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THE WORLD HEALTH ORGANIZATION AND THE GLOBAL SANITARY EMERGENCIES

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Table of Contents:

OVERVIEW: 3

INTRODUCTION: THE WHO IN BRIEF 5

1.1 THE WHO, WHAT IT IS AND ITS HISTORY 5
1.2 THE STRUCTURE OF THE WHO 10
1.3 THE NORMATIVE POWERS OF THE ORGANIZATION 14
1.4 THE POWERS OF THE WHO IN CASE OF SANITARY EMERGENCY UNDER THE CONSTITUTION 18

THE INTERNATIONAL HEALTH REGULATION OF 2005 22

2.1 WHAT IS THE IHR AND ITS LEGAL VALUE 22
2.2 THE POWERS OF THE DIRECTOR-GENERAL UNDER THE IHR 41

TEMPORARY RECOMMENDATIONS 47

3.1 THE DECLARATION OF PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN (PHEIC) 47
3.2. THE EMERGENCY COMMITTEE AND THE RECOMMENDATIONS 55
3.3. THE ISSUANCE OF TEMPORARY RECOMMENDATIONS 59
3.4. THE LEGAL VALUE OF THE RECOMMENDATIONS OF THE DIRECTOR-GENERAL 63

RECENT HEALTH CRISIS AND THE MEASURES UNDER THE IHR 72

4.1 INFLUENZA A (H1N1) IN MEXICO 72
4.2 EBOLA VIRUS DISEASE IN WEST AFRICA 75
4.3. WILD POLIOVIRUS (WPV1) IN AFRICA AND MIDDLE EAST 80
4.4. ZIKA VIRUS IN BRAZIL 82
4.5. EBOLA VIRUS DISEASE IN THE DEMOCRATIC REPUBLIC OF CONGO 83
4.6. COVID-19 IN CHINA 86

CONCLUDING REMARKS: 95

BIBLIOGRAPHY: 99

OVERVIEW:

The idea of this thesis was brough to me by Professor Pustorino in January when Covid-19 was something far away limited to China. Through the writing process the outbreak became a pandemic that now affects the whole world.

The aim of this thesis is to review and analyse the current framework of the World Health Organization when responding to health emergencies, in light of the behaviour held by States during a health crisis, and more specifically analysing this behaviour from the Influenza A (H1N1) outbreak to the Covid-19 pandemic. This in order to understand the legal value of both the International Health Regulations and of the recommendations of the Director-General issued under article 15 and 49 of the International Health Regulations.

The first chapter offers an overview of the history of the World Health Organization from the first International Sanitary Conference in 1851 to nowadays. The chapter follows by studying the structure of the Organization and its normative powers, with the aim of understanding its functioning, both during normal periods and during emergencies. Finally, mentions will be made of the emergency powers allocated to the Organization within the Constitution of the Organization itself and how they were modified by the response to the SARS outbreak in 2003.

The second chapter follows assessing the International Health Regulation (IHR) from its adoption, as the International Sanitary Regulations in 1951, until the 2005 amendment. The chapter will, furthermore, evaluate the legal value of the Regulation, the dichotomy treaty-regulation and will review the obligations, substantial and procedural, upon States Parties. The IHR requires the strengthening of the public health systems of their States Parties and with the 20015 amendment the respect of the human rights framework. Conclusively, this chapter will introduce the powers of the Director-General in case of a sanitary emergency.

The third chapter explores the powers of the Director-General under the IHR, namely the possibility to declare a Public Health Emergency of International Concern (PHEIC) and to issue temporary recommendations. This chapter reviews the procedural requirement the Director-General has to follow in order to utilize its emergency powers. It examines the PHEIC declarations, in order to identify the criteria at their basis, and the functioning

of the Emergency Committees and of the Reviews Committees. This chapter then follows by assessing the process to issue the temporary recommendations of the Director-General and their legal value.

The fourth chapter finally provides an overview of the recent health emergencies from the 2009 Influenza A (H1N1) outbreak to the 2019 Covid-19 pandemic. It assesses for each emergency the timeline of the events, the recommendations issued by the Director-General and the response of the States to such recommendations. Finally, this chapter reviews the possible remedies put forward in order to react to the violations of the International Health Regulation in the mists of the Covid-19 pandemic.

CHAPTER 1

Introduction: the WHO in brief

INDEX 1.1. The WHO, what it is and its history; 1.1.1. Historical background; 1.1.2. Establishment of the WHO; 1.2. The structure of the WHO; 1.3. The normative powers of the WHO; 1.3.1 Conventions; 1.3.2 Regulations; 1.3.3. Recommendations; 1.4. The powers of the WHO in case of emergency.

1.1 The WHO, what it is and its history

1.1.1. Historical background

The World Health Organization (hereinafter "WHO" of "the Organization") is the legacy of a number of International Sanitary Conferences[1], the first one was held in 1851 in Paris. The aim of these conferences was to harmonize the legislation, the practice and the response to several diseases and problems connected with the growing rate of international trade[2]. The main focus of the first Conference was to harmonize the system of maritime quarantine as a defence from cholera, an infectious disease that was first restricted to India and later has spread across the world[3]. Cholera was one of the most feared diseases of the times, it has fatality rates between 50 and 90% if left untreated. The result of this first Conference was a Convention comprising 11 Articles and 137 Regulations, the Convention covered plague, yellow fever cholera and other diseases that were feared to be imported in Europe[4]. Of the 12 governments that participated to the Conference only three ratified the Convention and two subsequently withdraw due to the logistical difficulties to implement the Regulations. One of the main difficulties in

[1] In the years between 1851 and 1938 have been organized fourteen conferences to discuss topics of health and communicable diseases. The main venue for these conferences was Paris, but they have also been convened in Constantinople, Vienna, Washington, Rome, Venice and Dresden.
[2] WHO, Global Health Histories, https://www.who.int/global_health_histories/background/en/
[3] M. CUERTO, T. BROWN, E. FEE. *The World Health Organization; A History*, Cambridge 2019
[4] The International Sanitary Convention was promulgated by the Emperor Napoleon III in 1853 with an Imperial Decree. France. Ministère de I'Agriculture, du Commerce et des travaux publics. *Acte et instructions pour I'exdcution de la Convention sanitaire internationale*, Paris, 1853.

reaching an agreement on the measures necessary to contain cholera was the lack of consensus on what the disease was and how it spread. The following Sanitary Conferences did not produce any substantive agreement on the topic.

The efforts in order to create a convention or agreement in order to regulate and harmonize infectious disease control continued during the 1892 Sanitary Conference in Venice[5]. During this Conference, States reached a consensus on the sanitary protocols to be applied to ships crossing the Suez Canal. The Venice Conference endorsed two principles which have shaped all of the following international health efforts. Firstly, a notification system for cholera outbreaks within the borders of the States Parties to the agreement and second a strong statement on the need of a 'central institution' for the exchange of the notifications and information about the outbreaks[6]. The purpose of the 1892 International Sanitary Convention is "to establish common measures for protecting public health during cholera epidemics without uselessly obstructing commercial transactions and passenger traffic"[7]. The Convention had been amended during the following years in order to cover not only maritime traffic but also land movements and to increase the health inspections permitted[8].

Subsequently, during the 1903 Paris Conference, agreement was reached by twelve States to establish a permanent international health bureau[9]. During these meetings, delegates decided to incorporate and combine all the previous agreements and regulations into a single document, the International Sanitary Regulations (hereinafter "ISR"). Following the decision to create an international health bureau, four years later[10] the *Office International d'Hygiène Publique* (hereinafter "OIHP") was established, with seat in Paris. The OIHP was composed of a Permanent Secretariat and a "Permanent Committee" whose functions were to "collect and bring to the knowledge of the participating States the facts and documents of a general character which relate to public health, and especially as regards to infectious diseases, notably cholera, plague and

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[5] J. YOUDE; *Global Health Governance*, Cambridge, 2012, page 14.
[6] M. CUERTO, T. BROWN, E. FEE *op. cit* p 13.
[7] International Sanitary Convention, 15 April 1893, 1894 Great Britain Treaty Series no.4, preamble.
[8] J. YOUDE, *op. cit* page 17.
[9] Article 181 of the International Sanitary Convention of 1903. 35 Stat. 1770; United States Treaty Series 466
[10] Rome Agreement Establishing the Office International d'Hygie`ne Publique, 9 December 1907, reprinted N. M. GOODMAN, *International Health Organizations and Their Work*, 2nd edn, 1971, page 101.

yellow fever, as well as measures taken to combat these diseases"[11]. The mandate of the OIHP was to administer the ISR, to collect data on heath by its member states and to maintain an epidemiological intelligence service. The main objective of the OIHP was not to promote "public health" in general, but to protect "its predominantly European signatory states from transmissible diseases that threatened to arrive from afar"[12]. According to Fidler about 71% of all the rules of the ISR focused on Africa, The Middle East and Asia[13]. The OIHP was however never intended to have executive powers or have the possibility to intrude in public health administration of the participating states[14]. The limited powers of the OIHP and the narrow scope of application of the agreement made Howard-Jones describe it as "a club of senior public health administrators, mostly European, whose main preoccupation was to protect their countries from the importation of exotic disease without imposing too drastic restrictions on international commerce"[15].

Following the end of World War I and the creation of the League of Nations, one of their first objective was to create a health organization. In 1923 the League of Nations established the Health Organization on the basis of Article XXIII(f) of the Covenant of the League of Nations[16] (hereinafter "LNHO"). The OIHP was not incorporated within the Health Organization because of the *veto* expressed by the Unites States of America, which were not part of the League of Nations.

The LNHO was composed by a Health Committee and Health Section[17]. The Health Section, the executive organ of the LNHO[18], had the task of informing the Member States about concerns regarding public health and to act as a link between national health administrations[19]. The medical director of the Health Section Ludwik Rajchman stimulated social and medical development even if these where out of the specific

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[11] N. M. GOODMAN, *International Health Organizations and Their Work*, London, 1952 p. 97.
[12] M. CUERTO, T. BROWN, E. FEE *op. cit* p 16
[13] D. P. FIDLER, International Law and Infectious Diseases, Oxford, 1999, page 19.
[14] M. CUERTO, T. BROWN, E. FEE *op. cit* p. 15
[15] N. HOWARD-JONES, *International Public Health Between the two World Wars: The Organizational Problems*, Geneva, 1978, page 17.
[16] The Article established that the members would "endeavor to take steps in the matters of international concern for the prevention and control of diseases".
[17] Archives of the League of Nations, Health Section Files. Reference code: ARC003
[18] League of Nations Secretariat, Information Section. The Health Organization of the League of Nations (Geneva: n.p., 1923), p 6
[19] Archives of the League of Nations, Health Section Files. Reference code: ARC003

mandate of the LNHO[20]. The LNHO was mainly funded thanks to the International Health Division of the Rockefeller Foundation[21] which funded a "personnel interchange program"[22].

Within the years between the two World Wars there where two organizations focused on health that operated and co-operated in Europe, the OIHP and the LNHO. The LNHO focused on a number of diseases not prioritized by the OIHP, and despite some cooperation and communications the two organizations remained always strongly independent[23].

During the same years in America operated the Pan American Sanitary Organization, an organization established in 1902 by Mexico, USA, Costa Rica, Guatemala and Uruguay. The Pan American Sanitary Organization – currently the Pan American Health Organization - was created in order to encourage the exchange of information about epidemics and to contrast the spread of transmissible diseases. The Bureau of the Pan American Health Organization became the WHO Regional Office after the agreement between the two organizations in 1949, retaining its functions and autonomy within the PAHO[24].

1.1.2. Establishment of the WHO

During the 1945 San Francisco Conference on International Organization, delegates from Brazil and China submitted a joint declaration recommending "that a General Conference be convened within the next few months for the purpose of establishing an international health organization... [and] that the proposed international health organization be brought into relationship with the Economic and Social Council"[25]. The

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[20] M. CUERTO, T. BROWN, E. FEE *op. cit* p 23

[21] The International Health Division of the Rockefeller Foundation was funded in 1913, its mobilized international support for public health programs. Before the creation of the World Health Organization it was considered one of the most important organizations of public health work.

[22] J. YOUDE, *op. cit* page 23.

[23] M. CUERTO, T. BROWN, E. FEE *op. cit* p 21

[24] Y. BEIGBEDER, The World Health Organization, Oxford Public International Law, Max Planck Encyclopedia of Public International Law. At: https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e575.

[25] International Health Conference, (Paris, March-April 1946). (1947). Minutes of the Technical Preparatory Committee for the International Health Conference held in Paris from 18 March to 5 April 1946. United Nations, World Health Organization, Interim Commission. No. 1, p. 39

declaration was unanimously approved by the Conference, and the Economic and Social Council convened a Technical Preparatory Committee composed of delegates from 16 countries and observers from the pre-existing health organizations.

The Committee planed the agenda for the Conference and prepared a draft of the Constitution of the future World Health Organization. The draft of the Constitution was developed on the suggestions of the United States, the United Kingdom, France and Yugoslavia[26] The proposals have been presented to the International Health Conference, that was held in New York from 19 June to 22 July 1946 and was attended by 51 delegations from Member States of the United Nations as well as observers from non-Member States and International Organizations[27]. During the Conference there was a harsh debate in order to decide the requirements for membership. The debate was whether to allow only members of the United Nations to be part of the newly created WHO or to permit universal membership. It was an important decision considering the fact that it was the first specialized agency of the UN to be created and it would set a precedent. At the end of the conference it was unanimously decided for universal membership[28].

The Conference adopted the official text of the Constitution, established an Interim Commission with the aim of preparing the first World Health Assembly and carry out urgent tasks until the entry into force of the WHO Constitution, the other documents regarded the incorporation of the other existing health organizations in order to avoid duplicates[29]. According to Article 80 of the WHO Constitution, "this Constitution shall come into force when twenty-six Members of the United Nations have become parties to it in accordance with the provisions of Article 79"[30], this happened the 7th of April of 1948, two years after the end of the Conference. Only two States signed the Constitution without reservations while 49 Member States of the United Nations and 10 non-Member States signed with clarifications or minor reservations.

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[26] M. B. SHIMKIN, The World Health Organization, *Science*, 1946, 104(2700), 281-283.
[27] *See* International Health Conference, (New York, June-July 1946). (1948). Summary report on proceedings, minutes and final acts of the International Health Conference held in New York from 19 June to 22 July 1946. United Nations, World Health Organization, Interim Commission. Page 7.
[28] K. LEE, *The World Health Organization,* London, 2009, page 21.
[29] G. L. BURCI, C. VIGNES, *World Health Organization*, The Hague, New York, 2004. Page 15.
[30] Constitution of the World Health Organization, article 80, July 22, 1948, 14 U.N.T.S. 185

The first World Health Assembly was held in Geneva on 24 June 1948 and was attended by delegates from 53 Member States[31]. The World Health Assembly decided to stop the special power of the Interim Commission, approved the budget and the agenda of the World Health Organization. The World Health Assembly also approved the draft agreements with the United Nations and other organizations.

1.2 The structure of the WHO

The World Health Organization is one of the sixteen specialized agencies of the United Nations. The WHO has 194 Member States, and according to Article 9 of the Constitution the organs of the WHO are: the World Health Assembly (herein "Health Assembly"), the Executive Board (herein "the Board) and the Secretariat. The main structure of the WHO never changed since its creation.

The Health Assembly is the main decision body of the WHO and is composed of delegates of Member States[32], observers and representatives of Associate Members, of the Executive Board and of the United Nations. There are two categories of observers: observers invited for a limited period of time[33] and "quasi-permanent observers"[34]. According to Article 13 of the Constitution the Health Assembly meets for regular annual sessions and each year it "shall select the country or region in which the next annual session shall be held". Most of the Health Assemblies are any ways held at the Geneva headquarters[35] in order to reduce costs[36]. The Assembly can also be convened for special sessions by the Executive Board or by the majority of the Members.

The provisional agenda of the Assembly is prepared by the Board on the proposal of the Director-General. The Health Assembly in carrying out its work is adjuvated by a

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[31] WHO, Origin and Development of health cooperation. At: https://www.who.int/global_health_histories/background/en/.

[32] According to article 11 and 12 of the Constitution the delegates number is limited to three, but they may be supported by an unlimited number of advisors and alternates

[33] Potential members of the Organization

[34] Holy See, the Order of Malta, the International Committee of the Red Cross, the International federation of Red Cross and Red Crescent Societies and Palestine.

[35] Exceptions are Rome (1949), Mexico City (1955), Minneapolis (1958), New Delhi (1961) and Boston (1969)

[36] G. L. BURCI, C. VIGNES, *op. cit*

number of committees with specific tasks such as: the Committee on Programme and Budget, and the Committee on Administration, Finance, and Legal Matters[37].

As stated in Article 18 of the Constitution the main functions of the Health Assembly are to establish the policies of the Organization, to supervise financial policies, to revise and approve the programmed budget and to appoint the Director-General. The Health Assembly has also the "authority to adopt conventions or agreements within the competence of the Organization"[38] and regulations on a number of topics enumerated in article 21 of the Constitution. The Health Assembly adopts the same voting system of the United Nations General Assembly "one state, one vote" this ideally would give an equal voice to all states in the determining the actions of the Organization. Practically most of the decisions are adopted by consensus.

The Executive Board is the organ that monitors the implementation of the decision of the Health Assembly, it is the executive body of the Organization and its main functions are to "give effect to the decisions and policies of the Health Assembly"[39] and to assist the Health Assembly by preparing their work[40]. In origin it was composed by 18 members, while since 2007 the Board is composed of "thirty-four persons designated by as many Members"[41], elected by the Health Assembly taking into consideration an equitable geographical distribution. The members of the Board serve as "government representatives, technically qualified in the field of health"[42]. The Health Assembly decides the States that will form the Board while the single State determines who are the delegates, the alternates and the advisors. The Board meets twice a year and the agenda of the meeting is drafted by the Director-General and the Chairman, addressing issues selected by both the Health Assembly and the Board itself. The Board has the possibility of taking emergency measure to tackle events requiring immediate action as epidemics and calamities by authorizing the Director-General to take the appropriate necessary steps.

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[37] K. LEE, *op cit.* Page 26.
[38] Article 19 of the Constitution
[39] Article 28 (a) of the Constitution
[40] G. L. BURCI, C. VIGNES, *op. cit* p. 47
[41] Article 24 of the Constitution
[42] WHO, Fifty-First World Health Assembly, 1998, Res WHA51.26 Status of members of the Executive Board: clarification of the interpretation of Article 24 of the WHO Constitution, WHA51/1998/REC/1, p. 29

The Secretariat is composed of the "Director-General and such technical and administrative staff as the Organization may require"[43]. It is the administrative and technical organ of the Organization. The Director-General is the representative of the Organization and is "the person to whom all business concerning it should be addressed"[44]. The Director-General is appointed by the Assembly on the nomination of the Board and is subject to its authority. The term in office if of five years renewable only once as decided by the Assembly in 1996[45]. The Secretariat is also composed of the administrative and technical staff recruited "on as wide a geographical basis as possible"[46]. As it can be expected by the organization entrusted with the coordination of the public health policies most of the staff present in the Secretariat has a medical background. As of the beginning of 2020 according to the Organization's website there are more that 7000 staff members from more than 150 countries in the world[47]. The Secretariat manages the Organization by carrying out indispensable activities as centralizing the notification and information related to the diseases under its surveillance program[48].

The Organization is further composed of regional offices, established by the Assembly in the areas it deemed necessary to. The regional offices are an integral part of the Organization and are composed of a Regional Committee and a Regional Office. The Member States of the Organization are clustered in six groups, each led by a Regional Office[49] headed by the Regional Director, elected by the Regional Committee for a five-years term, they can be re-elected once. Regional Committees "formulate policies governing matters of an exclusively regional character"[50] and may have an influence on the regional budget. The Regional Office is the administrative body of the Regional Committee and has to carry out the decisions of the Assembly and of the regional Board[51]. The staff of the regional organizations is appointed according to an agreement between

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[43] Article 30 of the Constitution
[44] G. L. BURCI, C. VIGNES, *op. cit* p. 50
[45] Health Assembly Rule 108, Basic documents: forty-ninth edition (including amendments adopted up to 31 May 2019). Geneva: World Health Organization; 2020. Page: 199.
[46] Article 35 of the Constitution
[47] WHO – Organization and Structure. At: https://www.who.int/about/who-we-are/structure
[48] G. L. BURCI, C. VIGNES, *op. cit*, p. 51-52
[49] Africa, Americas, South-East Asia, Europe, Eastern Mediterranean and Western Pacific.
[50] Article 50 (a) of the Constitution
[51] Y. BEIGBEDER, *The World Health Organization*. The Hague, Boston, 1998, p. 36

the Regional Director and the Director-General. States are divided in regional offices mainly according geographical lines, with some exceptions. Israel is part of European regional office due to political and ideological conflicts with the Arab states present in the Eastern Mediterranean regional office. North and South Korea are also divided, North Korea being part of the South East Asia region while South Korea is part of the Western Pacific one with Japan and China[52].

The WHO gathers further assistance on the technical aspects by collaborating with several institution designated as collaborating centres. This system of collaboration is inherited by the League of Nations which used national laboratories designated as reference centres in order to ensure the standardization of biological products. Upon the creation of the Organization, further reference centres have been nominated, such as the World Influenza Centre in London. Subsequently, the Health Assembly stated that research can be "best advanced by assisting, coordinating and making use of the activities of existing institutions"[53] rather than creating new institutions. Collaborating centre agreements are signed when there is a successful partnership ongoing with a research centre, that has the concrete prospective of continuing in the long run. The agreement is signed between WHO and the director of the institution, after consulting the government where the institution is established. All the agreements are signed on the initiative of the Organization[54]. Collaborating centres are essential for the cost-effectiveness of the Organization, they provide support and assistance in the achievement of the programs of the Organization as well as general technical and scientific guidance[55]. According to the website of the Organization there are over 800 collaborating centres in over 80 Member States[56], of which about 150 are in partnership with the Epidemic and Pandemic Alert Response (EPR). Several of these centres are designated in assisting the Organization on

[52] J. YOUDE, *op. cit* page 33.
[53] World Health Assembly, 2. (1949). Second World Health Assembly, Rome, 13 June to 2 July 1949: Decisions and resolutions: plenary meetings verbatim records: committees minutes and reports: annexes. World Health Organization. https://apps.who.int/iris/handle/10665/85600. Page 26.
[54] WHO, Guide for collaborating centres, 2014. At: https://www.who.int/collaboratingcentres/Guide_for_WHO_collaborating_centres_2014.pdf?ua=1._
[55] K. LEE, *op cit.* Page 36.
[56] WHO, Collaborating centers, at: https://www.who.int/about/partnerships/collaborating-centres.

specific diseases, such as viral haemorrhagic fevers, emerging infectious diseases etc., in all areas of work from information gathering to laboratory services[57].

1.3 The normative powers of the Organization

The Organization was conceived primarily with a coordinating and normative role: for these reasons it is granted with powers to indicate health related standards and to guarantee their uniform application world-wide. The normative powers of the Organization are set out in Chapter V of the Constitution which provides for three types of legal instruments: conventions and agreement; regulations; and recommendations.

1.3.1. Conventions and agreements

Under Article 19 of the Constitution the Assembly has the competence "to adopt conventions or agreements with respect to any matter within the competence of the Organization".

The Constitution prescribes a two-thirds majority for the adoption of a convention: this power is more onerous on the Member States that international law in general, which usually provides for the unanimity for the adoption of binding treaties. Each Member will then have to accept the convention according to its constitutional process for it to enter into force. When negotiation the text of the Constitution, it was proposed the adoption of a provision that was strongly inspired by article 19 of the International Labour Organization (ILO) Constitution[58], States later decided for a more general provision[59].

When the Organization adopts a Convention under article 20 of the Constitution each Member State has to take action by accepting or rejecting it. Member States have to notify the Director-General with the actions taken in order to accept the convention or the agreement or with a statement with the reasons for rejecting it. Neither article 19 nor

[57] WHO, The Global Network of WHO CCs working on infectious diseases. At: http://www.who.int/collaboratingcentres/networksdetails/en/index7.html.

[58] International Labour Organization (ILO), Constitution of the International Labour Organization (ILO), 1 April 1919.

[59] Article 19 of the ILO Constitution prescribes detailed and onerous obligations upon Member Stated for when it adopts Conventions and recommendations.

article 20 of the Constitution refer to the entry into force of the agreements, leaving this topic to the final provisions of the single agreements.

The treaty authority of the Organization is at a global level, the regional offices do not have the competence in order to adopt conventions[60]. Up until the 1990's there were resistances within the Organization in adopting a convention or agreement[61]. The first heath convention is the Framework Convention on Tobacco Control of 2003, this convention was politically possible only because of the unveiling of a number of internal documents of tobacco companies thanks to numerous lawsuits in the United States[62]. Before the adoption of this convention the Organization was involved in the drafting of several treaties, among others the 1961 Narcotics Convention and the 1976 Convention on Psychotropic Substances[63].

