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THE MISSING OPERATIONAL COMPONENTS OF THE IHR (2005) FROM THE EXPERIENCE OF HANDLING THE OUTBREAK OF COVID-19: PRECAUTION, INDEPENDENCE, TRANSPARENCY AND UNIVERSALITY

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ABSTRACT

In December 2019, there was an outbreak of pneumonia caused by Novel Coronavirus (COVID-19) in Wuhan City, China. It was unfortunate that the outbreak has taken so many lives. It was partly because that the handling of the outbreak by the World Health Organization (hereinafter "WHO") was not timely or appropriate. There are so many positive and negative lessons we can learn from the outbreak. At the international level, WHO is supposed to lead the world to fight against the outbreak based on the International Health Regulations (2005) (hereinafter "IHR (2005)"). However, it is apparent that there are many operational problems with the IHR (2005). The role of the IHR (2005) seems not to be critical in guiding States Parties for tackling the outbreak. The operation of the IHR (2005) can definitely be improved to make the system more capable of addressing life-threatening and life-saving issues. First, the compliance with the requirements of the IHR (2005) should be seriously addressed.

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Second, the independence of the Emergency Committee and that of the WHO Director-General should also be addressed so as to respect the desirable independence in performing their duties. Third, the transparency issue should also be addressed to help the country where the public health emergency of international concern (hereinafter "PHEIC") occurs to faithfully respect the disclosure requirement and to become more transparent. Fourth, the timeliness and precautionary principle should be dealt with so as to require a timely decision of a PHEIC and to ensure that the precautionary principle plays a supplementary role to help the declaration of a PHEIC in a timely and efficient manner. Fifth, WHO, its Director-General and States Parties of the IHR (2005) should also be expected to allow non-Parties' meaningful participation in the operation of the IHR (2005).

KEYWORDS: *communicable disease, COVID-19, Emergency Committee, International Health Regulations 2005, IHR (2005), MERS, Public Health Emergency of International Concern (PHEIC), SARS*

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I. INTRODUCTION

In December 2019, there was an outbreak of pneumonia caused by a new virus in Wuhan City, China. It was first called "Wuhan Pneumonia". The virus belongs to the large family of coronaviruses, but it was previously unknown. Prior to the outbreak, there had been several coronaviruses that caused severe respiratory infections, such as Severe Acute Respiratory Syndrome (hereinafter "SARS") and Middle East Respiratory Syndrome (MERS). The disease caused by this newly emerged virus was later named by the World Health Organization (hereinafter "WHO") the Novel Coronavirus Disease of 2019 or "COVID-19".[1]

Although COVID-19 is less deadly than SARS, it is far more infectious and is still life-threatening.[2] In the beginning stage of the outbreak, the rapidness of the spread, the severity of the disease and the challenges to the public health were significantly underestimated, partly because of the delayed actions taken by WHO. A lot of people were aware of the nature and seriousness of the spread only when the following news was intensively reported: China placed Wuhan and several other Chinese cities on lockdown in January 2020; the disease rapidly spread across continents; new cases sharply increased and the spread among communities of COVID-19 occurred in many more countries; many passengers and crew members in several cruise ships got infected; the entries from and travels to certain countries were banned, and many flights from and to China and some other countries were suspended. Within three months from the beginning of the outbreak (between December 2019 and 8 March 2020), the reported COVID-19 cases have reached more than 100,000 with the reported deaths reaching 3,600.[3] The figures are still rapidly increasing.

At the local level, the handling of COVID-19 and control of its spread are supposed to be the duties of the governments in the respective jurisdictions. At the international level, WHO is supposed to work closely with governments and to lead the world to fight against the outbreak based on the International Health Regulations (2005) (hereinafter "IHR (2005)" or "Regulations"), which were adopted by the World Health Assembly on 23 May 2005 as resolution WHA58.3[4] and formally entered into force on 15 June 2007.[5]

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[1] *Q&A on Coronaviruses (COVID-19)*, WORLD HEALTH ORGANIZATION [hereinafter WHO] (Mar. 9, 2020), https://www.who.int/news-room/q-a-detail/q-a-coronaviruses.

[2] *Id.*

[3] *COVID-19 Coronavirus Outbreak*, WORLDMETER, https://www.worldometers.info/coronavirus/ (last visited Mar. 12, 2020).

[4] *The International Health Regulations*, WHO (2005), http://www.who.int/csr/ihr/One_pager_update_new.pdf.

[5] The Regulations were revised from the IHR (1969), which was considered to be incapability of responding to the trend of globalization and ineffective in handling the outbreaks of new

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The Regulations govern the collaboration, control and prevention of serious communicable diseases. The adoption of the IHR (2005) was considered an important stage in the history of international health law. It was expected that WHO would lead and coordinate international efforts under the IHR (2005). The adoption also showed that the international community was able to cooperate in putting their joint efforts to handle critical health matters so that when there is an outbreak of a serious communicable disease, it can be quickly controlled and extinguished.

However, based on the experiences of handling COVID-19 up to the time of writing this paper, it is apparent that there are many operational problems with the IHR (2005). The role of the IHR (2005) seems not to be critical in guiding States Parties for tackling the outbreak. The mere existence of the IHR (2005) does not guarantee that an outbreak of a serious communicable disease will be effectively controlled and extinguished.

This paper argues that WHO should adopt some working procedures or guidelines to address the various operational problems of the IHR (2005), i.e., to ensure a precautionary attitude, to enhance the independence of WHO and the Emergency Committee, to promote transparency and to allow universal participation in the collaborative efforts of fighting against the spread of the disease.

It must be noted that this paper does not have any intention to criticize the works and measures taken and adopted by WHO, by its Director-General or by any particular country. Instead, it suggests to look forward so as to see whether there are certain operational aspects of the IHR (2005) that can be improved.

