# Implementing the International Health Regulations (2005) in Europe

G Rodier[1], M Hardiman[1], B Plotkin[1], B Ganter[2]

The adoption of the International Health Regulations (2005) (also referred to as IHR(2005) or the revised Regulations) provides a remarkable new legal tool for the protection of international public health. Upon entry into force on 15 June 2007, Article 2 ('Purpose and scope') provides that the overall focus of the efforts of States Parties (and World Health Organization's efforts under the revised Regulations will be to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with the public health risks and which avoid unnecessary interference with international traffic. Health measures under the revised Regulations will be implemented with respect for travellers' human rights, with several specific new requirements in this area. To comply with the IHR(2005), States Parties (WHO member states that will be bound by the IHR(2005)) will have to have core public health capacities in disease surveillance and response, as well as additional capacities at designated international ports, airports and land crossings. This unique collective commitment will require close collaboration between WHO and the States Parties, but also intersectoral collaboration within the States themselves, including collaboration among different administrative or governmental levels, a particular issue for federal states, and horizontally across ministries and disciplines. Collaboration among States Parties is a key aspect of the revised Regulations, whether among neighbours, or with trading partners, members of regional economic integration organisations or other regional groups, or simply members of the international community. This collaboration is particularly relevant for the Member States of the European Union.

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## Introduction to the IHR(2005)

On 23 May 2005, the World Health Assembly (WHA) adopted the revised IHR(2005) in resolution WHA58.3 [1]. The new text was the conclusion of intensive negotiations of an Intergovernmental Working Group (IGWG) which first met in Geneva in November 2004. The second session of the IGWG was split between deliberations in February and May 2005, with the new public health legal instrument finalised in the early hours of 14 May 2005. These negotiations were preceded by extensive input to the World Health Organization (WHO) from a series of regional consultations, including a consultation of Member States of the WHO Regional Office for Europe in June 2004, as well as a large number of written comments submitted to WHO. Under the new IHR(2005), WHO Member States have until 15 December 2006 to officially notify the WHO Director General of rejection of, or reservations about the IHR(2005), or they will become bound by the revised Regulations on 15 June 2007.

Although the IHR(2005) build in part upon the text of current IHR(1969)[2], they are primarily based on the most recent experiences of WHO and Member States in national surveillance systems, epidemic intelligence, verification, risk assessment, outbreak alert, and coordination of international response, all of which are part of WHO's ongoing work on global health security [3].

More than simply an updated text, the IHR(2005) introduce a range of innovative approaches in global surveillance and response [4,5]. For the first time, states across the globe have agreed on a set of legal rules and procedures to collectively deal with potential public health emergencies of international concern and other international public health risks. The revised Regulations move away from the automatic notification to WHO of a single case of cholera, plague or yellow fever to the notification of all events that may constitute a 'public health emergency of international concern' (PHEIC), taking into account the context in which an event occurs. In addition to assessment and notification requirements, the new Regulations contemplate ongoing communications between WHO and the State Party involved (State Party is the name given to WHO member states that will be bound by the IHR(2005)), and provide specifically for consultation with WHO on appropriate health measures for events which may not need to be notified (at least initially) depending upon evolution of the particular event. A new Emergency Committee will provide its views to the Director-General on whether an event constitutes a PHEIC, in those cases where an affected State Party does not agree that a PHEIC is occurring, and in all cases in which a PHEIC has been declared, on temporary recommendations of the most appropriate and necessary public health measures to respond to the emergency. WHO will play a central role in surveillance, public health response, information sharing, and coordination of international response efforts.

In order to be able to notify, or respond to potential PHEICs, states will have to be able to detect such events through improved national surveillance and response infrastructure that meet at least minimum core capacity requirements. Regarding detection, assessment and reporting of events, for example, Annex 1 of the revised Regulations outlines necessary core capacities for the local (community), intermediate and national levels, culminating at the national level in assessment of all reports of urgent events within 48 hours and reporting to WHO immediately through the National IHR Focal Point if required. Public health response capacity requirements are also indicated for each level; at the national level, for example, States Parties must have the capacities to determine rapidly the control

1. World Health Organization, Epidemic and Pandemic Alert and Response, Geneva, Switzerland
2. World Health Organization, Regional Office for Europe, Copenhagen, Denmark

measures required to prevent disease spread and provide on-site assistance to local investigations. More specifically, States will have to provide response support through specialised staff, laboratory analysis and logistical assistance; direct operational links with senior health and other officials and direct liaison with other relevant government ministries; communications links with hospitals, clinics, ports, airports, laboratories and other key operational areas for dissemination of information; and a national public health emergency response plan, all on a 24-hour basis. For certain international ports, airports and ground crossings designated by the State under IHR(2005), there are additional requirements, including access to appropriate medical service (with diagnostic facilities), services for the transport of ill persons, and trained personnel to inspect ships, aircraft and other conveyances. When health measures are being implemented with regard to travellers, they must be treated with courtesy and respect, taking into consideration their gender, sociocultural, ethnic and religious concerns, and supplied with appropriate food, water, accommodations and medical treatment if quarantined, isolated or otherwise subject to medical or public health measures. Additional provisions establish rules for treatment of personal data and other protections for individuals on international journeys.

