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Committee for Medicinal Products for Human use

# BWP ad-hoc influenza Working Group

## EU recommendations for the seasonal influenza vaccine composition for the season 2011/2012

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 2011/2012.

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 2011/2012 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:

As A/California/7/2009 (H1N1)-like viruses:

- reassortant virus NYMC X-179A, which is derived from A/California/7/2009
- reassortant virus NYMC X-181, which is derived from A/California/7/2009
- reassortant virus NIB-74, which is derived from A/Christchurch/16/2010
- A/Brisbane/10/2010 (wild type)

As A/Perth/16/2009 (H3N2)-like viruses:

- reassortant virus NYMC X-187, which is derived from A/Victoria/210/2009

As B/Brisbane/60/2008-like viruses:

- B/Brisbane/60/2008 (wild type)

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- reassortant virus NYMC BX-35, which is derived from B/Brisbane/60/2008
- reassortant virus NYMC BX-31B, which is derived from B/Brisbane/60/2008

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

CHMP informs the Marketing Authorisation holders of centrally approved seasonal influenza vaccines of the recommended deadline for submission of the annual strain change variation[1]: 13 June 2011.

[1] See: EMA fast track procedure for community human influenza inactivated vaccines annual strain(s) update according to art. 18 of Commission regulation (EC) no 1234/2008 (EMEA/CHMP/BWP/99698/2007 Rev. 1)

# ANNEX I

# Reagents for vaccine standardisation[2]

## *Available from NIBSC, UK[3]*

### *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 (NIBSC 09/294)

A/Christchurch/16/2010 (NIB-74) will be available from NIBSC (target date April 2011)

A/Brisbane/10/2010 antigen will be available from NIBSC if needed (target date June 2011 if requested)

A/California/7/2009 antiserum is available (NIBSC 10/230)

### *H3N2*

A/Perth/16/2009 (NYMC-X187) antigen is available (NIBSC 10/102)

A/Perth/16/2009 like antiserum is available (NIBSC 10/182)

### *B*

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

B/Brisbane/60/2008 (NYMC BX-35) antigen is available (NIBSC 10/106)

B/Brisbane/60/2008 (NYMC BX-31B) antigen will be available from NIBSC or another WHO Essential Regulatory Laboratory (ERL) if needed (target date undecided)

B/Brisbane/60/2008 like antiserum is available (NIBSC 10/146)

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

[3] For availability and progress in development of reagents, consult the following websites:
http://www.nibsc.ac.uk/spotlight/influenza_resource_centre/reagents.aspx;
http://www.who.int/csr/disease/influenza/vaccinerecommendations2/en/index.html