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FACULTY OF SECURITY STUDIES

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INTERNATIONAL AND NATIONAL LEGAL FRAMEWORK FOR RESPONDING TO PUBLIC-HEALTH THREATS AS EMERGENCY SITUATIONS[1]

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INTERNATIONAL AND NATIONAL LEGAL FRAMEWORK FOR RESPONDING TO PUBLIC-HEALTH THREATS AS EMERGENCY SITUATIONS

Summary: For emergencies of international concern, the most relevant document is the International Health Regulations (hereinafter: IHR). The World Health Organisation has decided to amend the IHR, as violation of them were identified during the pandemic and there were indications that it was not sufficiently effective. Reports presented at the WHA in May 2021 pointed out the need to develop stronger monitoring and evaluation mechanisms to identify and learn lessons from the COVID-19 pandemic. Perhaps most importantly, countries may have breached the IHR by failing to cooperate in the fight againstCOVID-19.

As far as Serbia is concerned, the 2016 Law on the Protection of Population from Communicable Diseases introduced novelties that bring it in line with international legislation. During the COVID-19 pandemic, stricter measures to protect population from communicable diseases, were introduced into the Law and implemented. During the pandemic, IT equipment was delivered to Institute of Public Health of Serbia and to 23 regional health institutes. The equipment should be used by infectious and other diseases experts to better coordinate their activities in the fight against the COVID-19 pandemic.

Although measures have been prescribed and implemented in Serbia and globally, the overall impression is that during the COVID-19 crisis numerous challenges for leadership at all levels of decision-making, lack of patterns and culture of communication, non-involvement of all interested parties important for problem identification and efficiency of the system have been revealed.

Keywords: *legal regulation, World Health Organisation, International Health Regulations, public-health emergency of international concern, international cooperation*

INTRODUCTION

The emergency situation (hereinafter: the ES) is defined by several national laws: the Law on Disaster Risk Reduction and Emergency Management (Art. 2, Para.1), the Law on Protection of the Population from Infectious Diseases (Art. 2, Para. 1) (hereinafter: the Law) and the Law on Public Health (Art. 2, P.1). In line with these laws, ES is a state that occurs by declaration of the competent authority when the risks and threats or consequences of disasters, extraordinary events and other hazards to the population, the environment and property are of such magnitude and intensity that their occurrence or consequences cannot be prevented or eliminated by regular measures of the competent authorities and services and it is therefore necessary to use special measures/forces and means with an enhanced work regime to mitigate

and eliminate them.

Public health emergency of international concern (hereinafter: PHEIC) is an extraordinary event that poses a threat to the public health of other States through the international spread of disease and may require a coordinated international response (International Health Regulations, 2005: 9).

There are also other national regulations that are relevant to public health: Public Health Strategy in the Republic of Serbia 2018-2026 and other health strategies (development of mental health, tobacco control, development of youth health, HIV strategy), the Law on Health Care, the Law on Health Insurance.

The most relevant international legal mechanism for the prevention for threats to public health is International Health Regulations (hereinafter: IHR). There are also several treaties that are relevant for human rights and thus also the right to health: Universal Declaration of Human Rights, International Covenant on Economic, Social and Cultural Rights and International Covenant on Civil and Political Rights. The World Health Assembly (hereinafter: WHA) can also issue recommendations and strategies in accordance with to Art. 23 of the Constitution of the World Health Organisation (hereinafter: the WHO) (Kreppenhofer, 2020/2021: 24).

In addition, there are relevant international and EU legal mechanisms in various areas that are considered to be of common importance for all EU Member States (communicable diseases, rare diseases, tobacco, cross-border healthcare, biomedicine, etc.). The competencies of the European Union are divided into exclusive competences (which belong exclusively to the EU), shared competences (with the Member States, which covers most areas) and coordinating competences (in which the EU supports, coordinates and complements the activities of the Member States in accordance with Art. 6 of the Treaty on the Functioning of the EU). Public health belongs to the last area of competence: the protection and improvement of human health – an area that remains largely a matter of national status policy and is thus managed by the Member States it in accordance with their own constitutional and cultural traditions (Sjeničić and Milenković, 2019: 506-507). Triggered by the COVID 19 pandemic, newly adopted EC regulations are already in place: Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU Regulation on the extended mandate of the European Centre for Disease Prevention and Control (ECDC) and the Emergency Framework Regulation to confer additional powers on the European Health Emergency Preparedness and Response Authority (HERA).