### Implementing IHR(2005)

Implementing the IHR(2005) will be a challenge for both WHO and the States Parties. It is a challenge for WHO in light of the broad scope of obligations and diseases under IHR(2005), which involve many technical areas and require consistency across a global organisation. WHO's existing alert and response operations [6] will play a key role. For the Member States of WHO, it is also a challenge in many ways. The new rights and obligations for States Parties are extensive. It may be an organisational, administrative or legislative challenge for some states to bring these kinds of infrastructure in line with the requirements of the revised Regulations. It may also present financial challenges for resource-poor countries implementing obligations to strengthen national surveillance and response systems. A WHO strategic implementation plan for IHR(2005) is being developed building on strategies already in place for epidemic-prone diseases in these critical implementation areas, including on-going preparedness efforts related to the threat of avian and pandemic influenza. Implementing IHR(2005) will require sustained national commitment, including budgetary measures, and international cooperation, bilateral and multilateral.

There is a deadline of five years, from entry into force, for States Parties to develop, strengthen and maintain their capacities to detect, assess, notify and report events in accordance with the Regulations, as specified in Annex 1. The same deadline applies to the establishment of capacities to respond promptly and effectively to public health risks and public health emergencies of international concern. More generally, each State Party, within two years of entry into force, must assess the abilities of their national structures and resources to meet the minimum capacity requirements specified in the Annex; based upon these assessments, they must then develop and implement a national implementation plan to achieve the capacities throughout their territories. On the basis of a justified need reported to WHO and the implementation plan, a two-year extension can be obtained by a State Party unable to complete the implementation within the initial 5 years; in exceptional circumstances, a further extension, not exceeding two years, can also be requested by a State Party. In brief, States Parties must establish such core capacities under the IHR(2005) as soon as possible, but have an initial, specific deadline of 15 June 2012 and at most, until 15 June 2016. In some cases, potential small variations may exist.

WHO's six Regional Offices and the recently established WHO IHR Coordination Programme, including its Office in Lyon, will support countries to meet the IHR core capacity requirements.

### Focal and contact points

Effective communications between WHO and the States Parties will be central to the rapid management of a possible public health emergency of international concern. Important innovations under the IHR(2005) are the requirements that notification and reporting by States Parties, as well as other urgent IHR communications, generally be transmitted through specific National IHR Focal Points (for States Parties) and IHR Contact Points (for WHO), which must be available at all times for these communications. The primary functions for National IHR Focal Points, which are national centres to be designated or established by each State Party, include sending to WHO IHR Contact Points these urgent communications, and disseminating information to, and consolidating input from, relevant administrative sectors of the State Party, such as those responsible for surveillance and reporting, points of entry (e.g. airports, ports), public health services, clinics, and hospitals. States Parties may also assign additional responsibilities to their focal points. Guidance on IHR national focal points is available on the WHO website; see http://www.who.int/csr/ihr/nfp/en/index.html.

### Notification and reporting

While the IHR(2005) contain multiple provisions for event-based reporting by States Parties to WHO, the primary obligation is to *assess* events occurring within their territories according to a specific algorithm contained in the *Decision Instrument* and additional provisions provided in Annex 2 of the revised Regulations, and then to *notify* WHO of all such 'events which may constitute a public health emergency of international concern', within 24 hours of assessment through its National IHR Focal Point. Essentially, the events which must be notified are those that fulfil at least any two of the four criteria in the Decision Instrument: whether the event has or is likely to have a serious public health impact, is unusual or unexpected, creates a risk of international disease spread, or creates a risk that travel or trade restrictions will be imposed by other countries [FIGURE]. There are also further questions and examples for guidance in applying the Decision Instrument.