1.3.2. Regulations

The Assembly has regulatory powers on a broad range of health topics such as: "(a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (b) nomenclatures with respect to diseases, causes of death and public health practices; (c) standards with respect to diagnostic procedures for international use; (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce"[64]. The Constitution does not provide for a definition of 'regulation', which is intended to have an intermediate legal status between binding rules and

[60] In 1999 it was adopted the Protocol on Water and Health to the 1992 Convention on the Protection and Use of Transboundary Watercourses and International Lakes with the support of the Regional Office for Europe of the WHO. The Regional Office for Europe has further jointly convened the ministerial conference where the Protocol was adopted. The Protocol was not a 'WHO treaty' because of the process followed for the adoption. Nevertheless, these events encouraged the Secretariat to refer to the Executive Board the question if the regional committees could be granted the authority to negotiate and conclude agreements and convention on strictly regional topics. The Executive Board strongly rejected the possibility of granting a general authority to the regional committees to conclude treaties but envisaged the possibility of an *ad hoc* authorization.
[61] J. YOUDE, *op. cit* page 41.
[62] G. L. BURCI, C. VIGNES, *op. cit* p. 126
[63] A. LAKIN, The Legal powers of the World Health Organization, *Medical Law International* (1997), Vol 3, p 25
[64] Article 21 of the Constitution

recommendations[65]. The regulations are adopted with a simple majority vote and enter into force for all Members after due notice is given of the Assembly's adoption[66]. In case Member States do not want a regulation to automatically enter into force, they have to notify the Director-General of any reservations or rejections[67]. The Constitution provides for a proactive "opt out" system for the entry into force of regulations. According to a draft resolution of the Director-General even if States are bound by regulations, they still have discretion in deciding how to implement and incorporate such regulation within their national legal system[68].

The first regulation, Regulation No 1[69], was adopted in 1948 during the first World Health Assembly. This Regulation regards the nomenclature of diseases and causes of death and a "unification of the statistical classification of morbidity and mortality for purposes of comparability"[70]. The second regulation adopted in 1951 was the International Sanitary Regulation[71] (now the International Health Regulation) regarding the prevention of the international spread of diseases as listed by article 21 (a) of the Constitution: this regulation can be considered the "heir" of the Sanitary Conferences of the previous century.

Both regulations have undergone major amendments and reforms during the years. There have been several discussions on the possibility to adopt further regulations in order to control the spread of malaria or on the International Pharmacopoeia and pharmacopeial formulas for potent drugs. The governing bodies of the Organization were not ready to utilize article 21 in order to regulate matters, that for a long time have been managed with non-binding instruments, such as recommendations[72]. Under article 62 of the Constitution, States have the ongoing obligation of reporting annually on the process of

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[65] A. LAKIN, *op cit* page 29

[66] Article 22 of the Constitution

[67] Article 22 of the Constitution

[68] Draft international code of marketing of breast milk substitutes to the Thirty-Fourth World Health Assembly, Annex 4, WHO Doc. A34/8.

[69] WHO, World Health Assembly, No. 1. (1948). WHO Regulations No. 1 Regarding Nomenclature (including the compilation and publication of statistics) with respect to disease and causes of death. At: https://apps.who.int/iris/handle/10665/97656

[70] G. L. BURCI, C. VIGNES, *op. cit* p. 132

[71] World Health Assembly, 4. (1952). Fourth World Health Assembly, Geneva, 7 to 25 May 1951: resolutions and decisions: plenary meetings verbatim records: committees minutes and reports: annexes. World Health Organization, Official Record No 35. p 50

[72] A. LAKIN, *op cit* page 31.

complying with the recommendations, conventions and regulations adopted under respectively articles 23, 21 and 19 of the Constitution.

1.3.3. Recommendations

For the most, even if the Organization has extreme normative powers, it prefers to act with soft law as guidelines codes or recommendations. This because States are more willing to comply with higher standard of health if they are not legally bound[73]. According to article 23 of the Constitution the Assembly has the power to adopt recommendations on “any matter within the competence of the Organization”. The two most important recommendations adopted under this article are the International Code of Marketing of Breast-Milk Substitutes (1981) and the Global Code of Practice on the International Recruitment of Health Personnel (2010). The Code of Marketing Breast-Milk Substitute has been adopted as a recommendation also because article 21 of the Constitution does not refers to food when allocating the powers to the Organization in order to adopt regulations[74]. Apart for these examples the Assembly has rarely adopted recommendations under article 23, this is of not great importance, given the non-binding nature of recommendation. Despite the non-binding nature of the recommendations these have been referred to as having “a facultative legal force” by Edward Yemin[75], giving them some legal force[76]. Moreover, the reporting obligations under article 62 of the Constitution have never been enforced by the Organization[77]. During the drafting of the Constitution it was proposed to adopt a reporting system similar to the one adopted by the International Labour Organization, which impose to the Member States to turn the recommendations to the national legislative authorities in order to take the appropriate actions. Nevertheless, the proposal of such mechanism has been considered as a duplication of other legislative powers of the organization and thus rejected[78].

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[73] L.O. GOSTIN, D. SRIDHAR, D. HOUGENDOBLER, The normative authority of the World Health Organization, *Public Health*, 129 (2015) 854-863. p 855

[74] A. LAKIN, *op cit* page 31.

[75] E. YEMIN, *Legislative powers in the United Nations specialized agencies*, Leyden, 1969. Page 183.

[76] A. LAKIN, *op cit* page 33.

[77] L.O. GOSTIN, D. SRIDHAR, D. HOUGENDOBLER *op. cit.* p 855

[78] A. LAKIN, *op cit* page 35.

The Organization has, however, a number of legal instruments other than constitutional recommendation to achieve the institutional purposes laid down in article 2 of the Constitution. These instruments can be more formal, as a code of practice, or less institutional. The Organization during the years has developed a number of systems and relations in order to advice and influence the Member States such as Resolutions of the Health Assembly, Codes of Conduct and technical standards.

1.4 The powers of the WHO in case of sanitary emergency under the Constitution

The Constitution ascribes to the Organization twenty-two functions, the "control and eradication of infectious diseases"[79] and "to assist Governments, upon request, in strengthening health services; […] to furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments"[80]. Even if sometimes these are neglected as a functions of the Organization, upon examining the history of the Organization it appears clear the importance of these duties[81]. This has been also stressed by several Health Assembly resolutions[82], the IHR of 2005 and the 2011 Pandemic Influenza Preparedness framework. But, according to Adam Kamradt-Scott it is impossible, anyways, to find in a specific document all the information responsibilities and powers of the Organization in relation to diseases eradication.

The Constitutions confers powers both to the Health Assembly and to the Board in order to prevent the international spread of diseases and to take emergency measures to deal with situations requiring immediate action[83]. The Board can authorize the Director-General to "take the necessary steps to combat epidemics"[84]. Despite the existence of such powers neither the Board nor the Director-General ever invoked article 28 of the

[79] Article 2 (g) of the Constitution.
[80] Article 2 (c) and (d) of the Constitution.
[81] See A. KAMRADT-SCOTT, *Managing Global Health Security: The World Health Organization and Diseases Outbreak Control,* 2015, Basingstoke.
[82] *See* World Health Assembly, 63. (2010). Sixty-third World Health Assembly, Geneva, 17 to 21 May 2010: resolutions and decisions: annexes. World Health Organization, WHA63/2010/REC/1; WHA63.1 Pandemic influenza preparedness: sharing of influenza viruses and acces*s*, Page 1; World Health Assembly, 59. (2006). Fifty-ninth World Health Assembly, Geneva, 22 to 27 May 2006: resolutions and decisions: annexes. World Health Organization, WHA59/2006/REC/1; WHA59.1 Eradication of poliomyelitis. Page 1.
[83] Articles 21(a) and 28 (i) of the Constitution
[84] Article 28 (i) of the Constitution.

Constitution in responding to emergencies or epidemics, not even during the SARS epidemic[85].

The Health Assembly has the normative power to create regulations dealing with, *inter alia,* the prevention of the international spreading of infectious diseases. It has adopted the first regulation on the topic in 1951 when it passes *WHA4.75 WHO Regulations No.2, the International Sanitary Regulations,* later amended in the 2005 International Health Regulation (hereinafter "IHR" or "Regulation"). The exercise of such function was subjected to several *de facto* innovations, later transferred into normative provisions.

In particular, during the 2003 SARS outbreak, before the 2005 amendment of the IHR, the Director-General of the Organization and the Secretariat took unprecedented steps in order to contain the outbreak. The Organization, first of all, adopted a policy of 'name and shame' states that did not adhered to its recommendations and information sharing procedure, it further adopted travel warnings without the consent and against the desire of the affected states[86].

The SARS outbreak was detected by the Organization's online surveillance networks when they started to spot rumours and reports of an outbreak of a mysterious disease in the Guangdong Province of China. Following the official request of information by the Organization on the 10th of February 2003, China confirmed the outbreak, but it downplayed the outbreak stating that it was already under control. The SARS outbreak spread mainly through hospitals starting from Hong Kong when a doctor, that worked in the Guangdong Province in China travelled for a wedding and felt sick. On the 12 of March 2003 the WHO reported the outbreak, wording the news in order not to link the outbreaks. Within days the Organization received communication by several states of atypical pneumonia. By the 15 of March the Organization decided to issue a travel warning for air travel without making the recommendation to restrict travel to and from countries that reported cases of SARS[87]. The Director-General autonomously declared

[85] C. KREUDER-SONNEN, *Emergency Powers of International Organizations: Between Normalization and Containment*, Oxfors, 2019, Page 159.
[86] C. KREUDER-SONNEN, *op cit.* Page 153
[87] D. P. FIDLER, *SARS: Governance and the Globalization of Disease*, 2004, New York, page 71 and ss.

the outbreak an emergency, advocating powers to his role, in a totally unprecedented occurrence[88].

Furthermore, the Director-General in issuing travel recommendations adopted emergency measures that were not provided for neither in the Constitution nor in the 1969 IHR. The Secretariat drew its powers solely from "role as an intelligence coordinator and informational hub"[89]. According to Kamradt-Scott the actions of the Secretariat of the Organization could have been covered by article 28 of the Constitution which gives the Board the power to adopt any emergency measure, within the functions and financial resources of the Organization to deal with situation requiring immediate response. In particular the Board may "authorize the Director-General to take the necessary steps to combat epidemics". On the contrary, as previously mentioned, not the Secretariat neither the Board claimed the actions taken in order to contain the SARS epidemic where adopted under article 28 of the Constitution. There is no definition of what constitutes 'emergency powers' or of their extent neither in the Constitution nor in the Board's regulations[90]. The only limit given in the Constitution are the financial resources of the Organization and its functions. This interpretation is questioned by Kreuder-Sonnen on the basis that the Board cannot delegate powers to the Director-General that it does not enjoy *per se*. The IHR is seen as a concretization of the emergency powers of the Organization. Consequently, the allocation by the Director-General of emergency powers in order to contain the SARS outbreak was outside of the authority it had within the Constitution[91]. Following the SARS outbreak the Organization completed the revision process of the IHR granting the Director-General the emergency powers it needed.

In conclusion the WHO is the directing and coordinating authority on global health and global health law within the United Nations system. In order to attain the goal of granting "all peoples the highest possible level of health"[92], the Organization has great

[88] The 1969 IHR provided for an obligation to notify the Organization of only three diseases, cholera, plague and yellow fever. For all other infectious diseases, the Secretariat could publicize and disseminate information only if received by Member States, which in practice had a *veto* power on which information to make public.
[89] C. KREUDER-SONNEN, *op. cit.* page 157.
[90] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit.* page 33.
[91] C. KREUDER-SONNEN, *op. cit.* page 160.
[92] Article 1 of the Constitution.

normative powers such as the possibility to adopt conventions, regulations and recommendations. In spite of this, the WHO has always been reluctant in adopting binding normative acts such as conventions and recommendations. The hesitation in adopting hard law or binding instruments can be attributed to the history of the Organization and the difficulties for States to agree on public health topics. The issues related to public health and health policies have always been regulated by national law. Under article 2 (g) of the Constitution the Organization has the mandate to stimulate the work in order to epidemics and other diseases. Since the 1800s government felt the necessity to develop a single universal framework in order to prevent the outbreak of communicable diseases. Despite the initial difficulties in order to adopt an international agreement on the topic prior to the creation of the WHO, the first 1951 International Sanitary Regulations have been adopted rather quickly. Following the adoption of the ISR there has been a shift in power from the States to the Organization during the following amendments, especially after the 2003 SARS outbreak with the 2005 revision. Even after all of this, as we will see in the next chapter, the powers exercised by the Organization during the 2003 SARS outbreak have been later limited.

CAPTER II

The International Health Regulation of 2005

INDEX 2.1. What is the IHR and its legal value; 2.1.1. The States Parties obligations under the IHR; 2.1.2. The IHR and human rights; 2.1.3. The implementation of the IHR; 2.2. The powers of the Director-General under the IHR.

The International Sanitary Regulations (now International Health Regulations 'IHR') are a legal instrument adopted in 1951 by the World Health Assembly in order to prevent the international spread of infectious diseases while minimizing the impact on international trade and considering human rights. The IHR has been amended several times during the years, lastly in 2005 by the 58th Health Assembly.

2.1 What is the IHR and its legal value

The history of the IHR can be traced back to the Sanitary Conferences held during the 1800's, which focused only on a small number of infectious diseases from the perspective of European countries.

The International Sanitary Regulations (herein after "ISR") of 1951, adopted by the Assembly, covered six so-called 'quarantinable' diseases[93]. The aim of the ISR at the time was to "to ensure the maximum security against the international spread of disease with minimum interference with world traffic[94]". The first amendment, approved in 1969, changed the name of the regulation to International Health Regulations and removed typhus and relapsing fever from the purpose of the Regulations. The (1969) IHR were intended to favour the use of epidemiological principles in responding to infections and "to improve sanitation in and around ports and airports, to prevent the dissemination of vectors and, in general, to encourage epidemiological activities on the national level so

[93] G. L. BURCI, C. VIGNES, *op. cit* p 135
[94] L. O. GOSTIN, *Global Health Law,* Cambridge, London, 2014; page 180

that there is little risk of outside infection establishing itself"[95]. The notification system in place in 1969 was not effective and in time States have diminished their compliance with the Regulations[96]. After the success of the Global Smallpox Eradication Program of the Organization[97], the amendment of 1981 removed this disease from the purpose of the IHR.

When revising the IHR during these years there was a total disregard for several newly discovered and highly dangerous diseases such as Ebola, hepatitis C and HIV/AIDS. This neglect towards the expansion of the application of the IHR was undermining the relevance of the Regulations. For example, when typhus and relapsing fever where removed from the IHR, these diseases were not eradicated in the whole world, but the States where these diseases were still present often did not notify the Organization of the new cases[98].

By 1995 the Health Assembly called for a fundamental revision of the IHR, which at this point covered the same diseases of the International Sanitary Convention of 1892: cholera, plague and yellow fever. The IHR at the time listed the maximum public health measures that could be enforced by states during an outbreak. These measures varied from vaccination certificates for travellers to specific measures for ports and airports, in order to prevent overreactions and embargos that could have a severe economic impact on States. The IHR was ineffective in limiting the overreaction of other Member States as demonstrated both during the epidemics of plague in South America and the Bovine Spongiform Encephalopathy ("mad cow disease") in the UK[99].

The Health Assembly of 1995 awarded the Director-General the task to revise the IHR[100], since doubts about the Regulations' effectiveness were present since 1969[101]. The

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[95] WHO, International Health Regulations (1969), 3rd ed. (Geneva: WHO, 1983), page 5.
[96] R. L. KATZ, J. FISCHER, The Revised International Health Regulations: A Framework for Global Pandemic Response, *Global Health Governance*, Volume III, No. 2 (SPRING 2010).
[97] WHO, The Smallpox Eradication Programme - SEP (1966-1980). At: https://www.who.int/features/2010/smallpox/en/.
[98] A. KAMRADT-SCOTT, *Managing Global Health Security, The World Health Organization and Disease Outbreak Control*; London, 2015; page 104.
[99] O. AGINAM, *Global Health Governance: International Law and Public Health in a Divided World*; Toronto, 2005, pp 74 ss
[100] World Health Assembly, 48. (1995). Forty-eight World Health Assembly, Geneva, 1 to 12 May 1995: resolutions and decisions: annexes. World Health Organization, WHA48/1995/REC/1; WHA48.7 Revision and Updating of the International Health Regulations. Page 7.
[101] D. P. FIDLER, L. O. GOSTIN, The New International Health Regulations: An Historic Development for International Law and Public Health, *The Journal of Law, Medicine & Ethics*, 2006 Vol 34, p 85

main concerns were the narrow scope of the Regulations and the lack of capacity and political will to react and report to infectious diseases. The first proposal of a new IHR was presented in 1998 and had a broader scope of application[102], but this draft was never approved. In the following years the focus of the international community shifted towards access to medicines and intellectual property rights, consequently the revision of the IHR had a less prominent role[103]. As a result of the outbreak of SARS of 2003 the revision process was accelerated. The negotiations of the revised text were completed in 2005 prior to the Fifty- Eight Health Assembly's meeting when the text was adopted[104], it then came into force in 2007. The delays in the revision of the Regulations are partly due to the lack of consensus on the new syndromic reporting system and the difficulties in preventing unnecessary restrictions in trade caused as an overreaction to a disease[105]. During the negotiations there was a fundamental tension between developed and developing states: developed States wanted to limit the authority of the Organization to intrude in their 'additional measures' while developing States wanted to limit the possibility for the Organization to utilize non-official sources and both group of States were in favour of what the other was opposed to[106]. Despite the fact that most of the States Parties were supportive and positive of the handling of the SARS pandemic, as was seen in the previous chapter "governments had collectively agreed to impose new restrictions on the Director-General's autonomy"[107]. The final text agreed by the States Parties undercut the authority of the Director General in order to propose a rapid response necessary to contain an outbreak.

The amended text is comprised of 66 articles and nine annexes, the articles are divided in ten parts. The purpose of the new Regulations, according to article 2, is "to prevent, protect against, control and provide a public health response to the international spread

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[102] WHO, Provisional Draft of the International Health Regulations (Geneva, Switzerland: World Health Organization, January 1998). This draft provided for the notification of six acute syndromes: respiratory, neurological, diarrheal, hemorrhagic fevers, jaundice and other syndromes with a suspected infectious disease origin.
[103] J. YOUDE, *op. cit* page 122.
[104] WHO, World Health Assembly , Revision of the International Health Regulations, WHA58.3 (May 23, 2005).
[105] A. KAMRADT-SCOTT, *Managing Global Health Security*; p. 110
[106] E. BENVENISTI, The WHO – Destined to Fail?: Political Cooperation and the COVID-19 Pandemic; *Legal Studies Research Paper Series*; Paper No. 24/2020, June 2020.
[107] A. KAMRADT-SCOTT, The International Health Regulations (2005): Strengthening Their Effective Implementation and Utilization, *International Organizations Law Review*, 16, 2019. 242-271.

of disease […]" in a way that does not disrupt international trade and commerce. The new IHR have five main changes within its text[108]. First of all, the scope of application of the IHR is now broadened to public health risks regardless of their origin or source[109]. This means that the IHR can apply to natural events but also to events that occur accidentally or intentionally[110]. Secondly, the Regulations now impose on State Parties the implementation of minimum core capacity requirements for the surveillance and response to events. Third, the sources available for the WHO in order to monitor events have been widened, the Organization can access non-governmental information. Fourth, the Organization has now the authority to declare a Public Health Emergency of International Concern and to issue temporary recommendations to the States. Lastly, human rights have been incorporated within the framework of the Regulations.

At the moment of its adoption the IHR of 2005 was considered as a tremendous achievement by numerous scholars[111]. The Regulations have been considered "arguably the most important global health treaty of the twenty-first century, with the WHO at the centre of the governance regime"[112]. Others, in contrast, criticized its focus on surveillance, lack of sufficient mechanisms for its enforcement[113] and its possible repercussions on States sovereignty[114]. It has been argued that the surveillance and notifications obligations, *inter alia*, intrude in the States right to decide how to monitor, asses and address domestic health threats[115].

The IHR is a regulation adopted under article 21(a) and 22 of the Constitution of the WHO, accordingly, is binding upon all Member States unless a specific statement on the contrary is made to the Director-General. During the adoption of the IHR, and only for

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[108] D. P. FIDLER, From International Sanitary Conventions to Global Health Security: The New International Health Regulations, *Chinese Journal of International Law*, Vol. 4 No. 2. September 2005.

[109] J. P. RUGER; Normative Foundations of Global Health Law, *The Georgetown Law Journal,* Vol. 96 pp. 423-443, 2008.

[110] Permanent Mission of the United States to the United Nations Office and Other International Organizations in Geneva, "Letter of IHR Reservation and Understanding," December 13, 2006

[111] A. KAMRADT-SCOTT, The International Health Regulations (2005), *op cit.*

[112] GOSTIN, *op cit* p 178

[113] J. L. STURTEVANT, A. ANEMA, J. S. BROWNSTEIN, The new International Health Regulations: considerations for global public health surveillance, *Disaster Medicine and Public Health Preparedness, Vol 1 Issue 2, 2007, p 117*

[114] E. MACK, The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-Fated Response to Global Health Issues, *Chicago Journal of International Law*, Vol 7 No. 1 Article 18, 2006.

[115] E. MACK, *op cit,* p 371-372.

these Regulations, the procedure laid down in article 22 was modified. Article 62 IHR states that "[r]eservations to these Regulations shall be notified to the Director-General" and "States formulating reservations should provide the Director-General with reasons for the reservations.". The reservations have to be accepted by the States Parties to the IHR which can provide the Director-General with their objection and the reasons for it. In the event one-third of the States Parties object to the reservation, and this is not withdrawn within three moth the Director-General shall seek the views of the Revie Committee on the request of the reserving States. The Review Committee recommends the Director-General on the practical implications of the reservation. Finally, the Director-General submits the reservation and the opinion of the Review Committee, if present, to the Health Assembly for its consideration. In the event the Health Assembly objects to the reservation by a simple majority vote the IHR does not enter into force for the reserving State unless the reservation is withdrawn. On the contrary if the reservation is accepted the Regulation enter into force for the reserving State[116]. The possibility for the Heath Assembly to accept the reservations was created to ensure uniformity in the application of the Regulations, to avoid pretentious reservations and to make sure the reservations were accepted by the other States. Following the 2005 amendment of the IHR only two States notified the Director-General with reservations, for neither of the reservation it was reached the number of objections necessary in order to start the process laid down in article 62 of the IHR consequently the Regulations entered into force for the reserving States, with the reservations with just a few month of delay[117].

Despite being named a 'regulation' and having followed the legislative process laid down in article 22 of the Constitution with a simple majority vote, numerous scholars[118] and State Parties to the Regulations them self[119], have referred to the IHR as a treaty or a simplified agreement[120]. In favour of a treaty definition of these Regulations there are several factors: the opting out procedure, the possibility to affix reservations, the

[116] Article 62 of the IHR.
[117] WHO, Strengthening health security by implementing the International Health Regulations (2005), States Parties to the International Health Regulations (2005). At: https://www.who.int/ihr/legal_issues/states_parties/en/.
[118] D FIDLER AND L. GOSTIN, H. G. SHERMERS AND N. M. BLOKKER, *International Institutional Law*, V ed., Leiden, Boston, 2011, p 795
[119] *See* A. KAMRADT-SCOTT, *Managing Global Health Security, op cit,* p 243.
[120] R. VIRZO, *Gli atti delle organizzazioni internazionali*, in A. DEL VECCHIO (eds.) *Diritto delle Organizzazioni Internazionali*, Naples, 2012. Page 130.

registration of the Regulations with the Secretariat of the United Nations and the possibility for non-Member States of the WHO to be part of the Regulations[121]. Even the negotiation process of the new Regulations has been compared to the negotiation of an international convention[122]. There could have been numerous reasons that made the WHO to choose the form of a regulation instead of a convention or treaty in the first place. The negotiation process of a convention, its entry into force and any amendment process are slow and difficult. The opting-out procedure provided for the regulations of the WHO allow for the avoidance of the ratification process which can be slowed or impaired by both political and administrative factors[123]. These also in in consideration of the small number of ratifications the first conventions on the topic had.