For emergencies of international concern, the IHR are the most important, which are analysed in the following text together with their implementation during the COVID-19 pandemic.

INTERNATIONAL HEALTH REGULATIONS – CONTENT AND IMPLEMENTATION

The IHR are a binding treaty that contributes to global public health security by providing a framework for coordinating the management of events that may constitute PHEIC and that can improve the capacity of individual countries to detect, assess, notify and respond to these emergencies. The IHR were adopted in 1969. The need for their revision resulted from the increase in international traffic and travel, and thus the increased risk of the spread of infectious diseases in the international environment. In 2005, an intergovernmental working group formed by the WHO expanded the IHR, which entered into force in 2007. Serbia is one of the 194 member countries of the WHO, and one of the 196 countries that ratified the IRC.

The IHR allow the WHO to coordinate a global disease surveillance network consisted of surveillance systems with each state to detect outbreaks that could escalate into international health emergencies and report them to the WHO (Hathaway and Phillips-Robins, 2020,: 1). States have internal laws that govern reporting in emergency situations and focus on threats that jeopardise public health within the state in emergency situations. When it comes to the obligations prescribed by the IHR, state signatory states should fulfil these until 2012, but the adoption could be postponed until 2016.

The IHR not only allow the WHO the ability to declare an emergency, but also impose four main requirements on the WHO members. first, they must notify the WHO within 24 hours of any public health event in their territory that might constitute an international public health emergency in accordance with the Annex 2 of the IHR (Figure 1). After states had sent a notification to the WHO, they must keep the WHO informed with "timely, accurate and sufficiently detailed" information about the public health event. Second, states must improve their national capacities to prevent, detect, and respond to the spread of diseases that pose a threat to the international community. States can decide for themselves how they will fulfil this obligation, but they must "uphold the purpose" of the regulations through their national efforts. Third, states are limited in in their ability to respond to disease outbreaks once they have occurred. The regulations instruct countries to only take those measures that are supported by scientific evidence, proportionate to the risks and respectful of human rights. In general, health measures must follow the WHO recommendations, although states are allowed to impose additional measures in certain circumstances. Finally, governments must notify the WHO of any public health measures they take that constitute a "significant interference" with international travel – i.e., delaying the entry or departure of travellers or goods by more than 24 hours – and provide the reasons and evidence for the measure (Hathaway and Phillips-Robins, 2020: 2).

