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Standing Recommendations under the International Health Regulations (2005)

Introduction

In May 2023, the World Health Organization's (WHO) Director-General, Dr. Tedros Adhanom Ghebreyesus, terminated the public health emergencies of international concern for both COVID-19 and monkeypox (mpox).¹ While temporary recommendations continued to be in place for both diseases for three more months, on August 9 and 21, 2023, respectively, the Director-General issued standing recommendations under the International Health Regulations (2005) (IHR) to address the long-term management of the two diseases.² This was a landmark step in the implementation of the WHO's IHR: it marked the first time since their adoption that the complex mechanism for issuing standing recommendations had been implemented.

This *Insight* offers some reflections on the legal framework applicable to standing recommendations issued under the IHR, the consequences deriving therefrom, and their potential interplay with other ongoing WHO normative processes. These reflections are based on the current IHR provisions and the limited practice that has developed in this area until now. They may be affected by future decisions of the World Health Assembly (WHA)—the supreme decision-making body of WHO, composed of all its member states—and any subsequent practice that may develop in connection with standing recommendations, in particular.

The IHR and Legal Framework Applicable to Standing Recommendations

The IHR are a legally binding instrument that were adopted by the WHA in 2005, and have been in force since 2007, pursuant to Articles 21 and 22 of the WHO Constitution.³

© American Society of International Law <u>asil.org/insights</u> They are intended to "prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."⁴ With 196 states parties (all the 194 WHO member states as well as the Holy See and Liechtenstein), the IHR are, at the time of writing, the only global legally binding instrument for the prevention and response to the international spread of diseases. They set out obligations for states parties and the WHO Director-General for the prevention and detection of, and response to, public health events that may spread diseases internationally.

As part of the international response to public health events, the IHR foresee two types of recommendations of health measures, both of which can be issued by the Director-General for consideration and implementation by states parties: temporary and standing recommendations. While both share a common objective—to prevent or reduce the risk of international spread of disease and avoid unnecessary interference with international traffic—they differ in several important respects.

Prerequisite for Issuing Standing Recommendations

Temporary recommendations may only be issued following the determination of a "public health emergency of international concern" in accordance with relevant IHR procedures, as was the case most recently for the COVID-19 pandemic.⁵ In contrast, a plain reading of the relevant provisions of the IHR⁶ suggests that the determination of a PHEIC is not a prerequisite for issuing standing recommendations. These may be issued if there is a specific ongoing public health risk, and the need for "routine or periodic application" of appropriate health measures are deemed necessary to prevent or reduce the international spread of disease. Provided these conditions are met, standing recommendations can be issued after the termination of a PHEIC, but also for an event that never reached PHEIC status. In practice, though, as illustrated by the COVID-19 and mpox situations, the most likely scenario to give rise to standing recommendations is when a PHEIC is to the long-term management of the public health risk.⁷

Duration

While temporary recommendations automatically expire after three months from their adoption unless they are renewed,⁸ the IHR are silent on the duration of standing recommendations. In the absence of specific IHR provisions addressing this aspect, the

WHO Director-General issued time-bound standing recommendations for <u>COVID-19</u> and <u>mpox</u>, which will now be in effect until 30 April 2025 and 20 August 2024, respectively. Both sets of standing recommendations may be modified or terminated earlier, if necessary.

Review Committee

In accordance with <u>Article 53</u> of the IHR, proposals for standing recommendations can be made by the Director-General or states parties to the IHR. Before issuing any standing recommendations, the Director-General is, however, required to seek the views and technical advice of a Review Committee convened for that purpose. Review Committees are expert bodies convened by the Director-General under the IHR. They are composed of international independent experts and are subject to the same rules applicable to Emergency Committees, which are convened to advise on whether an event constitutes or no longer constitutes a PHEIC as well as on the issuance of temporary recommendations.⁹

Scope

The scope of standing recommendations is "appropriate health measures for routine or periodic application." Pursuant to <u>Article 16</u> of the IHR, "[s]uch measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic." The list of possible measures that may be issued by WHO as temporary recommendations, as set out in Article 18 of the IHR, also applies to standing recommendations.

