WORLD HEALTH ORGANIZATION

FIFTY-SIXTH WORLD HEALTH ASSEMBLY A56/25
Provisional agenda item 14.16 24 March 2003

Revision of the International Health Regulations

Report by the Secretariat

BACKGROUND

1. The *International Sanitary Regulations* were adopted by the Fourth World Health Assembly in 1951 as the first single international code of measures for preventing the international spread of designated infectious diseases and of requirements for reports and notifications of cases of these diseases.[1] Measures were designed to ensure the maximum security against the international spread of disease with a minimum interference in world traffic. They were replaced in 1969 by the *International Health Regulations*, which were subsequently amended in 1973 with additional provisions for cholera, and revised in 1981 to exclude smallpox.

2. The Forty-eighth World Health Assembly expressed the need for further substantial revision in view of the resurgence of infectious diseases and the heightened risk of their international spread caused, in particular, by the growth of commercial air transport. Resolution WHA48.7 requested the Director-General to take steps to prepare a revision and urged broad participation and cooperation in this process. A series of expert consultations and working groups was held between 1995 and 1997 to secure consensus on the direction of the revision process.

3. A report on progress of the revision summarized the results of these consultations and working groups, including the proposal that the reporting of specific diseases be replaced by the immediate reporting of a number of defined clinical syndromes that are of international importance.[2] The approach was subsequently field-tested in 22 countries selected from each WHO region. Results, reported to the Fifty-fourth World Health Assembly, supported the conclusion that syndromic reporting, although valuable within a national system, was not appropriate for use in the context of a regulatory framework.[3]

4. The report noted that the Regulations serve as the framework for WHO's outbreak alert and response activities, and defined an approach to the revision process based on three main challenges that had been identified during alert and response activities.[4] The approach goes beyond notification of

[1] WHO Regulations No. 2, adopted in accordance with Article 21 of the Constitution.

[2] See document EB101/12.

[3] See document A54/9.

[4] These challenges are: ensuring that only public health risks (usually caused by an infectious agent) that are of urgent international importance are reported under the Regulations; avoiding stigmatization and unnecessary negative impact on international travel and trade of invalid reporting from sources other than Member States, which can have serious economic consequences for countries; and making sure that the system is sensitive enough to detect new or re-emerging public health risks.

specific diseases, although reporting by disease remains possible when the diagnosis is known. In adopting resolution WHA54.14, the Health Assembly supported ongoing work on the revision of the Regulations in the context of WHO's outbreak alert and response activities, and inclusion of criteria to define a public health emergency of international concern. It urged Member States to designate a focal point for the Regulations.

5. One of the major obstacles to effective implementation of the current Regulations arises from the reluctance of countries promptly and frankly to report outbreaks for fear of the economic repercussions in the form of lost trade and tourism. WHO has put in place a global system for epidemic alert and response, and developed the operational framework for epidemic intelligence, event verification, risk assessment, coordination of response and information management, in partnership with the global outbreak alert and response network, to support the Regulations. One positive consequence of the prompt support WHO now offers, through its outbreak alert and response activities, is an increasing tendency for countries to report outbreaks and seek WHO's cooperation in mobilizing and coordinating appropriate international support immediately. For example, during the largest recorded outbreak of Ebola virus haemorrhagic fever, WHO received immediate electronic notification from the affected country as soon as the first cases were suspected. Prompt support, combined with strong national efforts and a focus on the humanitarian consequences of the disease kept the country's borders open throughout the duration of the outbreak.

PROGRESS

6. Through a project with the Swedish Institute for Infectious Disease Control, WHO has determined criteria to define public health emergencies of international concern as directed by resolution WHA54.14. These criteria have been incorporated into a notification instrument to guide all Member States in identifying those emergencies that should be notified to WHO. This instrument has been tested internally in WHO in the context of outbreak alert and response activities and is now being formally tested with participating Member States.

7. Resolution WHA48.7 acknowledged the strengthening of epidemiological surveillance and disease control activities at national level as the main defence against the international spread of infectious diseases. The revised Regulations will contain statements describing the basic minimum capacities needed by Member States in a number of areas in order fully to implement the Regulations. These core capacities are needed to operate national systems for disease surveillance and response and to perform specific activities at international airports, seaports and major frontier crossings.

8. Following consultations in workshops and meetings held throughout 2001 and 2002, documents outlining these core capacities have been drafted, made available to Member States for further discussion and comment, and are being finalized.

9. It is expected that these core capacities will serve as both a driving force for strengthening national systems for disease surveillance and response and a benchmark for measuring progress. Such an internationally agreed target will also provide a clear focus for support provided by bodies other than WHO.

10. To further support implementation of the revised Regulations, WHO is preparing guidelines on the design and implementation of early warning systems as an essential component of national disease surveillance.

11. The existing Regulations make direct reference to the *Guide to ship sanitation* and the *Guide to hygiene and sanitation in aviation*. Current editions of these guides date back to 1967 and 1977 respectively. They are undergoing substantial revision to ensure that they fulfil their role in providing up-to-date and evidence-based support to the implementation of the revised Regulations. Revision of both guides, involving a broad consultation, is under way and new editions should be published in 2003.

12. The effectiveness of the Regulations as an international instrument depends primarily on the extent to which countries accept the legal framework and are able to work within it. Consultation with Member States on proposed technical amendments is therefore of central importance to successful revision of the Regulations. A series of meetings with selected Member States at country, subregional, regional and interregional levels has been held to validate permanent routine measures contained within the existing Regulations, and to test the new proposals.[1] Written comments have been received from Australia, Burkina Faso, China, Latvia, Turkey, and the United States of America.

PLANS FOR COMPLETING THE REVISION PROCESS

13. The report to the Fifty-fourth World Health Assembly set out the main steps envisaged to complete the revision of the Regulations. The first technical composite draft, which will include the comments provided by participating Member States, will be completed before May 2003, marking the end of the initial consultation phase. At the same time this draft will provide the basis for an appropriate legally worded text. It is planned to convene a legal workshop to consider issues such as compliance, possible conflicts with other international instruments and resolution of disputes.

14. The conclusions reached by the revision process must now be extended from the technical to the political level. This process will be fostered through a series of regional consensus meetings to be convened in 2003 under the guidance of the regional directors.

15. This extensive consultation process is felt to be the best method for arriving at a worldwide governmental consensus on the revised Regulations. The degree of consensus reached through the regional meetings will determine the extent of any subsequent meetings at global level. An open-ended working group of interested Member States can then be convened to finalize the draft revised Regulations for submission to the Health Assembly. It is expected that the revised Regulations will be ready for submission to the Fifty-eighth World Health Assembly in 2005.

16. These plans were submitted to the Executive Board for consideration at its 111th session in January 2003.[2] The Board adopted a resolution on this matter containing a draft resolution recommended to the Health Assembly for adoption.[3]

[1] Information on workshops and meetings is available in Global crises – global solutions. Managing public health emergencies of international concern through the revised International Health Regulations. Document WHO/CDS/CSR/GAR/2002.4, Appendix 2, and at http://www.who.int/emc/IHR/int_regs.html

[2] Document EB111/34.

[3] Resolution EB111.R13, see document EB111/2003/REC/1.

ACTION BY THE HEALTH ASSEMBLY

17. The Health Assembly is invited to consider the draft resolution contained in resolution EB111.R13.

= = =