II. COMPLIANCE ISSUES CONCERNING DECLARING COVID-19 AS A "PHEIC"

A. The Concept and Determination of a "PHEIC"

There are many kinds of human diseases. Only those which are serious enough, acute and communicable are potentially covered by the IHR (2005). The Regulations introduced the concept of a "public health emergency of international concern" (hereinafter "PHEIC") to decide on the application of the IHR (2005). It was created to serve as the basis to decide whether to initiate an IHR process and whether to adopt certain measures to address the

communicable diseases (such as Ebola haemorrhagic fever) and reemerging ones (such as cholera). The revision was also based on the experience of the SARS outbreak in 2002. The SARS epidemic spread from southern China to other 25 countries in different continents within a few weeks. There were approximately 8,500 people diagnosed with probable SARS, causing about 900 deaths. *See* Colleen M. Flood & Anthea Williams, *A Tale of Toronto: National and International Lessons in Public Health Governance from the SARS Crisis*, 12 MICH. ST. U. J. INT'L L. 229, 229 (2004).

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concern. This is to ensure that the scope of problems addressed by the IHR (2005) is strictly limited to those public health events which are serious enough to justify the need of international intervention and cooperation. The adoption of the concept of "PHEIC" also reflects the flexibility of having an international instrument to deal with many unexpected public health events.

Article 1 of the IHR (2005) defines the concept "public health emergency of international concern" 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* [emphasis added]".

From this definition, it is apparent that a "PHEIC" could be an outbreak of a communicable disease or other kinds of "event" which meet the requirement of being a "public health risk to other States through the international spread of disease". But such an event must have a potential to "require a coordinated international response". This definition allows the IHR (2005) to be used to address any serious bioterrorism event. However, it is also apparent that the key concern of the IHR (2005) is still to do with some serious communicable diseases. Hence, the listed public health risks in the IHR (2005) mainly arise from the outbreaks of communicable diseases.

Communicable diseases are categorized by the IHR (2005) into three groups. They are based on the serious nature of the diseases. The first category includes certain unusual and unexpected communicable diseases which may cause a serious public health impact. These diseases are: (1) Smallpox; (2) Poliomyelitis due to wild-type poliovirus; (3) Human influenza caused by a new subtype; and (4) SARS. These diseases are by their nature "serious enough". Hence, the outbreak of any such disease would immediately constitute a "PHEIC".

The second category includes those diseases which are capable of causing a serious public health impact and spreading rapidly internationally. They are: (1) Cholera; (2) Pneumonic plague; (3) Yellow fever; (4) Viral haemorrhagic fevers (Ebola, Lassa, Marburg); (5) West Nile fever; and (6) Other diseases that are of special national or regional concern, e.g., dengue fever, Rift Valley fever, and meningococcal disease. Although such diseases are serious by their nature, they might be limited to local spread. It is subject to the result of a decision-making process (as required by the Regulations) to decide whether an outbreak of any such disease will become a "PHEIC".

The third category includes events or diseases other than those listed above. If there is a previously unknown disease which is serious enough to give rise to international concern, it can be identified as a "PHEIC" after having completed the decision-making process. The current outbreak of COVID-19 falls within the third category.

The negotiators of the IHR (2005) invented a "decision instrument" to help decide whether an event under the second or the third category

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constitutes a "PHEIC" and therefore is subject to notification requirement.

There is a decision tree[6] attached to the IHR (2005) as Annex 2 (see below).[7] A list of questions must be answered under the decision tree. If there are two "yes" answers to any two of the following four questions, it means that such an event is a "PHEIC" and that the related country is required to notify the event to WHO: (1) Is the public health impact of the event serious? (2) Is the event unusual or unexpected? (3) Is there a significant risk of international spread? (4) Is there a risk of restrictions on international travel or trade?[8]

Although the final determination of a "PHEIC" is made by the Director-General, he or she is assisted by the Emergency Committee. The Regulations require the Director-General to establish an Emergency Committee which, at the request of the Director-General, shall provide its views on: (a) whether an event constitutes a "PHEIC"; (b) the termination of a "PHEIC"; and (c) the proposed issuance, modification, extension or termination of temporary recommendations.[9]

[6] Joshua D. Reader, *The Case Against China: Establishing International Liability for China's Response to the 2002-2003 SARS Epidemic*, 19 COLUM. J. ASIAN L. 519, 542 (2006).