The Vienna Convention on the Law of the Treaties defines a treaty as "an international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation"[124]. Furthermore, the International Court of Justice, following the opinion of the Permanent Court of Justice[125], stated that "terminology is not a determinant factor as to the character of an international agreement or undertaking"[126]. Lastly, for an agreement to be governed by international law its execution and the obligations to execute has to fall under international law[127]. This requirement is in order to distinguish between contracts and treaties. According both to scholars[128] and States

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[121] R. VIRZO, A. DEL VECCHIO *op cit*

[122] L. BOISSON DE CHAZOURNES, *Le pouvoir réglementaire de l'Organisation mondiale de la santé à l'aune de la santé mondiale: réflexions sur la portée et la nature du Règlement sanitaire international de 2005.* In: *Droit du pouvoir, pouvoir du droit: mélanges offerts à Jean Salmon*. Bruxelles: Bruylant, 2007. p. 1157-1181. Page 1161.

[123] UNITAR, Toward wider acceptance of UN Treaties, discussed by K. Narayana Rao, *Indian Journal of International Law*, Volume 11, 267-274 (1971)

[124] Article 2 (1) (a) of the VCLT

[125] Customs régime between Germany and Austria, Advisory Opinion, 1931, PCIJ, Series A/B, no. 41, p 47.

[126] South West Africa cases (Liberia v. South Africa), Preliminary Objections filed by the Government of the Republic of South Africa, ICJ Reports 1962, p 331.

[127] Yearbook of the International Law Commission 1959, vol II, Documents of the eleventh session including the report of the Commission to the General Assembly; A/CN.4/Ser.A/1959/Add.l. Page 95.

[128] *See* R. JENNINGS, 'General Course of International Law', *Recueil des cours. Hague Academy of International law*, 1967 Vol. II, p 531; G. DELAUME, *Transnational Contracts*, 1985, Vol. I, para. 1.10; PH. JESSUP, 'Modernization of the law of international contractual agreements', *American Journal of International Law*, 1947, p 394.

practice[129] any agreement between subjects of international law is governed by international law unless it is specifically stated the contrary. Considering that the Regulations where negotiated directly by the States, it has been approved in written form and in there is no mention against the fact that is regulated by international law; the IHR could fall under the definition of treaty of the VCLT. Consequently, its designation as a regulation does not hinder the possibility of the IHR to be considered a treaty.

In order to address the difficulties in the ratification process of conventions one of the solutions has been the adoption of a negative ratification process. States instead of having to ratify the convention and consequently 'op-it' have to 'op-out' by notifying the organization of their refusal to ratify. In certain organization this is discouraged, for example in the WHO article 22 of the Constitution requires consultation and a notification of the reasons in order to contract out from the regulations. The first example of the op-out clause in international law is the procedure followed by the International Civil Aviation Organization constitution when issuing international civil aviation standards that can be added to the constitution[130].

The absence of a ratification process is not against a treaty or convention definition of the regulations issued by the WHO under article 21 and 22 of the Constitution. Under the Vienna Convention on the Law of the Treaties[131] the consent of a State to be bound by an agreement can be expressed in any mean the States accept to[132]. Consequently, when the States negotiated, signed and ratified the Constitution of the WHO they expressed their consent in being bound by the regulations they would later agree on in the Heath Assembly. Furthermore, according to Pierre-Henri Imbert article 11 of the VCLT raises the possibility for the tacit consent to a treaty "especially since under international law there is no rule imposing on States to give their consent expressly"[133]. Finally, procedure

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[129] See A. AUST, 'The theory and practice of informal international instruments', *International and Comparative Law Quaterly*, 1986, p 797; Yearbook of the International Law Commission 1965, vol II, Documents of the first part of the seventeenth session including the report of the Commission to the General Assembly, A/CN.4/SER.A/1965/Add.l. Page 10.

[130] ICAO, Arts. 54(l), 90, 37, 38; ICAO Bulletin Volume 20 (1965) No. 7, at 14. *See* [130] L. BOISSON DE CHAZOURNES, *op cit,* page 1170.

[131] United Nations, Vienna Convention on the Law of Treaties, 23 May 1969, United Nations, Treaty Series, vol. 1155, p. 331. (VCLT)

[132] Article 11 of the VCLT

[133] P. H. IMBERT, Le consentement des Etats en droit international. Réflexions à partir d'un cas pratique concernant la participation de la CEE aux traités du Conseil de l'Europe, *Revue générale de droit international public*, 1995, page 361.

similar to the op-out procedure envisaged by article 22 of the Constitution is provided for in Part XI of the United Nations Convention on the Law of the Sea[134].

Against the treaty definition of the IHR, article 22 of the Constitution refers to ability of States to submit reservations, and this could be a factor in favour of a treaty definition, the VCLT allows for the submission of reservations only "when signing, ratifying, approving or acceding to a treaty"[135]. Consequently, according to Alexandrowich the procedure should not be referred to as a treaty procedure and the IHR should not be considered a treaty[136]. Furthermore, the IHR is an act attributable to the Health Assembly, which adopts them with a majority vote, and not to the Member States. Furthermore, the Health Assembly may decide to modify or to replace them with a simple majority vote regardless of the will of each Member State of the Organization. As suggested by Roberto Virzo, these Regulations have more in common with the UN Security Council resolutions as defined by the International Court of Justice[137] rather that with a treaty[138]. The IHR is one of the most widely adopted treaties in the world, having 196 State parties, including all the WHO Member States but also the Holy See and Liechtenstein[139].

According to the WHO Legal Office the interpretation of "the IHR (2005) lies with IHR State Parties"[140]. This is an unusual power to rest upon the members of an agreement and not upon the custodians of such agreement. Considering also that some of its Member States view the WHO as the sole authority upon the IHR. Resting the interpretation of the Regulation upon the States Parties can deprive the IHR of a fair and impartial

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[134] S. SZURE, *Volume I, Part II Conclusion and Entry into Force of Treaties, s.1 Conclusion of Treaties, Art.11 1986 Vienna Convention,* in O. CORTEN, P. KLEIN, *Oxford Commentaries on International Law,* Oxford, 2011. Page 208.

[135] Article 2 of the VCLT

[136] C. H. ALEXANDROWICZ, *The Law-Making Functions of the Specialized Agencies of the United Nations*, Sidney, 1973, page 51.

[137] The ICJ has distinguished the UN Security Council resolutions because, *inter alia,* they "are issued by a single, collective body and are drafted through a very different process than the one used for the conclusion of a treaty", so that "the final text of such resolutions represents the view of the Security Council as a body". ICJ, Advisory Opinion of 22 Jul. 2010, Accordance with International Law of the Unilateral Declaration of Independence in Respect of Kosovo, ICJ Reports 2010, 442, Section 94.

[138] R. VIRZO, *The Proliferation of Institutional Acts of International Organizations: A Proposal for Their Classification*. In Evolutions in the Law of International Organizations. Leiden, 2015. Page 312.

[139] "States Parties to the International Health Regulations (2005)" (as of April 23, 2020), WHO, http://www.who.int/ihr/legal_issues/states_parties/en/ (accessed 23/04/2020). The IHR (art. 64) permits non-Member States of the WHO to become parties of the Regulations as well as Members of the Organization.

[140] Review and update of the annex of the FAL Convention: Proposed amendments to section 3 of the FAL Convention, IMO Facilitation Committee, 43rd session, Agenda Item 4, IMO Doc FAL 43/3/2, 1 February 2019. WHO submission to FAL Convention, FAL43/4/2.

interpretation that could be better offered by the WHO Legal Office. Some of the rules contained in the IHR impose limitation on the actions of the State Parties consequently a third-party interpretation of these rules could bring greater clarity on the meaning of them. Several aspects of the Regulations can create ambiguities when interpreted, according to Gian Luca Burci this can be caused by the rapidity with which the Regulations where revised and the immense pressure caused by the latest SARS outbreak[141].

In conclusion, despite the similarities of the IHR to a treaty also in light of the provisions of the VCLT the Regulations are a unilateral act of the WHO. The Regulations have been adopted by a simple majority vote following the process laid down in article 22 of the Constitution, even if prior to the vote by the Heath Assembly took place a negotiation process similar to negotiating an international agreement. The IHR can be considered a *sui generis* normative act and cannot be classified with certainty as ether a unilateral act of an International Organization or as an international agreement.

2.1.1. The States Parties obligations under the IHR

Although the IHR is binding upon Member States without ratification, there is a need for the Member State's cooperation in order to implement the obligations contained in it. Especially there is a need for the adoption of national legislation and policies to implement and reinforce the national public health systems in order to promptly detect and isolate diseases[142]. The IHR acts both at an international and national level. Under the new approach adopted by the WHO in this Regulations, States have the duty to improve the public health system's capacity to detect, assess, notify and report events[143]. These obligations are defined as "protracted obligations" in contrast to the notification system that has been defined as "hard-and-fast" obligations[144].

Under article 5 of the IHR states shall "develop, strengthen and maintain […] the capacity to detect, asses, notify and report events in accordance with these Regulations".

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[141] A. KAMRADT-SCOTT, The International Health Regulations (2005), *op cit.*
[142] *See* GOSTIN, *op cit*
[143] Article 5(1) and annex 1 of the IHR
[144] P. VILLAREAL, COVID-19 Symposium: "Can They Really Do That?" States' Obligations Under the International Health Regulations in Light of COVID-19 (Part I), in B. SANDER & J. RUDALL (eds.), *Opinio Juris* Symposium, March-April 2020, p. 17

While article 13 of the IHR entails "the capacity to respond promptly and effectively to public health risks". An "event" is defined by the IHR as the appearance of a disease or an episode that can create the conditions for a disease to arise, while a disease is described as an illness or medical condition that could harm humans.

The Organization has developed several core capacities that States have to improve and strengthen in order to fully implement the Regulations[145].

The core capacities developed by the Organization are:

- National legislation, policy and financing: States must implement a suitable legal framework in order to realise the IHR obligations and safeguard rights. States have complete discretion in how to implement the IHR obligations, whether amending the legislation or using non-binding instruments.
- National focal point (NFP): States shall create a NFP with the assignment of communicating urgent information to the WHO IHR contact points and act as a communication channel. The NFP shall be able to communicate 24 hours a day 7 days a week.
- Notification: States have the obligation to report to the WHO within twenty-four hours from their occurrence of all events that may constitute a Public Health Emergency of International Concern under article 6 of the IHR.
- Planning and risk communication: States are encouraged to develop emergency plans in order to respond to health treats.
- Public health infrastructure: States shall advance and create a public health infrastructure that encompasses health workforce, equipped laboratories, a data system and cross-sector coordination in order to face any health risk that may arise.

The National IHR Focal Point has the task of regularly communicating with the Organization and carry the notifications under articles 6 and 7 of the IHR.

All States Parties have appointed a NFP, but most of them are not trained correctly on the implementation of the IHR or are not correctly entrusted with the task of routinely communicate with the headquarters of the WHO. The IHR impose not only the

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[145] GOSTIN *op cit p* 186; *see also* WHO, Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties (Geneva: WHO, 2011).

development and strengthen of the capacity to asses and detect events but also to notify and report them. States Parties must notify the Organization of "all events which may constitute a Public Health Emergency of International Concern within its territory"[146].

Annex 2 of the Regulations is the "decision instrument"[147] for the evaluation of the events and poses the guidelines for the decision on whether to notify or not an event. The final text of this Annex significantly differs from the first drafts, having occurred much debate on its formulation.

Several delegates did not want to include a list of diseases within the decision-making process. On the other hand, delegates from developing countries argued that without a list of diseases specifically covered by the Regulation they would not be able to provide funding for the surveillance system needed in order to implement the requirement of such Regulation. Discussion rose also on the possibility to include deliberate and intentional acts within the Regulations[148]. Under Annex 2 four diseases always have to be notified: smallpox, wild poliomyelitis, novel human influenza, and SARS. Furthermore, pandemic prone diseases, such as, but not limited to, cholera, pneumonic plague, yellow fever, and viral haemorrhagic fevers have to be notified if after the utilization of the decision instrument set out in Annex 2 since their outbreak could constitute a Public Health Emergency of International Concern (PHEIC).

Lastly, any event that could have an international effect on health, including those of unknown causes or sources and those involving other events or diseases, other than the above-mentioned ones, should trigger the application of the decision instrument in order to assess whether they could constitute a PHEIC. The main criteria of the decision instrument are the potential international spread of the disease or effects of the event, the fact that the event is unusual or unexpected and the presence of a significant risk of international travel and trade restrictions. The decision instrument poses a series of questions, if the answer is 'yes' to two or more the event has to be notified to the WHO through the IHR National Focal Point. The questions present in the decision instrument

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[146] Article 6 IHR.

[147] R. KATZ AND A. MULDOON; Negotiating the Revised International Health Regulations (IHR) in E. ROSSKAM AND I. KICKBUSCH (edited by), Negotiating and Navigating Global Health: Case Studies in Global Health Diplomacy, Singapore, 2011.

[148] R. KATZ AND A. MULDOON *op cit* p 92

are solely for guidance. The notification of an event that may constitute a PHEIC has to be followed by follow-up information as the situation develops.

According to article 6 of the IHR the States Parties shall notify the Organization of any extraordinary event if required after the assessment under the decision instrument contained in Annex 2. The notification shall be made in the most efficient way by means of the National IHR Focal Point not later that 24 hours from the assessment of the public health information. Succeeding the notification, the affected State should continue to update the WHO of the new information that may discover on the event and with the measures adopted in order to respond to the event[149]. In the eventuality the event notified is of the competence of the International Atomic Energy Agency (IAEA) the Organization will notify the IAEA. Furthermore, State Parties should notify the Organization of all public health events that are unexpected or unusual that happen within their territory if they could constitute a Public Health Emergency of International Concern, the State shall report all the relevant information already collected[150]. This provision overlaps with the previous article of the IHR but have the purpose of implementing the "all-hazards" approach[151].

Article 8 of the IHR provides for confidential consultations with the Organization on events that do not trigger the notification obligation under article 6: the logic of this provision is to inform the WHO of events in relation to which there are not enough information to complete the decision instrument provided in Annex 2. States should also, as far as practicable, inform the WHO of the acknowledgement of evidence of a public health risk happening outside their territory[152]. The evidence can be human cases of a disease, infected or contaminated vectors or contaminated goods. This reporting process also overlaps with article 6 of the IHR.

To incentivise the notification, reporting and consultations from State Parties the information shared with the Organization are confidential and shall not be shared with other Member States of the WHO. The Organization will share the information received if:

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[149] Article 6 IHR

[150] Article 7 IHR.

[151] N. M. M'IKANATHA, R. LYNFIELD, C. A. VAN BENEDEN, H. DE VALK; *Infectious Disease Surveillance a Cornerstone for Prevention and Control*, in *Infectious Disease Surveillance,* 2nd ed, 2013.

[152] Article 9(2) IHR

i) the event is declared a PHEIC by the Director-General;

ii) the information regarding the international spread of the disease or the contamination are confirmed;

iii) there is evidence that the control measures to avoid the international spread of the event are unlikely to succeed;

iv) the affected State Party lacks the technical and operational structures to avoid the international spread of the disease or contamination;

v) when there is the need to immediately apply international control measures because of the nature of the movement of travellers or goods that may be affected by the event.

In any case, if one of these conditions are met, the Organization will consult with the affected State before sharing the information. In the event that other information regarding the event are already public the Organization will also consider sharing the information received with the general public if there is the need of distributing data that is authoritative and independent[153]. The obligation to notify the WHO as laid down in the IHR is a substantiation of the more general "duty to cooperate" as laid down in the Charter of the United Nations and more specifically in the International Covenant on Economical Social and Cultural Rights which recognizes the right to health as a human right[154].

Similar procedural obligations as the ones present in the IHR and stemming from the same duty to cooperate have been introduced within environmental treaties since the 1970s[155]. The duty to notify to the affected States of any environmental emergency has been considered customary international law by the International Court of Justice in the 1949 Corfu Chanel case, in which this duty is described as being based on the principles of: "elementary considerations of humanity, even more exacting in peace than in war; the principle of the freedom of maritime communication; and every State's obligation not to allow knowingly its territory to be used for acts contrary to the rights of other States"[156].

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[153] N. M. M'IKANATHA *et al, op cit.*

[154] P. BASU, International law and public health crises, *Observer Research Foundation commentaries*, 15 June 2020.

[155] *See UNECE Convention on Long-Range Transboundary Air Pollution (ECE LRTAP Convention), 1979; Convention for the Prevention of Marine Pollution from Land-Based Sources, 1974.*

[156] ICJ, Corfu Channel (United Kingdom v. Albania), Merits, ICJ Reports (1949) 4, paragraph 22.

Since then the duty of early notification has been codified[157] it has also been introduced at a multilateral level where the affected parties are notified by the relevant institutions or international organizations[158].

As analysed by Mari Koyano there are several methods to ensure compliance with the procedural obligations in environmental law treaties and consequently with the emergency notifications[159]. Such methods to ensure compliance and enforcement are not present in the IHR. The Regulations lacks any enforcement mechanism and provide for no punishment for failure to implement the legal obligations contained in it. Furthermore, the avoidance or delay to notify the WHO of a potential PHEIC has no repercussions for the State that undertakes this conduct[160]. Currently the only enforcement mechanism adopted by the WHO is to publicly shame countries that fail to implement and comply with the IHR[161]. According to the FAQ about the IHR the "potential consequences of non-compliance are themselves a powerful compliance tool"[162]. Furthermore, they cite 'tarnished international image' and 'increased morbidity and mortality' as the consequence of the infringement of the IHR that should convince States to cooperate and comply. As we will see, this mechanism is not effective as once again the World is struck by a pandemic.

Indeed, the latest emergency, the Covid-19 outbreak, which allegedly started in China and then spread to the rest of the world becoming a pandemic, have provoked a strong debate on how to enforce the obligations under article 6 and 7 of the IHR and in case of their violation whether there is a remedy. Chinese authorities since the beginning of the outbreak have allegedly tried to withhold information and silence the whistle-blowers[163],

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[157] IAEA, Convention on Early Notification of Nuclear Accidents (IAEA Convention on Early Notification), 1986.

[158] E.g. UNCLOS; Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter 1972; IAEA, Convention on Early Notification of Nuclear Accidents, 1986.

[159] M. KOYANO, The Significance of Procedural Obligations in International Environmental Law: Sovereignty and International Co-Operation, *Japanese Yearbook of International Law*, 2011.

[160] R. KATZ AND J. FISHER, The Revised International Health Regulations, *op cit.*

[161] L. TONTI, COVID-19 The International Health Regulations: The Fallout of a Multinational Framework, Biolaw Journal, 26 March 2020

[162] WHO, Frequently asked questions about the International Health Regulations (2005), https://www.who.int/ihr/about/faq/en/#faq07

[163] *See* G. SHIH, E. RAUHALA AND L. H. SUN, Early missteps and state secrecy in China probably allowed the coronavirus to spread farther and faster, *The Washington Post*, 1 February 2020; J. BELLUZ, China hid the severity of its coronavirus outbreak and muzzled whistleblowers — because it can, *Vox*, 7 February 2020; J. KRASKA, China Is Legally Responsible for COVID-19 Damage and Claims Could Be in the Trillions, *War on the Rocks*, 23 March 2020;

violating their obligations under the IHR[164]. This is not the first-time accusations of withholding information and delaying the notification under the IHR have been moved against a country affected by an outbreak of an infectious disease that then have or have not resulted in the declaration of a PHEIC[165].

In the aftermath of the H1N1 pandemic it has been reported that, while Mexico's delays in notifying the WHO may have been caused by the lack of resources, numerous other countries intentionally delayed the notification under articles 6 and 7 of the IHR or imposed travel and trade bans violating article 43 of the IHR[166]. While during the 2013 outbreak of Ebola in West Africa it took two months for the Guinean authorities to notify the WHO since the first person developed Ebola symptoms[167]. Furthermore, the authorities of all involved countries in the Ebola outbreak have been accused of downplaying the outbreak to avoid economic repercussions[168].

Under customary international law a violation of an international legal obligation attributable to a State constitute an international wrongful act[169] and thus requires full reparation. Under the dispute settlement clause in the IHR[170] if an argument arises on the application or interpretation of the Regulations, this should be settled in first instance by means of negotiation, good offices, mediation or conciliation. In the event the dispute is not resolved by means of the conciliation mechanism, it should be referred to the Director-General of the Organization who shall make the effort to resolve it. At any time of a dispute, the States party involved can declare to accept an arbitration as compulsory. If the arbitration is requested the award shall be accepted as binding.

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[164] Other governments could have done the same.

[165] L. O. GOSTIN, R. KATZ, The International Health Regulations: The Governing Framework for Global Health Security. *Milbank Quarterly* 2016

[166] T. OTTERSEN, S. J. HOFFMAN AND G. GROUX; Ebola Again Shows the International Health Regulations are Broken: What can be done Differently to Prepare for the Next Pandemic?; *American Journal of Law and Medicine*, 2016

[167] See, e.g., WHO, Report of the Secretariat: Ebola Virus Disease epidemic in West Africa 2, 2014; D. FLYNN AND S. NEBEHAY, Aid Workers Ask Where Was WHO in Ebola Outbreak?, Reuters; 15 October 2014.

[168] *See* Médecins Sans Frontières, Pushed to the Limit and Beyond: A year into the largest ever Ebola outbreak, 23 March 2015. page 8. At: https://www.msf.org/ebola-pushed-limit-and-beyond; The Politics Behind the Ebola Crisis, International Crisis Group, Report No. 232, 28 October 2015. At: https://www.crisisgroup.org/africa/west-africa/politics-behind-ebola-crisis

[169] Article 3 of the International Law Commission's Draft Articles on State Responsibility.

[170] Article 56 IHR

2.1.2. The IHR and human rights

Under article 3(1) of the IHR "the implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons". This provision creates a connection between the IHR system and the human rights system, imposing to all parties the adoption of measures that are compatible with human rights. Nevertheless, article 3(1) IHR does not outline the obligation to safeguard human rights, it is only a guideline to follow, a policy statement. Furthermore, article 3(2) IHR provides that the implementation of the Regulations shall be guided by the Charter of the United Nations. The Charted provides for a more detailed *corpus juris* of human rights standards, embodying the human rights principles developed in the of the UN framework and UN expert bodies[171]. A peculiarity of the IHR is the criteria upon which relies in order to justify the infringement of human rights. The international human rights framework, to justify both a limitation or a derogation[172], requires as a criterion a compelling public interest, on the other hand, the Regulations requires that health measures limiting or derogating human rights are based upon scientific evidence or principles[173]. This allows for a limitation of discretion in deciding the infringement of human rights. The rights that under article 18 of the IHR are affected and could be limited pursuant to Director-General's temporary recommendations are the right to privacy[174], the right to liberty[175] and the freedom of movement[176]. Any limitation of these rights shall always fulfil the

[171] I. BANTEKAS AND L. OETTE, *International Human Rights Law and Practice*, Cambridge, 2013, pp 147-148.

[172] Limitations of human rights according to the Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights to be lawful must: a) be based on one of the grounds justifying limitation; b) respond to a pressing public or social need; c) pursue a legitimate aim; and d) be proportionate to the purpose. Derogations of human rights are subject to more stringent conditions. Under article 4(1) of the ICCPR States can derogate the obligations of the Covenant only in "time of public emergency which threatens the life of the nation".

[173] Articles 17(c) and 43(2) of the IHR. Scientific principles are defined by article 1(1) of the IHR as "the accepted fundamental laws and facts of nature known through the method of science" while scientific evidence is defined as "information furnishing a level of proof based on the established and accepted methods of science".

[174] Article 17 of the ICCPR

[175] Article 9 of the ICCPR, any limitation of the right to liberty cannot derogate the core principle of this right: the guarantee against arbitrary detention, *see HRC, General Comment No. 35, Article 9: Liberty and Security of Person, 16 December 2014, CCPR/C/GC/35, 19–20*

[176] Article 12 of the ICCPR

requirements in order to limit these rights as set out in the specific articles of the International Covenant on Civil and Political Rights.

2.1.3. The implementation of the IHR

The core capacity requirements of the IHR were supposed to be implemented in five years[177], by 2012, with the possibility of two postponements of 2 years, in 2012 and 2014, for "justified needs"[178] the first time and for "exceptional circumstances"[179] for the second[180]. State parties have significantly used this option both times[181], but still as of 2016 the Director-General acknowledged the fact that the capacities were not fully met in many countries, without naming them[182]. States have to report the implementation of the Regulations and the steps taken toward strengthening the core capacity of the public health system[183], but within the Organization there is a small team supervising the implementation of the Regulation[184]. In 2019 the Director-General of the Organization has delegated the responsibility to control the implementation of the IHR to an Assistant Director-General for Emergency Preparedness and International Health Regulations[185]. Both the annual reports of the Secretariat to the Assembly and the data on the level of compliance avoid assessing the implementation 'by State' but are usually consolidated. After the 'wake' of the outbreak of Ebola Member States of the WHO have shifted their preference, creating several initiatives to oversight and found the implementation of the IHR, also at an external level from the WHO[186].

