Implementation Guide for using the Model Law on Health Data Governance to Strengthen National Frameworks

SECTION 12: PANDEMICS AND OTHER HEALTH EMERGENCIES

The purpose of this section is to facilitate the incorporation and implementation of the Pandemic Prevention, Preparedness and Response Instrument (the "Instrument") into domestic law once it has been ratified by the relevant country. The Instrument, drafted and negotiated by the intergovernmental negotiating body, aims to enhance global health security by establishing comprehensive guidelines and obligations for countries to better prevent, prepare for, and respond to pandemics and other health emergencies. This section ensures that the relevant country aligns its domestic legal framework with international standards as set forth in the Instrument, and that any necessary adjustments are made to existing legislation and policies to ensure compliance.

RATIONALE

REVIEW OF EXISTING LEGISLATION AND POLICIES

The section requires the [relevant national authorities] to conduct a comprehensive review of existing legislation and policies to identify and address any conflicts or inconsistencies with the Instrument. The findings and recommendations from this review must be submitted to the [national legislature] for any necessary amendments. This review process is critical for ensuring that the relevant country's legal framework is coherent and aligned with the obligations set out in the Instrument. By identifying and rectifying any legal inconsistencies, the relevant country can avoid potential conflicts and ensure a smooth integration of the Instrument's provisions into domestic law.

EMPOWERMENT OF THE REGULATOR TO ISSUE DIRECTIVES AND GUIDELINES

Once the Instrument enters into force, the Regulator is empowered to issue directives and guidelines for the effective implementation of its provisions, particularly as they relate to health data. The Regulator's role in issuing directives and guidelines is essential for the practical application of the Instrument within the relevant country. These guidelines will help ensure that health data is managed and used in accordance with international best practices, particularly during health emergencies, where timely and accurate data is crucial for effective response efforts.

INCORPORATION OF THE INSTRUMENT INTO DOMESTIC LAW

This provision mandates that upon ratification of the Instrument by the relevant country, the provisions of the Instrument shall be automatically incorporated into domestic law. The provision also specifies that the Instrument will enter into force on a date set by the [relevant national authority]. The automatic incorporation of the Instrument ensures that the relevant country swiftly aligns its domestic legal framework with international standards for pandemic prevention, preparedness, and response. This alignment is crucial for ensuring that the relevant country is equipped to meet its international obligations and effectively manage health emergencies.

PUBLIC CONSULTATION ON IMPLEMENTATION

Before the Instrument comes into effect, the [relevant national authority] is required to engage in public consultation regarding the implementation of its provisions within the domestic context. This ensures that the views and concerns of various stakeholders, including the public, health professionals, and policymakers, are considered. Public consultation is essential for fostering transparency, inclusivity, and public trust in the implementation process. It allows for the identification of potential challenges and opportunities in adapting the Instrument's provisions to the specific needs and context of the relevant country.

OTHER OPTIONS OF FORMULATING THE SECTION

DELAYED INCORPORATION WITH PARLIAMENTARY APPROVAL

Instead of automatic incorporation upon ratification, the section could require parliamentary approval before the Instrument's provisions are incorporated into domestic law. This approach would provide an additional layer of legislative scrutiny but could delay the alignment with international standards.

PHASED IMPLEMENTATION

The section could allow for phased implementation of the Instrument's provisions, prioritising the most urgent aspects of pandemic preparedness and response while gradually integrating other elements. This would enable a more manageable and targeted approach to incorporating the Instrument.

SPECIFIC MONITORING MECHANISM

The section could include a requirement for the establishment of a specific monitoring mechanism to oversee the implementation of the Instrument's provisions. This mechanism could provide regular reports to the national legislature on progress and challenges.

NOTES ON INTERACTION WITH OTHER SECTIONS

HEALTH DATA COURT (SECTION 6)

The Health Data Court may play a role in resolving disputes related to the application of the Instrument, particularly in cases where there is a conflict between domestic law and the provisions of the Instrument. The Court's decisions will help ensure that the relevant country complies with its international obligations.

RIGHTS AND OBLIGATIONS OF HEALTH DATA GENERATORS (SECTION 10)

The incorporation of the Instrument may impose additional obligations on health data generators, particularly concerning data sharing and reporting during health emergencies. These obligations must be aligned with the proprietary rights and duties outlined in Section 10.

USING HEALTH DATA IN THE PUBLIC INTEREST (SECTION 11)

The Instrument's provisions may intersect with the use of health data in the public interest, especially during pandemics and health emergencies where access to critical health data may be necessary. The Health Data Court may need to consider the provisions of the Instrument when adjudicating public interest use-licenses.

INTEROPERABILITY STANDARDS (SECTION 13)

The Instrument may include specific requirements for the interoperability of health data systems during health emergencies. These requirements must be aligned with the interoperability standards determined by the Regulator to ensure seamless data exchange and coordination during crises.

