

## **Draft resolutions deferred from the Fifty-ninth World Health Assembly and the 118th session of the Executive Board**

### **Smallpox eradication: destruction of variola virus stocks**

#### **Report by the Secretariat**

1. Resolution WHA49.10 (1996) recommended that the remaining stocks of live variola virus maintained by WHO since 1984 should be destroyed on 30 June 1999, after a final decision to be taken by the Health Assembly in May 1999.
2. After having considered the report of the Secretariat and the report of the meeting of the WHO Ad Hoc Committee on Orthopox Virus Infections (January 1999), the Fifty-second World Health Assembly decided by resolution WHA52.10 to authorize temporary retention of the remaining variola virus stocks, subject to annual review, but up to no later than 2002, for the purpose of carrying out a programme of essential public-health research. The Fifty-fifth World Health Assembly noted that the research programme would not be completed by the end of 2002; by resolution WHA55.15 it authorized further temporary retention of these stocks for the purpose of continuing further international research.
3. After further debate on destruction of the remaining variola virus stocks by the Executive Board at its 115th session and at the Fifty-eighth World Health Assembly, the Executive Board at its 117th session agreed that a working group open to all members would review a draft resolution to be submitted to the Fifty-ninth World Health Assembly. The working group met on 5 April 2006 but could not reach consensus on a draft text and submitted to the Health Assembly a draft resolution reflecting the status of its discussions.<sup>1</sup>
4. At the Fifty-ninth World Health Assembly, a working group of Committee A considered the draft resolution without reaching a consensus on a final text. The Health Assembly therefore decided to submit the text of the draft resolution reflecting the status of the Committee A working group revisions and discussions to the Executive Board for further consideration at its 120th session.

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<sup>1</sup> Document A59/10.

5. The attention of the Board is drawn to the accompanying report on the eighth meeting of the WHO Advisory Committee on Variola Virus Research (Geneva, 16 and 17 November 2006).<sup>1</sup>

## **ACTION BY THE EXECUTIVE BOARD**

6. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report on destruction of variola virus stocks,<sup>2</sup>

RECOMMENDS to the Sixtieth World Health Assembly the adoption of the following resolution:<sup>3</sup>

[The Sixtieth World Health Assembly,

Recalling resolution WHA49.10, which recommended a date for the destruction of the remaining stocks of variola virus, subject to a decision by the Health Assembly, and resolution WHA52.10, which authorized temporary retention of the virus stocks to a later date, subject to annual review by the Health Assembly;

**Noting that the Health Assembly decided** in resolution WHA55.15 to authorize further, temporary, retention subject to all approved research being outcome-oriented, time-limited and periodically reviewed, **and to a proposed new date for destruction being set when research accomplishments and outcomes allowed consensus to be reached on the timing of destruction of variola virus stocks** ~~with the objective of reaching consensus on a proposed new date for destruction of variola virus stocks when the research accomplishments and outcomes allow consensus to be reached on the timing of destruction of variola virus stocks;~~

Noting that authorization was granted to permit essential research for **global** public health purposes, including **further international research into** antiviral agents and improved and safer vaccines, and for high priority investigations of the genetic structure of the virus and the pathogenesis of smallpox;

Noting that resolution WHA52.10 requested the Director-General to appoint a group of experts **which will establish what research, if any, must be carried out in order to reach global consensus on the timing for destruction of existing variola virus stocks;**

**[Recalling] the [decisions] of previous Health Assemblies that [the remaining stocks of the variola virus should be destroyed];]**

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<sup>1</sup> Document EB120/39.

<sup>2</sup> Document EB120/11.

<sup>3</sup> See document EB120/11 Add.1 for the administrative and financial implications for the Secretariat of this resolution.

[Recognizing that the destruction of all variola virus stocks is an irrevocable event and that the decision of when to do so must be made with great care;]

**Recalling resolution WHA55.16, which called for a global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health;**

**Further recognizing that unknown stocks of variola virus might exist, and that the deliberate or accidental release of any smallpox viruses would be a catastrophic event for the global community;**

Having considered the report on smallpox eradication: destruction of variola virus stocks<sup>1</sup> and the report of the eighth meeting of the WHO Advisory Committee on Variola Virus Research,<sup>2</sup>

Noting with satisfaction the [considerable progress]/[**success**] achieved in the development of [antiviral agents,] improved and safer vaccines, and sensitive and specific diagnostic tests, and in sequencing of entire genomes of viruses from numerous different strains, [**and that the WHO Advisory Committee on Variola Virus Research concluded that no further research requiring access to live variola virus was considered essential for these purposes;**]

[or]

