EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2014
EMA/CHMP/BWP/109993/2014
Committee for Medicinal Products for Human use

BWP Ad-hoc Influenza Working Group

EU recommendations for the seasonal influenza vaccine composition for the season 2014/2015

The meeting of the Ad hoc Influenza Working Group of the BWP was convened in order to recommend the virus strains for the manufacture of seasonal influenza vaccine for 2014/2015.

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 2014/2015 should be followed:

Trivalent vaccine containing:

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

— an A/Texas/50/2012(H3N2) like virus

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

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:

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)

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

As A/Texas/50/2012 (H3N2)-like viruses:

- 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)
- Reassortant virus NYMC BX-51B, which is derived from B/Massachusetts/2/2012

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 NYMC 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.

- A/California/7/2009
- A/Texas/50/2012
- B/Massachusetts/2/2012
- B/Brisbane/60/2008 (for quadrivalent formulation)

Reagents for vaccine standardisation are available (in some cases replacement reagents are in preparation) and 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[1]: 16 June 2014.

[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/99698/2007Rev. 2)

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 13/164)

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

A/California/7/2009 (NYMC X-181) egg derived antigen is available (NIBSC 12/168)

A/Christchurch/16/2010 (NIB-74) egg derived 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 replacement in preparation

H3N2

A/Texas/50/2012 (NYMC X-223) egg derived antigen is available (NIBSC 13/112)

A/Texas/50/2012 (NYMC X-223A) egg derived antigen is available (NIBSC 13/116)

A/Texas/50/2012 (NYMC X-223A) cell derived antigen is available (NIBSC 13/162)

A/Texas/50/2012 antiserum is available (NIBSC 13/178)

B/Yamagata/16/88 lineage

B/Massachusetts/2/2012 egg derived antigen is available (NIBSC 13/134)

B/Massachusetts/2/2012 cell derived antigen is available (NIBSC 13/152)

B/Massachusetts/2/2012 (NYMC BX-51B) egg derived antigen is available (NIBSC 13/106)

B/Massachusetts/2/2012 antiserum is available (NIBSC 13/114)

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

B/Brisbane/60/2008 egg derived antigen is available (NIBSC 13/234)

B/Brisbane/60/2008 (NYMC BX-35) egg derived antigen is available (limited availability due to low stock levels, NIBSC 10/106)

B/Brisbane/60/2008 like antiserum replacement in preparation

[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.org/Influenza/Reagents.aspx
http://www.who.int/influenza/vaccines/virus/en/