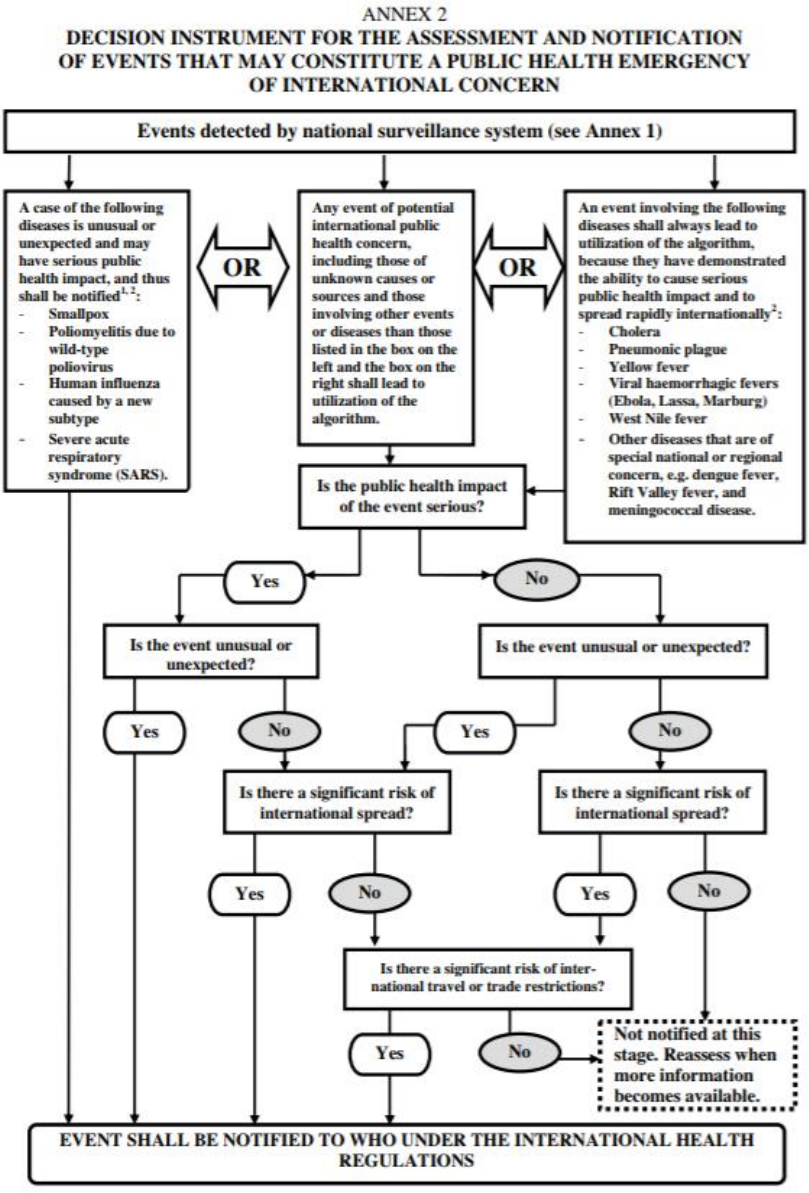
[7] The diagram is reproduced from WHO, INTERNATIONAL HEALTH REGULATIONS 43 (2d ed. 2005), https://apps.who.int/iris/bitstream/handle/10665/43883/9789241580410_eng.pdf?sequence=1.

[8] David P. Fidler, *Revision of the World Health Organization's International Health Regulations*, AMERICAN SOCIETY OF INTERNATIONAL LAW [ASIL] (Apr. 16, 2004), https://www.asil.org/insights/volume/8/issue/8/revision-world-health-organizations-international-health-regulations.

[9] The requirement is provided in Article 48.1 of the WHO, INTERNATIONAL HEALTH REGULATIONS (3d ed. 2005), https://apps.who.int/iris/rest/bitstreams/1031116/retrieve [hereinafter IHR (2005)].

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DIAGRAM 1: Decision Tree Attached as Annex 2 to the IHR (2005)



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B. A Struggle of Declaring or Not Declaring COVID-19 as a PHEIC

Based on Article 48.1 of the IHR (2005), WHO Director-General convened the meeting of the Emergency Committee on 22 and 23 January 2020 by teleconference to address the outbreak of COVID-19. According to the "Statement on the Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)", members of the Emergency Committee expressed divergent views on whether this event constitutes a PHEIC or not. The final advice from this first meeting was that the event did not constitute a PHEIC, but the Committee members agreed on the urgency of the situation and suggested that the Committee should be reconvened in a matter of days to examine the situation further.[10] In this meeting, the following elements were considered by the Emergency Committee as critical for its decision of not declaring COVID-19 as a PHEIC: "Human-to-human transmission is occurring and a preliminary R0 estimate of 1.4-2.5 was presented. Amplification has occurred in one health care facility. Of confirmed cases, 25% are reported to be severe. The source is still unknown (most likely an animal reservoir) and the extent of human-to-human transmission is still not clear."[11]

As quickly increasing numbers of cases of COVID-19 were reported, the WHO's Director-General convened the second meeting of the Emergency Committee on 30 January 2020. After discussions, the Committee suggested the Director General to declare COVID-19 as a PHEIC. According to the WHO's "Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)", the Committee indicated that "In line with the need for global solidarity, the Committee felt that a global coordinated effort is needed to enhance preparedness in other regions of the world that may need additional support for that." It agreed that "the outbreak now meets the criteria for a Public Health Emergency of International Concern". But it still advised WHO that the Organization "should continue to explore the advisability of creating an intermediate level of alert between the binary possibilities of PHEIC or no PHEIC, in a way that does not require reopening negotiations on the text of the IHR (2005)."

At the same time, the Committee "humbly" emphasized that "that the declaration of a PHEIC should be seen in the spirit of support and appreciation for China, its people, and the actions China has taken on the frontlines of this outbreak, with transparency, and, it is to be hoped, with

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[10] *Statement on the Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WHO (Jan. 23, 2020), 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).

[11] *Id.*

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success."[12]

Based on the Committee's advice, the Director-General declared on 30 January 2020 that the outbreak of COVID-19 constitutes a PHEIC.[13]

C. Requirements of the IHR (2005) Were Not Properly Followed in the Determination of COVID-19 as a PHEIC

Article 12.3 of the IHR (2005) requires that when the Director-General decides whether an event constitutes a "PHEIC", he or she shall consider: (a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) "scientific principles" as well as the available "scientific evidence" and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. The term "scientific principles" is defined in Article 1 of the Regulations as "the accepted fundamental laws and facts of nature known through the methods of science"; and the term "scientific evidence" is defined as "information furnishing a level of proof based on the established and accepted methods of science".

According to the WHO's "Statement on the meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)" and "Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)" mentioned above, the Director-General's decision that the outbreak of COVID-19 constitutes or did not constitute a PHEIC was based on the Emergency Committee's advices. The above Statements fail to mention that the Director-General considered the decision instrument contained in Annex 2 of the IHR (2005). Neither do the Statements address the WHO's assessments of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic, nor mention anything about any specific "scientific principles" or "scientific evidence" which lead to the Director-General's decision.

