EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2013
EMA/CHMP/BWP/116620/2013
Committee for Medicinal Products for Human use

BWP ad-hoc influenza Working Party

Amended[1] EU recommendations for the seasonal influenza vaccine composition for the season 2013/2014

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 2013/2014.

Having considered the information on international surveillance by WHO presented by the representative of the 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 2013/2014 should be followed:

Trivalent vaccine containing:

— an A/California/7/2009 (H1N1)pdm09-like virus

— an A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011*

— a B/Massachusetts/2/2012-like virus.

* A/Texas/50/2012 is an A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011.
It is recommended that A/Texas/50/2012 is used as the A(H3N2) vaccine component because of antigenic changes in earlier A/Victoria/361/2011-like vaccine viruses (such as IVR-165) resulting from adaptation to propagation in eggs.

The above recommendation is applicable also for live attenuated influenza vaccines.

For vaccine manufacturers considering the use of a B/Victoria/2/87 lineage vaccine virus in quadrivalent vaccines containing two influenza B viruses, a B/Brisbane/60/2008-like virus in addition to the strains mentioned above is considered appropriate.

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:

[1] Further to the interim recommendation dated 21 March 2013, this amended document includes a recommendation for suitable A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011 and B/Massachusetts/2/2012-like candidate vaccine viruses.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

As A/California/7/2009 (H1N1)pdm09-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
- reassortant virus NIB-74xp, which is derived from A/Christchurch/16/2010
- A/Brisbane/10/2010 (wild type)

As A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011:

- A/Texas/50/2012 (wild type)
- Reassortant virus NYMC X-223, which is derived from A/Texas/50/2012
- Reassortant virus NYMC X-223A, which is derived from A/Texas/50/2012

As B/Massachusetts/2/2012-like viruses:

- B/Massachusetts/2/2012 (wild type)

As B/Brisbane/60/2008-like viruses (for quadrivalent vaccines including two influenza B viruses):

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

Furthermore, for manufacture of live attenuated influenza vaccines, the group agreed that the following strains be accepted, provided that antigenic appropriateness is confirmed by a WHO collaborating centre.

- A/California/7/2009
- A/Texas/50/2012
- B/Massachusetts/2/2012

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

Submission time of variation in accordance with 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[2]: 17 June 2013.

[2] 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/99698/2007Rev. 2)

ANNEX I

Reagents for vaccine standardisation[3]

Available from NIBSC, UK[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 (NIBSC 12/168)

A/Christchurch/16/2010 (NIB-74) antigen is available (NIBSC 10/258), acceptable for use also with NIB-74xp

A/Brisbane/10/2010 cell derived antigen is available (NIBSC 11/134)

A/California/7/2009 antiserum is available (NIBSC 12/108)

H3N2

A/Texas/50/2012 antigen will be available

A/Texas/50/2012 (NYMC X-223) antigen will be available

A/Texas/50/2012 (NYMC X-223A) antigen will be available

A/Texas/50/2012 antiserum will be available

B/Yamagata/16/88 lineage

B/Massachusetts/2/2012 antigen will be available

B/Massachusetts/2/2012 antiserum will be available

B/Victoria/2/87 lineage (for quadrivalent vaccines including two influenza B strains)

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 like antiserum is available (NIBSC 11/136)

[3] 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.

[4] 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/influenza/vaccine/virus/en