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[177] Article 13 and 46 of the IHR.
[178] Article 13 of the IHR.
[179] Article 13 IHR.
[180] G. BARTOLINI, Are You Ready for a Pandemic? The International Health Regulations Put to the Test of Their 'Core Capacity Requirements', EJILTalk!, 1 June 2020.
[181] 118 States in 2012 and 81 in 2014
[182] WHO, Annual report on the implementation of the International Health Regulations (2005), HEALTH ASSEMBLYA/69/20, paragraph 16.
[183] Article 54 of the IHR.
[184] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit* p 253.
[185] World Health Organization, WHO Headquarters Leadership Team, https://www.who.int/dg/who-headquarters-leadership-team and WHO Delegation of authority - ADG Emergency Preparedness (WPE) 1 January 2020
[186] *See* A. KAMRADT-SCOTT, *Managing Global Health Security, op cit,* p 255

Both the IHR Review Committees on the H1N1 and 2014 Ebola outbreaks outlined the structural deficiencies and delays in the implementation of the Regulations[187]. Up util 2014 the monitoring system of the implementation of the national core capacities was solely base on self-evaluation by States. This has been considered unacceptable by several scholars in consideration of the fact that it could not provide for hight-quality uniform implementation by all States Parties to the Regulations[188]. The IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation called for the development of a new monitoring system of the implementation of the 2005 IHR considering "to move from self-evaluations to approaches that combine self-evaluation, peer review and voluntary external evaluation involving a combination of domestic and independent experts"[189]. Furthermore, the Review Committee on Ebola response found that the self-assessment by States Parties did not highlighted weaknesses in the implementation of the IHR nor did recognized them. Consequently, the Committee deemed necessary to utilize external evaluation of the implementation of the IHR[190]. The United States had launched in 2014 the Global Health Security Agenda (GHSA) in order "to promote global health security as an international priority, and to spur progress toward full implementation of the IHR"[191]. The GHSA at the time of lunching comprised representatives from 26 nations and several international organizations, at the time of writing it has 69 members as well as international and non-governmental organizations and private companies[192]. The GHSA and the WHO developed an external review system the Joint External Evaluation (JEE)

[187] WHO, WHA Doc. 64/10 "Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009"; 2011 and WHO, WHA Doc A69/21 "Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response", 2016

[188] L. O. GOSTIN, R. KATZ, The International Health Regulations: The Governing Framework for Global Health Security, *op cit.* and Ebola: what lessons for the International Health Regulations?, *The Lancet*, Editorial, Volume 384, ISSUE 9951, P1321, October 11, 2014

[189] WHO, Executive Board, 136. (2015). Implementation of the International Health Regulations (2005): report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation: report by the Director-General. World Health Organization.

[190] WHO, Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, *op cit*. Page 61.

[191] Centers for Disease Control and Prevention. Global Health Security Action Packages. CDC website. Updated January 21, 2016. http://www.cdc.gov/globalhealth/security/action packages/default.htm. Accessed 26 August 2020.

[192] Global Health Security Agenda, GHSA Members. Assessed 26 August 2020, at: https://ghsagenda.org/ghsa-members/.

which is a voluntary external assessment of the implementation of the IHR within the country[193]. The JEE is part of the IHR Monitoring Framework which is comprised also of annual reporting, after-action review and simulation exercise[194].

According to the website of the WHO as of 2019 the average implementation status of the IHR is of 63% with weakness mostly in the African Region and the main weaknesses at the moment are: chemical events, radiation emergencies and the lack of control at the points of entry into the single countries[195]. The European Union is the highest in compliance with 73% core capacity requirements implemented[196]. The success of the IHR in allowing the detection of diseases and avoiding their international spread depends on the health systems of the single State Party. This because the IHR requires States to utilize the existing funding and structures of the health system to meet the core capacities as outlined in Annex 1 of the IHR. Furthermore, the Regulation does not allocate funds to assist Member States in implementing it.

Lastly the obligations on the States to provide funding for the strengthen of their public health system are non-binding or weak, mostly requiring compliance only 'to the extent possible' as in article 13(5) and 44 (1) of the IHR. As argued by Eric Mack the implementation of these Regulations relies upon the existing infrastructure of the health system. Thus, making it extremely difficult for developing countries to fully implement the Regulations[197]. The difficulties in less developed countries and developing countries to implement the IHR core capacity requirement are predominantly due to a lack of funding and resources. As explained by Lawrance O. Gostin and Rebecca Katz, States that do not have the resources to meet the most basic needs of their population cannot allocate funding for the prevention of unknown and eventual threats[198]. Even if under article 44 of the IHR higher-income countries party to the IHR should cooperate and provide financial and technical assistance to countries unable to fund the full development

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[193] A. NARAYAN MENON, E. ROSENFELD, C. A. BRUSH, Law and the JEE: Lessons for IHR Implementation, *Health Security*, Volume 16, Supplement 1, 2018.
[194] WHO. Development, monitoring and evaluation of functional core capacity for implementing the International Health Regulations (2005): concept note http://www.who.int/ihr/publications/concept_note_201507/en/.
[195] IHR States Parties Annual Reporting global submission status per year (Updated on 17-04-2020), WHO, https://extranet.who.int/e-spar/#submission-details, (accessed 23/04/2020)
[196] WHO, Global Health Observatory: Health Emergencies, https://www.who.int/data/gho/data/major-themes/health-emergencies/GHO/health-emergencies (last visited 16 July 2020.).
[197] E. MACK, *op cit,*
[198] L. O. GOSTIN, R. KATZ, *op cit*

of the core capacity requirements. Within the years very few projects that explicitly aimed at strengthening the IHR core capacity requirements were funded[199].

These are the reasons for the discrepancies in the implementation of the Regulations in different regions of the world and the difficulties in monitoring and enforcement of the Regulations. Consequently, there is the need for a major reform of the International Health Regulations especially in the enforcement mechanism and in the monitoring system of the implementation.

2.2. The powers of the Director-General under the IHR

As discussed in the first chapter[200], during the 2003 SARS epidemic the response to the emergency was mainly intergovernmental and required the consent of the Member States for any regulatory measure. In this period of emergency, in absence of any other emergency power, the Secretariat took unprecedented measures imposing itself as the "primary decision-making authority during the outbreak"[201].

The 1969 IHR, as argued by Fidler, represented a classical "Westphalian system", it was State centred and based on the principle of non-intervention[202]. The old IHR lacked effective powers for the Organization and was solely based on a system of notifications of the outbreak of specific diseases and the attainment to certain standard of health at ports and airports. Consequently, the response of the Organization was based on the information, if any, that Sates Parties would share in relation to incidents and health risks. Furthermore, epidemics such as SARS where not covered by the IHR obligations of notify

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[199] T. D. PHU, V. N. LONG, N. T. HIEN, et al. Strengthening global health security capacity—Vietnam demonstration project, 2013. *Morbidity and Mortality Weekly Report,* Centre for Disease Control and Prevention, 2014 and A. G. LESCANO, G. SALMON-MULANOVICH, E. PEDRONI, D. L. BLAZES. Outbreak investigation and response training. *Science*. 2007

[200] Chapter 1 paragraph 1.4.

[201] C. KREUDER-SONNEN; *op cit.* Page 153.

[202] D. P. FIDLER; *SARS: governance and the globalization of diseases*; Basingstoke; 2004 p 32. The Westphalian system is the conception of the modern international political system following the Peace of Westphalia in 1648. This system has been defined as comprising states that interact in a condition of anarchy. Anarchy understood not as chaos, but it means that states do not recognize a common higher authority. In this conception of the international political system states are territorial, independent and sovereign. At the basis of the Westphalian system there is the principle of non-intervention as codified also in the Charter of the United Nations in article 2.1. The 1969 IHR did not address how states would prevent and react to infectious diseases in their territory. The 1969 Regulations provided mainly two sets of rules, the notification requirements and the obligation to maintain a minimum public health capacity.

the WHO of an outbreak[203]. Furthermore, States had the obligation to provide the WHO of continued information during an epidemic and to inform the Organization of the health measures implemented in relation to people and good arriving from the area of the outbreak[204]. Despite the fact that were considered an achievement at the time of the adoption the 1969 IHR had several weaknesses such as the limited scope of application, the widespread non-compliance with the notification obligation and the inability to utilize information coming from non-official sources[205].

The 2005 IHR provides for new powers both to the Organization itself and to the Director-General that were not present in the previous versions. The Director-General in order to respond to diseases is not bound, anymore, to the notifications of States Parties but can "take into account reports from sources other than notifications or consultations"[206]. This was proven of extreme importance during the SARS outbreak when States in fear of economical repercussion would withhold critical information[207]. The Organization can now access information from non-governmental organizations and independent scientists. The Director-General must share with the affected State the information received and should seek their verification; the source of the notification should be maintained confidential only if it is duly justified[208].

The Regulations do not provide the element to analyse in order to justify keeping a source confidential. This lack of confidentiality could undermine the effectiveness and importance of this provision because non-state actors could avoid making the notification in fear of repercussion especially if they live under an authoritative regime. An example of this are the recent happening in China during the first phases of the Covid-19 pandemic when doctors that tried to warn the world of the human-to-human transmission of the virus were threatened of incarceration[209]. One of the most important applications of this article is the possibility to utilize the information collected by the WHO's Global

[203] As discussed above the IHR above the 2005 amendments applied only to cholera, plague and yellow fever.
[204] Article 6 and 8 of the 1969 International Health Regulation.
[205] B. VON TIGERSTROM, The Revised International Health Regulations and Restraint of National Health Measures, *Health Law Journal*, 2005, page 37
[206] Article 9 IHR
[207] D. P. FIDLER, L. O. GOSTIN, *The New International Health Regulations, op cit.*
[208] Article 9 IHR
[209] S. HEGARTY, The Chinese doctor who tried to warn others about coronavirus, BBC News 6 February 2020, https://www.bbc.com/news/world-asia-china-51364382

Outbreak Alert and Response Network (GOARN)[210] which is at the basis of the functioning of the IHR's system of response[211].

The Director-General has the authority to determine whether an event reported under articles 6 and 7 of the IHR is a Public Health Emergency of International Concern or not, and to declare it[212]. In determining this the Director-General has to cooperate with the States in whose territory the events are occurring but is not bound by their absence of cooperation or lack of consensus over the declaration. In case that he considers an event to constitute a PHEIC the Director-General must convene an Emergency Committee[213]. The participants of the Committee are selected by the Director-General from the IHR Expert Roster. The Director-General considers the opinion of the Emergency Committee and of the affected State before making a final decision on the declaration of a PHEIC.

The Director-General is not bound by neither of the opinions, it is the only authority that can declare a PHEIC. In all the instances were an Emergency Committee was convened the Director-General has always accepted and adhered to the opinion of it. If the Director-General would have to avoid convening the Emergency Committee before declaring a PHEIC or would disregard the Emergency Committee's opinion, this could have political consequences for the Director-General and possibly legal consequences for the WHO[214]. The possible political consequences are, at the moment, more prominent that the legal consequences. In fact, in the event that the response to the outbreak is improved this could determine a growth of the confidence toward the Organization and its Director, while if the PHEIC was wrongfully declared at a political level this could negatively impact the IHR Review Committee's report and consequently the voluntary funding of the Organization. While, considering the legal consequences, article 56(5) of

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[210] The GOARN is a network of technical institutions and experts that connects human and technical resources for the timely identification and response to outbreaks with an international impact. At the moment the GOARN is comprised of more that 250 technical institutions and experts such as regional technical networks, United Nations organizations, the Red Cross and humanitarian non-governmental organizations.

[211] D. P. FIDLER, L. O. GOSTIN, *The New International Health Regulations, op cit.*

[212] Under articles 6 and 7 of the IHR events that may constitute PHEIC must be assessed using the decision instrument in Annex 2 and must be notified to the WHO trough the National IHR Focal Point. Following the notification States should continue to communicate with the Organization providing all relevant information.

[213] Article 12 (c) IHR

[214] A. VILLARREAL, Public International Law and the 2018-2019 Ebola Outbreak in the Democratic Republic of Congo, EJILTalk, 1 August 2019.

the IHR, which provides for a dispute settlement mechanism in case of a dispute on the application and interpretation of the Regulations between a State Party and the Organization itself, has never been used. Furthermore, the ILC's Draft Articles on the Responsibility of International Organization[215] are still not in force and the wrongful declaration of PHEIC, if the procedural requirements are respected, does not constitute an international wrongful act *per se*[216].

The emergency powers of the Director-General are a novelty in global administrative law, since they represent an increase of the executive powers normally delegated to the head of an international organization. These powers have been compared to the powers of the head of state or government under national laws in case of an emergency[217]. The increase of the powers of the Director-General are a direct consequence of the securitization of health laws[218]. Emergency powers have been initially theorized for governments of national states; these powers are the legal order thought which a State responds to emergencies. When utilizing the emergency powers the democratic procedures are bypassed and the laws recede in order to ensure the restoration of a political order. As explained by Carl Smith there "exists no rule that is applicable to chaos"[219]. Nowadays the emergency powers can be noted at an international level, considering that more often security threats such as pandemics, environmental disasters and other emergencies do not stop at borders[220]. The emergency powers that the Director-General possess nowadays are the result of a process of normalization of the powers that the Secretariat arrogated for itself during the 2003 SARS epidemic and a more recent process in the opposite direction following the 2009 H1N1 pandemic[221]. The emergency powers of the Organization are outside the direct control of the Member States of the

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[215] Draft Articles on the Responsibility of International Organizations, 3rd June 2011 (UN Doc A/CN.4/L.778), OXIO 11

[216] VILLARREAL *op cit.*

[217] A. ZIDAR; WHO International Health Regulations and human rights: from allusions to inclusion; in *The International Journal of Human Right,* 2015, p 505 ss

[218] S. ELBE, *Security and Global Health, Cambridge*, 2010, page 32.

[219] C. SCHMITT, *Political Theology: Four Chapters on the Concept of Sovereignty*. Chicago, [1922] 2005. Page 13.

[220] T. HANRIEDER, C. KREUDER-SONNEN, WHO decides on the exception? Securitization and emergency governance in global health, *Security Dialogue*, 2014, 45(4), 331–348.

[221] C. KREUDER-SONNEN, International Organizations' Emergency Powers: Ratchet or Rollback?, E-International Relations, 17 December 2019. At: https://www.e-ir.info/2019/12/17/international-organizations-emergency-powers-ratchet-or-rollback/.

Organization, as will be analysed in the next Chapter, the only review on the powers of the Director-General are the Emergency Committee and the IHR Review Committee, the first operated during the emergency the latter operates *ex post.* States may have some degree of control over the Director-General and the emergency decision making process in the event they have "professional or personal ties to WHO experts or the Director-General" or otherwise are necessary for the financing of the Organization[222].

In the event the Director-General declares a PHEIC, he or she has the authority and the powers to issue temporary non-binding recommendations on the most fitting way to respond to the emergency[223]. Both the recommendation and the declaration of PHEIC are valid for three months if not renewed and are usually part of the same decision process. Furthermore, the Director-General can release standing recommendations on "appropriate health measures in accordance with Article 53 for routine or periodic application"[224]. The Regulations provide for the criteria to follow when issuing temporary and standing recommendations. When issuing or modifying the recommendations the Director-General shall take into consideration: the assessments of the affected States, the opinion of the EC, scientific principles as well as available evidence.

The Director-General has mainly two powers under the IHR the possibility to declare an extraordinary event a Public Health Emergency of International Concern and to issue standing and temporary recommendations on how to respond to the emergency.

In conclusion the IHR is a *sui generis* binding legal instrument that poses both procedural and substantial obligation upon the States Parties. The Regulations provide also the emergency powers that allow the Organization to respond in case of Emergency. Despite the 2005 amendment of the IHR provided for great improvements in the legal framework with the inclusion of references to the human rights system and the increased powers delegated to the Director General, as we will further analyse in the following chapters there are still loopholes in the legal system. States in fear of economic repercussions due to the systematic violation of the trade and travel recommendations

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[222] J. BENTON HEATH, Global Emergency Power in the Age of Ebola, *Harvard International Law Journal*, Volume 57, Number 1, Winter 2016.
[223] Article 15 of the IHR
[224] Article 16 of the IHR

often delay the notification to the Organization of a possible PHEIC. States still do not trust each other not to impose unreasonable additional health emergencies in the event of the notification of an outbreak, has already happened countless times. Consequently, despite the 2005 amendment of the IHR has granted emergency powers to the Organization, as we have seen in this chapter of the thesis, the lack of an effective enforcement mechanism leaves the violation of the Regulations without repercussions.

CHAPTER III

Temporary recommendations

INDEX 3.1. The declaration of Public Health Emergency of International Concern (PHEIC); 3.2. The Emergency Committee and the recommendations; 3.3. The legal value of the recommendations of the Director-General.

3.1 The declaration of Public Health Emergency of International Concern (PHEIC)

A Public Health Emergency of International Concern is defined at article 1(1) of the IHR as an "extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response".

The text of the definition is a compromise between the delegates from the United States, the European Union, New Zealand, Nicaragua, Australia and Canada, that wanted the inclusion in the definition of all events despite of their origin, including intentional or accidental chemical, biological, radiological and nuclear (CBRN) events and the release of specific substances. On the other hand, the risk of a shift of focus from health to security of the Regulations, caused by the specific reference to CBRN events, made the delegated from the Eastern Mediterranean Area, Iran and African Countries contrary to the specific reference. These States were specifically opposed to the inclusion of the intentional release of CBRN. Cuba and China further criticized the States, such the United States, that wanted the inclusion of CBRN events in the IHR but were contrary to the inclusion of a verification system similar to the one that failed under the Biological Weapons Convention.

This created an impasse in the negotiation process that has been resolved thanks to the intervention of Switzerland which convened a small informal meeting with a limited number of States[225]. The final text reads "event of any origin". In a formal understanding

[225] R. KATZ AND A. MULDOON, Negotiating the Revised International Health Regulations (IHR) in E. ROSSKAM, I. KICKBUSCH (Eds.), Negotiating and Navigating Global Health: Case Studies In Global Health Diplomacy, 2011.

submitted by the United States a PHEIC is intended as any event "irrespective of origin or source, whether they involve the natural, accidental or deliberate release of biological, chemical or radionuclear materials"[226]. Likewise, after a contentious debate with Iran it was possible to include a reference to WHA 55.16 'Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health'[227].

In declaring a PHEIC the Director-General shall consider:

i) the information provided by the State Party thought the notification;

ii) the decision instrument present in Annex 2;

iii) the opinion of the Emergency Committee and

iv) a risk assessment concerning human health, international spread, and obstructions with international traffic and trade.

The purpose of the declaration of PHEIC is to convene timely evidence and to focus the international attention on a health risk that poses an imminent and serious threat to the world.

A 2020 original research[228] has analysed the different declarations of PHEIC by the Director-General of the WHO and events that triggered meetings by an Emergency Committee but did not resulted in the declaration of a PHEIC, since the enter into force of the IHR until the 2020 Covid-19 declaration of PHEIC[229]. The authors during the research have found "considerable inconsistencies" in the evaluation of the criterion for the declaration and the statements from the Emergency Committee convened for the events.

The first time an Emergency Committee was convened under the 2005 IHR was the 25 of April 2009 after the report from Mexico and the United States of cases of swine

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[226] Appendix 2 of the IHR Reservations and Understandings by the United States.

[227] World Health Assembly, 55. (2002). Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health. World Health Organization. https://apps.who.int/iris/handle/10665/78533.

[228] L. MULLEN, C. POTTER, L. O. GOSTIN, A. CICERO and J. B. NUZZO; An analysis of International Health Regulations Emergency Committees and Public Health Emergency of International Concern Designations; *British Medical Journal Global Health*, 2020

[229] 2010 influenza A (H1N1), 2013–2015 Middle East respiratory syndrome coronavirus (Mers-CoV), 2014 and ongoing poliovirus, 2014-2016 West Africa Ebola virus disease, 2016 yellow fever, since 2018 and ongoing for the ninth and tenth outbreak of the Ebola virus disease (EVD) in the Democratic Republic of Congo (DRC) in the Equateur province and in the North Kivu and Ituri provinces and the ongoing pandemic of Covid-19

influenza A (H1N1). Despite the lack of information regarding the clinical features, epidemiology, and virology of reported cases and the appropriate responses the Emergency Committee has agreed that the situation constituted a PHEIC. The Emergency Committee in the report of the meeting published on the WHO website did not consider any of the three requirements in order for a PHEIC declaration[230]. The Emergency Committee publicly assessed the requirements for a PHEIC declaration only when it was declared over, the Director-General in the statement following the meeting of the ninth Committee reported that the event was not 'extraordinary' anymore and that it did not require an international coordinated response[231].

Despite regular notifications of cases of Middle East Respiratory Ryndrome coronavirus have been reported already since 2012, the first Emergency Committee was convened by the Director-General on the 9th of June 2013, it was further convened nine times until the 2nd of September 2015 but a PHEIC was never declared, notwithstanding the fact it was a novel coronavirus the outbreak was never considered an "extraordinary event". Following the second meeting of the Emergency Committee, the Director-General at the time defined the MERS outbreak a 'serious' and of 'great concern' but accepted the advice of the Committee and did not declare a PHEIC[232].

Between the end of 2013 and the beginning of 2014, a wild poliovirus outbreak started in the Horn of Africa in a more virulent and with higher transmission rates that the previous clusters that happened in 2012 and at the beginning of 2013. This new outbreak of poliovirus, despite the limited number of cases, posed a risk to the eradication efforts, for this reason the Emergency Committee, that was convened the 28th of April 2014, deemed the outbreak an extraordinary event and a "public health risk to other States" for which a coordinated response was essential.[233].

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[230] WHO, First meeting of the IHR Emergency Committee, Pandemic (H1N1) 2009, Statement by WHO Director-General, Dr Margaret Chan, 25 April 2009. At: https://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/.

[231] WHO, Director-General statement following the ninth meeting of the Emergency Committee, 10 August 2010. At: https://www.who.int/csr/disease/swineflu/9th_meeting_ihr/en/.

[232] WHO, WHO Statement on the Second Meeting of the IHR Emergency Committee concerning MERS-CoV, 17 July 2013. At: https://www.who.int/mediacentre/news/statements/2013/mers_cov_20130717/en/.

[233] WHO, WHO statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus, 5 May 2014. At: https://www.who.int/mediacentre/news/statements/2014/polio-20140505/en/.

The 2014-2016 Ebola Virus Disease in West-Africa started in December 2013 when a little boy came into contact with the virus. The spread of the virus was not detected nor recognized until March 2014 when the NGO Médecins Sans Frontières (MSF) has raised the first alarm and the virus was already in Guinea, Sierra Leon and Liberia[234]. The notification to the WHO was made on the 23rd of March 2014 but the first Emergency Committee was convened only the 6th and 7th of August 2014 when the Emergency Committee has deemed necessary the declaration of PHEIC. The Emergency Committee had raised preoccupation of the consequences of the outbreak on the already weak health systems of the affected and surrounding States, it had held necessary a coordinated international response in order to stop and reverse the international spread of the disease. The Emergency Committee had further considered in order to assess the possible declaration of a PHEIC the consequences of the international spread of the disease also considering the "virulence of the virus, the intensive community and health facility transmission patterns, and the weak health systems in the currently affected and most at-risk countries"[235].

At the end of 2015 the PAHO and the WHO reported an abnormal increase of neurological disorders, such as microcephaly and Guillain-Barré syndrome, in areas affected by the Zika virus. The 1st of February 2016 a PHEIC was declared not for the virus itself, but for "the recent association of Zika infection with clusters of microcephaly and other neurological disorders"[236]. This meant that the focus of the international cooperation was to investigate the link between the malformations and the syndromes and the virus and not to stop the spreading of the virus *per se* which is now endemic in the region[237]. Within the statement of the Emergency Committee there was no mention of the requirements for a PHEIC declaration, the statement reads only "[t]he Committee advised that the recent cluster of microcephaly cases and other neurological disorders reported in

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[234] A. BINDENAGEL ŠEHOVIĆ; *Coordinating Global Health Policy Responses: From HIV/AIDS to Ebola and Beyond*, Warwick, 2017.
[235] WHO, Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa; 8 August 2014. At: https://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/.
[236] WHO statement on the first meeting of the International Health Regulations (2005) (IHR 2005) Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations, 1 February 2016
[237] B. MCCLOSKEY AND T. ENDERICKS, The rise of Zika infection and microcephaly: what can we learn from a public health emergency?, *Elsevier Public Health Emergency Collection*, 2017

Brazil, following a similar cluster in French Polynesia in 2014, constitutes a Public Health Emergency of International Concern (PHEIC)”[238].