Considering the COVID-19 experience, there is definitely significant room for improvement in the determination of a PHEIC based on the requirements of the IHR (2005).

First, in terms of procedure, the provisions in the IHR (2005) state

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[12] *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WHO (Jan. 30, 2020), https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).

[13] *Id.*

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clearly that the procedure of declaring a PHEIC must consider information provided by the State Party; follow the decision instrument contained in Annex 2; consider the advice of the Emergency Committee; collect and identify "scientific evidence" and appropriate "scientific principles"; and conduct an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. The above two Statements of the Emergency Committee failed to show that the Director-General had followed the procedural requirements.

Second, concerning scientific evidence and scientific principle, since the outbreak of COVID-19 occurred in December 2019 and the Emergency Committee held its meetings in late January of 2020, there had been plenty of time for the WHO to collect scientific evidence and to identify applicable scientific principles in order to support the advice of the Committee and the decision of the Director-General. The failure of mentioning any specific scientific evidence and scientific principles in the above Statements shows that either the WHO did not collect the necessary scientific evidence and identify scientific principles, or it was incapable of collecting and identifying such evidence and principles at that stage, or the scientific evidence (if there is any) was not considered as important. In any event, it impairs the Emergency Committee's image of professionalism and the WHO's leadership in fighting against serious communicable diseases. This situation would have a longtime negative effect on trusting that WHO can lead the collective effort of handling a PHEIC under the IHR (2005).

Third, concerning the risk assessment, it is the fundamental basis for the Emergency Committee to give advices and for the Director-General to make recommendations to countries about the needed measures to respond to a PHEIC. A comprehensive assessment of the risk to human health, the risk of international spread of disease and the risk of interference with international traffic is extremely important for countries to decide whether they should adopt the measures recommended by the Director-General. The failure of mentioning anything to do with the risk assessment conducted by WHO also impairs the trustworthiness of the Organization and reliability of the Director-General's recommendation.

Fourth, concerning the sources of information, as mentioned above, Article 12.3 of the IHR (2005) requires the Director-General to consider information provided by the State Party where an event occurs when he or she decides whether an event constitutes a PHEIC. Certainly, such information should provide a very important basis for the Emergency Committee to give advice and for the Director-General to make decisions. But it should not be the dominant basis for the advice and decisions. However, the above-mentioned Statements show that the epidemiological information presented by Chinese authorities and the "risk-management measures" taken by the Chinese government played a dominant role in the

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procedure. The Statements do not mention that the information had been verified. This shows that WHO was likely to have failed to put necessary efforts into having a second check on the provided information for security and accuracy purpose.

III. MISSING COMPONENTS OF INDEPENDENCE, TIMELINESS AND TRANSPARENCY

A. Independence of the Emergency Committee and that of the Organization Were Not Properly Respected

The independence problem exists at two levels in the IHR (2005). At the lower level, there is a concern about the independence of the Emergency Committee. At the higher level, there is also a real concern about the independence of WHO and its Director-General.

According to Article 48.2 of the IHR (2005), the Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. Although there is no explicit requirement in the IHR (2005) that members of the Emergency Committee should be independent from any political influence, it is still a common expectation that members individually and the Committee collectively should perform their duties independently and should follow the IHR (2005) strictly. First, WHO does publish the names of the Committee members and any other information that could be determined to be a potential conflict of interest.[14] This implies that members should avoid participating in the Committee if there is conflict of interest involved. Avoiding political influence can be seen as within the broad scope of avoiding an undesirable conflict of interest. Second, although the Emergency Committee only gives advisory opinions to the Director-General, the advices are the critical basis for the Director-General to make decisions. If the advices are politically influenced, the Director-General's decisions could be distorted and the ultimate purpose of timely and effective control of infectious diseases under the IHR (2005) could be seriously undermined.

However, the above Statements of the Emergency Committee reveal that members' attitudes were affected by the Chinese position. They were disinclined to offend China and its leaders. This situation is reflected in some paragraphs in the Statement of the second meeting. For instance, it states: "The Committee welcomed the leadership and political commitment of the very highest levels of Chinese government, their commitment to transparency, and the efforts made to investigate and contain the current

[14] *Frequently Asked Questions on IHR Emergency Committee*, WHO (Dec. 19, 2019), http://www.who.int/ihr/procedures/en_ihr_ec_faq.pdf.

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outbreak." "The measures China has taken are good not only for that country but also for the rest of the world", "The Committee emphasized that the declaration of a PHEIC should be seen in the spirit of support and appreciation for China, its people, and the actions China has taken on the frontlines of this outbreak, with transparency, and, it is to be hoped, with success."

More broadly, WHO and its head are also unwilling to upset China. For instance, when the WHO Director-General Tedros Adhanom Ghebreyesus met with the Chinese leader President Xi Jinping on 28 January 2020, at the time the number of COVID-19 cases was rapidly rising, he kept thanking China by saying: "We appreciate the seriousness with which China is taking this outbreak, especially the commitment from top leadership, and the transparency they have demonstrated."[15]

Although WHO is a mixture of a political and a public health organization (in the sense that WHO has never been able to escape from political influence and political consideration), when it comes to the matter of addressing life-threatening matters, the Organization should perform its duties in a genuine manner so that decisions can be objectively made and issues can be correctly dealt with.