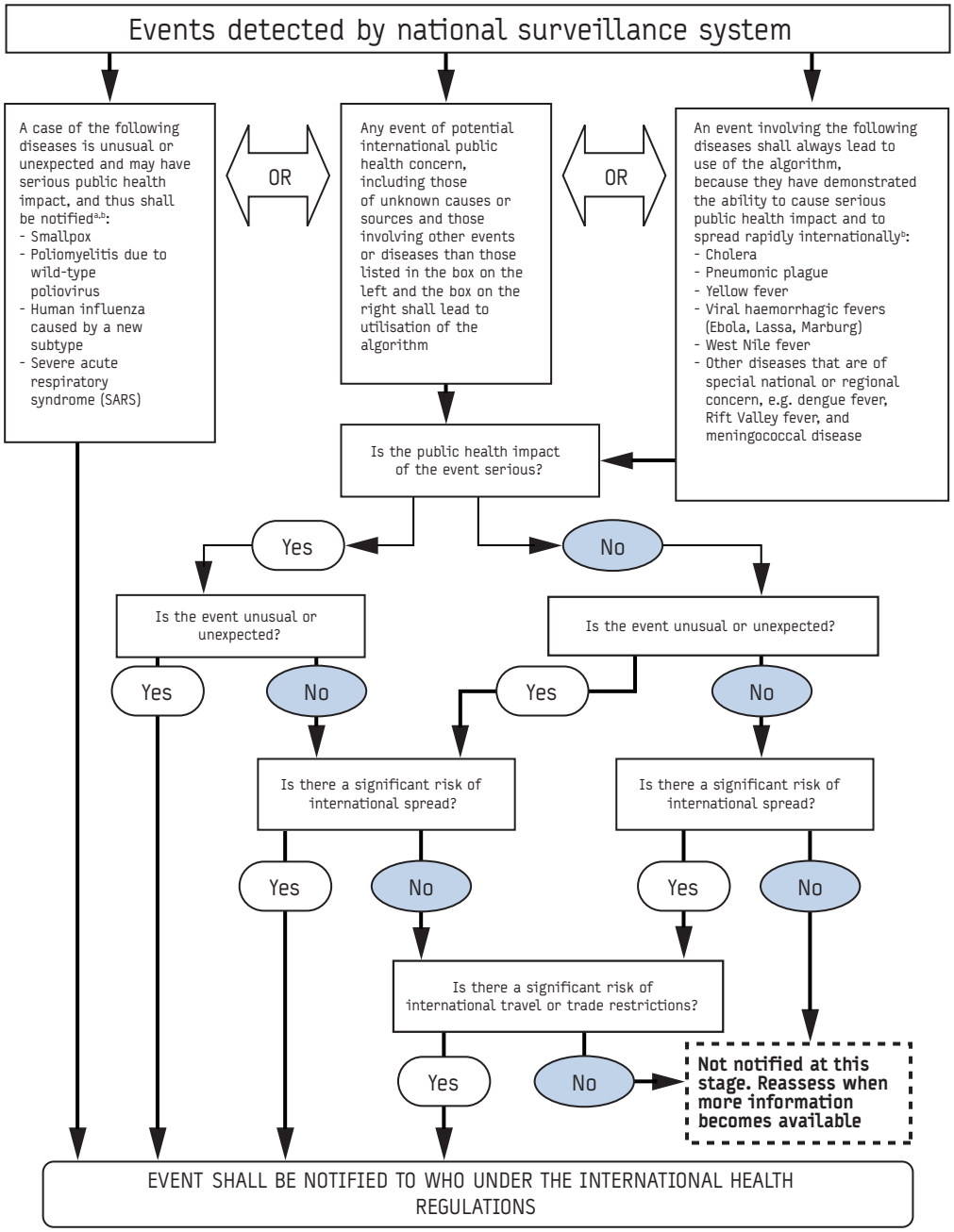
In addition to this broad scope for notification, two groups of diseases are deemed to raise particular concerns as potential international health emergencies of international concern:

1) For four critical diseases even one case, must be notified at all times independent of the context in which it occurs. These diseases are smallpox, poliomyelitis due to wild type poliovirus, human influenza caused by a new subtype and severe acute respiratory syndrome (SARS)
2) Several further epidemic-prone diseases, although not always notifiable, 'have demonstrated the ability to cause serious public health impact and to spread rapidly internationally'. Events involving these diseases must always been assessed using the Decision Instrument but only notified when fulfilling the requirements of the algorithm. Such diseases include cholera, pneumonic plague, yellow fever, viral haemorrhagic fevers, West Nile fever and other diseases that are of special national or regional concern.

Notification is one part of a consultation and assessment process involving the State Party and WHO to determine the appropriate response to an event. As noted, the IHR(2005) specifically provide for optional "consultations" between WHO and a State Party prior to any notification. States must also report to WHO evidence of public health risks occurring outside the State's territory such as, for instance, imported or exported human cases, or the identification of infected or contaminated vectors or contaminated goods.

