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

19 June 2009

CBER-RG2

A candidate reassortant vaccine virus (CBER-RG2) has been developed, using reverse genetics technology, from an A/California/04/2009 (H1N1)v virus**,** by the WHO Essential Regulatory Laboratory at Center for Biologics Evaluation and Research (**CBER/FDA**), USA.

The full characterization of this reassortant virus, including safety testing in ferrets, is currently being conducted by the WHO Collaborating Centre at CDC, Atlanta, USA. Antigenic and genetic analyses completed so far indicate that the CBER-RG2 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/04/2009 (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/227809829?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum
NA sequence
http://www.ncbi.nlm.nih.gov/nuccore/227809833?ordinalpos=1&itool=EntrezSystem2.PEntrez.Sequence.Sequence_ResultsPanel.Sequence_RVDocSum

The CBER-RG2 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 variant 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 WHO ERL at CBER/FDA at the address below:

Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)
8800 Rockville Pike, Bethesda, MD 20852
United States of America
Fax: +1 301 480 3157.
E-mail: zhiping.ye@fda.hhs.gov,
http://www.fda.gov/

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 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 WHO Technical Report Series No. 941.[4] Recipient laboratories must accept full responsibility for the use and disposal of all materials.

[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
[4] http://www.who.int/csr/resources/publications/swineflu/trs941_annex5/en/index.html