This paper does not mean to say that the efforts of the country where a PHEIC occurred should not be appropriately recognized and appreciated. Definitely, if real efforts and contributions from a particular country can be identified, such a country deserves appreciation. However, the expression of appreciation should not become the main theme of a critical international document which serves as the basis for declaring a PHEIC. Excessive expression of gratitude, approval and admiration to such country might lead to an undesirable situation where other countries and the general public are misled into believing that everything is perfectly under control. This would undermine the needed independence and trustworthiness of the Emergency Committee's advices to the Director-General and consequently weaken the professional decision of the Director-General.

B. Timeliness Was Not Considered as the First Priority by WHO

The Regulations do not explicitly require the Director-General to decide a PHEIC and to recommend countries within any specific timeframe. However, it is clear that a timely decision by the Director-General is critical. This is because the matter handled by WHO under the IHR (2005) is related to serious infectious and life-threatening diseases. Decisions made and measures recommended by the Director-General are key to the effective

[15] James Griffiths, *The Coronavirus Crisis Is Raising Questions over China's Relationship with the World Health Organization*, CNN (Feb. 17, 2020, 3:47 AM), https://edition.cnn.com/2020/02/14/asia/coronavirus-who-china-intl-hnk/index.html.

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control and prevention of further spread of the targeted disease.

As mentioned above, the Director-General declared that the outbreak of COVID-19 constitutes a PHEIC on 30 January 2020. However, when the first meeting was held by the Emergency Committee on 22 and 23 January 2020, there had already been the following facts:

- Globally, a total of 581 confirmed novel coronavirus (2019-nCoV) cases had been reported;
- Of the 581 cases reported, 571 cases were reported from China;
- Cases had been reported in Thailand, Japan, Hong Kong, Taiwan, Macau, United States and Korea. Persons of all reported cases had travel history to Wuhan;
- Of the 571 confirmed cases in China, 375 cases were confirmed from Hubei Province;
- Of the 571 cases, 95 cases were severely ill;
- Seventeen deaths had been reported.[16]

According to the decision-making instrument mentioned above, there had already been four "yes" answers at the time when the Emergency Committee held its first meeting. This situation should have enabled the Committee to give advice to the Director-General to declare a PHEIC. The answers to the four questions as of the date of the first Committee meeting should be as follows:

(1) Is the public health impact of the event serious?

Answer: Yes. Many people were severely ill and many people died because of the disease.

(2) Is the event unusual or unexpected?

Answer: Yes. The event was definitely unusual and unexpected, because the pneumonia was of previously unknown etiology.

(3) Is there a significant risk of international spread?

Answer: Yes. There had been reports of real cases of international spread of the novel coronavirus (2019-nCoV) from Wuhan. It was not merely a "risk" of international spread at the time when the first meeting of the Emergency Committee was held.

[16] WHO, NOVEL CORONAVIRUS (2019-NCOV) SITUATION REPORT – 3, at 1 (Jan. 3, 2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200123-sitrep-3-2019-ncov.pdf?sfvrsn=d6d23643_8.

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(4) Is there a risk of restrictions on international travel or trade?

Answer: Yes. Since the route of transmission of novel coronavirus is human to human, travelers are the main carriers of the virus to other countries. Hence there definitely was a high risk of restrictions on international travel even when the first meeting of the Emergency Committee was held.

Apparently, the decision-making of the Director-General for a PHEIC did not catch up with the high speed of the spread of the novel coronavirus from China to other countries and missed the opportunity to take preemptive action to effectively address the issue.

At the second meeting of the Emergency Committee, the Committee indicated that it "does not recommend any travel or trade restriction based on the current information available". Apparently, many countries decided not to follow the advice of the Emergency Committee.

Prior to declaring a PHEIC, there had been measures taken by some countries which foresaw the possible critical situation, based on their experience of dealing with SARS in 2003 and decided not to follow the recommendations by WHO. For instance, on 31 December 2019, Taiwan's cabinet had already declared that flights from Wuhan would be subject to quarantine inspection on board. On 13 and 14 January 2020, Taiwan sent a team of experts to visit Wuhan to collect information. On 16 January 2020, Taiwan declared tourist restrictions to Wuhan. On 23 January 2020, it declared an export restriction on face masks.[17] All these measures were adopted prior to the declaration of a PHEIC by the Director-General on 30 January and had been against the advices of the Emergency Committee.

The paper agrees with the statement of an article that "Proactive countries, societies and individuals are performing far better than reactive ones. Governments that engage in truth-telling are heading off dangers faster than those that obfuscate or delay."[18] This statement implies that countries should rely on their own judgement and efforts to "proactively" address COVID-19. The recommendations made by WHO could be too "reactive" in nature and should not be fully relied on.

From the perspective of the operation of the IHR (2005), the required timeliness of the Director-General's decisions and the activeness of the Director-General's proposing measures for countries to follow should be

[17] *Guanjian San Jueche Puguang, Fuyuan Chaoqianbushu Kang Wuhanfeiyan* [*Exposure of the Three Key Policies*], YAHOOXINWEN (Feb. 9, 2020, 7:06 AM), https://tw.news.yahoo.com/%E5%85%A8%E6%96%87%E9%97%9C%E9%8D%B53%E6%B1%BA%E7%AD%96%E6%9B%9D%E5%85%89%E5%BA%9C%E9%99%A2%E8%B6%85%E5%89%8D%E9%83%A8%E7%BD%B2%E6%8A%97%E6%AD%A6%E6%BC%A2%E8%82%BA%E7%82%8E-225859241.html.

[18] Frederick Kempe, *Op-Ed: The Coronavirus Outbreak Is Already Changing the World*, CNBC (Mar. 7, 2020, 1:04 PM), https://www.cnbc.com/2020/03/07/op-ed-the-coronavirus-outbreak-is-already-changing-the-world.html.

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included in certain practical guidelines of the IHR (2005).

