

Smallpox eradication: destruction of variola virus stocks

Report by the Secretariat

1. This document reports on work undertaken by the Secretariat in preparation for the Sixty-ninth World Health Assembly. It summarizes the conclusions of the Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox, which was established at the request of Member States and met in Geneva at the end of June 2015; describes the process of conducting the WHO's biosafety inspections of the two variola virus repositories; summarizes the work being carried out on the operational framework for access to WHO's smallpox vaccine stockpile; and provides information on the WHO Advisory Committee on Variola Virus Research.

SECRETARIAT ACTIONS

Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox

2. At the Sixty-seventh World Health Assembly, in May 2014, WHO was requested to provide additional information to the Health Assembly on the use and potential impact of technologies for synthetic biology on smallpox preparedness and control, to assist the Health Assembly in its deliberations on the timing of the destruction of existing variola virus stocks.¹

3. In response to that request, the Secretariat convened a meeting of a group of experts – the Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox – to provide an up-to-date assessment of technologies for synthetic biology and their potential impact on smallpox preparedness and countermeasure development.

4. Prior to that meeting, the Secretariat convened a meeting of a Scientific Working Group, which was held in Geneva on 16 and 17 April 2015, with the aim of providing the Independent Advisory Group with the most current scientific information on synthetic biology technology with regard to the variola virus. The report of the Scientific Working Group served as the background document for the meeting of the Independent Advisory Group.

¹ See document WHA67/2014/REC/3, summary record of the twelfth meeting of Committee A of the Sixty-seventh World Health Assembly, section 8.

5. The Independent Advisory Group met in Geneva on 29 and 30 June 2015. It concluded that the risk of the re-emergence of smallpox has changed and that there is a need to update preparedness efforts and to adapt research frameworks. A report has been submitted to the Director-General.

6. The full report of the Independent Advisory Group, including the conclusions of the Scientific Working Group, will be made available on the WHO website in due course.¹

Biosafety inspection of the repository sites

7. WHO biosafety inspection teams visited and inspected the containment facilities at the two WHO collaborating centres that are the authorized repositories of variola virus: the State Research Centre for Virology and Biotechnology (Koltsovo, Novosibirsk Region, Russian Federation) and the Centers for Disease Control and Prevention (Atlanta, Georgia, United States of America), in December 2014 and May 2015 respectively. The reports of these biosafety inspections are under preparation, currently pending the submission of self-assessment reports and supplementary information by the repositories to WHO. Once finalized, they will be submitted to the Secretariat to be made available on the WHO website prior to the Sixty-ninth World Health Assembly.

8. The protocol that was used followed the European Committee for Standardization's Laboratory Biorisk Management Standard CWA 15793:2011, which covers 16 elements of laboratory biorisk management. The biosafety inspection visits of 2014–2015 confirmed that this approach allows for effective inspections of the repositories, helping to assure the wider community that the research therein is being done safely and securely, in line with the highest standards of biosafety and biosecurity. The WHO inspection team included international experts and WHO staff and involved the other repository's staff as observers. The inspections included discussions with the respective repository's staff and with senior management; a detailed review of the facility; a review of the updates and corrective actions taken since the last inspection; and a review of documents, records, regulatory instruments and other materials of relevance. The next biosafety inspections of the two repositories of variola virus are planned for 2016.

Operational framework for access to WHO's smallpox vaccine stockpile

9. Work continues on an operational framework for access to WHO's emergency stockpile of smallpox vaccine in response to a smallpox event. The framework includes legal considerations for donating smallpox vaccines, standard operating procedures for donor countries as well as for recipient countries, logistical requirements and a vaccine request form, with terms and conditions for the donation and reception of smallpox vaccines. The Secretariat has begun discussions with the national regulatory agencies of donating countries on the creation of a regulatory framework for the donation of smallpox vaccines.

WHO Advisory Committee on Variola Virus Research

10. The Seventeenth meeting of the WHO Advisory Committee on Variola Virus Research will be held in Geneva on 12 and 13 January 2016.

¹ The Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox: meeting report. Geneva: World Health Organization; 2015 (document WHO/HSE/PED/2015. 1; <http://www.who.int/csr/resources/publications/smallpox/synthetic-biology-technology-smallpox/en/>).

11. The Advisory Committee will receive reports on the virus collections held at the two authorized repositories of variola virus, in the Russian Federation and the United States of America. It will also be provided with updates on the use of live variola virus for the development of diagnostic tests, one animal model, smallpox vaccines, and antiviral and therapeutic agents.

12. The full report of the Advisory Committee will be accessible on the WHO website prior to the Sixty-ninth World Health Assembly in May 2016.

ACTION BY THE EXECUTIVE BOARD

13. The Board is invited to note the report.

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