European Regional Consultation on Revision of the International Health Regulations

Copenhagen, Denmark, 9–11 June 2004
Abstract

The Consultation was intended to provide the Member States in the WHO European Regional with the opportunity to become familiar with the draft revision of the new International Health Regulations (IHR), to identify problems and to suggest improvements. The participants formed six working groups to discuss the current draft in detail. The groups highlighted:

- the need for accuracy in translations of the IHR;
- the need to review the definitions of a number of terms used;
- the scope of the IHR, which may be too broad at least with regard to response;
- the need to consolidate the different terms used for Member State structures, with a few exceptions; and
- the need to clarify which regulations are binding.

The working group at WHO headquarters would take account of the specific comments of Members States in updating the draft IHR for presentation at the meeting of the Intergovernmental Working Group in Geneva on 9–12 November 2004.

Keywords

COMMUNICABLE DISEASE CONTROL - legislation
DISEASE NOTIFICATION
DISEASE OUTBREAKS
INTERNATIONAL COOPERATION
LEGISLATION, HEALTH
TRANSIENTS AND MIGRANTS
Working groups

Two sessions of three working groups were held and the outcome of each was reported by the appointed rapporteurs or chairpersons in the following plenary session, which was recorded; recordings are available on request. The specific views of the working groups, as well as the comments made by the participants, were summarized and forwarded to the IHR project manager. Annex 2 includes the working group members, chairs and rapporteurs.

Conclusions

The working groups reached similar main conclusions on a number of issues. The groups covered many topics in their discussions, which were open and of high technical value. In this section, an overview of general topics precedes some specific remarks from each of the groups. All working groups addressed the following general topics:

- the use of language and translations
- definitions and terminology
- the scope of the revised IHR
- the structure of Member States
- legal requirements.

Language and translations

A number of issues were discussed in relation to problems with the Russian translation, which did not match the English text in several instances. At the Pan American Health Organization consultation on the revision of the IHR on 2–4 June 2004, a similar problem with the Spanish translation was observed.

Conclusion

It was important to ensure the accuracy of all translations, in order to avoid confusion in interpretation.

Definitions and terminology

Terms that may require standardized and precise definitions included:

- medical examination
- suspected traveller
- time limits
- without delay
- immediately
- rumour (information?)
- sufficiently important
- isolation (quarantine?)
- core capacity.
Although these terms were not difficult to explain and understand, they may be misinterpreted, particularly in translation. Some working groups suggested that “within 24 hours” be used instead of “immediately”; a discussion then followed on the meaning of “24 hours”. The creation of clear definitions that would satisfy everyone was not easy. Definitions often cause problems, irrespective of the circumstances in which they are used. It was suggested that, when a definition caused problems in following the IHR, the question be brought to the Review Committee. Perhaps definitions should be a fixed item on the Review Committee’s agenda.

**Scope**

All working groups concluded that answers to the questions raised about articles in the draft IHR were dependent on scope. Discussion revealed general agreement that the scope of the notification process was broad. As to response, however, a number of countries pointed out that other agencies should have a primary role.

**Conclusion**

There was general agreement that the broad scope of notification of events in the IHR included events involving biological, chemical and radiological agents and those of unknown origin. As regards response, there may be a lesser need for extended scope and other agencies should be involved, particularly when events were related to radiological or chemical sources.

**Member State structures**

The use of different terms for authorities in the Member States – such as “focal point”, “health administration” and “health authority” – had created some confusion. It was suggested that a single term to be used. Some working groups suggested that, in certain instances, there could be a need to identify a structure at lower levels. Almost every country supported the use of a single term to describe a “national authority” and said that it should be up to each Member State to decide how to organize its internal structures. This point had also been brought up in other regional consultations.

**Conclusion**

The terms used for the structures in Member States were: focal point, health administration and health authority. WHO could consider using one term unless this would be inappropriate.

**Legal requirements**

All working groups raised questions about the use and meaning of the words shall and should, and which legal terminology was binding. In addition, they discussed the level to which articles/core text and annexes should be structured in the revised draft of the IHR. Clarifying which rules were binding was very important. The clearer the IHR were, the more probable it was that optimal use would be made of them.

