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Fifty-first Session

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REVISION OF THE
INTERNATIONAL HEALTH REGULATIONS
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1. INTRODUCTION

The International Health Regulations (IHR) are based on the principle of maximum protection against the international spread of disease with minimum interference with international trade and travel. Originating in quarantine legislation dating as far back as 1377, the Regulations outline the obligations of WHO Member States to: notify WHO of specific disease outbreaks, maintain sanitation standards at international borders (i.e. ports and airports), and restrict measures taken by Member States to prevent the spread of disease to the maximum measures authorised under the Regulations.

In May 1995, in consideration of a changing international environment and the emergence of new diseases and the resurgence of old diseases, the World Health Assembly adopted a resolution calling upon WHO to undertake a revision of the IHR (WHA 48.7). The current Regulations have been in effect since 1969, with amendments relating to smallpox eradication, and alterations in the cholera vaccination requirements occurring in the interim period. With many of the concepts and wording in the existing regulations out of date in terms of public health and current disease prevention and practice, technological change and legislative wording, the Regulations require an extensive revision.

Recent examples of international and national responses to infectious disease outbreaks have identified problems that the revised IHR will seek to redress. These include: reluctance to report diseases for fear of excessive measures by other Member States that would adversely affect travel and trade; a lack of resources and health system capacity to identify and deal with disease outbreaks, and the restricted scope of the current Regulations which apply only to three diseases – cholera, plague and yellow fever.

The revised IHR will form an integral part of the global communicable disease monitoring and alert system currently being strengthened by WHO. The revised IHR will be developed as a mechanism for rapid notification of all outbreaks of communicable diseases of urgent international public health importance. This will supplement existing national and international disease surveillance systems and expedite the notification of disease outbreaks which constitute an international threat. However, it is important to note that the IHR will not replace regular systematic disease surveillance and reporting activities.

The Division of Emerging and other Communicable Diseases Surveillance and Control (EMC) is working with the Regional Offices and Member States to strengthen national disease surveillance capacities and develop a global network of collaboration. The IHR will provide a rapid reporting mechanism to capture disease outbreaks that pose an international threat in order to facilitate rapid response and containment. Guidance will be provided to assist Member States to apply control measures that are appropriate to the international threat involved.
2. THE IHR REVISION PROCESS

(1) An informal consultation of public health experts was convened in December 1995 to consider the revision of the IHR in the light of experience gained during outbreaks of cholera in Peru (1991), plague in India (1994) and Ebola haemorrhagic fever in Zaire (1995). The group recommended a broader base for disease notification, so that all outbreaks of urgent international importance would be reported. To facilitate rapid notification and response, it was proposed to introduce immediate notification of clinical syndromes, pending determination of the causal agent. In addition, the group recommended that operational guidelines should be provided to assist in the application of the revised IHR and that inappropriate as well as appropriate measures should be indicated.

(2) All Member States were invited early in 1996 to designate an official government focal point for liaison with WHO during the revision of the IHR. To date, 88 Member States have done so.

All other intergovernmental and non-governmental organizations having an interest in the IHR were also invited to designate an official focal point, and several have done so.

Member States are regularly informed on progress with the revision of the IHR through 6-monthly reports published in the Weekly Epidemiological Record (five reports published to date). Progress reports were submitted to the Executive Board in 1997 and 1998 and to the World Health Assembly in 1998.

(3) To further develop the concepts proposed by the informal consultation in December 1995, an informal working group of public health and legal experts met twice in 1996 and three times in 1997. The composition of the group changed during the period, according to the needs at different times, and the group completed its work in June 1997.

Based on the discussions of this group, the first provisional draft of the revised IHR was prepared in the latter part of 1997 by a small group of legal and public health experts. The provisional draft was distributed (in English) to all Member States and interested organizations in January 1998. The French version was distributed to francophone Member States in March 1998.

Following a detailed evaluation of all comments received, and consideration of interim results of the pilot study, the provisional draft will be reviewed and revised later this year by the Committee on International Surveillance of Communicable Diseases (CISCD).

(4) A pilot study has been arranged in 21 selected countries to evaluate the proposed notification of clinical syndromes. The participating countries were selected in consultation with the Regional Offices to include countries with extensive international links and different disease surveillance infrastructures.

