European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR HUMAN MEDICINAL PRODUCTS (CHMP)

REVISED[i] (29 MAY 2006) EU RECOMMENDATIONS FOR THE SEASONAL INFLUENZA VACCINE COMPOSITION FOR THE SEASON 2006/2007

EU recommendations for the seasonal influenza vaccine composition for the season 2006/2007

The meeting of the Ad hoc Influenza Working Group of the BWP was convened in order to implement Part A of the Note for Guidance on harmonisation of requirements for influenza vaccine i.e. the selection of virus strains for the manufacture of seasonal influenza vaccine for 2006/2007.

Having considered the information on international surveillance by WHO presented by Dr Alan Hay (WHO collaborating centre, Mill Hill), the CHMP BWP Ad hoc Influenza Working Group, consisting of experts on influenza from the Member States, considered that the WHO recommendation on the composition of vaccines for 2006/2007 should be followed:

Trivalent vaccine containing:
- an A/New Caledonia/20/99 (H1N1)-like strain;
- an A/Wisconsin/67/2005 (H3N2)-like strain;
- a B/Malaysia/2506/2004-like strain.

On the basis of cross reactivity and growth in eggs, the group agreed that for the purpose of vaccine manufacture, the following strains be accepted:

a) Reassortant virus IVR-116 which is derived from A/New Caledonia/20/99 as an A/New Caledonia/20/99-like strain;

b) Reassortant virus IVR-142 which is derived from A/Hiroshima/52/2005 as an A/Wisconsin/67/2005-like strain;

c) B/Malaysia/2506/2004 as a B/Malaysia/2506/2004-like strain.

Revisions of the EU strain recommendations, and more specifically the recommendation of alternative H3N2 reassortants, was made on the basis of additional information on the growth characteristics of the proposed viruses[ii]. In view of antigenic and growth properties, reassortants IVR-142, NYMCX-161 and NYMCX-161-B are suitable for use as the H3N2 component of EU influenza vaccines for the 2006/2007 season. Further to consultation of the Ad hoc Influenza Working Group of the BWP and the BWP, the following additional strains can be accepted:

- Reassortant virus NYMCX-161 which is derived from A/Wisconsin/67/2005 as an A/Wisconsin/67/2005-like strain.
- Reassortant virus NYMCX-161-B which is derived from A/Wisconsin/67/2005 as an A/Wisconsin/67/2005-like strain.

Reagents for vaccine standardisation will be prepared by NIBSC, UK (see Annex I).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int http://www.emea.eu.int

ANNEX I

Reagents for vaccine standardisation

Available from NIBSC, UK

H1N1

A/New Caledonia/20/99 (IVR-116) antigen is currently ready: NIBSC 04/256.
A/New Caledonia/20/99 antiserum is currently ready: NIBSC 04/260.

H3N2

A/Wisconsin/67/2005 (IVR-142) antigen should be available by end May 2006*.
A/Wisconsin/67/2005 (NYMCX-161) antigen should be available by mid June 2006*.
A/Wisconsin/67/2005 (NYMCX-161-B) antigen should be available by end June 2006*.

A/Wisconsin/67/2005 antiserum should be available by end May 2006.

B

B/Malaysia/2506/2004 antigen is currently ready: NIBSC 05/154
B/Malaysia/2506/2004 antiserum is currently ready: NIBSC 05/174

* Depends on timely supply of influenza antigen from industry and collaboration with WHO laboratories

[i] This (second) revision of the EU Recommendation for the seasonal influenza vaccine composition for the season 2006/2007 (originally published on 7 April 2006) is to include reassortant NYMCX-161-B as a suitable A/Wisconsin/67/2005 (H3N2)-like strain. The first revised EU recommendation (including reassortant NYCMX-161) was published on 24 April 2006.

[ii] In terms of virus yield most manufacturers indicated that the reassortants IVR-142 and NYMCX-161 were either equivalent in growth properties or they marginally favoured one or the other. However, one manufacturer found the growth properties of IVR-142 to be consistently lower than NYMCX-161. Information provided by some manufacturers after the publication of the revised strain recommendation showed that a third reassortant (NYMCX-161-B) had better growth characteristics than reassortant NYMCX-161.