European Medicines Agency
Evaluation of Medicines for Human Use

London, 30 March 2005
EMEA/CHMP/BWP/111233/2005

COMMITTEE FOR HUMAN MEDICINAL PRODUCTS (CHMP)

EU RECOMMENDATIONS FOR THE INFLUENZA VACCINE COMPOSITION FOR THE SEASON 2005/2006

EU recommendations for the influenza vaccine composition for the season 2005/2006

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 influenza vaccine for 2005/2006.

Having considered the information on international surveillance by WHO presented by Dr Yi Pu Lin (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 2005/2006 should be followed:

Trivalent vaccine containing:

- an A/New Caledonia/20/99 (H1N1)-like strain
- an A/California/7/2004 (H3N2)-like strain
- a B/Shanghai/361/2002-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 NYMC X-157 which is derived from A/New York/55/2004 as an A/California/7/2004-like strain

c) B/Jiangsu/10/2003 as a B/Shanghai/361/2002-like strain

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

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ANNEX I

Reagents for vaccine standardisation

Available from NIBSC, UK

H1N1

A/New Caledonia/20/99 (IVR-116) antigen. A new reagent should be available by end April 2005.
A/New Caledonia/20/99 antiserum reagent should be available by end April 2005.

H3N2

A/California/7/2004 antigen should be available by mid May 2005.
A/California/7/2004 antiserum should be available by mid April 2005.

B

B/Jiangsu/10/2003 antigen is currently available: NIBSC 04/110
B/Jiangsu/10/2003 antiserum is currently available: NIBSC 04/242