been noticed

¹⁷³ International Working Group on Financing Preparedness (2017), at VIII.

¹⁷⁴ Recommendation No. One of the Global Preparedness Monitoring Board (2019).

¹⁷⁵ *Id.*

¹⁷⁶ Budayeva and Others, *supra* note 28, at para. 135.

¹⁷⁷ When it comes to choosing the measures to be adopted by the States, the ECtHR has consistently held that “where the State is required to take positive measures, the choice of means is in principle a matter that within the Contracting State’s margin of appreciation. There are different avenues to ensure Convention rights, and even if the State has failed to apply one particular measure provided by domestic law, it may still fulfil its positive duty by other means”: ECtHR, Kolyadenko and Others, App. nos. 17423/05 et al., at para. 220.

¹⁷⁸ In Budayeva and Others, *supra* note 28, at para. 136, the ECtHR stated that “In assessing whether the respondent State had complied with the positive obligation, the Court must consider the particular circumstances of the case, regard being had, among other elements, to the domestic legality of the authorities’ acts or omissions...., the domestic decision-making process, including the appropriate investigations and studies, and the complexity of the issue, especially where conflicting Convention interests are involved....”.

recently,¹⁷⁹ the degree of respect for these obligations and recommendations is, with few exceptions,¹⁸⁰ still far from satisfactory, with the consequence that appropriate responses may be absent or delayed, potentially increasing the gravity of the pandemic event. According to the World Economic Forum Global Risk Report 2019,

the weakness of basic preparedness in individual countries is an important obstacle to pandemic responses. Progress has been made, particularly since the 2014–16 Ebola epidemic, but most countries have not yet reached minimum international standards of capacity to detect, assess, report and respond to acute public health threats as set out in binding regulations that took effect in 2007.¹⁸¹

6 Concluding Remarks

This article has identified several pandemic preparedness measures that States are requested /recommended to adopt. Overall, they are relevant, regularly updated and take into consideration almost all the different fields of action. Their primary, though not exclusive,¹⁸² role is to reduce the number of potential victims of a pandemic event, to protect the health of communities¹⁸³ and to mitigate risk among vulnerable populations. They always have to be carried out in full compliance with international law and, more specifically, with international

179 See more in WHO (2019) which contains extremely useful and updated statistics in this regard.

180 In a few States ad hoc structures/institutions have been created/tasked to deal with the preparedness issue: for example, in the UK the Centre for Emergency Preparedness and Response has been established within the United Kingdom's Health Protection Agency. A List of national influenza pandemic preparedness plans of the EU and EFTA Countries is available at <https://www.ecdc.europa.eu/en/seasonal-influenza/preparedness/influenza-pandemic-preparedness-plans>. In the USA, the White House Homeland Security Council issued in 2005 and 2006 the National Strategy for Pandemic Influenza and the National Strategy for Pandemic Influenza Implementation Plan. <https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/national-strategy-planning.html> (accessed May 27, 2020).

181 World Economic Forum (2019), p 48. According to the same report (at 50), "Governance challenges also exist in relation to "conventional" pandemic preparedness, despite advances such as the establishment of a Global Preparedness Monitoring Board and a Pandemic Emergency Financing Facility. The WHO's Contingency Fund for Emergencies, established in 2015 to enable rapid responses to disease outbreaks and health crises, is funded at only one third of its annual US\$100 million target." See also Gouglas et al. (2018).

182 Part of the measures is meant also to prevent serious environmental problems and major issues which might affect the stability of the societies and of their governments.

183 Gofin (2005).

human rights law, to which restrictions and derogation are permitted but only in conformity with the relevant treaty rules and procedures.¹⁸⁴

Unfortunately, available country-level data confirm “that most countries currently have low-to-moderate levels of national preparedness.”¹⁸⁵ State’s failures to implement preparedness obligations codified in an international binding treaty, amount, unless there are specific circumstances precluding wrongfulness, to a violation of international law. The consequences thereof might be diversified and give rise to an inter-State dispute (which so far has never happened) or, where appropriate, to an individual claim in front of an International Human Rights Court. In this frame it is important to remind that the EctHR has repeatedly confirmed that States have an obligation to ensure the proper organisation and functioning of the public hospital service, or more generally their health protection system. The Court has always emphasized that the States’ substantive positive obligations in this area are limited to a duty to put in place an effective regulatory framework compelling hospitals, whether private or public, to adopt appropriate measures for the protection of patients’ lives. Nevertheless the Court reserved the right to examine a particular case to check whether there has been a failure by the State. This might arise where a systemic or structural dysfunction in hospital services results in a patient being deprived of access to life-saving emergency treatment, provided that the authorities knew or ought to have known about that risk and failed to undertake the necessary measures to

184 Although making reference to the response phase, the UNGA, in its Res. 74/270, U.N. Doc. A/RES/74/270 (Apr. 2, 2020), emphasized “the need for full respect for human rights, and stresses that there is no place for any form of discrimination, racism and xenophobia in the response to the pandemic.”