ANNEX 2
DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN

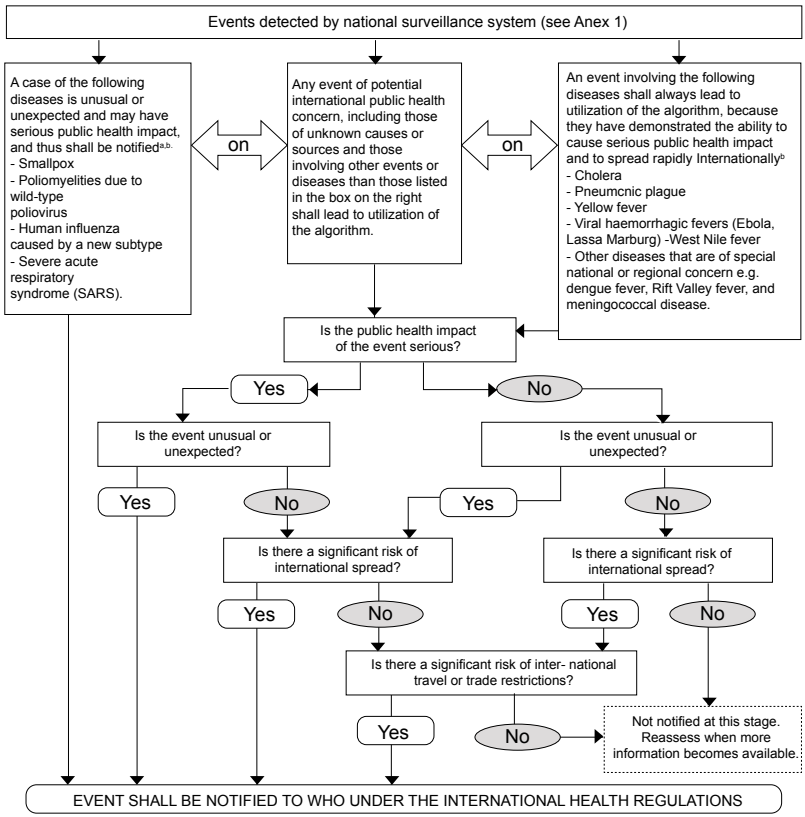

Figure 1: Annex 2 of the IHR

The WHO Director-General determines whether an event is a PHEIC in accordance with the criteria and the procedure set out in the IHR (the IHR, 2005, Art. 12) on the basis of information received, in particular from the State Party on whose territory the event occurs, and issue recommendations. The basic activities of the WHO appointing a focal point; assisting signatory states in assessing public health risks through information, consultations and verification process; informing states on the existence of risk; recommending public health measures; assisting states in investigating the existence of epidemics and fulfilling the requirements of the IHR.

The WHO has set up an IHR Emergency Committee for the coronavirus disease pandemic, which met on 13 October 2022 for its last, thirteenth meeting to date (the WHO, 2022). In addition to recommendations to strengthen COVID-19 surveillance, it was decided that the IHR should be amended due to the identified breaches during the pandemic and evidence of their possible insufficient effectiveness.

POTENTIAL VIOLATION OF THE IHR DURING THE COVID-19 PANDEMIC AND THE INITIATIVE TO AMEND THEM

Despite various reforms implemented over years that have enhanced the WHO's normative, technical and operational capabilities in relation to public health threats, the outbreak of the COVID-19 has demonstrated that the WHO was unable to prevent the international spread of the pandemic (Müller et al., 2021: 32). China first reported a cluster of novel coronavirus-like infections to the WHO on 31 December 2019, but the disease was already circulating in Wuhan a few weeks earlier. Even after China reported the cluster of cases on 31 December, it took the WHO a month to declare a PHEIC (Hathaway and Phillips-Robins, 2020: 3). The Emergency Committee withheld the declaration because it did not know the source of infection and was reluctant to declare a pandemic to prevent transmission (Sohn et al., 2021: 3). Incidentally, the same critic criticism also applies to the delayed declaration of the Ebola outbreak in West Africa as a PHEIC in 2014, while the WHO's overall response to the SARS outbreak was evaluated positively overall (Müller et al., 2021: 24).

The WHO's regulations require states to generally follow its recommendations when responding to disease outbreaks. When states take health measures that go beyond WHO recommendations, these measures must be as effective as (or more than) WHO's recommendations, follow scientific principles and evidence, not be more disruptive to international travel or "more invasive or intrusive to people" than "reasonably available alternatives" and be implemented with "full respect" for "human dignity, human rights and fundamental freedoms." (Hathaway and Phillips-Robins, 2020: 4). The introduction of measures to protect the public health of the population, such as movement restrictions, curfews, work restrictions for businesses in various sectors, bans on gatherings and events, travel restrictions, quarantine, isolation, social distancing measures, etc., have been the way to reduce virus transmission in most countries. The application of these measures had an impact on restriction of human rights, but also on the state of democracy in certain countries (Nikolić Popadić and Milenković, 2021: 188). The IHR restrictions stipulate that each country is able to detect and notify the WHO of new infections. In reality, however, it is not possible for all countries in the world to accurately detect the substance of new infections and even identify and report their countermeasures to WHO (Sohn et al., 2021: 3).