C. Transparency Was Not Properly Complied with by China

There are various aspects to transparency issues in the operation of the IHR (2005), including the transparency followed by the Emergency Committee's decision-making and the transparency followed by the country where a public health event is occurring. Here, the paper focuses on the latter one.

In the IHR (2005), the provisions related to the transparency to be followed by the country where an event occurs are about the collection of "information" and notification. Article 7 of the IHR (2005) requires a State Party to provide to WHO all relevant public health information, in case it has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern.

When there is an event[19] occurring within the territory of a State Party, it has the obligation to assess such an event by using the decision instrument in Annex 2 (as shown above). In case the event constitutes a PHEIC within its territory in accordance with the decision instrument mentioned above, it has the obligation to notify WHO, by the most efficient means of communication available, by way of its National Focal Point, and within twenty-four hours of the assessment of public health information. It shall also notify any health measure[20] implemented in response to those events. Furthermore, the State Party has obligations to continue communicating to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.[21]

Although the above IHR provisions do not mention the term "transparency" in relation to the State Party's obligations concerning "information", the requirement of providing "timely, accurate and sufficiently detailed public health information" actually implies that the relevant State Party is expected and obliged to be as transparent as possible.

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[19] The term "event" is defined in Article 1 of the IHR (2005) to mean "a manifestation of disease or an occurrence that creates a potential for disease."

[20] The term "health measure" is defined in Article 1 of the IHR (2005) as "procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures."

[21] These obligations are provided in Article 6 of the IHR (2005).

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This is crucial to the effective handling of a PHEIC not merely for the relevant State Party, but also for WHO and other countries.

However, looking at the timeline and the whole situation of the COVID-19 outbreak, the information provided by China, especially that in the beginning stages of the outbreak, was not timely and not sufficiently detailed enough for WHO and for other countries to assess and to properly respond to.

It was reported that a man living in Wuhan, who became ill on 1 December 2019, was the first patient infected by the novel coronavirus.[22] Chinese authorities failed to reveal the situation in December 2019. For this whole month, citizens living in Wuhan were totally not aware of the existence of the novel coronavirus and the strong infectious nature of it. On 30 December 2020, a Chinese doctor Li Wenliang who worked at Wuhan Central Hospital posted a message in his "WeChat" group to indicate that there had been seven patients from a local seafood market diagnosed with a SARS-like illness and were quarantined in his Hospital. He was soon accused of mongering rumor and was subject to a police disciplinary measure of a warning. Li was widely considered as a whistleblower. Sadly, he was hospitalized in January 2020 and died of the novel coronavirus on 7 February 2020.[23] On 31 December 2019, China informed the WHO China Country Office of the cases of the pneumonia of unknown etiology detected in Wuhan.[24] This was exactly one month after the first patient got ill on 1 December 2019.

Most people in Wuhan chose to trust their government about the spreading of the new virus being a rumor and that there was no risk of human-to-human transmission. They were not vigilant about the risk of getting infected. People still actively engaged in preparing for the upcoming Chinese New Year (which was on 25 January 2020), returning to their home town to visit their families, traveling to other cities or provinces for vacation, participating in family gatherings and practicing other traditional New Year events. When the head of China's National Health Commission, Zhong Nanshan, confirmed human-to-human transmission of the novel coronavirus, it was as late as 20 January 2020 when millions of Wuhan people were

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[22] Julia Belluz, *A Coronavirus Outbreak is Spreading Quickly. Here's What You Need to Know*, VOX (Jan. 29, 2020, 6:28 AM), https://www.vox.com/2020/1/21/21075017/coronavirus-sars-wuhan-china-pneumonia. Holly Secon, *Chinese Social-Media Platform WeChat Saw Spikes in the Terms "SARS," "Coronavirus,"and "Shortness of Breath," Weeks Before the First Cases Were Confirmed, a Study Suggests*, BUSINESS INSIDER (Mar. 1, 2020, 1:48 AM), https://www.businessinsider.com/wechat-users-posted-coronavirus-before-china-confirmed-cases-2020-2.

[23] Yong Xiong et al., *Wuhan Hospital Announces Death of Whistleblower Doctor Li Wenliang*, CNN (Feb. 7, 2020, 8:06 AM), https://edition.cnn.com/2020/02/06/asia/li-wenliang-coronavirus-whistleblower-doctor-dies-intl/index.html.

[24] WHO, NOVEL CORONAVIRUS (2019-NCOV) SITUATION REPORT – 1, at 1 (Jan. 21, 2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf?sfvrsn=20a99c10_4.

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already traveling for the New Year holiday.[25] The general public suddenly realized the seriousness of the situation. Fears sharply raised when a lockdown was placed on Wuhan on 23 January 2020. The massive amount of travelling was the main cause contributing to the rapid spread of COVID-19. If China's policy of "maintaining stability" were not an absolute principle being prioritized over the health and life of the people in China, if the authorities could treat the disclosure of information as a positive phenomenon, if the information disclosed was timely and sufficiently detailed enough for WHO and other countries to assess and to properly respond, and if Doctor Li's whistle blowing was treated seriously, China's reputation and economy would not have been affected so deeply and the rest of the world would not have to suffer the great fear and possible loss of lives because of this highly infectious disease.

Definitely, if the Regulations are to function effectively, the transparency requirement in relation to the provision and disclosure of information should be more strictly and faithfully respected.

IV. THE PRECAUTIONARY PRINCIPLE WAS NOT PLAYING ANY ROLE

A. The Precautionary Principle as a Principle to Guide International Health Law

The precautionary principle is well-recognized in international environmental law to address various kinds of environmental issues (such as air pollution, climate change, preservation of the environment and environmental resources, management of waste and hazardous substances, and prevention and control of pollution, among others). In the fields outside environmental field, consensus is still developing and the principle is yet to be agreed upon by the international society.[26]

Concerning international health law, this paper is of the view that the precautionary principle should serve as the guiding principle for some areas of public health matters. But for some other areas of public health matters, the science-based principle should serve as the guiding principle. The proper balance lies in whether there is scientific uncertainty in the related matters and whether such uncertainty would cause a threat to public health.

