



The European Agency for the Evaluation of Medicinal Products  
*Pre-authorisation Evaluation of Medicines for Human Use*

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**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)**  
**EU RECOMMENDATIONS FOR THE INFLUENZA VACCINE COMPOSITION FOR THE**  
**SEASON 2004/2005**

**EU recommendations for the influenza vaccine composition for the season 2004/2005**

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 2004/2005.

Having considered the information on international surveillance by WHO presented by Dr Alan Hay (WHO collaborating centre, Mill Hill), the CPMP 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 2004/2005 should be followed:

Trivalent vaccine containing:

- an A/New Caledonia/20/99 (H1N1)-like strain
- an A/Fujian/411/2002 (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 X-147 which is derived from A/Wyoming/3/2003 as an A/Fujian/411/2002-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).

## 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 mid April 2004.

A/New Caledonia/20/99 antiserum is currently available.

##### H3N2

A/Wyoming/3/2003 (X-147) antigen and antiserum are currently available.

##### B

B/Jiangsu/10/2003 antigen and antiserum will be made available by mid May 2004.