The questions were already being asked during the pandemic: what approaches have proven effective in addressing the global health challenges associated with COVID-19, what efforts need to be scaled up to end this pandemic, and what can we learn from these findings about preventing future pandemics. Three reports presented at the WHA in May 2021 were tasked with answering these questions: (i) the IHR Review Committee, (ii) the Independent Panel for Pandemic Preparedness & Response, (iii) and the Independent Oversight and Advisory Committee. Among other conclusions,

the three reports point out the need to develop stronger monitoring and evaluation mechanisms to identify and learn lessons from the COVID-19 pandemic. Perhaps most importantly, countries may have breached the IHR by failing to cooperate in fight against the COVID-19 (Seidler and Wientzek, 2021: 2-3). The control and sovereignty that members have retained undermines the WHO's ability to act efficiently and effectively in the event of a public health emergency, especially in a global political climate where some individual states choose to go it alone and forego global solidarity initiatives (Müller et al., 2021: 40).

Among the IHR problems that were continuously raised, the COVID-19 highlighted: 1) the provision of notifications and information based on the evaluation of potential PHEICs. 2) the timing of WHO's PHEIC decisions and declaration, procedures and warning systems, 3) infectious disease response measures against the IHR, 4) the WHO's lack of funds (Sohn et al., 2021: 4).

Holistically, when considering the purpose of the IHR and the intentions of its drafters, it is clear that, the IHR as a legal instrument does not place the WHO or its individual members in the strongest position to deal with unknown, contagious, and long-lasting and large-scale disease outbreaks. The IHR have not been drafted in such a way that the WHO has the necessary tools and, above all, sufficient flexibility to act in such circumstances. The IHR are characterised by rigidity and constraints that allow members to retain decisive control. In addition, although the IHR contain provisions for the prevention and control of disease outbreaks and their international spread, they hardly contain any permanent and wide-scale response measures. (Müller et al., 2021: 40-41).

FURTHER STEPS AND WHERE WE ARE

The actions related to the IHR that were proposed at the 73rd WHA session, held in November 2020, and that were to follow after the evaluation process, were, in short:

First, in terms of compliance: 1) the states failure to comply with certain obligations under the IHR, particularly in terms of preparedness, contributed to the COVID-19 pandemic becoming a protracted global health emergency; 2) Responsibility for implementing the IHR must be transferred to the highest level of government, as the WHO found that it had little power to convince states to follow the provisions of the IHR in the midst of a crisis (Hathaway and Phillips-Robins, 2020, p.6); 3) A robust accountability mechanism to assess and improve compliance with the IHR obligations would strengthen preparedness, international cooperation and timely notifications of public health events.

Second, in terms of early warning, notification and response: 4) Early warning is important to initiate timely action; 5) Early response requires better collaboration, coordination, and trust; 6) Applying the precautionary principle in the implementation of travel-related measures would enable early action against an emerging pathogen

with pandemic potential.

And the third, in terms of funding and political commitments: 7) Effective implementation of the IHR requires predictable and sustainable funding at both national and international levels; 8) A new era of international cooperation is needed to better support the implementation of the IHR.

The potential benefits of coordinated multilateral approaches, but also the slow pace and frustrations of reaching consensus between different countries, were clearly visible at the WHA session held in May 2022. Health leaders from around the world wrestled with relatively incremental changes to health security mechanisms, agreeing only to initiate a two-year process to modernise the IHR (Bristol, 2022: 1). Perceived failures in the response to COVID-19 and other health emergencies, have highlighted the need for faster and more effective communication between counties affected by outbreak and the WHO, as well as mechanisms to improve the compliance with the IHR. Decisions adopted at this year's WHA session call on the countries to submit proposals for amendments to the IHR to a newly designated Working Group on Amendments to the IHR by the end of September. The working group will develop a package of targeted amendments for the 2024 WHA session based on those proposals and input from the IHR Review Committee convened by the WHO. A separate decision specifies how much time countries have to express reservations about new amendments and sets the effective date to one year after approval (Bristol, 2022: 1).

