



WHO Advisory Committee on Variola Virus Research

Report of the Fifteenth Meeting

Geneva, Switzerland

24–25 September 2013



**World Health
Organization**

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WHO Advisory Committee on Variola Virus Research
Report of the Fifteenth Meeting, Geneva, Switzerland, 24–25 September 2013

Executive Summary

On 24 and 25 September 2013 the Advisory Committee on Variola Virus Research held its fifteenth meeting. In addition to its regular annual review of the virus stocks held in the two authorized repositories, the research undertaken and the proposals submitted, the Advisory Committee took the opportunity to review all research conducted over the past three years. The intention behind this in-depth review was to contribute to preparations for the forthcoming discussion at the Sixty-seventh World Health Assembly in May 2014 on the timing of the destruction of variola virus stocks.

The Advisory Committee was provided with reports on the virus collections held at the two WHO Collaborating Centres that are authorized as 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 (CDC) Atlanta, Georgia, United States of America.

The Advisory Committee was also provided with updates on the use of live variola virus for the development of: diagnostic tests, one animal model, smallpox vaccines, and antiviral agents and therapeutics. Representatives of two pharmaceutical companies described candidate antiviral agents (tecovirimat and brincidofovir) that were in an advanced stage of development. Information presented included data on efficacy, safety, stability and large-scale manufacturing capacity. Work is continuing to provide the data that are needed to satisfy the requirements for regulatory approval. A representative of another pharmaceutical company provided an update on its vaccine that had been licensed in the 28 Member States of the European Union, plus Iceland, Liechtenstein and Norway, in August 2013, with the indication for active immunization against smallpox of all adults.

Members of the Committee were asked to consider whether live variola virus was needed for further essential research for public health benefit on diagnostics for smallpox. The majority view within the committee was that there was no need to retain live variola virus for development of further diagnostics for smallpox.

Members of the Committee were asked to consider whether live variola virus was needed for further essential research for public health benefit on vaccines against smallpox. The majority view within the committee was that there was no need to retain live variola virus for the development of safer smallpox vaccines beyond those studies already approved.

Members of the Committee were asked to consider whether live variola virus was needed for further essential research for public health benefit on antivirals for smallpox. The majority view within the committee was that live variola virus was needed for the further development of antiviral agents against smallpox.

The CDC's "use to completion" of 70 of its 420 variola virus stocks in the process of approved research has set a potential precedent for the progressive reduction of all live virus material being held in the two repositories as a means of meeting the request of the World Health Assembly.

The Advisory Committee was appraised of other consultations, the outcome of which would have relevance to discussions to be held at the Sixty-seventh WHA. These consultations were as follows:

- The Advisory Group of Independent Experts to review the smallpox research programme (AGIES) would be reconvened in November 2013 to consider the recommendations and decisions of the Advisory Committee.
- An expert consultation aimed at reviewing the evidence on smallpox vaccines and proposing recommendations for the size and composition of the WHO smallpox vaccine stockpile had been convened on 19 and 20 September 2013. That consultation will present its conclusions and recommendations to the Strategic Advisory Group of Experts (SAGE) on Immunization for consideration at meeting in November 2013.

In further preparation for the discussions at the World Health Assembly in May 2014, the reports of 15th meeting of ACCVR, AGIES and SAGE, as well as that of the Secretariat, would be submitted to the Executive Board of WHO for consideration at its 134th session in January 2014.

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