The objectives of the pilot study are:

- to evaluate proposed notification criteria and case definitions of the notifiable syndromes;

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1 now the Democratic Republic of the Congo
• to assess operational issues in WHO arising from the proposed notification arrangements;
• to provide guidance on the development of training materials to assist countries when the revised IHR come into force, and
• to advise on the preparation of operational guidelines that will accompany the revised IHR.

The pilot study is a joint project involving WHO and the central disease surveillance service of the participating countries. The intention is to test at central national level the proposed arrangements for syndromic notification within the existing surveillance infrastructure of the countries. The pilot study also tests WHO’s capacity to manage and respond to the information received. The study does not involve any change in current arrangements for disease surveillance and reporting within the selected countries. The study will continue at least until the end of 1998 and a full evaluation will be carried out in the first half of 1999. The following countries are taking part in the study:

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The Committee on International Surveillance of Communicable Diseases (CISCD) is the Expert Committee which will prepare the final text of the revised IHR. The Members have been selected and appointed by the Director-General in accordance with the Regulations of this Committee, to include expertise in different aspects of public health and representation from all WHO regions.

The Committee has received the provisional draft of the revised IHR for review. A meeting of the CISCD will be held in November 1998 to: consider the progress of the revision process; carry out an interim evaluation of the pilot study; discuss legal aspects of the IHR with legal advisers drawn from the WHO regions; and review and revise the provisional draft IHR text.

A revised version of the provisional draft of the IHR will be sent to all Member States early in 1999.

It is envisaged that a second meeting of the CISCD will be arranged in 1999 to finalize the revised IHR for submission to the Executive Board and World Health Assembly in 2000. The timeframe for completion of the revision has been extended to allow sufficient time to carry out and evaluate the pilot study and to hold further consultations on technical and legal aspects of the IHR.
3. PRINCIPAL CHANGES PROPOSED IN THE REVISED IHR

(1) The objective of the revision is to develop IHR that will provide a mechanism for rapid alert to all disease outbreaks that pose an international threat. To facilitate and expedite notification and response, the revised IHR will introduce the possibility of notification of a series of defined clinical syndromes.

These clinical syndromes may be notified pending the determination of the disease agent involved. The objective is to alert attention to a problem at the earliest possible time and to promote rapid investigation and containment of the outbreak. Subsequently, when the causal agent has been identified, the specific disease should also be reported.

Notification of syndromes is proposed as an alternative to specific disease notification. Clearly, it is desirable to establish the precise diagnosis as soon as possible so that control measures can be optimized. In outbreaks where the diagnosis has already been confirmed at the time of notification, the specific disease should be notified.

It is proposed that regularly occurring endemic diseases should not be notified unless an outbreak occurs having particular features that would indicate urgent international importance.

The case definitions for the notifiable syndromes have been devised to capture all diseases that could potentially cause outbreaks of urgent international importance. The case definitions are being evaluated by the countries participating in the IHR pilot study and will be refined if necessary. The detailed case definitions will be included in an annex to the IHR and kept under review.

The syndromes to be notified where an outbreak is of urgent international public health importance are:

- acute haemorrhagic fever syndrome
- acute respiratory syndrome
- acute diarrhoeal syndrome
- acute jaundice syndrome
- acute neurological syndrome.

In addition, any other syndrome of severe illness not included in the above should be notified if an outbreak is of urgent international public health importance.

Criteria for assessment of urgent international public health importance may include one or more of the following:

- rapid transmission in the community
- unexpectedly high case fatality rate
- newly-recognized syndrome
- high political or media profile
- trade and travel restrictions.
In broadening the base for mandatory notification and including the option of notifying clinical syndromes prior to determination of the causal agent, it is recognised that there will be both increased sensitivity and reduced specificity in the initial notification. It may not be clear whether an outbreak is of urgent international public health importance until further investigation has been carried out. For this reason, syndromes or disease outbreaks notified to WHO will not be reported automatically in the *Weekly Epidemiological Record*. Notification will be followed by consultation with the Member State, involving collection of additional information and verification if necessary. The outbreak will be reported by WHO only after such consultation. In the case of notified and reported outbreaks, once the outbreak is over, a report to this effect will also be published.