SERBIAN LEGISLATION AND IMPLEMENTATION OF THE IHR IN SERBIA 2021

As already mentioned, the prevention and control of infectious diseases in Serbia is regulated by the Law on Protection of Population from Infectious Diseases and a number of regularly adopted by-laws, as well as by-laws adopted in connection with COVID-19. The Law regulates the list of notifiable infectious diseases, measures to protect against infectious diseases, and other related issues. Law and stemming by-laws mainly regulate conventional surveillance of infectious diseases, which is based on structured data that is reported regularly. The surveillance of infectious disease is carried out by the Centre for Disease Prevention and Control, a department of the Institute of Public Health of Serbia „Dr. Milan Jovanović Batut" (hereinafter: IPHS). The epidemiological reporting and monitoring of public health threats is based on structured, but also unstructured data from various (in)formal sources of information. The IPHS has established the Communication Centre (hereinafter: the CC) as a National Focal Point within the Centre for Disease Prevention and Control. The tasks of the CC are: data collection, threat assessment and verification, archiving and dissemination of information, support to regional institutes and institutes for public health (Tiede et al., 2013: 76), reporting on infectious diseases that pose a

potential threat, communication and cooperation with relevant institutions and support to the implementation of the IHR. The CC is the channel, the tool for data collecting, processing and exchange and for supporting the regional institutes for public health (Sjeničić and Miljuš, 2014: 5).

Regional institutes for Public Health play an active role in epidemiological reporting and they appointed Coordinators for the IHR. At the level of the Republic of Serbia (hereinafter: the RS), the network of Coordinators was formed to enable fast and efficient communication. This network is important for communication with the CC in the IPHS, but also for contact between regional institutes. Coordinator notifies the CC of the occurrence of a specific event in the territory for which s/he is responsible (Sjeničić and Miljuš, 2014: 6).

The 2016 Law introduced novelties that brought it in line with international legislation: surveillance and reporting in accordance with case definitions; measures prohibiting travel, movement, traffic in the event of infection; appointment of the IPHS as the National Focal Point for IHR. During the COVID-19 pandemic (in 2020), stricter measures for protection of population from communicable diseases, were included in the Law.

The United States Agency for International Development, in partnership with the United Nations Development Program, delivered equipment to the IPHS and to 23 regional health institutes. The provided IT equipment was to be used by infectious and non-infectious disease experts to better coordinate their activities in the fight against the COVID-19 pandemic.

In addition, at the time of the COVID-19 pandemic, a number of related by-laws (decisions, orders) were adopted related to restrictions on entry into the RS, movement within the RS and other precautionary measures. They stipulate, for example, that a written notice with a health warning about the measures to be followed to prevent the occurrence, spread and suppression of COVID-19 would be posted at the entrance to the RS, in visible places at border crossings. It was also regulated that other written notifications in the form of a health warning could be delivered during passport control. Bus carriers with valid international licences for the transport of passengers by road transport were only allowed to deviate from the approved timetable, which is an integral part of the license, if there was a declared need for certain international passenger transport and the approval of foreign countries to carry out passenger transport on their territory in accordance with the current epidemiological situation (Zekavica and Sjeničić, 2020: 56; Sjeničić, 2020: 64-67; Sjeničić, 2021: 28-30).

The social distancing measures were all prescribed in binding documents, and were gradually introduced, from the date of the declaration of the emergency situation on 16 March 2020. On 16 March 2020 the checks for travellers at airports and other border crossings and quarantine measures were introduced. The Commission, which allowed transit traffic, as an exception to entry into Serbia and movement within

the country, was formed. The city and intercity local transportation were reduced to minimum (Sjeničić, 2020: 36).

Although many measures were prescribed and implemented, the overall impression is that during the COVID-19 crisis, numerous challenges for leadership at all levels of decision-making, lack of patterns and culture of communication, non-inclusion of all interested parties important for problem recognition and efficiency of the system were revealed ever since the beginning of the crisis development.

CONCLUSION

When considering the purpose of the IHR and the intentions of its drafters, it becomes clear that the IHR as a legal instrument do not put the WHO or its individual members in the strongest position to deal with unknown, contagious, and long-lasting large-scale disease outbreaks. The IHR have not been not drafted in such a way that the WHO has necessary tools and, above all, sufficient flexibility to act in such circumstances. The IHR allows members to retain decisive control, and what is more, while the IHR contain provisions to prevent and control disease outbreaks and their international spread, they hardly contain any permanent and wide-scale response measures. Future global health governance reforms should aim to improve and enhance prevention, preparedness, and response to a wide-range of health emergencies that may arise in the future. To this end, the WHO has initiated the process to amend the IHR. So far, world health leaders agreed on relatively incremental changes to health security mechanisms, agreeing only to initiate a two-year process for modernising the IHR.

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