

## Part II: Legislative assessment and potential follow-up

### II.1 How may an assessment of national legislation, regulations and other instruments for IHR (2005) purposes be conducted?

Note:  
The term "legislation, regulations and other instruments" (at times shortened to "legislation") is used in this document generally to refer to the broad range of legal, administrative or other governmental instruments which may be available for States Parties to implement the IHR (2005) and which are not necessarily limited to instruments adopted by the legislature. (see also User's Guide and Box II above)

The following part of this toolkit provides guidance for consideration by States Parties in assessing whether they are able fully and efficiently to exercise their rights and to fulfil their obligations provided in the IHR (2005) under their existing national legislation, regulations and other instruments. The actions outlined below are intended to assist States Parties when planning and conducting a legislative assessment.

#### II.1.1 Suggested preparatory actions

##### II.1.1.1 Intersectoral legislative assessment committee

States Parties may ensure that the assessment of existing legislation, regulations and other instruments covers all the subject areas and functions of the IHR (2005) by establishing an intersectoral committee for legislative assessment. If that is not appropriate in the particular national context, the State Party should nevertheless ensure comprehensive intersectoral participation in assessment efforts.

The composition of the legislative assessment committee should reflect all the sectors affected by the broad scope of the IHR (2005). All relevant governmental structures and, if appropriate, other interest groups (such as transport operators) should be included. The committee should bring together legal advisers and technical officials from all applicable levels (national and sub-national (e.g. state, regional, provincial, and local)) responsible for implementing the functions and obligations covered by the IHR (2005), including in the following and other relevant sectors:

- public health
- environment
- international ports, airports and ground crossings (including quarantine)
- customs
- food safety
- agriculture (including animal health)
- radiation safety
- chemical safety
- transportation (including dangerous goods)

- collection, use and disclosure of public health-related information.

#### **II.1.1.2 Distribution of the legislative reference and assessment tool**

States Parties should ensure that the legislative reference and assessment tool contained in section II.3 of this document is distributed to all members of the intersectoral legislative assessment committee and/or other relevant ministries, departments and government officials and legal or legislative advisers responsible for implementing functions and obligations covered by the IHR (2005) for their information and action. The tool should also be distributed to those officials or authorities with relevant responsibilities in sub-national governmental bodies.

#### **II.1.1.3 Obtaining information on national legislation, regulations and other instruments, requirements and practices**

States Parties should contact all relevant government legal and legislative advisers to ensure that all information relevant for assessment of legislation is at the disposal of the Users of the tool. Such information may include existing laws and possible draft legislation, cabinet papers and regulatory assessments that may have already been conducted. Relevant information may also concern the legislative process and overall constitutional or general legal issues, or other arrangements.

#### **II.1.1.4 Required resources**

It is important for States Parties to identify and mobilize, if needed, technical, governmental, financial, personnel or other resources. Contacts with WHO Regional Offices, Development Banks and other relevant institutions may be considered.

#### **II.1.1.5 International collaboration**

States Parties should contact other States that are preparing, or have recently successfully conducted, legislative assessment or reform for IHR (2005) implementation, for collaboration.

## II.1.2 Key legislative assessment tasks

(The legislative reference and assessment tool contained in section II.3 of this document has been prepared to support many tasks described in this section.)

- Identify all legislative subjects and operational functions at all governmental levels relevant for your State Party to implement the IHR (2005).
- Identify all existing domestic legislation, regulations and other instruments relevant to each of the subject areas and functions covered under the IHR (2005). This includes any legislation adopted to implement the prior IHR (1969), as amended, keeping in mind the broader scope and other differences in this 2005 version.
- Specify any legislation, regulations and other instruments which may potentially interfere or conflict with full or efficient IHR (2005) implementation.
- Specify any necessary enabling or authorizing legislation which may be required to exercise rights or fulfil obligations.
- With regard to these tasks, pay particular attention to:
  - the priority subject areas for implementation indicated in Box III below;
  - the specifically mandatory IHR (2005) requirements; and
  - the rights and functions in the IHR (2005) particularly relevant to your State's individual context, including its public health infrastructure and priorities, its trade and travel flows, points of entry, and its economic and geographical characteristics.
- Cross reference other WHO guidance documents on the Regulations.<sup>15</sup>
- Keep a written record of the results of the assessment. Consider using the legislative reference and assessment tool in section II.3 below for this purpose.
- Agree on follow-up action when revision of existing legislation, regulations and/or other instruments, or adoption of new ones, is considered appropriate.<sup>16</sup>

