



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)
FINAL EU RECOMMENDATIONS FOR THE INFLUENZA VACCINE
COMPOSITION FOR THE SEASON 2003/2004**

EU recommendations for the influenza vaccine composition for the season 2003/2004

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 2003/2004.

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 2003/2004 should be followed:

Trivalent vaccine containing:

- an A/Moscow/10/99 (H3N2)-like strain
- an A/New Caledonia/20/99 (H1N1)-like strain
- a B/Hong Kong/330/2001-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 RESVIR-17, which has been derived from A/Panama/2007/99 as an A/Moscow/10/99-like strain
- b) Reassortant virus IVR-116 which is derived from A/New Caledonia/20/99 as an A/New Caledonia/20/99 -like strain
- c) B/Shandong/7/97, which is a B/Hong Kong/330/2001-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 2003.

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

H3N2

A/Panama/2007/99 (RESVIR-17) antigen is currently available.

A/Panama/2007/99 antiserum. A new reagent should be available by mid April 2003.

B

B/Shandong/7/97 antigen is currently available.

B/Shandong/7/97 antiserum. A new reagent should be available by April 2003.