(2) The structure of the IHR will be altered to provide:

- a framework document containing general principles on appropriate public health measures and legal provisions relating to the operation and amendment of the IHR
- a series of annexes describing technical provisions and specific requirements, which will form an integral part of the IHR
- operational guidelines to accompany the revised IHR and assist in their application.

The IHR will stipulate the public health measures to be taken to control outbreaks of disease subject to the Regulations, health organization at international ports and airports, and measures relating to individuals, goods and means of transport during a journey and on arrival. The specific technical details of the measures to be taken will be described in the annexes to the IHR. The annexes will be subject to regular review and will be updated as necessary. Thus, this new structure for the IHR will provide basic regulations of a generic nature which should remain valid for many years. At the same time, the specific public health measures contained in the annexes can be modified rapidly according to changing needs and new knowledge. The intention is to ensure longevity of the IHR together with adaptability of the technical provisions.

4. THE WORLD TRADE ORGANIZATION AND THE IHR

The World Trade Organization (WTO), through its Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), seeks to ensure that countries apply measures to protect human, animal and plant health based on assessment of risk. Areas of common interest in the IHR and in the SPS Agreement are likely to be reinforced under the revised IHR. All the Member States of the WTO are also Member States of WHO and consequently have rights and obligations under both the IHR and the SPS Agreement.

The fundamental principle behind the IHR is maximum protection against the international spread of disease with minimal interference with traffic and trade. This principle will be retained in the revised IHR. The objective of the IHR is therefore fully consistent with WTO's purpose in reducing barriers to international trade. Harmonizing the IHR and SPS Agreement would reflect this common purpose and avoid any potential conflict in the obligations of Member States. WHO could assist WTO with respect to public health aspects of disputes arising as a result of disease outbreaks.
At a meeting of the SPS Committee in March 1998, WHO presented information on the IHR and the work in progress on revision of the IHR, and proposed that the possibility of coordinating the IHR and SPS Agreement could be usefully explored. Following this meeting, WTO submitted a series of written questions to WHO concerning the IHR, the revision process and procedures for decision-making in WHO. The WHO response was the subject of informal discussions with the SPS Committee in June 1998, followed by another presentation by WHO to the Committee at its formal meeting in the same month.

It was concluded that WHO should continue to report regularly to the SPS Committee on progress on the revision of the IHR. The possibility of including a formal recognition of the IHR will be explored if it is decided to revise the SPS Agreement in the future.

Member States who are also Members of WTO are encouraged to discuss areas of mutual interest in the IHR and SPS Agreement with their countries’ trade departments and SPS representatives. Discussions on health-trade issues have been included in recent IHR seminars held in countries participating in the pilot study.

5. SUMMARY OF IHR REVISION PROCESS

- Resolution of World Health Assembly calling for revision of the IHR (WHA 48.7), 1995
- Informal Consultation to consider revision of the IHR in the light of recent disease outbreaks, December 1995
- Member States and other organizations invited to designate official focal points for liaison with WHO on revision of the IHR, January 1996
- Members of the Committee on International Surveillance of Communicable Diseases (CISCD) selected and appointed by the Director-General, 1996
- Informal working group discussions on concepts for the revised IHR, 1996-1997
- Pilot study to evaluate syndromic notification arranged in 21 selected countries, 1997-1998
- Provisional draft of the revised IHR prepared and distributed to all Member States, other interested organizations and members of the CISCD, January 1998
- Progress report on revision of the IHR submitted to the Executive Board and World Health Assembly, 1998
- Discussions with World Trade Organization (SPS Committee) on relationship between IHR and the SPS Agreement, from 1998
- Meeting of CISCD to review progress of pilot study, consider public health and legal aspects of the revised IHR, and prepare second version of the provisional draft IHR, November 1998
- Second version of the provisional draft IHR to be distributed to Member States early in 1999
- Pilot study to be completed and a full evaluation carried out, first half of 1999
- Annexes to the IHR and operational guidelines to be completed, 1999
- Second meeting of CISCD to finalize revised IHR, 1999 (tentative)
- Revised IHR to be submitted to Executive Board and World Health Assembly, 2000 (tentative)