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<sup>15</sup> See guidance documents available at [www.who.int/ihr](http://www.who.int/ihr), or at applicable WHO Regional Office websites.

<sup>16</sup> See section II.2.2.5 below.

**Box III**

**Selected priority subject areas for IHR (2005) implementation**

- National IHR Focal Points: designation and operation
- Detection, reporting, verification, and control of events, as well as related communications, domestically and internationally
- Communications and collaboration with WHO
- Implementation of IHR (2005) documents:
  - Ship Sanitation Certificate (Annex 3)
  - International Certificate of Vaccination and Prophylaxis (Annex 6)
  - Maritime Declaration of Health (Annex 8)
  - Health Part of Aircraft General Declaration (Annex 9)
- Designation of Points of Entry (ports, airports and ground crossings) for development of core public health capacities
- Identification (and informing WHO) of ports authorized to issue Ship Sanitation Certificates and provide related services

## II.2 Use of the legislative reference and assessment tool

### II.2.1 Purpose

The legislative reference and assessment tool in section II.3 below has dual purposes:

- It supports assessment by States Parties of their relevant existing legislation against all of the rights and obligations States Parties have under the IHR (2005), as well as consideration of potential follow-up actions.<sup>17</sup>
- It may be used as a reference tool to identify or locate State Party provisions in the Regulations on particular key subjects. One part of the tool lists and organizes the IHR (2005) provisions into specific subject matter sections, rather than by article number. The tool also includes keywords to facilitate reference.

Table II  
Extract from the legislative reference and assessment tool

IHR (2005) State Party provisions by subject matter for national implementation	Keywords	Legislative assessment
		<p>For each applicable IHR provision listed at left below, record:</p> <p>1. If revision or new legislation is appropriate to facilitate full and efficient implementation of this provision and</p> <p>2. All relevant existing or planned legislation (as appropriate).</p>
<ul style="list-style-type: none"> <li>• SPs shall notify WHO of all events which may constitute a PHEIC within its territory, within 24 hours of assessment, by most efficient means of communication, through their NFP, of all events that may be a PHEIC in accordance with decision instrument, as well as any response measures. (Art. 6.1)</li> </ul>	<ul style="list-style-type: none"> <li>• Notification</li> <li>• Assessment</li> <li>• PHEIC</li> <li>• NFP</li> <li>• Response measures</li> </ul>	<p>1.</p> <p>2.</p> <p><input type="checkbox"/> Follow-up appropriate    <input type="checkbox"/> No follow-up appropriate</p>

<sup>17</sup> See also section II.2.2.5 below.

## II.2.2 Features

### II.2.2.1 Organization of IHR (2005) State Party provisions by subject matter

The main feature of the legislative reference and assessment tool is that it summarizes and organizes key IHR (2005) provisions for States Parties (including their rights and obligations) by *subject matter* so that their legislation can be more easily assessed (see Table II above for an extract from the tool). For example, the tool is arranged so that all provisions on a particular subject, such as surveillance or ports and airports, can be provided separately to the relevant State Party officials or advisors involved in those particular functions.

