International health regulations

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PURPOSE: to set out the Commission's views implementing the revised "International Health Regulations (2005) – the IHR.

CONTENT: the IHR is an international legal instrument the purpose of which is to prevent, protect against, and control the spread of disease. It provides a public health response that is proportionate to the risks, whilst at the same time seeking to avoid any unnecessary interference with traffic and trade. It enters into force on 15 June 2007 and is to be implemented gradually by 2016.

To make the IHR work in practice, close co-ordination between the Commission and the Member States will be necessary. The European Centre for Disease Prevention and Control (ECDC) as well as the EU Early Warning and Response System for public health threats (EWRS) will also help with the implementation of the IHR.

This Communication, in brief,:

- sets out the Commission's interpretation of the EU's legal position vis-à-vis IHR reservation and early implementation of flu-related aspects;

- clarifies the EU's role in IHR implementation, particularly through the ECDC and the EWRS;

- reminds the Member States of the restrictions the IHR places on national measures which can be taken on public health grounds; and

- encourages the Member States to develop and share their own plans for IHR implementation.

Legal competences: The IHR, an international legal instrument, involves matters of mixed responsibility between national governments and the European Community. It is not the purpose of this Communication to lists all the IHR articles that are subject to national, Community or shared responsibilities – but rather how the IHR should be implemented in a co-ordinated manner across the Community. For example, IHR Article 45 covers the processing of personal data – an exclusive Community responsibility. Article 41, on the other hand, covers charges for the application of health measures to ships and aircraft – this is not specifically dealt with under Community law and is therefore not a Community power.

Reservations: States that are party to the IHR may lodge reservations to indicate that they can not, or will not, implement particular aspects of the IHR. The Commission notes that the Member States and the Commission worked in close and effective co-operation throughout the IHR negotiations to ensure that the final IHR would be consistent with EC and national law. As a result, the Commission is satisfied that there will be no need for any EU IHR reservation. In the event that a Member State wishes to make a reservation then EU co-ordination will be necessary.

Voluntary early application of flu-related aspects: States that are party to the IHR are called upon to comply, immediately and on a voluntary basis, provisions relating to avian and potential human pandemic influenza. Within the EU context the following provisions will require early application: the designation of IHR national focal points within 90 days of adoption; follow-up mechanisms and procedures in the IHR relating to diseases which may constitute a "Public Health Emergency of International Concern" or PHEIC; notifying WHO and communicating with them any probable or confirmed case of avian influenza; the dissemination to WHO collaborating centres information and biological material related to

highly pathogenic avian influenza and other novel influenza strains; developing domestic influenza vaccine production capacity or work with neighbouring states to establish regional capacity; strengthening collaboration on human and zoonotic influenza among national organisations; respecting IHR time frames for activities, particularly for reporting human cases of avian influenza; and strengthening influenza surveillance in countries affected by avian and pandemic influenza.

The Commission urges the Member States to implement the above uniformly in a co-ordinate time frame. This will require co-ordination at an EU level and as such the Commission will take any initiative which could be needed in order to facility this implementation.

Full implementation – EU role: The report states that it would be desirable to adopt an administrative memorandum of understanding between the Community and WHO in order to ensure that arrangements are clearly defined in respect of the IHR. The Commission would be responsible for drafting, negotiating and signing this memorandum.

The role of the EWRS: The scope of the EWRS is limited to communicable diseases, including those of unknown origin. It is therefore not as broad as the IHR, which includes events of unknown cause or source and the spread of toxic, infectious or otherwise hazardous materials. However, in order to maximise efficiency the Commission proposes the following working practices: nominating the same national focal point for EWRS as for IHR; simultaneously informing the EWRS and WHO about events within their territory, which are notifiable under IHR but are not potential PHEICs; informing the EU Communicable Disease network in advance of making a formal IHR notification of a potential PHEIC; and using the EWRS and or the Health Committee to help co-ordinate health risk management and response (particularly for multi-state outbreaks) prior to communicating with the WHO.

The role of the ECDC: The surveillance activities undertaken by the ECDC will be very relevant in the case of a public health threat requiring IHR notification. The ECDC can also assist the Member States with their IHR implementation. As such, the Commission proposes that the ECDC's role in the IHR should be formalised, particularly regarding the collection of data on issues within its mandate. Its role should include, for example, remaining accessible at all times, sharing information during unexpected or unusual public health events and responding to requests for WHO verification.

Roster of experts, emergency & review committees: The Commission recently wrote to the WHO proposing Commission and ECDC experts for the IHR roster. Thus, in the event of a potential PHEIC in the EU it would be appropriate for the WHO to invite the Commission and/or ECDC expert onto the IHR roster to form part of the emergency committee.

Border measures: A key objective of the IHR is to balance the need for restrictions on arbitrary border measures with the right of States to carry out necessary checks on travellers. Certain EU provisions allow the Member States to deny EU citizens entry if they are considered a threat to public health. Where Member States do intend to adopt measures for the control of communicable diseases they must inform other Member States and the Commission in advance. This is considered an important issue requiring further discussion within the Council.

Contact tracing: Under IHR provisions States may require travellers to provide information about their destination for public health purposes. There is currently no standard international approach to contact tracing. The Commission is therefore working with the aviation industry and Directors General for Civil Aviation to discuss a possible EU approach to contact tracing.

To conclude, this Communication proposes a number of working practices for EU implementation of the IHR. Taking into account the views of the European Parliament and Council, the Commission will develop these proposals further, working together with the both the Member States and the ECDC.