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

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

BWP AD-HOC INFLUENZA WORKING GROUP

EU RECOMMENDATIONS FOR THE SEASONAL INFLUENZA VACCINE COMPOSITION FOR THE SEASON 2009/2010

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 2009/2010.

Having considered the information on international surveillance by WHO presented by Dr Alan Hay (WHO collaborating centre, NIMR, Mill Hill, UK), 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 2009/2010 should be followed:

Trivalent vaccine containing:
— an A/Brisbane/59/2007 (H1N1)-like virus;
— an A/Brisbane/10/2007 (H3N2)-like virus;
— a B/Brisbane/60/2008-like virus.

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-148, which is derived from A/Brisbane/59/2007, as an A/Brisbane/59/2007 (H1N1)-like strain.

b) Reassortant virus NYMC X-175C, which is derived from A/Uruguay/716/2007, as an A/Brisbane/10/2007 (H3N2)-like strain

c) B/Brisbane/60/2008 and reassortant virus NYMC BX-31 or NIB-58, which are derived from B/Brisbane/60/2008, as B/Brisbane/60/2008-like strains.

Reagents for vaccine standardisation will be supplied by NIBSC, UK and TGA, Australia (see Annex I).

Submission time of variation in according to Article 7 of Commission Regulation (EC) No 1085/2003

CHMP informs the Marketing Authorisation holders of centrally approved seasonal influenza vaccines of the deadline for submission of the annual strain change variation[1]: 15 June 2009.

[1] See: EMEA fast track procedure for community human influenza inactivated vaccines annual strain(s) update according to art. 7 of Commission regulation (EC) no 1085/2003 (EMEA/CHMP/BWP/99698/2007)

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ANNEX I

Reagents for vaccine standardisation[2]

Available from NIBSC, UK[3] and TGA, Australia[4]

H1N1

A/Brisbane/59/2007 (IVR-148) antigen is available (NIBSC 08/100)
A/Brisbane/59/2007 antiserum is available (NIBSC 08/112)

H3N2

A/Uruguay/716/2007 (NYMC X-175C) antigen is available (NIBSC 08/278)
A/Uruguay/716/2007 antiserum is available (NIBSC 08/246)

B

B/Brisbane/60/2008 antigen is available from TGA (target for NIBSC availability is mid-May 2009)
B/Brisbane/60/2008 antiserum is available from TGA (target for NIBSC availability is mid-May 2009)

[2] Manufactures may use reagents for standardisation prepared by TGA, Australia and CBER, USA following discussion and agreement with the concerned OMCL and provided that the same reagents are used for the entire production campaign.

[3] For availability and progress in development of reagents, consult the following website: http://www.nibsc.ac.uk/flu_site/index.html

[4] TGA, Australia: http://www.tga.gov.au