London, 19 March 2007 Doc. Ref. EMEA/CHMP/BWP/108182/2007

COMMITTEE FOR HUMAN MEDICINAL PRODUCTS (CHMP) BIOLOGICS WORKING PARTY (BWP)

BWP AD-HOC INFLUENZA WORKING GROUP Chairperson: Dr. John Wood

EU RECOMMENDATIONS FOR THE SEASONAL INFLUENZA VACCINE COMPOSITION FOR THE SEASON 2007/2008

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 2007/2008.

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 2007/2008 should be followed:

Trivalent vaccine containing:

- an A/Solomon Islands/3/2006 (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-145 which is derived from A/Solomon Islands/3/2006 as an A/Solomon Islands/3/2006-like strain.
- b) Reassortant virus IVR-142 which is derived from A/Hiroshima/52/2005 or Reassortant virus NYMCX-161-B which is derived from A/Wisconsin/67/2005 as A/Wisconsin/67/2005-like strains.
- c) B/Malaysia/2506/2004 as a B/Malaysia/2506/2004-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/Solomon Islands/3/2006 (IVR-145) antigen will be made available* A/Solomon Islands/3/2006 antiserum will be made available*

H3N2

A/Wisconsin/67/2005 (IVR-142) antigen is currently available: NIBSC 05/234 A/Wisconsin/67/2005 antiserum is currently available: NIBSC 05/236

A/Wisconsin/67/2005 (NYMCX-161-B) antigen is currently available: NIBSC 06/120 A/Wisconsin/67/2005 antiserum is currently available: NIBSC 05/236

\mathbf{B}

B/Malaysia/2506/2004 antigen is currently available: NIBSC 06/126 B/Malaysia/2506/2004 antiserum is currently available: NIBSC 05/174

^{*} Progress in development of reagents will be communicated by NIBSC on a weekly basis (via email). The timing of reagent availability depends on a timely supply of influenza antigen from industry and collaboration with WHO laboratories.