[**Noting with satisfaction that considerable progress has been achieved in the development of antiviral agents, and that cidofovir and its analogues continue to be most promising compounds either already licensed or in advanced experimental studies;**]

**Further noting with satisfaction that the WHO-led inspections in 2005 of the two authorized repositories reaffirmed the safety and security of the virus stocks;**

Aware that no antiviral agents for smallpox have been licensed, that live variola virus will be needed to ensure efficacy testing in vitro, and that further refinement of the animal model might be needed to make it more suitable for efficacy testing of these agents;

Noting that the WHO Advisory Committee on Variola Virus Research at its seventh meeting perceived an urgent need to review all proposals for further research using live variola virus against the considerable progress made to date;<sup>1</sup>

Further noting that the Secretariat, as requested by the WHO Advisory Committee, has identified a format for research proposals and has established a protocol and time frame for their submission to the Committee for its consideration, and that approved research is reported to WHO according to an established protocol;

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<sup>1</sup> Document A59/10.

<sup>2</sup> Document EB120/39.

1. STRONGLY REAFFIRMS the ~~view~~ **decisions** of previous Health Assemblies that the remaining stocks of variola virus should be destroyed;
2. FURTHER REAFFIRMS:
  - (1) the need to reach consensus on a proposed new date for the destruction of variola virus stocks[, **when research outcomes crucial to an improved public-health response to an outbreak so permit**];
  - (2) the decision in resolution WHA55.15 (to continue the work of the Advisory Committee on Variola Virus Research with respect to the research involving variola virus stocks and to ensure that the research programme is conducted in an open and transparent manner) **that the research programme shall be conducted in an open and transparent manner only with the agreement and under the control of WHO**;
3. DECIDES [to propose in its annual report to the Sixty-first World Health Assembly a date for conducting a major review of the research ~~achievements~~ **programmes in order to decide on when the destruction of all existing stocks of live variola virus could be performed**];

[or]

**[DECIDES to review in 2010 the results of the research currently under way and the requirements for further research, taking into account the recommendations of the WHO Advisory Committee on Variola Virus Research, with a view to reaching global consensus on the timing for the destruction of existing variola virus stocks;]**

[or]

**[DECIDES to ~~make annual~~ review of annually the results for the research currently under way and the requirements for further research, taking into account the recommendations of the WHO Advisory Committee on Variola Virus Research, with a view to decide by 2010 whether or not variola virus stocks should be destroyed based upon the outcomes of the annual review;]**

[or]

[DECIDES:

- (1) to assess, annually, the need for further temporary retention of the existing stocks of variola virus at the current two repositories;
- (2) to carry out a major review of the research that has been completed, research being undertaken and research being planned at the two repositories;
- (3) to include annually, as a substantive agenda item: “Smallpox eradication: destruction of variola virus Stocks”;

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4. REQUESTS the Director-General:
- (1) to continue the work of the WHO Advisory Committee on Variola Virus Research;
  - (2) to review the membership of the WHO Advisory Committee, and the representation of advisers and observers at meetings of this Committee, in order to ensure balanced geographical representation, with the inclusion of experts **from developing countries, and substantial representation of public health experts** ~~/[, also in public health, from developing countries ]~~, **and the independence of the members of this Committee from any conflict of interest;**
  - (3) to ensure that **approved research proposals**, research outcomes and the benefits of this research are made available to all Member States;
  - (4) to maintain **biannual** inspections of the two **authorized** repositories in order to ensure that conditions of storage of the virus and of research conducted in the laboratories meet the highest requirements for biosafety and biosecurity;
  - (5) **to develop continually the operational framework for WHO's smallpox vaccine reserve;**
  - (6) to continue to report annually on progress in the research programme, **biosafety, biosecurity** and related issues to the Health Assembly, through the Executive Board, **and on implementation of the recommendations of the WHO Advisory Committee on Variola Virus Research accepted by the Director-General;**
  - (7) **to ensure that any research undertaken does not involve genetic engineering of the variola virus;**
  - (8) **to ensure that the two repositories do not distribute variola virus DNA for non-diagnostic purposes;**
  - (9) **to submit an annual detailed report to the Health Assembly, through the Executive Board, of the research that has been completed, results of such research, research being undertaken, and research being planned at the two repositories;**
  - (10) **to submit a report to the Sixty-first World Health Assembly on the legal status of the variola virus strains held at the two repositories with respect to their ownership;**
  - (11) **to submit a report to the Sixty-first World Health Assembly, through the Executive Board, on measures to ensure that the Member States have equal access to the outcomes of the research and proprietary claims arising out of the research outcomes. ]**