**FIGURE**

**Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern**




a. As per WHO case definitions

b. The disease list shall be used only for the purposes of these Regulations

## Surveillance and verification

WHO has both general surveillance obligations, as well as ongoing responsibilities to receive, assess and respond as required to notifications, reports and requests for consultations from States Parties. A complement to the obligation to notify is the express mandate for WHO to seek *verification* from States Parties of unofficial reports or communications (e.g. the media) of potential events within their territories which may constitute a public health emergency of international concern. States have reciprocal obligations to respond to WHO, within 24 hours, with an initial reply or acknowledgement, and the available public health information on the status of the referenced events, and must also communicate the detailed assessment information required for *notifications* of such events including, for examples, case definitions, laboratory results, number of cases and deaths.

## IHR(2005) in Europe

In the European Union (EU), the implementation obligations under the IHR(2005) will apply to each of the EU Member States, and will therefore have some relation to the relevant EU institutions. As all EU Member States are also WHO Member States, the two organisations' respective roles and activities will have to be closely analysed in order to maximise synergies and avoid unnecessary duplication of work, consistent with the requirements of the revised Regulations. The revised Regulations contemplate that generally WHO coordinates and cooperates, as appropriate, with other

competent intergovernmental organisations and international bodies. More specific to the context of the EU, Article 57.3 of the IHR(2005) provides that States Parties that are members of a regional economic integration organisation shall apply in their mutual relations the common rules in force in that regional organisation; the article also specifies however that this provision does not prejudice the obligations of the States Parties under the IHR(2005).

In this context a number of areas may be considered for possible collaboration in support of EU Member States in fulfilling their individual obligations as (future) States Parties under the IHR(2005):

1) The European Commission could play an active role in supporting EU Member States in meeting their IHR(2005) obligations in surveillance and response as well as at their designated ports, airports and ground crossings. The European Community, through its technical EU agencies such as the European Centre for Disease Prevention and Control (ECDC) [7], may provide technical guidance. For instance, taking advantage of a number of well-established disease-specific surveillance networks, the ECDC can play a central role in European data collection and analysis, with a focus on communicable diseases. Within its own resources, or through its European networks of technical institutions, the ECDC can provide EU Member States with access to the best European technical expertise in disease surveillance and response.
2) The EU already has a network mechanism for reporting unusual events that may constitute a public health emergency. Community reportable events are reported to the Early Warning and Response System (EWRS) operated by ECDC and the information automatically shared with all other EU Member States. As noted, the IHR(2005) obligate all States Parties to notify WHO of 'any event that may constitute a public health emergency of international concern'. Although the related IHR(2005) include a range of specific limitations and requirements, the potential for establishing an appropriate technical arrangement between the two reporting mechanisms, again consistent with the States' IHR(2005) requirements, is worth exploring.
3) The national focal points for communicating to WHO or the Community EWRS share some similar requirements. For purposes of efficiency, and to avoid potential confusion arising from parallel channels of information during risk assessment and epidemic response, it may be desirable that the national institutes nominated as National IHR(2005) Focal Points, coordinate closely with, or be the same as, the EWRS Focal Points.
4) A further area for support of the IHR is the potential appointment of relevant scientists from regional economic integration organisations, such as scientists from EU technical agencies, to the IHR Roster of Experts, as described in Article 47.
5) Last but not least, the EU could play a key role in supporting the implementation of IHR(2005) globally, in countries outside of its borders.

## Immediate voluntary implementation

On 26 May 2006, the World Health Assembly, concerned about the potential emergence of an influenza pandemic, called upon Member States to comply immediately, on a voluntary basis, with provisions of the IHR(2005) relevant to the risks posed by avian and pandemic influenza [8]. One practical implication of the resolution, for European States as well as others, is the Health Assembly's urging of each WHO Member State to designate immediately its National IHR Focal Point. WHO is also to designate its IHR Contact Points.

Another implication of the resolution has been the endorsement by the Health Assembly of the WHO Influenza Pandemic Task Force which met for the first time on 25 September 2006 in Geneva. This Task Force, with members from all WHO regions, is tasked with advising, upon request, on key international public health issues related to avian and pandemic influenza. Such issues include, for instance, the appropriate phase of pandemic alert and recommended response, the declaration of an influenza pandemic, and the appropriate international response measures to a pandemic. The Task Force can also advise on other technical questions involving avian or pandemic influenza related to WHO influenza activities. The members of the Task Force act as independent international experts in an advisory capacity to the Director General. Under the mandate from the Health Assembly, the Task Force is temporary until the entry into force of the IHR(2005).

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