The ten categories in which the provisions are organized are:

- A. **General provisions** (purpose and scope; principles; transparency, promptness and non-discriminatory implementation of health measures; general requirements) (Arts. 2, 3, 42, 44.1)
- B. **Responsible authorities including National IHR Focal Points (NFPs) and competent authorities** (in particular Arts. 4 and 22, and Annex 7.2 (f))
- C. **Notification and reporting of events to WHO** (Arts. 5.1-.2, 6.1-.2, 7, 8, 9.2, 10.1-.2 and 46, and Annex 1)
- D. **Public health response** (Arts. 13.1, 13.5, and 46, and Annex 1. See also articles and annexes listed under section E below.)
- E. **Public health emergencies of international concern (PHEIC)**, temporary recommendations and related national capacities (see articles and annexes listed under sections C and D above and Arts. 10.3, 12, 13.4, 15, 17, 18, 43, 48-49, and Annex 1)
- F. **Points of entry** (international ports, airports and ground crossings) (Annex 1B, Arts. 19-23)
- G. **International goods, containers and container loading areas** (Arts. 23.1(b), 33-35, 41)
- H. **Conveyances** (international aircraft, shipping, ground vehicles) **and conveyance operators** (Arts. 23.1(b), 24-28, 35, 37-39, 41, 43, and Annexes 3-5, 8 and 9)
- I. **International travellers (persons)**: applying health measures and traveller protections (including human rights) (Arts. 3.1, 23, 30-32, 35-36, 40, 43, 45, Annexes 6 and 7)
- J. **National core capacity requirements** (surveillance, response and designated points of entry) (Arts. 5.1, 13.1, 19(a), 20.1, 21, and Annex 1)

Selected key definitions of the IHR (2005) are contained in Table II below.

### **II.2.2.2 Specification of the IHR (2005) obligations for States Parties using the mandatory term "shall"**

The tool identifies the specific IHR (2005) provisions explicitly using the term "shall" to designate mandatory requirements for States Parties, indicated by highlighting the term "**shall**" in bold in relevant articles and annexes, as compared to other provisions which use terms such as "should" or "may."<sup>18</sup>

### **II.2.2.3 Keywords**

The legislative reference and assessment tool provides keywords for each of the listed State Party provisions for reference and to highlight their main content. These keywords also serve to facilitate retrieval and review of provisions on particular subjects.

### **II.2.2.4 Instructions for use of the legislative reference and assessment tool for legislative assessment purposes**

Based upon review and analysis of

- the State Party provisions in the IHR (2005) (see the list on the left side of the tool),
- the technical and operational actions that these IHR (2005) provisions require the State Party to take, and
- the State Party's relevant existing and pending legislation at all governmental levels,

the User of the tool is encouraged to assess and record for each provision,

1. If revision or new legislation is appropriate to facilitate full and efficient implementation of the specific provision (including a check in the applicable box), and
2. All relevant existing or planned legislation (as appropriate).

(Pages may be added if additional space is needed for entries.)

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<sup>18</sup> For the use of these terms, see Table I. "Selected terms concerning the legal nature of IHR (2005) provisions: "shall", "should", "may", and section 1.4, above. As noted above, determining the legal significance of these and other provisions in the Regulations may require consideration of the entire texts of these and other relevant provisions, the context, and other relevant factors.

In this process, the following further considerations (which have already been described above<sup>19</sup>) should also be kept in mind:

- Any legislation which may potentially interfere or conflict with full or efficient IHR (2005) implementation;
- Any enabling or authorizing legislation potentially needed to fully and efficiently exercise rights or fulfil obligations;
- The mandatory IHR (2005) obligations for States Parties, including provisions with the term "shall" in bold (see sections I.4 and II.2.2, above);
- General priority subject areas for IHR (2005) implementation, such as NFPs, surveillance and response, communications with WHO, documents required for international travel and transportation, and designation of points of entry (see Box III above);
- State-specific priorities -- rights and functions in the IHR (2005) particularly important to your State's individual context, including current infrastructure, traffic flows, points of entry and geography; and
- Other relevant WHO guidance documents on the Regulations.