Angola notified the WHO of an outbreak of yellow fever the 21st of January 2016, four month later the outbreak had spread to China, Kenya and Democratic Republic of Congo. On the 19th of May 2016 the Director-General convened an Emergency Committee, which although noted the serious international risk posed by the outbreak and the need for the strengthen of the national action and for an international response, it determined that the conditions to declare a PHEIC were not met[239].

The Democratic Republic of Congo has experienced two outbreaks of Ebola Virus Disease between May 2018 and the current days: the first outbreak was limited in size and the Emergency Committee convened on the case noted that there was no risk of international spread and suggested that the conditions to declare a PHEIC were not met. The Emergency Committee for the second outbreak of Ebola Virus Disease in the Democratic Republic of Congo was convened the 17th of October 2018 but a PHEIC was not declared until July 2019. The EC’s opinion in order not to declare a PHEIC was that it could have been detrimental to the response or that it would have “no added benefit”. Even if at the third meeting there were reports of cases in Uganda, an international spread and the outbreak was considered an extraordinary event, the Emergency Committee stated that “the ongoing response would not be enhanced by formal Temporary Recommendations under the IHR”[240]. Only in the following meeting on the 17th of July 2019 the Emergency Committee stated the necessity to declare a PHEIC.

During the first phases of the Covid-19 outbreak, China notified the WHO under article 6 of the IHR on the 31th of December 2019, the first Emergency Committee was held on the 22nd of January of 2020 but it could not reach a consensus on whether to

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[238] WHO, WHO statement on the first meeting of the International Health Regulations (2005) (IHR 2005) Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations, 1 February 2016. At: https://www.who.int/news-room/detail/01-02-2016-who-statement-on-the-first-meeting-of-the-international-health-regulations-(2005)-(ihr-2005)-emergency-committee-on-zika-virus-and-observed-increase-in-neurological-disorders-and-neonatal-malformations.

[239] WHO, Meeting of the Emergency Committee under the International Health Regulations (2005) concerning Yellow Fever, 19 May 2016. At: https://www.who.int/mediacentre/news/statements/2016/ec-yellow-fever/en/.

[240] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo, 14 June 2019. At: https://www.who.int/news-room/detail/17-10-2018-statement-on-the-meeting-of-the-ihr-emergency-committee-on-the-ebola-outbreak-in-drc.

declare a PHEIC stating a lack of information from China, the meeting was postponed to the following day. In only twenty-four hours the confirmed cases had risen from 309 in mainland China and five confirmed cases in four other counties, with six death to 571 confirmed cases in mainland China and ten confirmed cases in seven other counties with 17 death. Nonetheless, the Emergency Committee could not reach a unanimous decision on what to suggest to the Director-General. Furthermore, the Director-General stated that the Covid-19 outbreak was an emergency in China but at the time being was not a global emergency[241]. The outbreak was finally declared a PHEIC the 30th of January 2020 when there were 12167 suspected cases in China with 70 death and 83 cases in 18 countries, of which 7 had no history of travel in China[242].

The criterion of "requiring a coordinated international response" was interpreted in the H1N1, the poliovirus and the West Africa Ebola Virus Disease outbreak as requiring such coordination by improving and strengthening the already in place response. While during the ninth Democratic Republic of Congo Ebola Virus Disease outbreak the coordination at an international level was deemed necessary but a declaration was not required because the outbreak was considered almost under control following the ongoing response. Furthermore, the possible negative reaction of other States to the declaration was considered more counterproductive than the benefit the response could receive from the declaration. This criterion was not even considered when the Emergency Committee declared a PHEIC the Zika virus outbreak on the other had it was deemed necessary during the yellow fever outbreak but in this case, as already mentioned, a PHEIC was never declared.

One of the factors of an event being considered extraordinary during the H1N1 and the Zika outbreaks was the insufficient knowledge about the virus, while this factor was never taken into consideration, nor the fact that they constitute an extraordinary event, during the Mers-CoV and Covid-19 outbreaks.

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[241] D. N. DURRHEIM, L. O. GOSTIN AND K. MOODLEY; When does a major outbreak become a Public Health Emergency of International Concern?, *Lancet Infectious Diseases*, 2020

[242] WHO, Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 30 January 2020. At: https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

The third and last criterion to determine a PHEIC, the international spread of the disease, was also interpreted incoherently. The contention is on whether the international spread of the disease has to have already occurred or it being a risk that could occur. A factor that the Emergency Committee has considered in the evaluation of the risk of an international spread of the disease is the human-to-human and community transmission[243]. Nevertheless, during the Mers-CoV outbreak, the Emergency Committee even without a significant and sustained human-to-human transmission has considered a risk of international spread. Occasion of mass gathering have been considered factors for a possible international spread[244] while during the Mers-CoV the same event was not considered a risk of further spreading the disease.

In two occasions, the Emergency Committee has advised non to declare a PHEIC despite the fact that the requirements were met[245]. Furthermore, the Emergency Committee stated in the official statement on the Ebola Virus Disease outbreak in the Democratic Republic of Congo that "there is no added benefit to declaring a PHEIC at this stage"[246] and despite a very high risk of regional spread of the disease there is still not a risk of international spread of it. As noted by Mark Eccleston-Turner and Adam Kamradt-Scott the concept of added benefit is not part of the IHR definition of PHEIC and for this reason is unnecessary to the Regulations' legal requirements[247].

The main concerns and critiques to the 2005 IHR are the lack of transparency in the decision-making process of declaring a PHEIC and the 'all-or-nothing' nature of the declaration[248]. Since the 2009 outbreak of influenza A (H1N1) the transparency of the decision-making process of deciding whether an event constitutes a PHEIC and the

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[243] H1N1, polio, West Africa EVD, yellow fever, ninth DRC EVD outbreak, 10th DRC EVD outbreak.
[244] Polio outbreak during the Hajj and the Olympics during the Zika outbreak.
[245] M. ECCLESTON-TURNER, A. KAMRADT-SCOTT, Transparency in IHR emergency committee decision making: the case for reform; *British Medical Journal Global Health*, 2019; WHO, Statement on the October 2018 meeting of the IHR emergency Committee on the Ebola virus disease outbreak in the Democratic Republic of the Congo on 17 October 2018, at: https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo; WHO, Statement on the Meeting of the international health regulations (2005) emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 12th April, 2019, at: https://www.who.int/news-room/detail/12-04-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo-on-12th-april-2019.
[246] WHO, Statement on the Meeting of the international health regulations (2005) emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 12th April, 2019
[247] M. ECCLESTON-TURNER, A. KAMRADT-SCOTT, *op cit.*
[248] D. N. DURRHEIM, L. O. GOSTIN AND K. MOODLEY; *op cit.*

possible conflict of interest of the members of the Emergency Committee is one of the major critiques moved to the IHR. Until 2011 even the names of the members of the Emergency Committee were not public, if that has changed, the lack of transparency of the decision-making process not. The only publicly available documents of the meeting are the Official Statement published on the WHO website and the press conference that follows the meetings. There have been suggestions to follow the same method used for the UN Security Council meetings, live webcast and the publishing of the verbatim records of the meeting redacting the sensible information[249].

These factors raise questions on the method followed by the Emergency Committee in deciding whether to suggest the declaration of a PHEIC and the factors taken into consideration. In several instances the delay of the declaration of PHEIC makes think and suspect strong political influences in the decision-making process of it. Several scholars have suggested a different approach to a PHEIC, making it a scale and not an all-or-nothing declaration[250] and basing it on standard criteria in order to interpret the data[251]. Some of the amendments recommended do not need the revision of the text of the Regulations, hence the vote of the World Health Assembly and lengthily negotiations, but only the insertion of a new annex and the modification of the existing ones[252].

Despite not creating further legal obligations upon the States Parties of the IHR[253], it showed during the 2014-2016 outbreak of Ebola Virus Disease in West Africa and during the 2018 outbreak in Democratic Republic of Congo that the declaration of a PHEIC has the effect of rallying international response and funding. After the PHEIC declaration in West Africa the United Stated have sent military personal to help with the logistic of the response while the UN Security Council adopted a resolution calling this outbreak a threat to international peace and security[254].

In the aftermath of the 2013 Ebola Virus Disease outbreak the WHO and other organizations such as the World Bank have instituted emergency funds that are available

[249] M. ECCLESTON-TURNER, A. KAMRADT-SCOTT, *op cit.*
[250] D. N. DURRHEIM, L. O. GOSTIN AND K. MOODLEY; *op cit.*
[251] L. MULLEN *et al, op cit.*
[252] L.O. GOSTIN, M. C. DEBARTOLO and E. A. FRIEDMAN; The International Health Regulations 10 years on: the governing framework for global health security; *The Lancet*, 2015.
[253] P. A. VILLARREAL, Public International Law and the 2018-2019 Ebola Outbreak in the Democratic Republic of Congo, EJILTalk, 1 August 2019.
[254] L. O. GOSTIN, R. KATZ, *op cit.*

when a declaration of PHEIC happens, but especially before. The WHO has instituted in 2015 the Contingency Fund for Emergencies which enables the WHO respond to an emergency in less than 24 hours: this was necessary since one of the reasons for the delays in the response to the 2013 Ebola outbreak in West Africa were the difficulties in diverting the funds in order to start the response[255]. While the World Bank has instituted the Pandemic Emergency Financing Facility and the Crisis Response Window which help IDA countries to respond to extraordinary events such as natural disaster, economic crises and diseases outbreaks[256]. These funding mechanisms have been implemented after the difficulties in rallying funding for a timely response during the 2013 Ebola outbreak in West Africa.

It goes to show that there are inconsistencies and discrepancies in the evaluation of the criteria in order to determine a Public Health Emergency of International Concern and there is the need for a revision of the International Health Regulations.

3.2. The Emergency Committee and the recommendations

The Emergency Committee is an advisory body convened at the request of the Director-General in order to provide analyses on a possible declaration of a Public Health Emergency of International Concern or its termination, to propose the issue, amendment, extension or the cessation of the temporary recommendations[257].

The main function of the Emergency Committee is to provide a procedural control over the otherwise complete discretion of the Director-General[258]. As explained in the previous Chapter, in the aftermath of the 2003 SARS outbreak the 2005 IHR have granted extraordinary powers to the Director-General of the WHO[259].

During the Inter-Governmental Working Group (IGWG) on the revision of the IHR one of the main problems in the negotiations were the concerns over the limitation of state

[255] A. BINDENAGEL ŠEHOVIĆ; *op cit.*
[256] *See* International Development Association, Crisis Response Window, https://ida.worldbank.org/financing/crisis-response-window and The World Bank, Pandemic Emergency Financing Facility: Frequently Asked Questions, https://www.worldbank.org/en/topic/pandemics/brief/pandemic-emergency-facility-frequently-asked-questions
[257] Article 48 (1) of the IHR.
[258] C. KREUDER-SONNEN, *op cit.* page 168.
[259] Chapter 2 paragraph 2.

sovereignty. Prior to the SARS outbreak, the declaration of an emergency and the recommendations to the general public where made by States themselves, while now this power has been shifted to the World Health Organization[260].

According to one of the early drafts of the IHR, at the beginning of 2004, the Secretariat of the WHO would simply inform State Parties of the "occurrence of a Public Health Emergency of International Concern and of the control measures taken by the health administration concerned"[261] and would make the appropriate temporary recommendations. According to Adam Kamradt-Scott, by the second day of the IGWG meeting this was changed. After several meetings the Secretariat of the Organization and the Member States agreed on the creation of a completely new entity, the Emergency Committee, to review and advise on the process of declaring a Public Health Emergency of International Concern[262]. In front of this Committee any affected State can be consulted prior to the final decision of the Director-General. The Emergency Committee also advises the Director-General on the issuing of temporary recommendations, which was another salient point in the negotiations. States were preoccupied in entrusting the Director-General of the possibility to issue recommendations that could possibly damage the reputation and economic situation of any State affected by an outbreak or emergency[263].

The Director-General should convene an Emergency Committee when he considers declaring a Public Health Emergency of International Concern[264]. Considering the above-mentioned 'all-hazards approach' adopted by the IHR, the Emergency Committee should be convened to discuss events, despite their origin, that could spread internationally and could pose a threat to international trade and traffic. The Emergency Committee has been convened sixty-six times by the Director-General for nine different emergencies and resulted in six declarations of public health emergency of international concern[265]. For many other global health crises, the Director-General has decided not to convene an Emergency Committee, for example for the cholera outbreak in Haiti in 2010 following

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[260] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit*, p 117-120.
[261] WHO, International Health Regulations, Working paper for regional consultations, IGWG/IHR/Working paper/12.2003, 12 January 2004, article 9.
[262] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit* p 119
[263] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit*, p 120.
[264] Article 12 of the IHR.
[265] L. MULLEN, C. POTTER, L. O. GOSTIN, et al, *op cit.*

the catastrophic earthquake that hit the island, for the Fukushima nuclear disaster in Japan in 2011 and for the use of chemical weapons in Syria since 2013[266]. All of these events would fall under the purpose of the IHR considering the definition of 'event' that is the "manifestation of a disease or an occurrence that creates a potential for disease"[267], and the definition of disease that is "an illness or medical condition, *irrespective of origin or source,* that presents or could present significant harm to humans" (emphasis added)[268]. There is still confusion and difficulties in understanding what falls under the purpose and scope of the IHR.

In appointing the IHR Emergency Committee the Director-General follows the WHO Regulations for Expert Advisory Panels and Committees[269] ("the Regulations for Experts") unless it is stated otherwise in the IHR[270]. The Regulations for Experts provide also for the rules of proceeding of the meetings[271], especially stating that are private. The meetings can be made public only "by the express decision of the committee with the full agreement of the Director-General"[272].

When the Director-General convenes a meeting of the Emergency Committee, he provides the agenda and all relevant information needed to discuss the topic; he delivers also to the Emergency Committee a proposition of the temporary recommendations that he is considering issuing[273]. The Emergency Committee is composed of experts appointed by the Director-General selected from the IHR Expert Roster[274] and from other advisory panels of the WHO. The IHR Expert Roster is appointed by the Director-General according to the provisions of the IHR and of the WHO Regulations for Experts.

Within the Committee at least one member shall be appointed by the State Party affected by the event and the principle of equitable geographical representation and

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[266] L. O. GOSTIN AND R. KATZ *op cit*, page 275.
[267] Article 1 of the IHR.
[268] Article 1 of the IHR.
[269] WHO, Basic documents: forty-ninth edition (including amendments adopted up to 31 May 2019), Geneva; 2020, page 155.
[270] Article 47 of the IHR and WHO, International Health Regulations Committees and Expert Roster web site at: https://www.who.int/ihr/procedures/ihr_committees/en/.
[271] Annex of the WHO Regulations for Expert Advisory Panels and Committees
[272] WHO, 'Rules of Procedure for Expert Committees, Annex to Regulations for Expert Advisory Panels and Committees', rule 1
[273] Article 49 of the IHR.
[274] The IHR Expert Roster is composed of experts in all relevant field of expertise nominated by the Director-General also at the request of State Parties or of relevant intergovernmental and regional organizations.

gender balance should be respected at all sessions[275]. The members of the Emergency Committee are selected by the Director-General for every particular session depending from the experience and expertise needed[276]. The Committee can be assisted and advised by one or more technical experts appointed by the Director-General on her or his initiative or at the request of the Committee itself[277]. The Emergency Committee elects its Chairperson and redacts a brief summary of the proceedings of the meeting that will be made public after its approval by the Director-General[278]. As discussed in the previous Chapter the sole authority to declare a Public Health Emergency of International Concern is the Director-General of the Organizations, the recommendation and opinion of the Emergency Committee is non-binding on the Director-General. There is no responsibility of the Director-General in the event he does not follow the advice of the Committee, if the procedural requirement of convening the Committee in a timely manner from the notification of the affected State are respected.

Throughout the years every Emergency Committee that was appointed has faced criticism and backlash due to an alleged lack of transparency. The first and most controversial Emergency Committee was convened the in 2009 for the H1N1 outbreak in Mexico. Despite being designed as an independent body to limit and review the powers of the Director-General the Committee during this first emergency faced huge backlash due to a politicization and undue influence it allegedly suffered. The recommendations of the Director-General under the advice of the Emergency Committee pressured States to buy large amounts of vaccines and antiviral medications. When the outbreak resulted much less virulent and deadly that expected European parliamentarians and journalists criticized the lack of transparency in the decision-making process of the WHO and of the Emergency Committee[279].

The names of the members of the Emergency Committee and their possible conflict of interest was not made public during the emergency, leading to speculations and criticism because of the financial ties of some members with pharmaceutical houses that produce

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[275] WHO Regulations for Expert Advisory Panels and Committees
[276] Article 48 (2) of the IHR and WHO Regulations for Expert Advisory Panels and Committees.
[277] Article 48 (3) of the IHR.
[278] Article 49 (3) of the IHR.
[279] T. HANRIEDER AND C. KREUDER-SONNEN, *op cit.*

vaccinations and antivirals[280]. Even if several investigations were launched, they all absolved the Secretariat of any wrongdoing[281] and both the Organization and the pharmaceutical companies have strongly negated any influence[282].

Since 2011, following the report of the Review Committee the names of the members of the Emergency Committees are made public at the time of their appointment as well as the possible conflict interests they carry[283]. Still as today the decision-making process of the Emergency Committee in advising on the declaration of a Public Health Emergency of International Concern and issuing temporary recommendations is not transparent. As discussed by Mark Eccleston-Turned and Adam Kamradt-Scott transparency and accountability are at the crucial in 'good governance' and in allowing States and the civil society to trust the decision on a delicate and essential topic such as health emergencies[284]. Furthermore, neither the agenda, the which basis the members are selected nor the contributes of each member of the Committee to the discussion are made public[285]. Consequently, much more can still be done to increase the transparency of the decision-making process of the Emergency Committee.

3.3. The issuance of temporary recommendations

In the event the Director-General declares a Public Health Emergency of International Concern he or she has the obligation to issue temporary recommendations on the best way to respond to the emergency[286]. The temporary recommendations are "non-binding advise" issued by the Director-General containing the most appropriate health measures to be applied to the emergency in order to prevent and reduce the international spread of

[280] F. GODLEE, Conflicts of interest and pandemic flu: WHO must act now to restore its credibility, and Europe should legislate, *British Medical Journal*, Vol. 340, No. 7759 (12 June 2010).
[281] A. KAMRADT-SCOTT, *Managing Global Health Security, op cit*, p 22.
[282] C. ALPHONSO, 'World Health Organization fires back at critics of H1N1 response', *Globe and Mail*, 8 June 2010.
[283] WHO. Implementation of the International Health Regulations (2005) - Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 (2011) A64/10.
[284] M. ECCLESTON-TURNER, A. KAMRADT-SCOTT, *op cit*.
[285] O. JANSEN, Increasing the Legitimacy of the World Health Organization, *The Regulatory Review*, 22 April 2020.
[286] L. O. GOSTIN, Global Health Law, *op cit,* page 195.

the disease[287]. The political and social importance of these recommendations is drawn by their authority, credibility and strength which is dependent from the scientific evidence and principles that are considered in order to issue them[288]. The process to issue the temporary recommendations by the Director-General, following a Public Health Emergency of International Concern, is laid down in article 49 of the IHR. It is the same procedure followed in order to declare a Public Health Emergency of International Concern and both the declaration and the recommendations have a validity of three month if not renewed[289].

In order to issue the temporary recommendations, the Director-General has to consider a number of factors in addition to the opinion of the Emergency Committee. He or she shall consider the views of the affected States, the principles and scientific evidence and any relevant international standards[290]. The recommendations can be directed both to the affected State on how to manage the outbreak and to other countries on how to avoid the international spread of the disease[291]. In any case according to article 17 of the IHR the health measures recommended by the Director-General cannot be more restrictive and intrusive than "reasonably available alternatives that would achieve the appropriate level of health protection". The Regulations then include at article 18 a number of examples of possible health measures that the Director-General can recommend in respect of persons, baggage, cargo containers etc. Although the Director-General and the Emergency Committee usually speak with only one voice, the final decision is always of the Director-General[292].

The Director-General can issue recommendations, outside the IHR framework, that do not differ from the temporary recommendations under the IHR. Often the Director-General issues normal recommendations when considering an outbreak if it does not declare a Public Health Emergency of International Concern. This happened both when the Director-General decided not to declare the spread of the Middle East Respiratory

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[287] Article 1 and 15 of the IHR.

[288] D. P. FIDLER, To declare or not to declare: the controversy over declaring a Public Health Emergency of International Concern for the Ebola outbreak in the Democratic Republic of Congo. *Asian Journal of WTO & Health Law and Policy*, Vol 14, N. 20, pp. 287-330, September 2019.

[289] L. O. GOSTIN, R. KATZ, The International Health Regulations: The Governing Framework for Global Health Security, *op cit.*

[290] O. JANSEN, *op cit*.

[291] Article 15 of the IHR

[292] O. JANSEN, op cit.

Syndrome to Korea a PHEIC or when the current Director-General advised against trade and travel restrictions during the Ebola outbreak in the Democratic Republic of Congo, before declaring it a PHEIC[293]. The Director-General issued also recommendations after the first Emergency Committee during the first phases of the Covid-19 outbreak[294].

The Director-General can also issue standing recommendations in relation to persons, baggage, cargo or goods in order to regulate and to guide State Parties on "specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic"[295]. These recommendations are issued for periodic or routine application. The procedure followed in order to issue these standing recommendations is different from the process to issue temporary recommendations. According to article 53 of the IHR the Director-General shall seek the opinion of the Review Committee when considering issuing or modifying standing recommendations on a specific health topic. The standing recommendations are used in the context of the ongoing risk of the spread of a disease[296]. In 2006 the Advisory Committee on Poliovirus Eradication suggested the use of such recommendations in order to enforce polio immunization on travellers prior to arriving or departing from polio-infected areas[297]. Ultimately, the standing recommendations on poliovirus were not adopted, as a compromise was reached with India's representatives, the Health Assembly adopted a resolution urging the Director-General "to continue to examine and disseminate measures that Member States can take for reducing the risk and consequences of international spread of polioviruses, including, if and when needed, consideration of temporary or standing recommendations under the International Health Regulations (2005)"[298]. The use of standing recommendations has also been considered to fight

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[293] A. von Bogdandy, P. A. Villarreal; International Law on Pandemic Response: A First Stocktaking in Light of the Coronavirus Crisis, *MPIL Research Paper Series*, No. 2020-07.

[294] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 23 January 2020. At: https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

[295] Article 16 of the IHR

[296] M. Hardiman, A. Wilder-Smith, The Revised International Health Regulations and Their Relevance to Travel Medicine, *Journal of Travel Medicine*, Volume 14, Issue 3, 1 May 2007, Pages 141–144

[297] WHO, Conclusions and recommendations of the Advisory Committee on Poliomyelitis Eradication, Geneva, 11–12 October 2006, Part I 81(48):453–460

[298] WHO, Poliomyelitis: mechanism for management of potential risks to eradication, resolution WHA60.14.

against antimicrobial resistance at an international level in order to avoid the establishment in non-affected countries of new resistant strains[299] and again against XDR-Tuberculosis[300]. During this last emergency, the use of standing recommendations has been considered in order to introduce vaccination certificates, when a vaccination will be available, to fight a 'second wave' of Covid-19[301]. Conclusively, standing recommendations are issued by the review body of the emergency, once this is ended, in order to provide a guide to State parties in the aftermath of the emergency.

The Regulations provide for an external review, carried by the Review Committee, on the functioning of the Regulations in general in order to provide the Director-General with the technical recommendations on possible amendments of the IHR. Furthermore, the Review Committee when convened provides also technical advice on issuing, modifying and terminating standing recommendations and on any other topic or problem referred to it by the Director-General. The Committee is composed of experts selected and appointed by the Director-General from the IHR Experts Roster and "other expert advisory panels"[302]. The Review Committee has higher standards of transparency than the Emergency Committee.