The reasons for relying on the precautionary principle to guide certain areas of public health include: First, it is of high importance to protect human

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[25] *China Confirms Human-to-human Transmission of New Coronavirus*, AL JAZEERA (Jan. 21, 2020), https://www.aljazeera.com/news/2020/01/china-confirms-human-human-transmission-coronavirus-200120162507948.html.

[26] Chang-fa Lo, *Risks, Scientific Uncertainty and the Approach of Applying Precautionary Principle*, 28(2) MED. & L. 283, 289 (2009).

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life and human health. Second, in certain areas of public health, there could be unknown risks involved. Scientific uncertainty leads to no conclusive scientific evidence to support either the positive or negative finding of a certain result. Hence it is not possible to always strictly rely on the scientific principle to decide whether to adopt a measure to cope with the related public health issues. In such areas, certain precautionary measures could be needed to address the related issues.

On the other hand, in the areas where scientific evidence is already available and those where scientific evidence can be timely established before a precautionary measure is needed, a public health policy and measures should be formulated and adopted based on certain scientific principles.

Hence, it would not be correct to state that all public health measures should be "science-based". Neither is it correct to state that the precautionary principle should be applied to all public health matters due to the importance of human life and human health protection. The proper balance must be struck between the need for precautionary measures to address scientific uncertainty, the emergent nature of the situation, the need for timely adoption of effective measures to protect human health and life. Also the proportionality should not be breached when adopting the measures.

B. The Precautionary Principle Should Play a Role in the Determination of a PHEIC

This paper argues that the precautionary principle should play a supplementary role in the determination of a PHEIC for the following reasons.

First, the determination of a PHEIC is the key step in the mechanism for fighting against communicable diseases under the IHR (2005). When a PHEIC is declared by the WHO Director-General, authorities in different countries cannot overlook the situation. People will attach high importance to the outbreak. Governments will be more prepared for the event. Unfortunately, the situation of COVID-19 has been that the declaration of a PHEIC for the outbreak was delayed, and that authorities in most countries overlooked the seriousness and were not well prepared for the crisis, at least in the beginning stage of the outbreak. People also ignored the seriousness of the outbreak partly because of being misled by the delayed declaration of a PHEIC.

Second, a declaration of a PHEIC concerns saving human lives and health. The Emergency Committee and the Director-General should not solely rely on scientific evidence to show the need of declaring a PHEIC. If the decision of a PHEIC is postponed until there is solid scientific evidence to show that the outbreak of a disease will become uncontrollable, the critical

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time to massively save human lives and health could be missed.

This paper does not suggest to totally ignore scientific evidence and scientific principles. Instead, it suggests that under the following circumstances, insufficient scientific evidence should not become a barrier for the Emergency Committee or the Director-General to suggest or decide the declaration a PHEIC. A PHEIC should be declared if:

1. The virus causing an outbreak of communicable disease is novel;
2. There is scientific uncertainty with the outbreak at the early stages of the outbreak. Scientifically, the possibility cannot be ruled out that such a communicable disease will become uncontrollable if there is no international cooperation to fight against the disease;
3. The disease caused by the virus could be life-threatening;
4. The situation is urgent enough (considering the sharp increase of infected people and the rapid spread to other regions in a country or to other countries); and
5. There has been a risk assessment conducted to address the above factors.

For COVID-19, it was unfortunate that the Emergency Committee and the Director-General did not have the precautionary principle in mind when they performed their duties in deciding a PHEIC. They chose not to take action to declare a PHEIC when it had been crystal clear in early January 2020 that the coronavirus was novel; that scientifically, the possibility cannot be ruled out that COVID-19 could become uncontrollable if no international cooperation to fight against the disease was coordinated; that the disease caused by the novel coronavirus had been life-threatening; and that the situation had been urgent enough considering the sharp increase of infected people in Wuhan and the whole of China, and the rapid spread to its neighboring countries and even to other continents.

The paper argues that a separate set of guidelines drawing on the precautionary principle should be established to include the following deciding factors: the novelty of the virus and disease, the scientific uncertainty of the outbreak, the life-threatening nature of the disease, and the urgency of the situation. Based on these guidelines, the precautionary principle will play a supplementary role to help the Emergency Committee and the Director-General to recommend and declare a PHEIC in a timely and efficient manner.

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V. THE PRINCIPLE OF UNIVERSALITY WAS IGNORED

A. The Principle of Universality in IHR (2005)

Article 3.3 of the IHR (2005) provides: "The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease."

The provision of universality in Article 3.3 was introduced into the text of the Regulations at a very late stage during the negotiations of the IHR (2005). It did not appear prior to the final round held in February 2005. The chairperson's proposal in January 2005 (entitled "Review and approval of proposed amendments to the International Health Regulations")[27] did not include this universal application principle. Its inclusion closely related to Taiwan's participation in the new IHR. Many negotiators considered that the participation of the new IHR by non-parties is necessary to prevent any leak in the global mechanism to fight against communicable diseases.

This universality principle was proposed by the United States to reconcile different views about whether to establish a scheme to allow Taiwan to participate as a formal party and to respond to the need of including non-member partners in the operation of the Regulations.