DEVELOPING MECHANISMS AND GUIDELINES

The Regulator is tasked with developing directives and guidelines to ensure the effective implementation of the Instrument's provisions as they relate to health data management during pandemics and other health emergencies. These directives and guidelines will translate the broad principles of the Instrument into specific, actionable policies that can be applied within the relevant country. Below are important considerations for the Regulator in developing directives and guidelines:

REFERENCE DOCUMENTS

The Regulator should refer to international standards and best practices in pandemic response, such as the WHO guidelines on data management during health emergencies. Additionally, the Regulator may consider existing national frameworks that have proven effective in managing previous health crises, adapting them to meet the requirements of the Instrument.

STAKEHOLDER ENGAGEMENT

In developing these directives and guidelines, it is crucial to engage with key stakeholders, including public health authorities, healthcare providers, data protection agencies, and civil society organizations. Their input will help ensure that the directives are practical, context-specific, and have broad support.

ENSURING COMPLIANCE

The guidelines should include clear procedures for ensuring compliance with the Instrument's provisions, including mechanisms for monitoring and reporting, as well as penalties for non-compliance. This will help maintain the integrity of the health data management system during emergencies.

INTEROPERABILITY

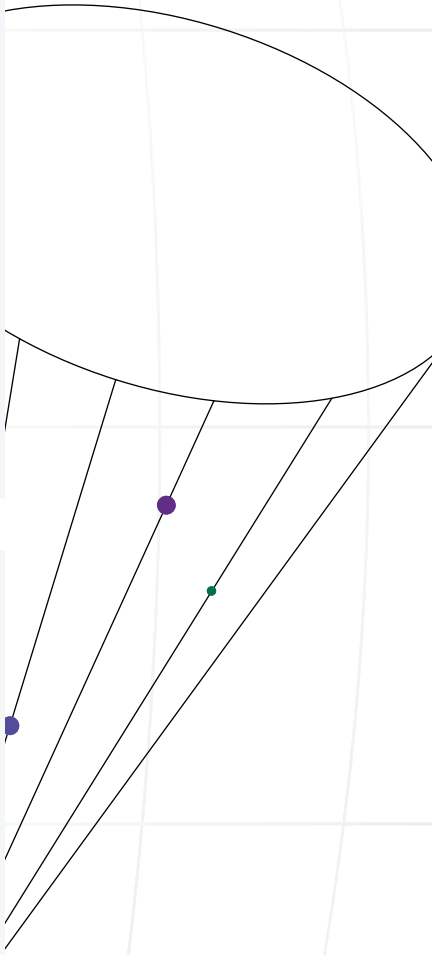
One of the critical aspects of the guidelines should be ensuring that health data systems are interoperable, as required by the Instrument. The Regulator should establish specific standards that align with both the Instrument and existing national interoperability frameworks, ensuring seamless data exchange during emergencies.

ADAPTABILITY

The directives and guidelines should be adaptable to changing circumstances, such as new pandemics or technological advancements. The Regulator should establish a process for regularly reviewing and updating these guidelines to ensure they remain relevant and effective in addressing emerging challenges.

INTERNATIONAL CONSIDERATIONS

The incorporation of the Instrument into domestic law is dependent on the existing framework of international health law, particularly the IHR of 2005, which is a legally binding agreement under the WHO. The IHR provides the foundational structure for global health security, including requirements for disease surveillance, reporting, and response. The implementation of the Instrument will need to be harmonized with the IHR, ensuring that any new obligations or guidelines do not conflict with or duplicate existing commitments. International standards, such as those developed in the context of the WHO's PIP Framework or other WHO guidelines, would need to be integrated into domestic law. This ensures that national legislation is consistent with global best practices for managing pandemics and other health emergencies. In addition, this section is dependent on existing global health security agreements, such as those under the GHSA, which includes commitments by countries to strengthen their capacities to prevent, detect, and respond to infectious disease threats. National pandemic preparedness plans, which are often developed in line with WHO guidelines, would also be directly influenced by the Instrument, introducing new obligations for resource allocation, reporting, and coordination that need to be reflected in national plans. A country must ensure that its domestic implementation of the Instrument does not conflict with its obligations under agreements like the TRIPS Agreement (especially regarding access to medicines) or the Universal Declaration of Human Rights (especially regarding the right to health).



IMPLEMENTATION TIPS

Although the Covid-19 pandemic was a terrible event, it did provide valuable evidence of the lack of preparation of many countries to be able to respond appropriately to emergency events. Before this section is put into effect, significant work will be required to ensure that the response by the country to a health emergency is:

- Able to be integrated internationally with other countries,
- Consistent with any international obligations (such as treaties),
- Has been developed in close consultation with healthcare providers and other stakeholders, in particular with disaster management teams,
- Is consistent or compatible with existing disaster management and emergency laws,
- Is able to be implemented quickly in order to make the interventions effective.

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Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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