The meetings of the Review Committee are not private, actually the Director-General "shall invite Member States, the United Nations and its specialized agencies and other relevant inter-governmental organizations or NGOs in official relations with WHO to designate representatives to attend the Committee sessions"[303]. Furthermore, the plenary sessions of the Review Committee are open to the media. The only private part of the Review Committee are deliberations. According to article 54 (2) of the IHR these reviews shall be periodical and the first should be conducted not later than five years from adoption of the Regulations. This time limit ended just after the Director-General declared the first Public Health Emergency of International Concern, consequently the Director-General at the time, Margaret Chan, convened a Review Committee to assess the

[299] D. WERNLI, T. HAUSTEIN, J. CONLY, et al., A Call for Action: The Application of the International Health Regulations to the Global Threat of Antimicrobial Resistance, *Plos Medicine*, 19 April 2011.
[300] P. CALAIN AND D. P. FIDLER, XDR Tuberculosis, the New International Health Regulations, and Human Rights, *Global Health Governance*, Vol. I, No. 1 (January 2007).
[301] A. L. PHELAN, COVID-19 immunity passports and vaccination certificates: scientific, equitable, and legal challenges, *The Lancet*, Vol. 395, pages 1595-1598, 23 May 2020.
[302] Article 50 of the IHR.
[303] Article 51 (2) of the IHR.

implementation of the IHR and the actions of the Organization during the H1N1 pandemic[304]. The report of this Committee was highly anticipated and awaited by the international community because it addresses, *inter alia,* the transparency criticisms faced by the Organization during this first emergency. The Director-General has further convened the Review Committee in 2014 in order to evaluate the second extension period in the implementation of the IHR[305] and in 2015 after the West Africa Ebola outbreak, this time the mandate was from the Health Assembly[306].

3.4. The legal value of the recommendations of the Director-General

Since the increase in the last century of the number of international organizations and the powers delegated to them, recommendations and soft law in general is a growing and common phenomenon[307]. For example, The Organization for Economic Co-operation and Development relies almost only on soft law instruments such as model agreements and guidelines also for regulating important topics. Interestingly these are some of the most successful legal instruments in terms of compliance, despite being technically non-binding[308]. These acts are often relied on and applied to, both at an international[309] and national[310] level, in order to address specific situations. Recommendations are usually defined in a 'negative' prospective as being non-binding. A rare 'positive' definition of

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[304] E. BRUEMMER, A TAYLOR, Institutional Transparency in Global Health Law-making: The World Health Organization and the Implementation of the International Health Regulations. In A. BIANCHI & A. PETERS (Eds.), *Transparency in International Law* (pp. 271-294). Cambridge, 2013. *See* WHO, Implementation of the International Health Regulations (2005), Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, A64/10, 5 May 2011.
[305] WHO, Implementation of the International Health Regulations (2005), Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation, EB136/22 Add.1, 16 January 2015.
[306] WHO, Implementation of the International Health Regulations (2005), Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, A69/21, 13 May 2016.
[307] C. SCHREUER, Recommendations and the Traditional Sources of International Law, *German Yearbook of International Law* 20. 103 (1977).
[308] J. KLABBERS, *An Introduction to International Organizations Law*, third ed, Cambridge, 2015,, page 167.
[309] S. ENGEL, 'Living" International Constitutions and the World Court, *International and Comparative Law Quarterly*, 1967, 865-910., A. J. P. TAMMES, Decisions of International Organs as a Source Of International Law (Volume 94), *Collected Courses of the Hague Academy of International Law,* 1958.
[310] K. SKUBISZEWSKI, Recommendations of the United Nations and Municipal Courts, *BYIL*, 1972-73, 353; C. H. SCBREUER, The Impact of International Institutions on the Protection of Human Rights in Domestic Courts, *Israel Yearbook on Human Rights*, 1974, 60 at 76 et seq.

recommendations is given by Michel Virally, which defines recommendations as: "*les résolutions d'un organe international adressées à un ou plusieurs destinataires qui lui sont extérieurs et impliquant une invitation à adopter un comportement déterminé, action ou abstention*"[311]. These acts do not carry the same consequences of a treaty or a regulation and are usually non-binding. Nevertheless, States are reluctant to infringe upon recommendations such as the resolutions of the United Nations of the General Assembly[312]. Even in the event of the infringement of the recommendations they do not rely on the claim of their legal irrelevance but usually "deny violations, assert the inapplicability of a recommendation to the specific case or will claim that the particular recommendation was irregular or *ultra vires"*[313].

The distinction between hard and soft law is not always easy. In the last years, soft law contains enforcement and compliance mechanism, once typical of hard law instrument[314]. This phenomenon can be also seen in the recommendations of the Director-General, in case of the violation of such recommendations it applies a 'comply or explain' mechanism established under article 43 of the IHR but there is not an enforcement mechanism[315]. The temporary and standing recommendations of the Director-General are not legally binding[316], but the Regulations contain a compulsory limit on the health measures Member States can take in regard to an emergency[317].

During the drafting of the 2005 IHR, in the January 2004 draft it was suggested that the recommendations of the Director-General would prohibit to Member States to adopt specific actions in the absence of such recommendations. This was not accepted by Member States, they feared that a binding prohibition could create confusion on the legal status of the recommendations and of the internal measure taken in excess or differently from the recommendations issued by the Director-General. Furthermore, States were concerned in restricting their sovereignty by entrusting the Organization of the authority

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[311] M. VIRALLY; La valeur juridique des recommandations des organisations internationales, *Annuaire français de droit international*, volume 2, 1956. Page 68.
[312] C. SCHREUER, *op cit.*
[313] C. SCHREUER, *op cit.*
[314] S. DINAH, *Introduction: Law, Non-Law and the Problem of 'Soft Law'*, In *Commitment and Compliance: The Role of Non-binding Norms in the International Legal System,* ed. by D. SHELTON, Oxford 2003, Oxford Scholarship Online, 2010.
[315] Article 43 of the IHR.
[316] Article 1 of the IHR.
[317] D. P. FIDLER AND L. O. GOSTIN, The new International Health Regulations, *op cit.* page 91.

to issue recommendations that prohibit certain measures. Consequently, during the revision process all the references to binding prohibitions and the need of an authorization in order to adopt certain additional measures have been eliminated from the draft[318].

Even if the reference to any binding prohibition has been redacted from the final version of the IHR, it still imposes constrains on the measures that States can take additionally to what is endorsed in the recommendations. As explained by Barbara von Tigerstrom this refusal by the contracting States to give a 'binding status' to the recommendations is partially due to the 'classic status' of international law according to which States assume obligations under international law only on a voluntary basis, with little exceptions such as *jus cogens* norms. Even the negotiation of a binding treaty is an exercise of sovereignty by the States, while the acceptance of binding recommendations enacted by the administrative organ of an International Organization would challenge this conception of international law[319]. Furthermore, in the United Nations Specialized Agencies and in the WHO's framework especially, there is a preference towards regulating using soft-law instruments rather that hard law[320]. As explained in the first Chapter, the WHO is hesitant in using binding legal documents in order to achieve its objectives.

In classifying legal acts, it is important not to consider only the denomination of such acts, but the important aspect of such acts are the legal consequences and effects associated with them, often acts with the same 'name' have completely different legal effects[321]. As an example, the North East Atlantic Fishery Commission's 'recommendations' become legally binding on States that do not object them, the same effect of the regulations adopted under article 22 of the Constitution of the WHO[322]. The normative acts that international organizations can issue, expressing an autonomous will, can be binding, non-binding or partially binding and can be classified in two major categories: internal acts of international organizations and acts addressed to its Member States. The former are acts that regulate the functioning of the organization in question

[318] WHO, Review and approval of proposed amendments to the International Health Regulations: explanatory notes, A/IHR/IGWG/4, 7 October 2004, paragraph 10.
[319] B. VON TIGERSTROM, *op cit,* page 57
[320] J. E. ALVAREZ, The Varied Forms of International Institutional Law. In: International Organizations as Law-makers, Oxford, 2006.
[321] R. VIRZO, The Proliferation of Institutional Acts of International Organizations, *op cit,* page 295.
[322] J. KLABBERS, *op cit*, page 161.

and of its organs. While the lattes are usually aimed at pursuing the objectives of the organization. In this second category we can divide binding acts[323], acts binding on the Member States that accepts them[324], authorizations[325] and non-binding acts[326]. The recommendations of the Director-General issued under the IHR fall within the category of non-binding exhortatory acts[327]. Exhortatory acts are addressed from an Organization to its Member States urging them to do or refrain from doing something. The recipients of the recommendations can be the all the members of an organization or only specific members.

The recommendations issued by the Director-General are non-binding acts, as stated at article 1 of the IHR. Furthermore, these recommendations are usually general to all States party to the IHR with some provision referring to the States affected by the emergency in particular. They can contain both provisions that impose to States to do something such as "require medical examinations" or "implement quarantine or other health measure for suspected persons" or provisions that require States to refrain from doing anything such as "no specific health measure is required"[328]. Even if these are non-binding acts and States can decide whether to implement them or not and there should be no legal consequence, some commentators have argued that recommendations should at least considered and examined in good faith[329]. A similar opinion can also be found in the ICJ Whaling in the Antarctic case in relation to the recommendations of the International Whaling Commission when the Court ruled that States "have a duty to co-operate with the IWC and thus should give due respect to recommendations"[330].

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[323] *See eg* directives of the European Union adopted under article 288(3) of the TFEU, the recommendations of the International Labor Organization and of UNESCO, the regulations adopted by the Assembly of the ISA under article 160 (2) (f) UNCLOS etc.
[324] *See eg* the regulations of the WHO adopted under article 22 of the Constitution.
[325] *See eg* the resolutions of the Security Council of the UN authorizes the use of force, or other measures in order to restore international peace and security or the decisions of the Dispute Settlement Body of the WTO under article 22 (2) of the Understanding on the Rules and Procedures Governing the Settlement of Disputes.
[326] *See eg* exhortatory acts and non-binding opinions and interpretations.
[327] R. VIRZO, The Proliferation of Institutional Acts of International Organizations, *op cit,* page 304.
[328] Article 18 of the IHR.
[329] H. LAUTERPACHT, Separate Opinion, Admissibility of Hearings of Petitioners by the Committee of South West Africa, ICJ Reports 1995, 35.
[330] ICJ, Whaling in the Antarctic (Australia v. Japan: New Zealand intervening), Judgment, I.C.J. Reports 2014, p. 226, paragraph 83.

Despite being soft law, the recommendations of the Director-General issued under the IHR can "alter both the behaviour of individuals and the legal obligations of states"[331]. Consequently, despite having a non-binding legal value, these recommendations have a political status that allows them to influence the behaviour of States and individuals. The temporary recommendations, even if addressed to the States Parties to the IHR, have often a greater effect on individuals, considering the fact that are published on the WHO's website. The recommendations can also create a political pressure on States in order to provide certain additional measures[332].

The temporary recommendations of the Director-General, and the IHR more in general, are not the minimum standard of protection that States should adopt, on the contrary these provisions and recommendations should be the maximum limit of health measures a State can and should adopt. When the Director-General issues temporary recommendations the balancing between the right to health and the economic interests involved in the outbreak has already been evaluated. When complying with the temporary recommendations of the Director-General, States can take two types of measure, health measure taken 'according to Regulations' and 'additional health measures'[333]. The measures taken pursuant to the Regulations that directly implement the recommendations do not created further obligations. While the measures taken additionally to what is recommended trigger the application of article 43 of the IHR. Consequently, States have to notify and justify the measures to the WHO having also to consider if the 'additional health measures' are not "more restrictive of international traffic and not more invasive or intrusive to persons that reasonably available alternatives"[334]. The additional health measures implemented by States should "achieve the same or greater level of health protection" than the temporary recommendations of the Director-General and should be implemented considering scientific principles, scientific evidence and any available

[331] J. BENTON HEATH, Global Emergency Power in the Age of Ebola, *op cit.*
[332] *See* S. GAY STOLBERG, Shortage of Vaccine Poses Political Test for Obama, *New York Times*, Oct. 28, 2009 and U. BECK, World at Risk: The New Task of Critical Theory, *Development and Society*, Vol.37 No.1, pp. 1-21 (2008). During the H1N1 outbreak under the pressure of the recommendations of the Director-General, States Parties to the IHR have started to buy large quantities of vaccines and antivirals.
[333] In previous drafting of the IHR these measures have also been defined as 'excessive', 'alternative', 'different' or 'which differ from'. Personal notes, IHR IGWG, Article 43 Drafting Group, 2nd session, 3rd meeting, 12 May 2005.
[334] Article 43 of the IHR.

guidance from the Organization[335]. The additional health measures implemented by States shall be revise after three month and the State implementing such measures should enter in consultation with States affected by such measures[336]. The *ratio* of these limitations on additional health measures, according to Andrea Spagnolo, are threefold: they should protect the affected States or States from disproportionate reactions of other States; consequently encouraging States to adhere to their notification obligations under articles 6 and 7 of the IHR and they underline the importance and centrality of the Organization in determining health standards universally accepted[337].

As described by J. Benton Heath adhering the national measures to what is recommended by the Director-General is a "safe harbour" for States in order not to trigger the compliance mechanisms under article 43 of the IHR[338]. The existence of such mechanism of justification for measures that go beyond what is recommended has been considered to suggest the presence of a duty to 'comply or explain'[339]. Which implies that despite being defined as 'non-binding advice' these recommendations may have a different legal status. However, the absence of an enforcement mechanism makes the legal value of such recommendations and the obligations under article 43 of the IHR uncertain and ambiguous[340].

As noted by Roberto Virzo, the decision of a Member State to disregard an exhortatory act of an International Organization is not an international wrongful act *per se* and should not have any legal consequence[341]. When the Director-General issues temporary recommendations, the health measures suggested should be implemented by the States parties to whom are directed. States can also adopt health measures that differ from the one recommended if they "achieve the same or greater level of health protection" and are not more intrusive of the liberty of people and disruptive of trade and commerce that

[335] Article 43 (1) – (2) of the IHR.
[336] Article 43 (6) – (7) of the IHR.
[337] A. SPAGNOLO, *Contromisure dell'Organizzazione Mondiale della Sanità come Conseguenza di Violazioni dei Regolamenti Sanitari Internazionali in Contesti Epidemici*, in L. PINESCHI (ed.), *La tutela della salute nel diritto internazionale ed europeo tra interessi globali e interessi particolari*, Naples, 2017. Page 400.
[338] J. BENTON HEATH, Global Emergency Power in the Age of Ebola, *op cit.*
[339] A. VON BOGDANDY, P. A. VILLARREAL; *op cit.*
[340] G. L. BURCI et al, The Outbreak of COVID-19 Coronavirus: are the International Health Regulations fit for purpose?, *EJILTalk*, 2020.
[341] R. VIRZO, The Proliferation of Institutional Acts of International Organizations, *op cit.*

reasonably available alternatives[342]. Some scholars have argued that the implementation of additional health measures in violation of the recommendations of the Director-General without any specific scientific justification, is in violation not only of the recommendation, but also of article 43 of the IHR[343].

Notwithstanding the fact that the IHR provide for no sanctions for the violation of the Regulations, this is still an international wrongful act by a State and should trigger the application of the norms on States responsibility. In the aftermath of the 2018-2019 Ebola outbreak the Seventy-Second Health Assembly was presented with reports containing the assessment of the measures taken in violation of the recommendations but there was no decision nor resolution on the topic. Consequently, even if the disregard of the temporary recommendation of the Director-General can be considered a violation of article 43 of the IHR and thus an international wrongful act at the moment there is no consequence for the States.

The requirements of article 43 of the IHR in order to implement additional health measures are parallel to the obligations under the General Agreement on Tariffs and Trade[344] and to the Agreement on the Application of Sanitary and Phytosanitary Measures[345]. Article XX of the GATT allows for the implementation of measures that would otherwise violate the GATT when "necessary to protect human […] life"[346]. These measures shall not be "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade"[347]. Furthermore, the measures that can be taken under the recommendations of the Director-General according to the IHR are subject also to the SPS Agreement. The SPS Agreement applies, *inter alia*, to measures "to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment

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[342] Article 43 of the IHR.
[343] *See* P. A. VILLAREAL, The (not-so) Hard Side of the IHR: Breaches of Legal Obligations, *Global Health Law Groningen*, Blog, 26 February 2020.
[344] General Agreement on Tariffs and Trade, 30 October 1947, 58 U.N.T.S. 187, incorporated into the WTO Agreement as the General Agreement on Tariffs and Trade 1994, Annex 1A to the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 3 [GATT].
[345] Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A to the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1867 U.N.T.S. 3 [SPS Agreement].
[346] Article XX (b) of the GATT.
[347] Article XX of the GATT.

or spread of pests" and to measures "to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms"[348].

When implementing additional measures under article 43 (1) of the IHR States such measures should "achieve the same greater level of health protection" and should not be more restrictive on trade or travel than "reasonably available alternatives". While article 5 (6) of the SPS Agreement states that in order to implement measures restrictive of trade these measures shall not be "more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection".

When adopting measures that restrict trade under all three agreements there is the need that these measures are based upon scientific evidence and principles[349]. In the event the evidence is insufficient it is possible to adopt the measures with the available information, given that such measures are analysed when further information and evidence is discovered[350]. These parallels between the IHR framework and the GATT framework could allow negatively affected States to challenge the restrictive measures in front of the dispute settlement mechanism of the World Trade Organization[351].

With the current uncertainties on the legal value and effect of the recommendations issued by the Director-General under the IHR framework, States are less incentivized to adhere to such recommendations and avoid imposing unnecessary measures that disrupt trade and traffic. There is the need for the temporary recommendations of the Director-General to be more effective in order to achieve their purpose[352].

In this chapter we have the shortcoming of the current legal system that regulates health emergencies. The declaration of a PHEIC does not carry any legal consequence other than the possibility to issue non-binding advice. As seen in the previous chapter and as we will see in more detail in the next one, States do not trust neither the WHO nor

[348] Annex 1 article 1 (a) and (c) of the SPS Agreement.
[349] Article 43 (2) IHR and articles 5 (1) and 5 (2) of the SPS Agreement.
[350] Article 5 (7) SPS Agreement and articles 43 (2)(b) and 43 (6) of the IHR. Under the SPS Agreements the measures shall be revised "within a reasonable period of time" while the IHR requires all additional measures to be reviewed in three months.
[351] A. VON BOGDANDY, P. A. VILLARREAL, *op cit.*
[352] L. VIERCK, P. A. VILLARREAL, A. K. WEILERT, The Governance of Disease Outbreaks: International Health Law: Lessons from the Ebola Crisis and Beyond, 2018.

other States in the health measures that are or will be implemented in order to contain an emergency. Furthermore, both the recommendations of the Organization and the PHEIC declarations are heavily influenced by political rather than scientific reasons. The Regulations lack of an unbiased, predetermined and objective set of rules and criteria in order to determine whether an event constitutes a PHEIC. These uncertainties in the declarations render the ability of a coordinated world-wide response to an outbreak delayed also by political considerations. The undue influence by political consideration happens in spite of the improvements in the transparency of the decision-making process of the Emergency Committee, although further advancements are necessary.

CHAPTER IV

Recent health crisis and the measures under the IHR

INDEX 4.1. Influenza A (H1N1) in Mexico; 4.2. Ebola Virus Disease in West Africa; 4.3. Wild Poliovirus (WPV1) in Africa and Middle East; 4.4. Zika virus in Brazil; 4.5. Ebola Virus Disease in the Democratic Republic of Congo; 4.6. Covid-19 in China.

In the first 15 years since the adoption of the IHR in 2005 the Director-General of the WHO has declared six diseases' outbreaks a Public Health Emergency of International Concern. Two of these emergencies are still ongoing. All of the declarations of a PHEIC resulted in the issuing of temporary recommendations with different levels of adherence to them by States Parties depending on the emergency.

4.1 Influenza A (H1N1) in Mexico

In March 2009 Mexico started experiencing an unusual number of acute respiratory infections, with the Mexican authorities informed by the surveillance system. The outbreak was first detected in the small village of La Gloria in the Velacruz region. On April 11 the Pan American Health Organization (PAHO) was notified of these infections by the Mexican IHR Focal Point of a potential Public Health Emergency of International Concern[353]. Just a week later, on April 18, the United States notified the PAHO of two cases of human influenza A (H1N1)[354].

The first Emergency Committee was convened the 25th of April 2009 and on their recommendation the Director-General declared the outbreak a PHEIC. The temporary recommendations following the first meeting advised "all countries intensify surveillance for unusual outbreaks of influenza-like illness and severe pneumonia"[355] but did not

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[353] World Health Organization. Influenza-like illness in the United States and Mexico. 24 April 2009. At: https://www.who.int/csr/don/2009_04_24/en/

[354] Pan American Health Organization. Situation report #3. Influenza-like illness in the United States, Mexico, 26 April 2009, at: http://new.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=1302&Itemid=.

[355] World Health Organization. Statement by Director-General, Dr Margaret Chan. Swine influenza. 25 April 2009. http://www.who.int/mediacentre/news/statements/2009/h1n1_20090425/en/index.html

recommend any travel or trade restrictions[356]. Mexico and the United States continued updating the WHO by means of the IHR Focal Points, while PAHO coordinated the response to the outbreak between Mexico, the United States and Canada. Reports of suspected or confirmed cases of H1N1 influenza started arriving daily to the WHO from IHR Focal Points all around the world[357].

During the press conference following the meeting of the Emergency Committee of the 27th of April Dr Fukuda, Assistant Director-General ad interim for Health Security and Environment, explained that in order to contain the outbreak measures such as quarantine and the use of antivirals and prophylaxis treatments could be useful[358]. Furthermore, he added that "the Director-General recommends not closing borders or restricting travel; however, it is prudent for people who are sick to delay travel and it is also prudent for returning travellers, who are coming back from any parts of the world and who have become ill to seek medical attention in line with the guidance from their national authorities"[359].

On June 11 the Emergency Committee advised the Director-General to raise the alert to Phase 6, pandemic, according to the WHO guidance. Over the next month the temporary recommendations of the Director-General were reiterated but not modified. At the end of November, the Emergency Committee met again to decide if renew the temporary recommendations, the recommendations were all upheld, but the third recommendation, which was changed from "if ill, it is prudent to delay international travel; if ill after travel, seek care" to "if ill, it is prudent to delay travel".

At the Emergency Committee of the 23rd of February 2010, it was recommended to maintain the surveillance capacity rather than intensify it. The final meeting of the Emergency Committee was held the 10th of August when only a small number of states was still experiencing large outbreaks of influenza A (H1N1) while in the majority of the world this strand of influenza was transitioning to seasonal patterns of transition. The

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[356] World Health Organization. Swine flu illness in the United States and Mexico, update 2; 29 April, at: http://www.who.int/csr/don/2009_04_26/en/index.html.

[357] World Health Organization, situation updates, 24 April – 8 May 2009, at: http://www.who.int/csr/disease/swineflu/updates/en/index.html

[358] Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 *op cit*, page 55.

[359] World Health Organization. Transcript of virtual press conference with Dr Keiji Fukuda, Assistant Director-General *ad interim* for Health Security and Environment. 27 April 2009. http://www.who.int/mediacentre/swineflu_presstranscript_2009_04_27.pdf

Committee recommended to the Director-General to end the PHEIC declaration, to lower the alert level from pandemic Phase 6 and to end all the temporary recommendations[360].

Despite the fact that trade and travel restrictions were never recommended and the numerous determinations that the consumption on cooked pork does not carry nor transmit the virus[361], a number of countries advised against the travel to North America and interrupted the trade of pork from the areas affected by the H1N1 virus. China interrupted the trade of pork meat and dairy from Mexico, Canada and several areas of the United States. The Chinese authorities imposed such measures disregarding completely the recommendations of the Director-General and as if there were no obligations at an international level if such measures where implemented[362]. China justified the measures implemented on the basis of the burden that an outbreak of an 'highly pathogenic' flu could have on its public health system and on the fact that pork was the most produced and consumed meet within the country[363]. Similar trade limitations have been imposed also by the Philippines and by Indonesia. Indonesia did not limit trade of swine products only from the affected areas but also from France, Spain, New Zealand and Israel justifying such measures with the necessity to "protect its territory and industries from the virus"[364]. Furthermore, some States imposed a quarantine on citizens coming from North American countries, defending their decision on the basis that the United States and Mexico did not implement screenings at the borders[365]. This despite the fact that border screening was never recommended by the Organization[366]. Egypt went as far as culling most of, if not all, the pigs in the country as a 'preventive measure' despite the fact that the meat of the pig does not carry the virus and that at the

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[360] Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 *op cit*, page 60 and following.

[361] World Health Organization, Influenza A(H1N1) - update 7, 1 May 2009, at: https://www.who.int/csr/don/2009_05_01/en/

[362] P. ACCONCI, The Reaction to the Ebola Epidemic within the United Nations Framework: What Next for the World Health Organization?, *Max Planck Yearbook of United Nations Law*, vol. 18, 2014, page 405 ss.;

[363] WTO, Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting Of 23-24 June 2009, Note by the Secretariat. G/SPS/R/55, 23 September 2009. Page 6

[364] Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting Of 23-24 June 2009, *op cit,* paragraph 22.

[365] R. KATZ, Use of Revised International Health Regulations during Influenza A (H1N1) Epidemic, 2009, *Emerging Infectious Diseases*, Volume 15, No. 8, August 2009.