185 WHO (2019), at p. 4. Making more specific reference to preparedness to deal with new pandemics, the 2014 Report of the WHO Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation stated that, though progress had been made in many areas, there was still a multitude of unresolved or only partially resolved issues. According to this Report, “countries in every Region still face significant challenges to fully implement the IHR. Key impediments to IHR implementation include: insufficient authority/capacity of NFPs; the misconception that implementation of the IHR is the sole responsibility of ministries of health; limited involvement/awareness of sectors other than human health; limited investment of national financial and human resources; high staff turnover; ongoing complex emergencies/conflict; the specific needs of small island states and States Parties with overseas territories; the focus on IHR extensions of the deadlines rather than on an expansion of capacities; a perception that implementation is a rigid, legal process with less emphasis on operational implications and learning from experience; and limited international solidarity to support the weakest countries in building capacities. States Parties’ self-assessment of their implementation of the IHR is limited by the variable quality and reliability of information that is provided”. Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation, *supra* note 123.

prevent that risk from materialising, thus putting the patients' lives in danger.¹⁸⁶ In similar cases (which might well happen during a pandemic event, especially when, as in the current COVID-19 one, several waves are expected), the Court did not hesitate to condemn the State for violating article 2 of the ECHR and to order the State to pay the applicant given amounts in respect of non-pecuniary damage. A¹⁸⁷ Although these conclusions formally apply only to the specific cases in front of the ECtHR, they have a strong general impact on the interpretation of the ECHR rules and, thanks to the cross-fertilization among international courts, might even have a wider influence.

Discrepancies in the degree of preparedness among States are often correlated to level of development. As to be expected, "countries with greater levels of national income have higher levels of national preparedness. Thirty-nine low-income countries have the lowest levels of preparedness, while higher-income countries score the highest capacity levels for preparedness."¹⁸⁸ Notwithstanding commitments to share lessons learned and technologies, and to offer technical and financial assistance to the States in greatest need, the gap is still significant.¹⁸⁹

Having in mind the worldwide impact of pandemics, which do not know any artificial or natural border, these discrepancies represent a threat to humanity. The urgent implementation of the universal governance and coordination mechanisms for health emergency preparedness and response is urgently needed¹⁹⁰ and recent initiatives undertaken in this direction are to be welcomed.¹⁹¹ Considering that, differently from the past, it is presently possible "to build an arsenal of new

186 ECtHR, *Case of Lopes de Sousa Fernandes v. Portugal* (Application no. 56080/13), Judgment, 19 December 2017.

188 WHO (2019), at p. 17.

189 Delays in the implementation of the preparedness measures have been noticed as well in Europe: In two recent studies, an urgent need surfaced to establish central of regional stockpiles of vaccines and therapeutics for post exposure prophylaxis of pathogens: European Parliament (2018).

190 In the G7 2016 Ise-Shima Declaration, *supra* note 152, the G7 Leaders confirmed that prompt and effective responses to public health emergencies "will also require World Health Organization (WHO) reforms, funding mechanisms that enable speedy disbursement for prompt response, coordinated implementation of action among relevant stakeholders and systems, and better implementation of the International Health Regulations (IHR)." See more also in University of Oxford (2019) and Gostin and Katz (2016).

191 In a recent letter, sent on 9 June 2020, the leaders of France, Germany, Poland, Spain, Belgium and Denmark requested the European Commission chief Ursula von der Leyen to reinforce the preparedness measures to fight future waves of the pandemic. In the letter, it is suggested, among others, to adopt specific measures to guarantee "a sufficient supply of personal protective equipment (PPE), medical devices, critical medicines, and vaccines": <https://europost.eu/en/a/view/eu-needs-to-prepare-common-response-for-next-pandemic-29511> (accessed June 15, 2020).

weapons—vaccines, drugs, and diagnostics”¹⁹² and that we can count on new “technology platforms that leverage recent advances in genomics to dramatically reduce the time needed to develop vaccines,”¹⁹³ inaction in fulfilling universal pandemic preparedness obligations can no longer be justified, whether in legal, political or moral terms. To use the recent words of the WHO Secretary General referred to the COVID-19 pandemic, history will judge all of us “not only on whether we got through this pandemic, but also on the lessons we learned and the actions we took once it was over.”¹⁹⁴ It is time to act.

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¹⁹² Bill Gates, Speech at the Munich Security Conference, *supra* note 153.

¹⁹³ “These new platform technologies essentially create a delivery vehicle for synthetic genetic material that instructs your cells to make a vaccine inside your own body. And the great thing is that once you’ve built a vaccine platform for one pathogen, you can use it again for other pathogens. You only need to substitute a few genes” (*id.*).

¹⁹⁴ WHO Director-General’s opening remarks at the media briefing on COVID-19 – 6 May 2020. <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—6-may-2020> (accessed June 3, 2020).

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