**Conclusions**

There were concerns about the way in which the words shall and should were used, and a need to clarify which regulations would be binding. Concern was expressed that the annexes might include too many technical issues. A review was needed to determine what should be included in the articles/core text and what should be in the annexes or guidelines.
Working group 1 – Scope of the IHR

The group discussed the following issues and articles in the draft IHR:

1. extended definition of illness:
   - Article 1. Definitions
   - Article 2. Purpose
   - Article 5. Notification
   - Annex 2;

2. intentional release:
   - Article 41. Information sharing during a suspected intentional release;

3. other issues:
   - Article 40. Infection control
   - Article 43. Armed forces
   - Article 48. Existing conventions, regulations and similar, agreements
   - Article 53. Non-WHO Member States.

There was general acceptance of the proposed algorithm for determining potential public health emergencies of international concern. A few countries would like to see the revised IHR include a disease list, but were not precise as to whether the list should be binding or only provide examples. This question would probably be discussed at the meeting of the Intergovernmental Working Group in November. Other WHO regions now favoured a less binding list than in the past. Nevertheless, the algorithm seemed to suffice for most countries in the European Region.

In Article 48, all previous international health and sanitary regulations remained in force. As most of the participants of the Consultation were from the health sector, though there were also a few from legal departments, not much information was available to identify the extent to which the previous regulations were part of national legislation.

**Highlights**

- There was general acceptance of the proposed algorithm for determining potential public health emergencies. Some Member States advocated adding a specific list of diseases.
- Article 48 needed further review of the legal aspects by countries’ foreign ministries to find out whether the legislation was still relevant.

Working group 2 – Resources/Capacity building

The group discussed the following issues and articles:

1. human and financial resources of Member States and WHO:
   - Article 4. Surveillance
   - Article 10. Response
   - Annex 1.

The working group was concerned about the capacity of Member States to carry out all the notification procedures and the capacity of WHO to follow up on all the information. The revised
IHR would require a greater workload than the current ones. This meant that current capacity would be more easily strained than previously. Both WHO and Member States needed to consider this issue.

The term “core capacity” was not well defined and its interpretation from country to country varied greatly. Clarification of its meaning was requested. For example, working group 6 presented its discussion on ground crossings; differences in neighbouring countries’ definitions of a “ground crossing of international importance” could create major problems.

Discussion of Article 10, on response, raised the question of balance between the rights of WHO and of Member States. This balance needed to be acceptable to all parties. This was a sensitive issue on which there were many views. Most countries realized that, in a critical situation, the views of WHO should probably have greater weight than usual. Working group 2 felt that Article 10 needed to express this very precisely.

**Highlights**

- Concern was expressed that the revised IHR required a considerable increase in workload and this may exceed the capacity of both WHO and Member States.
- Clarification of core capacity requirements for designated airports, ports and ground crossings is desirable.
- In revising Article 10, consideration needed to be given to ensuring a balance between the sovereignty of Member States and the legal rights of WHO.

**Working group 3 – Sovereignty I**

The group discussed the issues related to Member States in the following articles:

- Article 8. Verification
- Article 10. Response
- Article 18. General provisions
- Article 19. Ships in transit
- Article 20. Affected conveyances
- Article 21. Conveyances at points of entry
- Article 24. Goods in transit
- Article 34. Excessive measures
- Article 35. Cessation or full implementation of measures
- Article 39. Transport of biological materials
- Article 41. Information sharing during a suspected intentional release
- Article 42. Special arrangements between Member States
- Article 49. Period for rejection or reservations
- Article 50. Reservations
- Article 51. Withdrawal of rejection or reservation
- Article 52. Entry into force.
The question was raised as to whether the WHO recommendations constituted the ceiling for what countries could do. This point was also brought up in discussions in other WHO regions. Working group 3 felt that countries might need to go beyond the WHO recommendations, but also to give justification for doing so.

Some participants felt that the text covering the cooperation between Member States and WHO did not emphasize the mutual interest involved in this cooperation, and that clear and appropriate wording was needed in the second draft, to prevent misunderstandings.

Another request was for very clear procedures to be followed in a confrontational situation. Working group 3 wished to see a clear, step-wise process. As it stood, the text could be interpreted to mean that there would be either good cooperation or none at all. WHO headquarters clearly indicated that a step-wise approach would be used. This needed clarification in the relevant articles.

**Highlights**

- There was a general feeling that Member States could go beyond the WHO recommendations if they provided justification for doing so.
- The relationship between countries and WHO needed to be cooperative, and this needed to be appropriately reflected in the text of the second draft.
- In their current state, the articles did not clearly describe the procedure to follow in a confrontational situation.