The United States issued the "U.S. Statement for the Record Concerning the World Health Organization's Revised International Health Regulations" after the negotiation stating in part that:

> United States agrees with other Member States that the current International Health Regulations (IHRs) are insufficient in view of today rapid, high-volume international migration, emerging infections, and threats of terrorism. Accordingly, the United States has participated actively in the Intergovernmental Working Group (IGWG) and in sub-regional and regional meetings. The United States believes that the revised IHRs will provide an effective mechanism to respond to new global health threats in a manner that is consistent with the principles embodied in Article 3. We attach particular importance to the universal application of the IHRs for the protection of all people of the world from the international spread of disease . . . .[28]

[27] WHO, Review and Approval of Proposed Amendments to the International Health Regulations, A/IHR/IGWG/2/2, Jan. 24, 2005.

[28] The statement can be found at U.S. DEPARTMENT OF STATE: ARCHIVE, https://2001-2009.state.gov/p/io/rls/rm/46714.htm (last visited Mar. 12, 2020).

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B. The Principle of Universality Was Not Given Any Appropriate Role by WHO in Handling COVID-19

As mentioned above, WHO is a mixture of a political and a public health organization. It has never escaped from political influence and political consideration. This is the reality of the world and is understandable (although undesirable). However, concerning the handling of life-threatening matters, the Organization and its members should perform its duties in an objective and genuine manner. At least, they should show certain respect to the principle of universality provided in Article 3.3 of the IHR (2005).

Taiwan's situation under the IHR (2005) is a salient example of the failure to respect the principle of universality by WHO. Currently, Taiwan is prevented from any meaningful participation in the operation of the IHR (2005), including not being able to directly receive or submit information concerning COVID-19 from or to WHO. This definitely delays the timely exchange of critical data and other important information relating to COVID-19. It could become a detrimental leak to the international network fighting against infectious diseases.

Also, Taiwan's data has been compiled and is treated as part of China's data. This is not merely unfair to Taiwan and its people, but also could mislead other countries and their people into believing that the situation in Taiwan is as serious as that in China. As of 10 March 2020, the confirmed numbers of coronavirus cases for China and Taiwan are 80,754 and fourty-seven respectively, and the associated numbers of deaths for China and Taiwan are 3,136 and one respectively.[29] The sharp contrast between the COVID-19 situation in China and that in Taiwan is a reflection of their respective domestic systems and attitudes of treating the spread: China was less transparent in handling the related information, whereas Taiwan disclosed all data and measures based on its democratic system. If the neighboring countries of Japan and Korea are taken into account, the low numbers of Taiwan's cases are also recognizable. As of 10 March 2020, the confirmed numbers of coronavirus cases for Japan and Korea are 530 and 7513 respectively, and the associated numbers of deaths for Japan and Korea are nine and fifty-four respectively.[30]

Preventing Taiwan from participating and treating Taiwan as part of China for the purpose of the IHR (2005) lead to very undesirable situations. First, viruses do not recognize States or non-States. Neither do they recognize State-borders. They can be transmitted between Taiwan and other countries, especially considering Taiwan's citizens' active engagement in

[29] *Lu Xinguan Feiyan Yiqing* [*China Novel Coronavirus Pneumonia Epidemic*], UDN (Mar. 10, 2020, 1:53 PM), https://udn.com/news/story/120936/4299961.
[30] *Id*.

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international travel, and Taiwan being an important spot for international business and tourist activities. Preventing a country to participate is the equivalent of purposely creating a leak for the virus to travel. Second, timely provision of information is critical for an effective response to the spread of viruses to other countries. The delayed and indirect exchanges of information between Taiwan and other countries could distort government decisions and their adoption of effective measures. Third, the exchange of experiences in dealing with the spread of viruses between countries is also extremely important. The lack of direct communication between Taiwan and other countries concerning an outbreak of any communicable disease undermines the swift adoption of effective measures based on the experiences in different countries.

This paper suggests that an additional set of guidelines for the interpretation and application of the term "universal application" under Article 3.3 of the Regulations should be established to clearly require WHO, its Director-General and States Parties to the IHR (2005) to allow non-Parties' meaningful participation in the operation of the IHR (2005), which is similar to the participation of States Parties in the operation of the Regulations.

VI. CONCLUDING REMARKS

The outbreak of COVID-19 is unfortunate. There are so many positive and negative lessons we can learn from the handling of the outbreak by individual countries, WHO, the Director-General and the Emergency Committee. From the perspective of improving the international framework for the control of infectious diseases, the operation of the IHR (2005) can definitely be improved to make the system more capable of addressing life-threatening and life-saving issues.

First, the compliance with the requirements of the IHR (2005) (including not following the decision instrument, identifying scientific evidence and appropriate scientific principles, conducting an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic, and verifying the information provided by the country where the event is occurring) should be seriously addressed. A peer-review procedure could be established to revisit compliance issues after the PHEIC of COVID-19 ends.

Second, the independence of the Emergency Committee and that of the Director-General should also be addressed. There could be certain guidelines established under the IHR (2005) to urge States Parties and the Director-General to respect the desirable independence in performing their duties.

Third, the transparency issue should also be addressed. There could also be certain guidelines established under the IHR (2005) to help the country

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where the PHEIC occurs to faithfully respect the disclosure requirement and to become more transparent.

Fourth, the timeliness and precautionary principle should be dealt with. There should be a set of guidelines to require a timely decision of a PHEIC and to ensure that the precautionary principle plays a supplementary role to help the Emergency Committee and the Director-General to recommend and declare a PHEIC in a timely and efficient manner.

Finally, this paper suggests that a set of guidelines for the interpretation and application of the term "universal application" under Article 3.3 of the Regulations should be established to clearly require WHO, its Director-General and States Parties of the IHR (2005) to allow non-Parties' meaningful participation in the operation of the IHR (2005), which is similar to the participation of States Parties in the operation of the Regulations.

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