[366] R. KATZ, *op cit.*

time there was no reported case of human H1N1 case within the country[367]. Following the Egyptian decision, the Iraqi government ordered the killing of the three boars present in the zoo. When the Iraqi government was asked the reasons of this act, there was no scientific evidence justifying them, but the only motivation given was to interrupt the cycle of fear for the visitors of the zoo[368]. The WHO asked justifications for the measures implemented in violation of the recommendations of the Director-General only to one country, for the most other states have had no consequences for violating the IHR[369]. The trade and travel restriction were imposed by about 15% of the Members of the WHO and about half of it did amend the measures later during the emergency. Most of the restrictions were imposed at the beginning of the outbreak[370]. This first test for the 2005 IHR has shown a tendency of the States Parties to violate the Regulations and in particular article 43 regarding additional health measures. The reasons for the violation of the Regulations are multiple: the lack of trust toward the recommendations of the Director-General and towards the measures implemented by other States; and the internal political tension caused by the necessity to provide answers to the population[371].

4.2 Ebola Virus Disease in West Africa

The Ebola Virus Disease outbreak of 2013 started in a small village in Guinea when a 2 years old child got infected, due to the burial procedures the virus started to spread also to neighbouring villages and across the porous borders with Sierra Leone and Liberia[372]. The virus was not recognized nor detected in the early phases of the outbreak, allowing it to spread during the cleaning rituals and at the funerals. The identification was further delayed by the similarities between the Ebola symptoms and the symptoms of malaria,

[367] A. KAMRADT-SCOTT, What Went Wrong? The World Health Organization from Swine Flu to Ebola. *Political Mistakes and Policy Failures in International Relations*, 2017, 193–215.
[368] J. KARADESH,. Wild Boars Killed in Iraq Over Swine Flu Fears, 2009, CNN. Available at http://edition.cnn.com/2009/WORLD/meast/05/03/iraq.boars/
[369] K. WILSON, J. S. BROWNSTEIN, D. P. FIDLER; Strengthening the International Health Regulations: lessons from the H1N1 pandemic, *Health Policy Planning*, vol. 25,6 (2010): 505-9.
[370] S. E. DAVIES, A. KAMRADT-SCOTT, S. RUSHTON, *Disease Diplomacy: International Norms and Global Health Security*; Baltimore, 2015, page 103-104
[371] A. SPAGNOLO, *op cit.* Page 404.
[372] S. E. DAVIES, A. KAMRADT-SCOTT, S. RUSHTON

which is endemic in the region. Despite the similarities, the infection pattern should have been an indication of the fact that a different disease was the cause of the outbreak.

By the time the NGO Médecins Sans Frontières alerted the world of the outbreak, in March, the virus had already spread and was almost uncontrollable. After the alarm of MSF, a spokesperson from the WHO downplayed the outbreak and stated that the outbreak was not out precedent[373].

The 22nd of March Guinea declared the existence of an epidemic of Ebola within the country after the confirmation by MSF of eight cases. In the following months up to May, the WHO had deployed about 112 experts in the countries affected by the outbreak[374]. The Organization declared a Public Health Emergency of International Concern the 8th of August at the end of the fist Emergency Committee on the topic[375]. In September 2014 the outbreak was completely out of control and the President of Liberia asked the United States to intervene with the military in order to create and run an hospital for Ebola patients. At the end of September, the United Nations Security Council passed the resolution 2177 calling for immediate resources both from public and private donors in order to counter the outbreak in West Africa[376]. The Resolution called also for the lift of all the travel bans in place towards the affected States despite the recommendations of the WHO against the restriction of trade and travel[377]. Furthermore, the Secretary General of the United Nations, with the assent of the Security Council and of the General Assembly, created the UN Mission for Ebola Emergency Response (UNMEER)[378]. In the following month the outbreak is out of control and the foreign ministers and presidents of several countries appoint Special Representatives for Ebola and send the military to

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[373] Y. BEIGBEDER, The World Health Organization: Achievements and Failures, New York, 2018, page 57.
[374] Y. BEIGBEDER, *op cit*
[375] A. BINDENAGEL ŠEHOVIĆ; *op cit.*
[376] UNSC, "With Spread of Ebola Outpacing Response, Security Council Adopts Resolution 2177 (2014) Urging Immediate Action, End to Isolation of Affected States" (September 18, 2014), available at: http://www.un.org/press/ en/2014/sc11566.doc.htm.
[377] WHO, "Statement on the 1st Meeting for the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa" (8 August 2014), available at: http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/ en/.
[378] UN Mission for Ebola Emergency Response (UNMEER), available at: http://ebolaresponse.un.org/un-mission-ebola-emergency-response-unmeer.

help in the response to the outbreak[379]. The 31st of July 2015 the outbreak is under control and the UNMEER ceases its activities after achieving its objectives[380].

The recommendations of the Director-General following the declaration of a PHEIC of the Ebola outbreak were directed to: "States with Ebola transmission," "States with a potential or confirmed Ebola case," "unaffected States with land borders with affected States" and "all States"[381]. For the affected countries the recommendations included the declaration from the authorities of national public health emergency, the maintenance and reinforcement of exit screening and the tracing of the passenger's contacts. The controls should comprise all passengers at international points of entry for unexplained fever and other symptoms consistent with Ebola[382]. For non-affected countries, the recommendations were not to interrupt commercial flights and not to close the borders, considering that these actions cause a delay in the shipment of medical equipment and medial personal.

By the second meeting of the Emergency Committee it was noted that non affected countries had cancelled flights and closed their borders to countries suffering the Ebola outbreak. The Committee in extending the previous recommendations had further stressed the need to provide health workers the appropriate personal protection equipment and to train them on the appropriate safety measures[383]. Between the second and third Emergency Committee (September – October 2014) States with no Ebola transmission started imposing entry screenings for passengers arriving from Ebola affected countries. Canada implemented a travel ban on the 31st of October 2014 by stopping to process temporary and permanent visa requests from citizens of the States affected by the Ebola outbreak or from foreign citizens that have travelled or transited in one of these States[384].

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[379] "Von der Leyen sucht Freiwillige aus Bundeswehr," Handelsblatt (September 22, 2014), available at http://www.handelsblatt.com/politik/ deutschland/kampf-gegen-ebola-von-der-leyen-sucht-freiwillige-aus-bundes wehr/10735184.html.

[380] A. BINDENAGEL ŠEHOVIĆ; *op cit*

[381] WHO, "Statement on the 1st Meeting for the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa" (8 August 2014), *op cit.*

[382] M. A. SOGHAIER, K. M. I. SAEED, K. K. ZAMAN. Public Health Emergency of International Concern (PHEIC) has Declared Twice in 2014; Polio and Ebola at the Top. *AIMS Public Health*. 5 June 2015; 2(2): 218-222.

[383] WHO, Statement on the 2nd meeting of the IHR Emergency Committee regarding the 2014 Ebola outbreak in West Africa, 22 September 2014. At: https://www.who.int/mediacentre/news/statements/2014/ebola-2nd-ihr-meeting/en/ .

[384] Ministerial Instructions (31 October 2014) Canada Gazette I (Immigration and Refugee Protection Act), Extra Vol. 148 No. 8 Part I.

Within the Ministerial Instructions there is no reference of scientific evidence that could justify of such restrictive measures, nor to specific public health rationales that could support such measure, other that the fact that “the introduction or spread of the disease would pose an imminent and severe risk to public health in Canada”[385]. Furthermore, no reference is made to the IHR or any other international standard that could justify these measures. Consequently, these measures did not meet the requirement of article 43 of the IHR in order to impose additional health measures against or further than what recommended by the WHO. Despite the fact that these measures were never recommended, the Committee asked for a report on the experience of States imposing them. The Committee further warned such States of the limited effect of entry screening in comparison to the resource demanded in order to implement these controls.

In addition, the Committee has reiterated the recommendation to avoid general bans on international trade and travel to and from affected countries. These bans have the sole effect of increasing the international migration of people in an uncontrollable way by means of land borders, raising the possibilities for the spread of the disease to unaffected countries[386]. In January 2015 the Emergency Committee noted that more that 40 countries imposed quarantine requirements or refusal to entry for passengers arriving from affected areas. As already stressed these measures have the sole outcome of hindering the ability of medical personnel to assist in the outbreak[387]. The following Committee, on the 10th of April 2015, upheld the previous recommendations stressing the need to continue entry and exit screening of passengers for at least two incubation periods of the disease, 42 days, since the last case has tested negative two times for Ebola[388]. The 9th of May 2015 Liberia is declared free from Ebola transmission[389], despite this enormous achievement the temporary recommendations for the affected countries still apply within its borders. The recommendations were extended with virtually no change for the following month

[385] Ministerial Instructions, *op cit.*
[386] WHO, Statement on the 3rd meeting of the IHR Emergency Committee regarding the 2014 Ebola outbreak in West Africa, 23 October 2014. At: https://www.who.int/mediacentre/news/statements/2014/ebola-3rd-ihr-meeting/en/.
[387] WHO, Statement on the 4th meeting of the IHR Emergency Committee regarding the 2014 Ebola outbreak in West Africa, 21 January 2015. At: https://www.who.int/mediacentre/news/statements/2015/ebola-4th-ihr-meeting/en/.
[388] WHO, Statement on the 5th meeting of the IHR Emergency Committee regarding the Ebola outbreak in West Africa, 10 April 2015. At: https://www.who.int/mediacentre/news/statements/2015/ihr-ec-ebola/en/.
[389] WHO, The Ebola outbreak in Liberia is over, 9 May 2015. At: https://www.who.int/mediacentre/news/statements/2015/liberia-ends-ebola/en/.

when the 9th of March 2016 the PHEIC declaration was ended after to the end of transmission in the three most affected States[390].

According to the report of the Review Committee established by the Director-General in the after math of the Ebola outbreak the flaws recorded during this last outbreak mirrored the one registered during the H1N1 influenza outbreak. There was a general disregard of the recommendation to not impose a general ban on international trade and travel. As of the 1st of April 2015, according to the Review Committee, there were rumours or reports from 69 countries of the implementation of measures against the Director's General recommendations.

Another factor that has contributed at slowing the effectiveness of the response of the Organization is the lack of variety in the background of its staff. Patients affected by Ebola have the highest viral load at the time the illness kills them consequently the traditional burial practices are unsafe in preventing the further spreading of the disease within the family members and those who participate to the funeral. For these reasons the WHO has developed guidelines for the health responders in order to safely burry the cadavers of patients' dead of Ebola. The guidelines issued by the Organization have been summarized as follows: "while the guidelines were formatted in line with the current scientific knowledge of the disease, it is obvious that not much attention was given to the cultural implications of some of the prescribed measures to the affected communities"[391]. The absence of cultural sensitivity in the guidelines of the WHO led the local communities to mistrust Ebola responders and to avoid reporting Ebola symptoms or bribing officials in order to modify the death cause in the death certificate or hiding cadavers[392]. When public health officials hired anthropologists in order to advise them on culturally sensitive safe burials these practices were safely resumed[393].

The Review Committee in its recommendations and findings stressed the importance of strengthening the process to ask for justification of additional health measures and the

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[390] WHO, Statement on the 9th meeting of the IHR Emergency Committee regarding the Ebola outbreak in West Africa, 9 March 2016. At: https://www.who.int/en/news-room/detail/29-03-2016-statement-on-the-9th-meeting-of-the-ihr-emergency-committee-regarding-the-ebola-outbreak-in-west-africa.

[391] A. MANGUVO, B. MAFUVADZE, The impact of traditional and religious practices on the spread of Ebola in West Africa: time for a strategic shift, *22 The Pan African Medical Journal 2,* 2016.

[392] A. MANGUVO, B. MAFUVADZE, *op cit.*

[393] A. KAMRADT-SCOTT, The International Health Regulations (2005), *op cit.*

operations of the Secretariat to ensure the lifting of excessive measures[394]. In the aftermath of the outbreak, in addition to the Review Committee convened by the WHO, there have been also a number of independent reviews of the response to the outbreak. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola suggested in order to strengthen the compliance with the temporary recommendations of the Director-General on trade and travel to enact at least a 'name and shame' policy for countries implementing trade and travel bans[395]. According to another independent review on the functioning of the IHR during the Ebola outbreak there have been structural problems with the implementation of the temporary recommendations. First was the lack of funding and infrastructures in order to implement the recommendations by the affected countries. Second, non-affected countries disregarded the recommendations due to the internal political pressure for them to act in some way[396].

4.3. Wild Poliovirus (WPV1) in Africa and Middle East

Within the same year of the Ebola declaration as a PHEIC, the increase in the rates of the international spread of wild poliovirus type 1 (WPV1) within central Asia, the Middle East and central Africa was considered by the Emergency Committee, convened the 5th of May 2014, a PHEIC[397]. The concerning fact were the hight rates of transmission in the low virus transmission period, posing a threat to the eradication of such a dangerous disease. The exportation of cases from countries where polio is endemic and with fragile health systems to countries declared polio-free is a risk for the Global Polio Eradication Initiative. This specially in comparison to the transmission rates between 2012 and 2013. The Emergency Committee was convened, at the time of writing, twenty-five times and

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[394] WHO, Implementation of the International Health Regulations (2005), Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response; A69/21.
[395] S. MOON, D. SRIDHAR, M. A. PATE, et al, Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola; *Lancet* 2015; 386: 2204–21.
[396] L. O. GOSTIN, M. C. DEBARTOLO, E. A. FRIEDMAN; The International Health Regulations 10 Years On: The Governing Framework for Global Health Security; 386 *Lancet* 2222 (2015).
[397] WHO, Statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus, 5 May 2014. At: https://www.who.int/mediacentre/news/statements/2014/polio-20140505/en/.

the PHEIC declaration is still in place[398]. The temporary recommendations, since the start of the emergency have been divided between countries experiencing and exporting the outbreak and countries infected by poliovirus but still not exporting. In infected and exporting countries, Pakistan, Cameroon and the Syrian Arab Republic, the recommendations included official governmental declaration that Polio transmission is an emergency and additional immunization for residents and long-term visitors. Furthermore, are recommended vaccination for travellers and documentation with international vaccination certificate as per IHR[399]. The Emergency Committee suggested that these recommendations should be in place for at least six months without exportation of new cases and if there is proof of the full and high-quality eradications activities; in the absence of such proof the recommendations should be in place for 12 months[400]. The last recommendations updated the 23rd of June 2020 divide the countries in three groups: "States infected with WPV1, cVDPV1 or cVDPV3 with potential risk of international spread", "States infected with cVDPV2s, with potential or demonstrated risk of international spread" and "States no longer infected by WPV1 or cVDPV, but which remain vulnerable to re-infection by WPV or cVDPV". The recommendations are still almost the same as the one first enacted in 2014 considering the effectiveness of the immunization with the vaccine. One of the problems in order to effectively carry out the needed vaccination program is the mistrust towards the vaccine and the health workers. In Pakistan and Nigeria several workers carrying out the polio vaccinations have been killed following the revelation of the cover story used to identify Osama Bin Laden by the CIA, a vaccination campaign for hepatitis B. This has started in Pakistan in 2012 and caused the stop for several month of the vaccination program, the Taliban have killed 63 health workers and members of their escort. On the same ground the extremist group Boko Haram has also attacked the health workers providing the vaccinations. These acts of violence are causing difficulties in fully implementing the temporary recommendations

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[398] WHO, Statement of the twenty-fifth polio IHR Emergency Committee, 23 June 2020. At: https://www.who.int/news-room/detail/23-06-2020-statement-of-the-25th-polio-ihr-emergency-committee.

[399] M. A. SOGHAIER, K. M. I. SAEED, K. K. ZAMAN, *op cit.*

[400] WHO, Statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus, 5 May 2014.

in all countries affected by the virus and thus ending the spread of this preventable disease[401].

4.4. Zika virus in Brazil

The first large outbreak of Zika virus was in Micronesia in 2007 while between the end of 2013 and February of 2014 an outbreak in French Polynesia of Zika virus started having worrying complications, there was an increase in the number of neurological complications. During this outbreak there was also, for the first time, evidence of the transplacental transmission of the virus. In May 2015 Brazil confirmed the presence of Zika virus within its territory, but probably the virus was circulating much earlier, the phylogenetic analysis showed that probably the virus was already in Brazil since 2013[402]. The PAHO recommended countries in South America were the *Aedes aegypti,* the natural vector for Zika virus, was present to implement and strengthen a surveillance mechanism for Zika[403]. Not long after the confirmation of the presence of Zika in the country, Brazil started experiencing a rise in the neurological disorders, including Guillain-Barré syndrome[404], which was notified to the WHO. In October 2015 there was also an increase of the new-borns suffering of microcephaly which escalated so quickly that in November 2015 microcephaly was declare a national public health emergency. Between the end of November 2015 and January 2016 the evidence of the association between microcephaly and Zika virus grew. The 1st of February 2016 an Emergency Committee was convened by the Director-General according to the IHR. The Committee recommended the Director-General that: "the recent cluster of microcephaly cases and other neurological disorders reported in Brazil, following a similar cluster in French Polynesia in 2014,

[401] Y. BEIGBEDER, *op cit,* page 106.
[402] B. MCCLOSKEY, T. ENDERICKS, *op cit.*
[403] PAHO, Epidemiological Alert, Zika virus infection; 7 May 2015. At: www.paho.org/hq/index.php?option=com_docman&task=doc_view&Itemid=270&gid=30075=en%20%28accessed%2002%20Feb%202016%29.
[404] According to the National Institute of Neurological Disorders and Stroke the "Guillain-Barré syndrome (GBS) is a rare neurological disorder in which the body's immune system mistakenly attacks part of its peripheral nervous system—the network of nerves located outside of the brain and spinal cord. GBS can range from a very mild case with brief weakness to nearly devastating paralysis, leaving the person unable to breathe independently".

constitutes a Public Health Emergency of International Concern"[405]. On the advice of the Emergency Committee the Director-General recommended that the surveillance system for microcephaly and GBS should be standardized and improved, especially in areas with known or suspected Zika virus transmission and that research on new clusters of microcephaly and GBS should include research on a possible causative link to Zika. The Director-General also recommended that research and development on a vaccine for Zika should be enhanced and strengthen. Such a timely and prompt response to this cluster of neurological disorders, even before a link with Zika virus was confirmed, was driven by the critiques moved against the Organization regarding the Ebola response. The WHO was not the only to rapidly react, the US Centers for Disease Control and Prevention (CDC) shifted to its highest level of activation the emergency-response operations centre enhancing research and surveillance on Zika. Furthermore, The United Kingdom initiated a Zika research fund and President Obama requested 1.8 billion dollars in order to undertake Zika response activities[406]. The 1st of September 2016 it was confirmed that the Zika virus during pregnancies was the cause of severe abnormalities such as microcephaly. The PHEIC declaration was in relation to the increase of cases of microcephaly and GBS and not Zika virus *per se*, thus most of the temporary recommendations of the Director-General in the aftermath of the declaration were directed in the strengthen of research and development of the link between such neurological disorders and the virus and not on the containment of the outbreak. The Zika virus had a different impact on the behaviour of states following the declaration. Countries did not implement general travel and trade bans following the 2016 declaration of a PHEIC and generally developed travel advice to their population rather that implementing additional health measures[407].

4.5. Ebola Virus Disease in the Democratic Republic of Congo

[405] WHO, WHO statement on the first meeting of the International Health Regulations (2005) (IHR 2005) Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations, 1 February 2016. At: https://www.who.int/news-room/detail/01-02-2016-who-statement-on-the-first-meeting-of-the-international-health-regulations-(2005)-(ihr-2005)-emergency-committee-on-zika-virus-and-observed-increase-in-neurological-disorders-and-neonatal-malformations.
[406] E. CHECK HAYDEN, Spectre of Ebola haunts Zika response, Agencies rush to show that outbreak tactics have improved, *Nature*, Vol 531, 3 March 2016.
[407] B. MCCLOSKEY, T. ENDERICKS, *op cit.*

The Ministry of Health of the Democratic Republic of Congo notified the WHO of an outbreak of Ebola in the North Kivu and Ituri provinces the 1st of August 2018[408], this notification has been made just a week later the declaration of the end of an outbreak of the same disease the Equateur province in western DRC[409]. One of the major problematics of this cluster is the fact that the area is an active conflict zone[410]. The first Emergency Committee was convened the 17th of October 2018, three months after the notification to the Organization. The Committee despite recommending not to declare a Public Health Emergency of International Concern suggested to strengthen the response to the outbreak at a national level and to increase the security of health workers involved in the containment of the outbreak. It furthermore advised to increase the regional preparedness and surveillance system due to the high risk of regional spreading of the outbreak caused by porous borders between the eastern regions of the DRC and Uganda, Rwanda, and South Sudan[411]. The second Emergency Committee, while still considering that the outbreak did not constitute a PHEIC despite the fact that the outbreak had spread to Uganda, reiterated the public health advice given seven months prior, stressing the need to "redouble efforts to detect cases as early as possible"[412]. The Committee delayed the declaration of a PHEIC and the temporary recommendations under the IHR due to fear of the reaction of other countries and the devastating impact that travel and trade restrictions could have on the economy of the states affected by the outbreak. During this

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[408] WHO. Cluster of presumptive Ebola cases in North Kivu in the Democratic Republic of the Congo, 1 August 2018. At: https://www.who.int/news-room/detail/01-08-2018-cluster-of-presumptive-ebola-cases-in-north-kivu-in-the-democratic-republic-of-the-congo .

[409] WHO Africa Regional Office. Ebola virus disease: Democratic Republic of the Congo, external situation report 17: declaration of the end of the outbreak, 25 July 25. At: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwidjLWV5YvrAhWP6aQKHVLdClEQFjAAegQIARAB&url=https%3A%2F%2Fapps.who.int%2Firis%2Fbitstream%2Fhandle%2F10665%2F273348%2FSITREP_EVD_DRC_20180725-eng.pdf%3Fua%3D1&usg=AOvVaw0gAiFyVc-Pj3thB5ad6dZf.

[410] WHO. Cluster of presumptive Ebola cases in North Kivu in the Democratic Republic of the Congo, 1 August 2018.

[411] WHO, Statement on the October 2018 meeting of the IHR Emergency Committee on the Ebola virus disease outbreak in the Democratic Republic of the Congo, 17 October 2018. At: https://www.who.int/news-room/detail/17-10-2018-statement-on-the-meeting-of-the-ihr-emergency-committee-on-the-ebola-outbreak-in-drc.

[412] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 12th April 2019, 12 April 2019. At: https://www.who.int/news-room/detail/12-04-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo-on-12th-april-2019.

same time frame there have also been several attacks toward treatment facilities that were then followed by a spike in the number of cases[413]. By July 2019 the situation had further worsened, the continuous attacks toward health workers and the lack of funding were slowing and hindering the response. The Committee advised the Director-General to declare a PHEIC the 17th of July 2019, almost a year after the notification by the Health Ministry of the DRC. The temporary recommendations were directed to the "affected countries", to "neighbouring countries" and to "all States". The recommendations for the affected countries mirrored the public health advise already provided for in the previous Emergency Committee, mainly strengthen of the response and contact tracing. For neighbouring countries, the recommendations included strengthening of the surveillance system and to initiate the approval process in order to utilize the vaccine. For all other countries, in fear of the adverse reaction that the declaration of a PHEIC had during the Ebola outbreak in West Africa, the recommendations included the advice to start working "with airlines and other transport and tourism industries to ensure that they do not exceed WHO's advice on international traffic"[414]. During the West Africa outbreak commercial airlines interrupted flying to and from affected countries delaying the response and the ability for health workers to reach the area of the outbreak[415]. During the fifth Emergency Committee it was noted and complimented the effort of States in keeping the borders open and the general compliance with the temporary recommendations. The committee further reiterated all the recommendations previously issued underlining the importance of strengthening the surveillance system and the vaccination program[416]. One of the main concerns of most of the Emergency Committees during this outbreak was the security of the health workers involved in the response. There have been continuous attacks towards

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[413] L. O. GOSTIN, A. PHELAN, A. G. COUTINHO *et al*, Ebola in the Democratic Republic of the Congo: time to sound a global alert?, *The Lancet,* Vol. 393, Issue 10172, p. 617-620, 16 February 2019.

[414] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 17 July 2019, 17 July 2019. At: https://www.who.int/ihr/procedures/statement-emergency-committee-ebola-drc-july-2019.pdf?ua=1&ua=1.

[415] C. FERRELL AND P. AGARWAL, Flight Bans and the Ebola Crisis: Policy Recommendations for Future Global Health Epidemics, *Harvard Public Health Review*, Fall 2018;14.

