Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development

4 June 2009

IVR-153

A candidate reassortant vaccine virus (IVR-153) has been developed, using classical reassortment technology, from an A/California/7/2009 (H1N1)v virus**,** by CSL Limited, Parkville, Victoria, Australia**.**

The full characterization of this reassortant virus, including safety testing in ferrets, is currently being conducted by CSL Limited, the WHO-Collaborating Centre for Reference and Research on Influenza, Melbourne, and the Australian Animal Health Laboratories (AAHL) in Geelong, Victoria, Australia. Antigenic and genetic analyses completed so far indicate that the IVR-153 reassortant virus meets the specifications in the recent WHO recommendation on viruses to be used in vaccine development.[1]

The haemagglutinin (HA) and neuraminidase (NA) sequences of the A/California/7/2009 (H1N1)v virus can be found on the public web site of GenBank via the following links:

HA sequence
http://www.ncbi.nlm.nih.gov/nuccore/227977171?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum

NA sequence
http://www.ncbi.nlm.nih.gov/nuccore/229396468?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum

The IVR-153 reassortant virus is available for distribution to manufacturers under certain biocontainment conditions.[2] Institutions, companies and other parties interested in developing vaccines to the novel influenza A (H1N1) virus, who wish to receive this candidate reassortant vaccine virus, should contact either the WHO Global Influenza Programme at GISN@who.int or the Therapeutic Goods Administration, Australia or National Institute for Biological Standards and Control, UK or CSL Limited, Australia, at the addresses below:

Immunobiology
Office of Laboratories & Scientific Services
Therapeutic Goods Administration, PO Box 100
Woden ACT 2606, Australia
E-mail: influenza.standards@tga,gov.au

Division of Virology
National Institute for Biological Standards and Control
Blanche Lane, South Mimms, Potters Bar
Hertfordshire, EN6 3QG, United Kingdom
E-mail: enquiries@nibsc.hpa.org.uk or standards@nibsc.hpa.org.uk
http://www.nibsc.ac.uk/flu_site/viruses_reagents.html

CSL Limited, 45 Popular Road,
Parkville, Victoria 3052, Australia
E-mail: peter.schoofs@csl.com.au

Biocontainment requirements for handling the candidate reassortant vaccine virus

The candidate reassortant vaccine virus contains infectious materials and should be handled only in appropriate containment facilities (until completion of the above-mentioned safety tests, it is recommended to use biosafety level 2 plus [BSL-2 plus] facilities with biosafety level 3 [BSL-3] practices)[3] using fully trained and competent staff in accordance

[1] http://www.who.int/csr/disease/swineflu/guidance/laboratory/en/index.html
[2] http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/en/index.html
[3] http://www.who.int/csr/resources/publications/swineflu/LaboratoryHumanspecimensinfluenza/en/index.html

with national safety guidelines. Further guidance will be provided to recipient laboratories when the safety tests have been completed. If, as expected, attenuation is demonstrated, vaccine production may proceed at BSL-2 enhanced level, as described in the WHO biosafety risk assessment and guidelines for the production and quality control of human influenza pandemic vaccines.[4] Recipient laboratories must accept full responsibility for the use and disposal of all materials.

[4] http://www.who.int/biologicals/publications/trs/areas/vaccines/influenza/H1N1_vaccine_production_biosafety_SHOC.27May2009.pdf