EXECUTIVE BOARD 111th Session Provisional agenda item 5.12

EB111/34 15 December 2002

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. 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. 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; making sure that the system is sensitive enough to detect new or re-emerging public health risks.

specific diseases, though 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 hindering effective implementation of the current Regulations arises from the traditional reluctance of countries promptly and frankly to report outbreaks for fear of the economic repercussions in the form of lost trade and tourism. One positive consequence of the prompt support WHO can now offer, through its outbreak alert and response activities, is a breaking down of this reluctance and a tendency for countries to report and seek WHO's and, when appropriate, international, cooperation 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, 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. (See the Annex for information on revision procedures.)

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. Written comments have been received from Australia, Burkina Faso, China, Latvia, Turkey, and the United States of America.

PLANS FOR COMPLETING THE REVISION PROCESS

- 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 reflects the consensus reached by Member States participating in the revision, should be completed by the end of 2002, 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 will be fostered through a series of regional consensus meetings to be convened in 2003 under the guidance of the regional directors.
- This extensive consultation process, which will also consider the need for any additional global 15. level meetings, is felt to be the best method for arriving at a worldwide governmental consensus on the revised Regulations. 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.

ACTION BY THE EXECUTIVE BOARD

The Board is invited to consider adoption of the following draft resolution: 16.

The Executive Board,

Having considered the report on the revision of the International Health Regulations,²

RECOMMENDS to the Fifty-sixth World Health Assembly the adoption of the following resolution:

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.

The Fifty-sixth World Health Assembly,

Recalling resolutions WHA48.7, WHA48.13, WHA54.14, and WHA55.16, which respond to the need to ensure global health security at a time when the threat of infectious diseases is resurging;

Affirming the additional threat posed by the substantial growth in international travel and trade, which provide greater opportunities for infectious diseases to evolve and spread;

Underscoring the continued importance of the International Health Regulations as an instrument for ensuring the maximum possible protection against the international spread of disease with minimum interference in international traffic;

Acknowledging the close links between the Regulations and WHO's outbreak alert and response activities, which have identified the principal challenges to be met in revising the Regulations;

1. EXPRESSES its satisfaction with the procedures and activities planned for finalizing the draft revised Regulations;

2. DECIDES:

- (1) in accordance with Rule 42 of its Rules of Procedure, to establish an intergovernmental working group open to all Member States to draw up a draft revision of the International Health Regulations for consideration by the Health Assembly;
- (2) that regional economic integration organizations constituted by sovereign States, Members of WHO, to which their Member States have transferred competence over matters governed by this resolution, including the competence to enter into treaties in respect to these matters, may actively participate, in accordance with Rule 55 of the Rules of Procedure of the Health Assembly, in the work of the intergovernmental working group referred to under paragraph (1);
- 3. URGES Member States to give high priority to the work on the revision of the International Health Regulations and to provide resources and cooperation necessary to facilitate the progress of such work;

4. REOUESTS the Director-General:

- (1) to complete the technical work required to facilitate reaching agreement on the revised International Health Regulations;
- (2) to keep Member States informed about the technical work on the revision of the Regulations through the regional committees and other mechanisms;
- (3) to convene the intergovernmental working group on revision of the International Health Regulations at the appropriate time, having regard to the

progress achieved on the technical work and the other commitments of the Organization;

- (4) to facilitate the participation of the least developed countries in the work of the intergovernmental working group and in intergovernmental technical consultations;
- (5) to invite, as observers at the sessions of the intergovernmental working group on the revision of the International Health Regulations, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who will attend the sessions of that body in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly.

ANNEX

UPDATING OF WHO TECHNICAL GUIDANCE

- 1. The WHO *Guide to ship sanitation* is the official global reference on health requirements for ship construction and operation and is directly referenced by the International Health Regulations (Article 14). The *Guide* was first published in 1967 and was reprinted with minor amendments in 1987. The 1967 edition was based on models of good practice and is in the process of being updated on the basis of scientific evidence.
- 2. The contents and format of the new *Guide* were agreed at a meeting (Miami, United States of America, October 2001) attended by representatives of the shipbuilding industry, cruise ship operators, seafarers associations, Member States participating in the revision of the Regulations, and regulatory agencies. A follow-up meeting was held in Vancouver, Canada in October 2002. Experts from Australia, Brazil, Canada, China, Egypt, Finland, the Netherlands, Russian Federation, South Africa, Thailand, Turkey, the United Kingdom of Great Britain and Northern Ireland and the United States of America are involved in the project to update the *Guide*. The revised *Guide* is planned for publication in 2003.
- 3. The WHO *Guide to hygiene and sanitation in aviation* was first published in 1960 with a second edition in 1977. It is directly referenced by the International Health Regulations (Article 14). The present volume deals primarily with food, water safety and sanitation, and vector control. It predates the recognition of a number of important risk factors, such as exposure to ionizing radiation and in its present form fails adequately to support public health protection. It has failed to keep pace with developments in other normative areas such as water, air, noise and chemical safety.
- 4. An informal meeting with the airline industry, Members States participating in the revision of the Regulations and other concerned parties (Geneva, January 2002) identified a number of issues relating to aircraft or airports for consideration during the revision of the Regulations and initiated review of the *Guide*.
- 5. The meeting proposed that the *Guide* should be based on evidence and not only include a description of measures adequate to satisfy the requirements of the Regulations, in relation to hygiene and sanitation in aviation, but also provide guidance on other public health matters associated with aviation and travel. The revised *Guide* is planned for publication in 2003.

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