

**EB120.R8      Smallpox eradication: destruction of variola virus stocks**

The Executive Board,

Having considered the reports on smallpox eradication: destruction of variola virus stocks,<sup>1</sup>

SUBMITS to the Sixtieth World Health Assembly for its consideration the following draft resolution:<sup>2</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;

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 that would 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;

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 live 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 and the report of the eighth meeting of the WHO Advisory Committee on Variola Virus Research;<sup>1</sup>

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<sup>1</sup> Documents EB120/11 and EB120/39.

<sup>2</sup> See Annex 6 for the financial and administrative implications for the Secretariat of this resolution.

Noting with satisfaction the considerable progress 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;

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;

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

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>2</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;

1. **STRONGLY REAFFIRMS** the 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 include a substantive item: “Smallpox eradication: destruction of variola virus stocks” on the provisional agenda of the **[Sixty-third/Sixty-fourth]** World Health Assembly;
4. **REQUESTS** the Director-General:
  - (1) to undertake a major review **[in 2009/2010]** of the results of the research undertaken, currently under way, and the plans and requirements for further essential research for global public health purposes, taking into account the recommendations of the WHO Advisory Committee on Variola Virus Research, so that the **[Sixty-third/Sixty-fourth]** World Health Assembly may reach global consensus on the timing of the destruction of existing variola virus stocks;

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<sup>1</sup> Documents EB120/11 and EB120/39, respectively.

<sup>2</sup> See document A59/10.

- (2) to continue the work of the WHO Advisory Committee on Variola Virus Research, and to disseminate its recommendations more widely to the scientific community;
- (3) 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, and the independence of the members of this Committee from any conflict of interest;
- (4) to ensure that approved research proposals, research outcomes and the benefits of this research are made available to all Member States;
- (5) 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;
- (6) to develop continually the operational framework for WHO's smallpox vaccine reserve;
- (7) 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;
- (8) to ensure that any research undertaken does not involve genetic engineering of the variola virus;
- (9) to ensure that the two authorized repositories of live virus, and any other institution that has fragments of variola virus DNA, distribute such DNA only for purposes of research on diagnostics, treatment and vaccines, in accordance with recommendations of the WHO Advisory Committee on Variola Virus Research;
- (10) to submit an annual detailed report to the Health Assembly, through the Executive Board, on the research that has been completed, the results of such research, research being undertaken, and research being planned at the two authorized repositories;
- (11) to submit to the Sixty-first World Health Assembly a report on the legal status of the variola virus strains held at the two repositories with respect to their ownership;
- (12) to submit a report to the Sixty-first World Health Assembly, through the Executive Board, on measures that promote in Member States the widest and most equitable access possible to the outcomes of the research, including antiviral agents, vaccines and diagnostic tools.

(Eleventh meeting, 27 January 2007)