A review of the standing recommendations issued in 2023 shows for example that, with respect to COVID-19, states parties are recommended, inter alia, "to revise and implement, as appropriate, national COVID-19 plans and policies that take into account the WHO COVID-19 Strategic Preparedness and Response Plan April 2023-April 2025," "to sustain collaborative surveillance for COVID-19," and "to continue reporting COVID-19 data, particularly mortality data, morbidity data, SARS-CoV-2 genetic sequences with meta-data, and vaccine effectiveness data to WHO or in open sources."¹⁰ As to the standing recommendations concerning mpox, they include recommendations "to develop and implement national mpox plans that build on WHO strategic and technical guidance"

and "to establish and sustain laboratory-based surveillance and diagnostic capacities to enhance outbreak detection and risk assessment."¹¹

Consequences Arising from Standing Recommendations

Like temporary recommendations, standing recommendations constitute technical advice offered by the WHO through its chief technical and administrative officer—the Director-General—and are therefore not legally binding on states parties.¹² At the same time, they can be considered a benchmark for the adoption of health measures at the national level, including additional measures under Article 43 of the IHR.

In other words, states parties are expected to adopt health measures that are at least as stringent as those recommended through standing recommendations (or temporary recommendations during a PHEIC) even though they may, under Article 43, adopt "additional health measures" that deviate from WHO's recommendations or may even breach a number of IHR provisions if they have to respond to public health risks or PHEICs. The latter point is modelled on the similar approach of Article XX of the General Agreement on Tariffs and Trade which also allows contracting parties to adopt or enforce measures that are, inter alia, "necessary to protect human, animal or plant life or health," provided such measures are not applied in an arbitrary or discriminatory manner.

Implementation and Monitoring

Notably, the Regulations do not provide for a mechanism to monitor implementation of either temporary or standing recommendations at the domestic level, nor do they delegate this function to the Secretariat. As a result, the Secretariat's annual report to the WHA on implementation of the IHR does not provide any information about the uptake of temporary recommendations by individual states parties; rather, it limits itself to providing consolidated figures or statistics that are at most broken down by WHO region. It can be expected that this will be the case for standing recommendations as well.

Consideration by the World Health Assembly

Another notable difference in the legal framework applicable to temporary and standing recommendations is that the latter must be submitted to the WHA, i.e., to member states, "for its consideration" pursuant to Article 53(g) of the IHR. This provision was probably meant to ensure some kind of political oversight on the part of the WHA over potentially long-term measures that can affect international traffic and trade. The recommendations

on COVID-19 and mpox will therefore be submitted to the 77th WHA in May 2024. It remains to be seen in the absence of previous practice what action, if any, the Assembly will take on this matter. Possible actions could range from merely noting the recommendations issued by the Director-General, to providing guidance on the duration and/or scope of the recommendations, to requesting that the Director-General report the implementation of those standing recommendations after a certain period of time.

Ongoing WHO Negotiating Processes

Finally, the question arises as to whether the standing recommendations for COVID-19 and mpox might influence the negotiations that are currently underway in the framework of WHO's Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response and the Working Group on Amendments to the IHR (WGIHR). The INB and WGIHR are separate intergovernmental processes, which were established by and each report to the WHA.¹³ Since 2022, the INB has been negotiating a "pandemic agreement" which is also expected to be submitted to the 77th WHA in May 2024. The WGIHR is considering more than 300 amendments to the IHR and is also expected to submit a package of proposed amendments in May 2024 at the Assembly.

The standing recommendations issued by the Director-General are respectful of those processes and "are not intended to interfere with or unduly influence [their] work," as the standing recommendations for COVID-19 explicitly state. At the same time, some of the standing recommendations issued by the Director-General bear on matters which are being addressed in the context of the INB and WGIHR. For example, one of the standing recommendations on COVID-19 is "to continue to work towards ensuring equitable access to safe, effective and quality-assured medical countermeasures for COVID-19," which is an issue that is also being discussed in the framework of the INB. Given the controversies surrounding the question of equitable access to medical countermeasures and, more generally, the critical role of equity in the context of the ongoing INB and WGIHR discussions, it is possible that the foregoing standing recommendation may be referred to—and acquire political weight—in the context of those processes.

Conclusion

The adoption of standing recommendations marking the end of the COVID-19 and mpox PHEICs is a positive development for WHO's role in global health security. In its practice thus far, WHO's actions have revolved around emergencies, with the main difference being whether a particular outbreak constituted a PHEIC or not. With the adoption of standing recommendations under the IHR, and the possible future addition of more recommendations on poliovirus, WHO is signaling a more nuanced and proactive approach, aiming both at closing public health and regulatory gaps as well as at reducing the risk of renewed outbreaks.

This more nuanced approach could also respond to recent criticism that the binary nature of the IHR is unrealistic and only foresee PHEICs as formal alert and guidance tools. A number of states, including the United States, have proposed a more gradual system with intermediate alerts in the context of the IHR amendment process, but the final outcome is unclear at this stage, and the status quo could well prevail. In that case, standing recommendations may acquire an even greater relevance as measures that seek to address early and upstream prevention of public health situations that could otherwise escalate into emergencies.