### **II.2.2.5 Potential follow-up actions**

If the assessment results indicate that national legislation does not, in some important regard, facilitate full and efficient implementation of the IHR (2005), potential follow-up actions need to be considered by the State Party. The extent and nature of appropriate follow-up actions will depend upon the specific IHR and national legislation provision(s) at issue. As with assessment, it will be important to prioritize resulting legislative efforts, including many of the same concerns listed above: some follow-up action is necessary if, for example, there is concern about potential non-compliance with the mandatory requirements under the IHR (2005); urgent efforts may also include the need for legislation to exercise critical rights under the IHR (2005) for your State Party, or the other priorities noted above in sections II.1.2 and II.2.2.4.

The results of the assessments may present a number of scenarios, including:

A. *Existing legislation supports full and efficient implementation of the specific provision:* No follow-up action is required. At the same time, a State Party may still consider potential revisions to its domestic legislation in order to update or otherwise improve these related legal capacities.

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<sup>19</sup> See section II.1.2 ("Key legislative assessment tasks").

B. *Existing legislation partially supports implementation of the specific provision:* Follow-up action may be appropriate. Such action may include further assessment or study of the issue with a view to potential legislative reform (consistent with the ongoing requirements of full compliance with the IHR (2005)). Moreover, revisions may be necessary where States Parties are developing or otherwise improving their core public health capacities in accordance with Annex 1A, or newly-designated points of entry under the IHR (2005) Annex 1B, and updated legal frameworks are required to support these new technical capacities.

C. *Relevant new or revised legislation is contemplated or pending but not yet in force:* Follow-up actions should include staying informed about the status of the legislative process, and consideration of emergency legislation or other short term measures if necessary in the specific circumstances. The situation may be re-evaluated the situation once the legislation has been adopted and is in force, or rejected.<sup>20</sup>

D. *New or revised legislation is contemplated, but there is need for immediate action for full or efficient implementation:* Where revisions are contemplated, it is advisable to determine whether immediate action may be appropriate in line with national governmental and legal structures and legislative processes. Users should consider investigation of the legislative or administrative mechanisms outlined in Box II above for implementing critical legal and administrative measures as rapidly and efficiently as possible, including:

- (1) emergency legislation (often faster to adopt but may be of limited duration or application);
- (2) administrative regulations (often faster to adopt, fewer legislative procedures);
- (3) non-legislative guidelines or standards (similar advantages as administrative regulations, flexible);
- (4) non-legislative agreements or arrangements, e.g. for intersectoral links (same potential advantages as non-legislative guidelines or standards).

E. *New or revised legislation contemplated--long-term planning.* In addition to potential short term approaches as indicated in paragraph D above, it may be advisable to consider also longer term legislative actions to adopt more extensive legislation, regulations or other instruments. Follow-up actions may involve, for

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<sup>20</sup> On the legislative process, see e.g. *Enhancing Health Policy Development: A practical guide to understanding the legislative process*. World Health Organization, Regional Office for the Western Pacific, 2004, available at [http://www.wpro.who.int/NR/rdonlyres/5BC69BF8-E232-4BC0-B5CE-296BA9DBB145/0/Enhancing\\_health\\_policy\\_dev.pdf](http://www.wpro.who.int/NR/rdonlyres/5BC69BF8-E232-4BC0-B5CE-296BA9DBB145/0/Enhancing_health_policy_dev.pdf). See also Appendix of this document containing a list of selected secondary sources on drafting, revising and implementing public health legislation.

example, further assessments, studies or the initiation of a legislative process to revise existing or to adopt new legislation.<sup>21</sup>

As noted, the States Parties have been required to fulfil their obligations under the IHR (2005) since 2007, regardless of any process to revise their domestic legislation. At the same time, States Parties are not required to have any particular legislation, regulations or other instruments, provided they comply with their obligations under the IHR (2005).

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<sup>21</sup> Other priorities may include any legislation necessary to coordinate and harmonize with other related international public health initiatives, such as those of the International Maritime Organization at international ports. See [www.imo.org](http://www.imo.org).