**Working group 4 – Process of the IHR**

The group discussed the following issues and articles:

1. **focal point definition:**
   - Article 3. Communications;
2. **notification:**
   - Article 5. Notification
   - Article 6. Consultation
   - Article 7. Information;
3. **legal obligations of Member States:**
   - Article 11. Temporary recommendations
   - Article 12. Standing recommendations
   - Article 33. General provisions;
4. **public health emergency of international concern (PHEIC):**
   - Article 9. Determination of a public health emergency of international concern;
5. **decision procedures:**
   - Article 44. Reporting
   - Article 45. Review
   - Article 46. Amendments and additional annexes
   - Article 47. Settlement of disputes
One of the main issues discussed was the function and responsibilities of WHO’s Review Committee and its relationship to the WHO Executive Board and the World Health Assembly. When a timely response is required, an ad hoc decision may be used; otherwise, the regular procedures should be followed. There were also questions about Member States’ roles in and influence on these governing bodies.

**Highlights**

- Concerns were raised about the function and responsibilities of WHO governing bodies.
- Ways were needed to strengthen the role of Member States in determining the membership of these bodies.

**Working group 5 – Entry requirements**

The group discussed the following issues and articles:

1. **facilities:**
   - Article 13. Health administration
   - Article 14. Airports and ports
   - Article 15. Ground crossings
   - Article 16. Health authority
   - Article 18. General provisions
   - Article 19. Ships in transit
   - Article 20. Affected conveyances
   - Article 21. Conveyances at points of entry
   - Article 24. Goods in transit
   - Article 25. Container and container loading areas;

2. **health documents:**
   - Article 26. General provisions
   - Article 27. Certificates of vaccination or other prophylaxis
   - Article 28. Maritime Declaration of Health
   - Article 29. Health part of the Aircraft General Declaration
   - Article 30. Bills of health
   - Article 31. Charges for medical examinations, vaccinations or other prophylaxis
   - Article 32. Certificates on measures applied to travellers and their baggage
   - Annexes 6 and 7;
3. **Consistency with other international obligations/treaties:**
   - Annexes 4, 5, 8 and 9.

Working group 5 focused on very technical, but important, issues. Most of those working in the health care system were not aware of the extent to which public health work was conducted at borders or of the requirements that already existed.

One topic discussed related to the need for authorized ports, concluding that these already existed and had proved to be useful. The requirements for border control on a public health basis in the proposed revision of the IHR were more comprehensive than before. This meant that dedicated personnel would need more training to meet the new requirements. Also, as soon as discussion about capacity building and the new requirements started, the question of resources would be raised.

The group also raised the issue of the need for close cooperation with other international organizations dealing with public health issues related to international travel and trade. Such cooperation was underway but it would be useful if WHO would clarify how it had been done at the November meeting, as requested by Member States.

**Highlights**

- It would be useful to continue using an up-to-date list of authorized ports and airports.
- There was concern about resources needed for following the revised IHR; extended training for dedicated personnel would be needed to comply with them.
- Further consultations with IMO, the International Labour Organization (ILO) and the International Civil Aviation Organization (ICAO) on the IHR texts were recommended.

**Working group 6 – Sovereignty II**

The group discussed issues related to individual travellers and the following articles:

- Article 17. Traveller investigations;
- Article 22. Surveillance of travellers;
- Article 23. Medical examination, vaccination or other prophylaxis;
- Article 27. Certificates of vaccination or other prophylaxis;
- Article 36. Rights of persons;
- Article 37. Migrants, nomads, seasonal workers or persons taking part in periodic mass congregations; and
- Article 38. Persons enjoying diplomatic status.

Human rights issues were very important and needed to be remembered. In addition to the need to balance the sovereignty of Member States and the rights of WHO, there was also a need to balance public health requirements and human rights. The working group discussed this issue in depth, and concluded that adequate reference to the international conventions on human rights would cover the requirements of the IHR. In the current draft, there appeared to be slight limitations for public health that were not feasible when working with communicable diseases. Working group 6 considered that, as long as the established conventions were adhered to, this would be acceptable.
**Highlight**

- The addition of “integrity and legal security of persons should be respected” – with adequate reference to the international conventions on human rights in Article 36 – would cover the needs of IHR.

**Addendum:**
All written comments have been forwarded to WHO headquarters for further consideration.