EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Committee for human medicinal products (CHMP)

BWP ad-hoc influenza working group

EU recommendations for the seasonal influenza vaccine composition for the season 2010/2011

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 2010/2011.

Having considered the information on international surveillance by WHO presented by Dr John McCauley (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 2010/2011 should be followed:

Trivalent vaccine containing:

- an A/California/7/2009 (H1N1)-like virus
- an A/Perth/16/2009 (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 NYMC X-179A and reassortant virus NYMC X-181, which are derived from A/California/7/2009, as A/California/7/2009 (H1N1)-like viruses

b) Reassortant virus NYMC X-187 and reassortant virus NIB-65, which are derived from A/Victoria/210/2009, as A/Perth/16/2009 (H3N2)-like viruses

c) B/Brisbane/60/2008 and reassortant virus NYMC BX-35, which is derived from B/Brisbane/60/2008, as B/Brisbane/60/2008-like viruses.

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

Submission time of variation in according to Article 18 of Commission Regulation (EC) No 1234/2008

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CHMP informs the Marketing Authorisation holders of centrally approved seasonal influenza vaccines of the deadline for submission of the annual strain change variation[1]: 14 June 2010.

[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)

Annex I

Reagents for vaccine standardisation[2]

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

H1N1

A/California/7/2009 (NYMC X-179A) egg derived antigen is available (NIBSC 09/146)

A/California/7/2009 (NYMC X-179A) cell derived antigen is available (NIBSC 09/174)

A/California/7/2009 (NYMC X-181) antigen is available from TGA and will be available from NIBSC (target for NIBSC is mid May 2010)

A/California/7/2009 antiserum is available (NIBSC 09/152)

H3N2

A/Perth/16/2009 (NYMC-X187) antigen will be available from NIBSC (target for NIBSC is mid May 2010)

A/Perth/16/2009 (NIB-65) antigen will be available from NIBSC (target for NIBSC is mid May 2010)

A/Perth/16/2009 like antiserum is available (NIBSC 09/270)

B

B/Brisbane/60/2008 antigen is available (NIBSC 08/352)

B/Brisbane/60/2008 (BX-35) antigen will be available from NIBSC if needed (target for NIBSC is mid May 2010)

B/Brisbane/60/2008 antiserum is available (NIBSC08/354)

[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/spotlight/influenza_resource_centre/reagents.aspx
[4] TGA, Australia: http://www.tga.gov.au