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³ International Health Regulations (2nd ed. 2005),

https://iris.who.int/bitstream/handle/10665/43883/9789241580410_eng.pdf?sequence=1 [hereinafter

¹ For COVID-19, *see* Statement of the fifteenth meeting of the IHR (2005) Emergency Committee on the COVID-19 pandemic (May **5**, 2023), <u>https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic. For mpox, *see* Statement of the Fifth Meeting of the International Health Regulations (2005) (IHR) Emergency Committee on the Multi-Country Outbreak of mpox (monkeypox) (May 11, 2023), <u>https://www.who.int/news/item/11-05-2023-fifth-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-on-the-multi-country-outbreak-of-monkeypox-(mpox).</u></u>

² Standing recommendations for COVID-19 issued by the Director-General of the World Health Organization (WHO) in accordance with the International Health Regulations (2005) (Aug. 9, 2023); <u>https://cdn.who.int/media/docs/default-source/documents/ihr/covid-19_standing-recommendations_9-</u> <u>august-2023.pdf?sfvrsn=805ad4e4_8&download=true</u>). Standing recommendations for mpox issued by the Director-General of the World Health Organization (WHO) in accordance with the International Health Regulations (2005) (Aug. 21, 2023), <u>https://cdn.who.int/media/docs/default-source/documents/ihr/mpox-</u> <u>standing-recommendations-082023.pdf?sfvrsn=f2f9f54_6&download=true</u>.

<u>IHR</u>]. The IHR were adopted by the by the Fifty-eighth World Health Assembly on May 23, 2005, through resolution WHA58.3 "Revision of the International Health Regulations." ⁴ IHR art. 2.

⁵ The latest temporary recommendations for COVID-19 were issued on May 5, 2023,

https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic.

⁶ Namely, the definition of "standing recommendations" in Article 1 ("standing recommendation' means non-binding advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic") and Article 16 ("WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.").

⁷ This scenario could soon apply to poliovirus, too. While the PHEIC on poliovirus has been ongoing since May 5, 2014, the relevant Emergency Committee recognized in December 2023 "the concerns regarding the lengthy duration of the polio PHEIC and the importance of exploring alternative measures, including convening a polio IHR Review Committee to advise the WHO Director-General on the possible issuance of standing recommendations." *See* Statement of the Thirty-seventh Meeting of the Polio IHR Emergency Committee (Dec. 22, 2023), <u>https://www.who.int/news/item/22-12-2023-statement-following-the-thirty-seventh-meeting-of-the-ihr-emergency-committee-for-polio</u>.

⁸ IHR art. 15.

⁹ In accordance with this procedure, the standing recommendations made with respect to COVID-19 and mpox were based on the views and technical advice provided by the Review Committees on Standing Recommendations, convened by the Director-General under Article 50 of the IHR. *See* Report of the Review Committee regarding standing recommendations for COVID-19 (Aug. 4, 2023),

https://cdn.who.int/media/docs/default-source/documents/ihr/final-report-rc-srs-covid-19_4-august-2023.pdf?sfvrsn=763ce4f5_3&download=true; and Report of the Review Committee regarding standing recommendations for mpox <u>https://cdn.who.int/media/docs/default-source/documents/ihr/report-rc-srs-</u> mpox.pdf?sfvrsn=cd6067d4_19&download=true_

¹⁰ Standing recommendations for COVID-19, *supra* note 2, items A, B, and C.

¹¹ Standing recommendations for mpox, *supra* note 2, items A, B, and D.

¹² It may be noted that one of the proposed amendments to the IHR (2005), which are being considered in the context of the Working Group on Amendments to the International Health Regulations (2005), is to amend the definition of "standing recommendations" (as well as that of "temporary recommendations") to delete the explicit reference to the "non-binding" nature of the advice. *See* Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005) submitted in accordance with decision WHA75(9) (2022), proposed amendment to Article 1,

https://apps.who.int/gb/wgihr/pdf_files/wgihr1/WGIHR_Compilation-en.pdf.

¹³ The INB was established in decision SSA2(5), *The World Together: Establishment of an intergovernmental negotiating body to strengthen pandemic prevention, preparedness and response* (Dec. 1, 2021), <u>https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2(5)-en.pdf</u>. The WGIHR was established in decision WHA75(9), *Strengthening WHO preparedness for and response to health emergencies* (May 27, 2022), <u>https://apps.who.int/gb/ebwha/pdf_files/WHASGA2/SSA2(5)-en.pdf</u>.