[416] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 18 October 2019, 18 October 2019. At: https://www.who.int/news-room/detail/18-10-2019-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo.

health personal both in the facilities and at health check points. The Committee continued to consider the outbreak a PHEIC despite the encouraging trend both for the numbers of new cases and for the geographic spread. The Director-General upheld the previous recommendations maintaining them both in February and in April and underlining the importance of international cooperation and funding in order to overcome the outbreak[417]. The Director-General declared over the PHEIC on the 26th of June 2020, almost two years after the notification to the WHO of the beginning of the outbreak. The outbreak involved 3470 Ebola cases of which 2287 people died; this has been the second largest Ebola outbreak in history[418]. Despite some exceptions[419], most countries respected the temporary recommendations of the WHO, both on avoiding the closure of borders and on the implementation of vaccination policies with the newly discovered Merck EVERBO and with the Janzen vaccine[420].

4.6. Covid-19 in China

China notified the WHO on the 31st of December 2019 of a cluster of pneumonia of unknown aetiology in the city of Wuhan in the Hubei province, by the 3rd of January there were 44 reported cases. Within the outbreak news the Organization advised on strengthening the surveillance system in the area in order to detect any further cases of unknown pneumonia and against travel and trade restrictions[421]. The 12th of January the WHO published a new disease outbreak news confirming the cause of the cluster of pneumonias, a novel corona virus. The recommendations associated with this new

[417] WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee for Ebola virus disease in the Democratic Republic of the Congo on 12 February 2020, 12 February 2020. At: https://www.who.int/news-room/detail/12-02-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-for-ebola-virus-disease-in-the-democratic-republic-of-the-congo-on-12-february-2020. WHO Director-General's statement on the 7th meeting of IHR Emergency Committee on Ebola Virus Disease in the Democratic Republic of the Congo, 14 April 2020. At: https://www.who.int/news-room/detail/14-04-2020-who-director-general-s-statement-on-ihr-emergency-committee-on-ebola-virus-disease-in-the-democratic-republic-of-the-congo.

[418] H. ROHAN, G. MCKAY, The Ebola outbreak in the Democratic Republic of the Congo: why there is no 'silver bullet', *Nature Immunology* 21, 591–594 (2020).

[419] Saudi Arabia suspends Hajj visas for DR Congo over Ebola, *Aljazeera*, 26 July 2019. At: https://www.aljazeera.com/news/2019/07/saudi-arabia-suspends-visas-people-dr-congo-ebola-190726143929586.html

[420] H. ROHAN, G. MCKAY, *op cit.*

[421] WHO, Pneumonia of unknown cause – China, disease outbreak news, 5 January 2020. At: https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/.

information remained the same[422]. The 14th of January, Thailand reported the first case imported from the Hubei province, there was still no evidence of human-to-human transmission of the novel corona virus[423]. The Organization continued to receive updates and notifications of cases both from China and from other countries, mainly for imported cases from the Hubei province.

The first Emergency Committee was convened the 23rd of January 2020, it could not reach a consensus on whether the outbreak constituted or not a PHEIC. Despite not declaring a PHEIC, the Emergency Committee made recommendations differentiated for the WHO, for the People's Republic of China, to other countries and to the global community. The recommendations for the WHO were mainly areas that needed further research in order to better understand and contain the virus. Most of the recommendations towards China were oriented at increase the information sharing both of the epidemiological situation and of the measures taken in order to contain the outbreak. To other countries in was recommended to enhance the surveillance system given the high probability of international spread of the disease and to avoid travel and trade restrictions[424].

On the 30th of January 2020, following the second meeting of the Emergency Committee, the Director-General declared a PHEIC. The temporary recommendations following the declaration were still directed to the WHO, to the People's Republic of China, to other countries and to the global community. The recommendations mainly reiterated the same advice given by the previous Emergency Committee, it further suggested to the WHO to analyse the advisability of creating an intermediate level between the binary possibility of a PHEIC or no PHEIC. The Organization further recommended to start implementing measures directed at contact tracing and implementing social distancing in order to avoid secondary transmission[425]. In just a

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422 WHO, Novel Coronavirus – China, disease outbreak news : update, 12 January 2020. At: https://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/.

423 WHO, Novel Coronavirus – Thailand (ex-China), Disease outbreak news, 14 January 2020. At: https://www.who.int/csr/don/14-january-2020-novel-coronavirus-thailand/en/.

424 WHO, Statement on the meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 23 January 2020. At: https://www.who.int/news-room/detail/23-01-2020-statement-on-the-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

425 WHO, Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV), 30 January 2020. At: https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-

month following the declaration of a PHEIC, and with no travel and trade restrictions suggested, 38 State notifies the WHO of the implementations of additional health measures that affect international traffic, most of the measures are directed towards China and less frequently towards other countries affected by outbreaks of Covid-19[426]. Travel restrictions have proved not effective in avoiding the international spread of an infectious disease while having catastrophic effects on the economy and society of the affected countries.

Italy implemented a travel ban, prohibiting all travels coming from China, on the 30th of January 2020, on the same day that the Organization reiterated its recommendation to avoid travel bans. The Italian *Ordinaza del Ministero della Salute*[427] that implemented the travel ban had a validity of 90 days, in accordance with article 43 of the IHR that states that any measure that delays travel for more that 24 hours should be implemented for no more than 3 months. Contrary to the Ministerial Instruction implemented by the Canadian authorities during the 2013 Ebola outbreak, the Italian *Ordinaza* considers the IHR and specifically mentions the requirements of the IHR in order to implement travel restrictions. The Italian authorities justified the travel ban on the basis of the necessity to implement "*ogni ulteriore utile misura per prevenire, ridurre e contenere il rischio di diffusione dell'infezione da nuovo Coronavirus (2019-nCoV), tra la popolazione, anche in considerazione delle indicazioni dell'OMS e del Centro europeo per la prevenzione e il controllo delle malattie"*[428]. At the time of issuing this travel ban the recommendation of the WHO was to avoid imposing trade and travel restrictions in general. In a subsequent update of the WHO recommendations in relation to international traffic of the 29th of February 2020, travel bans are considered of some usefulness in a limited number of situations such as: in areas with limited international connections and with a weak health

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international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov). This possibility of an intermediate level of alert was already suggested by the IHR Review Committee that followed the 2013 Ebola outbreak, but this recommendation never entered into the final text of the Decision WHA71(15) that followed the Report of the Review Committee.

[426] G. PERRONE, Il Regolamento Sanitario Internazionale dell'OMS alla prova dell'emergenza CoViD-19, *Rivista di BioDiritto*, Special Issue 1/2020.

[427] Ministero della Salute, Ordinanza 30 gennaio 2020, Misure profilattiche contro il nuovo Coronavirus (2019 - nCoV). (20A00738) (GU Serie Generale n.26 del 01-02-2020).

[428] Misure profilattiche contro il nuovo Coronavirus, *op cit,* preambol.

system or at the beginning of the outbreak in order to delay the possible spread of the disease while implementing preparedness measures[429].

The 11th of March the Director-General of the Organization declare the Covid-19 a pandemic. This declaration is based on the WHO Pandemic Guidelines[430] and despite being non-binding can have some legal consequences[431]. By April 2020 the countries that notified the WHO of additional health measures were 180 of the 196 States Parties to the IHR. The additional health measures notified to the Organization ranged from denial of entry to quarantine requirements for travellers[432]. The recommendations enacted following the third Emergency Committee's meeting, the 30th of April 2020, were addressed to the WHO and to "all State Parties". Differently from previous temporary recommendations, the recommendations were divided for areas of interest, ranging from "coordination, planning and monitoring" to "surveillance" and "trade and travel". The Director-General did not advice any more on avoiding travel restrictions while suggested avoiding trade and transport restrictions of "food, medical and other essential supplies and permit the safe movement of essential personnel required for an effective pandemic response"[433]. As of March 21st, about 54 governments has imposed some sort of trade restrictions on medical supplies and medicines used to treat Covid-19 patients[434]. The Covid-19 outbreak was considered to still constitute a PHEIC as of the 1st of August 2020. The temporary recommendations of the Emergency Committee were directed to the WHO Secretariat and the State Parties.

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[429] WHO, Updated WHO recommendations for international traffic in relation to COVID-19 outbreak, 29 February 2020. At: https://www.who.int/news-room/articles-detail/updated-who-recommendations-for-international-traffic-in-relation-to-covid-19-outbreak.

[430] WHO, Pandemic Influenza Risk Management. A WHO Guide to inform and harmonize national & international pandemic preparedness and response, 2017. At: https://www.who.int/influenza/preparedness/pandemic/PIRM_update_052017.pdf

[431] D. COHEN AND P. CARTER, WHO and the pandemic flu 'conspiracies', 340 *The British Medical Journal 1279, 2010.*

[432] E. PETERSEN et al, COVID-19 travel restrictions and the International Health Regulations – Call for an open debate on easing of travel restrictions, *International Journal of Infectious Diseases* 94 (2020) 88–90.

[433] WHO, Statement on the third meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 May 2020. At: 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).

[434] S. J. EVENETT, Tackling coronavirus: The trade policy dimension (Report 51). Global Trade Alert 23 March 2020. At: https://www.globaltradealert.org/reports/51.

The recommendations are mainly about communications towards the Organization and the general public and the use of best-practices in order to reopen the societies mitigating possible resurgence of Covid-19[435]. As of the time of writing, 15 of September 2020, the global number of confirmed cases is 29 155 581 according to the WHO web site[436]. While part of the World is reopening to social events and easing travel restrictions, the Organization is still stressing the importance of social distancing and avoiding what are defined as the three Cs', crowded places, close-contact settings and confined and enclosed spaces[437]. According to the report of the UN World Tourism Organization 40% of the tourist destinations are now easing travel restrictions while 115 destinations continue to be in long-term lockdown with all borders closed[438]. Conclusively, despite the initial recommendations from the Organization advised against trade and travel restrictions most of the governments imposed them anyways, with mixed outcomes and while probably these measures where violations of the IHR this is still a sign of the inadequacy of the IHR framework and underlines the importance of updating it[439].

During the past years, and especially after the outbreak of the Covid-19 pandemic, scholars have started to propose options in order to seek reparation for a violation of the IHR or sanction its violation. These possibilities are considered in the event that the dispute settlement mechanism provided for in the IHR at article 56 does not resolve an eventual dispute and that the accused State does not accept the compulsory arbitration under the IHR. Most of these propositions are in relation to the Covid-19 pandemic, consequently they are addressed toward a possible violation of the IHR carried out by China.

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[435] WHO, Statement on the fourth meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of coronavirus disease (COVID-19), 1 August 2020. At: https://www.who.int/news-room/detail/01-08-2020-statement-on-the-fourth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19).

[436] WHO, Coronavirus disease (COVID-19) pandemic. At: https://www.who.int/emergencies/diseases/novel-coronavirus-2019. (Last visited 15 September 2020)

[437] WHO, Coronavirus disease (COVID-19), Situation Report – 204, 11 August 2020. At: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200811-covid-19-sitrep-204.pdf?sfvrsn=1f4383dd_2.

[438] UNWTO, Report Travel Restrictions 6th, Tourism Restarts: 40% of Destinations Have Now Eased Travel Restrictions, 30 July 2020. At: https://www.unwto.org/news/tourism-restarts-40-per-cent-of-destinations-have-now-eased-travel-restrictions.

[439] B. von Tigerstrom, K. Wilson, COVID-19 travel restrictions and the International Health Regulations (2005). *British Medical Journal, Global Health,* vol 5, 2020.

The first proposal is to resort to the international jurisdiction of the ICJ. This possibility has numerous flows, including the jurisdiction basis. China has repeatedly refused to accept the jurisdiction of the Court, making this option almost impossible[440].

A second option considered was a proceeding in front of a national jurisdiction, as it is already happening in Missouri[441]: this second possibility is not feasible due to principle of immunity of States from civil jurisdiction of other States that has been recently reiterated by the ICJ[442].

The final and last option considered by Graff are non-jurisdictional forms such as sanctions of the UN Security Council, where China is a permanent member and thus has a *veto* prerogative, or the adoption of unilateral economic sanctions as has already been done by the European Union and the United Stated following the annexation of Crimea by Russia.

Haris Huremagić and Fritz Kainz considers the possibility to seek reparation from China under the Chicago Convention on International Civil Aviation (the Chicago Convention)[443]. According to the Authors, the reference of article 14 of the Chicago Convention ("Prevention of spread of diseases") read in conjunction with the standard and recommended practices laid down in Annex 9 of the Chicago Convention, and with articles 6 and 7 of the IHR, could mean that a violation of the latter could be considered also a violation of the Chicago Convention. Thus, it might trigger the application of the mandatory dispute settlement procedure regarding the interpretation or application of the Chicago Convention. If a State Party to the Chicago Convention infringes its obligations, the ICAO Council has the power to suspend their vote[444]. The only way to appeal this decision by the affected State is in front of the ICJ, but only if the dispute "cannot be settled by negotiation"[445]. According to the jurisprudence of the ICJ a similar provision

[440] T. F. GRAFF, Quelles sont les obligations internationales des États en matière de santé publique?, *Le Club des Juristes*, 2020.
[441] J. WOLFE, In a first, Missouri sues China over coronavirus economic losses, *Reuters*, 21 April 2020.
[442] ICJ, Jurisdictional Immunities of the State (Germany v. Italy: Greece intervening), Judgment, I.C.J. Reports 2012.
[443] H. HUREMAGIĆ AND F. KAINZ, COVID-19, China and International Aviation Law: A ticket to The Hague?, EJIL:Talk!, 2020
[444] Article 88 Convention on International Civil Aviation
[445] Article 84 Convention on International Civil Aviation

has been interpreted as entailing a "genuine attempt to negotiate"[446], consequently making it a feasible option.

In the aftermath of the 2013 Ebola outbreak it was analysed the possibility for the WHO to resort to countermeasures in order to fill the gap of the missing enforcement mechanism. The absence of a reference to such measure both in the Constitution and in the IHR render this mechanism deficient of a legal basis. The ILC Draft Articles on the Responsibility of International Organizations at article 22 in regulating the countermeasures an organization can adopt against its Member States these are subject to the rules of the organization. Consequently, despite being in general a useful tool in order to ensure compliance for international organization, this remedy is not possible for the WHO[447]. Besides, the fact that the WHO heavily relies on voluntary funding provided for by States and private donor make the Organization reluctant at initiating any action that could hinder such donations.

Following the same outbreak, it was further proposed the possibility for the Security Council of the United Nations to pressure States in order to cooperate with global health law and to respect the provisions contained in the IHR[448]. The violation of the IHR framework during an emergency and the adoption of additional health measures usually encompasses the infringement of the duty to cooperate in good faith and of the human right framework. The Security Council has already condemned the violation of the IHR urging States to implement the temporary recommendations issued by the Director-General[449]. The actions of the Security Council can be justified by the broad interpretation of the Security Council and the Secretariat General of "threats to health security" as well as the reference to security by the preamble of the WHO Constitution and the mention of the Charter of the United Nations and the WHO Constitution by article 3 (2)b of the IHR. Consequently, the Security Council could, as it has already done, stress the necessity to adhere to the temporary recommendations of the Director-General by not imposing

[446] Application of the International Convention on the Elimination of All Forms of Racial Discrimination (Georgia v. Russian Federation), Preliminary Objections, Judgment, I.C.J., paragraph 157.
[447] A. SPAGNOLO, *op cit.* pages 411-415.
[448] G. L. BURCI, B. TOEBES; *Research Handbook in Global Health Law*, Cheltenham, Northampton, 2018. Page 296.
[449] UNSC, Resolution N. 2177 of the 18 September 2014. S/RES/2177 (2014). Page 5.

additional health measures that impair the ability of health responses to manage the emergency and consequently threaten peace and security.

Within the Covid-19 emergency China is not the only country that has allegedly violated their obligations under the IHR[450]. Several nations implemented travel bans from affected countries and closed their national borders to all non-citizens[451]. These tactics are often in violation of article 43 of the IHR which provides that additional 'health measures'[452] "shall not be more […] invasive or intrusive to person then reasonably available alternatives"[453]. Furthermore, at least two thirds of the countries that have implemented travel bans did not notify these additional health measures to the WHO, further violating article 43(3) and 43(5) of the IHR[454], with virtually no consequences in consideration of the lack of an enforcement and sanctioning mechanism of the IHR.

Having analysed all the recent health emergencies that have been declared a PHEIC it can be noted that the response of States and of the Organization to such emergencies is often significantly different from one to the other. During the 2009 H1N1 outbreak the Organization has been accused of overreacting while during the 2013-2015 Ebola outbreak it has been criticized for initially downplaying the emergency and so delaying the international response. States also have reacted in opposites ways in some instances ignoring the recommendations of the Organizations in other adhering to them and collaborating in bringing the emergency under control. These instances may be determined by greater willingness to adhere to policy decisions such as in the case of the poliovirus outbreak. During the major health emergencies that have had global impact, States have mostly disregarded the temporary recommendations of the Director-General, issued under the IHR, weakening the Regulations and the WHO more in general. The handling of the Covid-19 outbreak by the Organization, has been harshly criticized and the WHO has been used as a 'scapegoat' to cover, not only its flaws, but also the

[450] L. TONTI, The International Health Regulations: The Past and the Present, but what future? *Harvard International Law Journal*, 2020.
[451] A. SALCEDO, S.YAN AND G. CHERELUS; Coronavirus Travel Restrictions, Across the Globe; *The New York Times,* 16 July 2020.
[452] "procedures applied to prevent the spread of disease or contamination" article 1 IHR
[453] Article 43(1) IHR
[454] R. HABIBI, G. L. BURCI, T. C. DE CAMPOS et al; Do not violate the International Health Regulations during Covid-19 outbreak, *The Lancet*, 13 February 2020.

mishandling of the emergency at a national level. The 'scapegoat' approach was most evident in the US handling of the emergency, culminating in their leaving the WHO[455].

[455] Z. COHEN, J. HANSLER, K. ATWOOD, V. SALAMA AND S. MURRAY; Trump administration begins formal withdrawal from World Health Organization; *CNN,* 8 July 2020. At: https://edition.cnn.com/2020/07/07/politics/us-withdrawing-world-health-organization/index.html.

CONCLUDING REMARKS:

The first chapter analyses the history, the structure and the normative powers of the World Health Organization providing the necessary background to understand the International Health Regulations and the response of their States Parties to health emergencies. It provided the contextual explanation on the purpose of the Organization and how it has developed in time since its funding. Furthermore, the first chapter analyses the powers set out in the Constitution in case of emergency. In particular, we can see, the development of the principles that are at the basis of the current 2005 International Health Regulations. Succeeding this necessary introduction, the second chapter reviews the history of the IHR, its legal value and the powers it confers upon the Director-General in order to respond to health emergencies. This chapter follows by analysing the current text of the Regulations and the obligations upon States Parties. It further investigates the connections between the system of the Regulations and the human rights framework. The third chapter reviews the PHEIC declarations, evaluating the work of the Emergency Committees since the entry into force of the IHR in 2007. It examines the improvements adopted following the Review Committees, both on the implementation of the IHR and on the transparency of the Emergency Committees. It further analyses the legal value of the recommendations of the Director General and their impact on the response of the State Parties to the Regulations. Lastly, the fourth chapter has reviewed all the recent PHEICs analysing both the temporary recommendations of the Director-General and the behaviour of States following these recommendations.

After fifteen years from their adoption there are still doubts and speculations upon the legal value of the International Health Regulations. Despite being named a regulation and having characteristics that makes it more similar to a treaty most States do not comply with it. It can be questioned the exact legal classifications of the IHR, but until States do not fulfil their obligations and implement the core capacity requirements within their health systems these Regulations do not serve the purpose they were negotiated for. Despite the numerous amendments, since their issuing in 1951, the IHR still has numerous deficiencies, principally the lack of an enforcement mechanism and the possibility to issue more formal recommendations. The problems faced by the 1969 Regulations did not disappeared overnight with the revision of 2005. States are still

reluctant to accept limitations to their ability to implement health measures when facing an emergency. Consequently, the ongoing absence of any mechanism to ensure compliance with the Regulations makes the ‘old problems’ resurface. The IHR are in need of a structural reform in order to provide them with a more effective and efficient way to response to emergencies. Until States do not accept the new problems of the always more connected society the WHO will always be short-handed and overwhelmed by the reactions of States in emergencies.

The ambiguities in the legal value of the recommendations issued by the Director-General make inadequate the response of the Organization in case of an emergency. The recommendations are defined as ‘non-binding advise’, but there is a comply or explain mechanism safeguarding their acceptance. States disregard the recommendations not complying with the mechanism by implementing additional health measures dictated by social pressure rather than scientific evidence. The Organization is not able to enforce the explain mechanism nor can pressure States in other ways in fear of losing the already few funding it receives.

The Organization lacks the ability to send teams of doctors in order to assess an event in the States Parties, without their consent, often delaying the identification of the causative agent of such event rendering more difficult the initial response. In the modern world events with cross borders effects are more frequent, and the ability to respond in an efficient and fast way is crucial for the purpose of stopping such events before they become global. The World Health Organization in responding to such emergencies need a set of rules that allow for some degree of intrusion in the State sovereignty in order to better coordinate a uniform approach. As we have seen in the last chapter of this thesis uniformity in the response in necessary to avoid delays in the response and consequently save human lives. Furthermore, the ability to understand the cause of the emergency within a limited timing would allow the Organization to issue more precise recommendations for the beginning of the outbreak. Thus, increasing the trust in the recommendations of the Director General and consequently the adherence of States to them.

The Regulation require States Parties to improve their public health system without providing funding aimed at carrying out this obligation. As we have seen in chapter 3 paragraph 1, several less developed States have difficulties in allocating the necessary

funding for surveillance, when they are not able to provide for the most basic needs of their population. In order to contain and avoid epidemics and other health emergencies, there is the need for adequate surveillance all around the world. Therefore, a central organization capable of responding within short time frames is of vital importance. However, at the moment, both the Organization and the less developed States have funding deficiencies. WHO's funding system is mostly based on voluntary funding and private donations that are allocated to specific projects. As it has been seen during the Ebola outbreak in 2013, this system of funding does not allow for a rapid response. Despite the creation of an emergency funding system the Organization remains more a coordinator that an actor when responding to emergencies. Following the 2013 Ebola outbreak, other organizations have started to help in funding the response to emergencies, as the World Bank has instituted an emergency fund. In any case, these funding mechanisms that have been created both by the WHO and by other organizations are available only during emergencies and are not intended to fund the implementation of the core capacity requirements by States.

In order to improve the authority of the PHEIC declaration and to raise a stronger alarm on an event, the criteria that determine the existence of a PHEIC should be interpreted coherently both by the Emergency Committees and by the Director-General. There is the need for the Organization to issue standard criteria for all the future Emergency Committees on how to interpret the PHEIC requirements. Furthermore, the decision process necessary to declare a PHEIC has been harshly criticized during and following all the emergencies. Notwithstanding the fact that some improvement has been implemented following the H1N1 pandemic, the decision process is still strongly influenced by political rather that scientific consideration. The funding system present within the Organization does increase the possibilities for the decisions to be influenced by political reasonings.

Having analysed the Regulations, the handling of the Covid-19 pandemic can be considered the 'perfect storm'. The Regulations heavily rely on collaboration and information sharing by States Parties. The long-known reluctance of the Chinese authorities in making public information and the propensity to downplay emergencies has probably delayed the identification of the causative agent of the outbreak. Moreover, the non-democratic environment where the outbreak has started has allowed the government

to 'muzzle' whistle-blowers, further retarding the useful spread of information that would have allowed other countries to prepare the response to this new disease. Adding to the scenario, the outbreak probably started between November and December. The winter months are the high point of the influenza season in the Northern Hemisphere. This has allowed for a probable confusion of symptoms, retarding at the beginning the identification of the outbreak and allowing the spread of the virus if mistaken for a flu or a cold, especially in cases of mild infection. The virus itself has also been defined the 'perfect storm' considering the long incubating period, the high risk of inter-human transmission and the challenges it poses to the health care systems[456]. This outbreak has highlighted all the flows and difficulties in the current IHR framework and managing of an emergency by the WHO. The Organization was conceived mostly with coordinating powers, while the lack of an enforcement mechanism or a sanctionatory system, paralyze the ability of the WHO to cooperate with the State Parties. Experts call for a reform of the IHR since the 2013 Ebola outbreak in West Africa has shown that the world was not prepared for an outbreak. The Organization should convene a Review Committee in order to assess the shortcomings of the response by the Organization and by the Member States. This unfortunate pandemic should be the reason to initiate the long-awaited amendment process of the Regulations in order to be prepared for the next pandemic.

[456] G. LIPPI, F. SANCHIS-GOMAR, B. M. HENRY. Coronavirus disease 2019 (COVID-19): the portrait of a perfect storm; *Annals of Translational Medicine*, Vol. 8 No. 7, April 2020.

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Constitution of the World Health Organization, July 22, 1948, 14 U.N.T.S. 185

Draft Articles on the Responsibility of International Organizations, 3rd June 2011 (UN Doc A/CN.4/L.778), OXIO 11

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