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EMA/CHMP/BWP/216216/2017
Committee for Medicinal Products for Human use

BWP Ad-hoc Influenza Working Group

Amended[1] EU recommendations for the seasonal influenza vaccine composition for the season 2017/2018

The meeting of the Ad hoc Influenza Working Group of the Biologics Working Party (BWP) was convened in order to recommend the virus strains for the manufacture of seasonal influenza vaccine for 2017/2018.

Having considered the information on international surveillance by WHO presented by the representative of the WHO Collaborating Centre, The Worldwide Influenza Centre at the Francis Crick Institute (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 2017/2018 should be followed:

Trivalent vaccines should contain:

– an A/Michigan/45/2015 (H1N1)pdm09-like virus;

– an A/Hong Kong/4801/2014 (H3N2)-like virus;

– a B/Brisbane/60/2008-like virus.

For vaccine manufacturers considering the use of a B/Yamagata/16/88 virus lineage vaccine virus in **quadrivalent vaccines** containing two influenza B viruses, a B/Phuket/3073/2013-like in addition to the strains mentioned above is considered appropriate.

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

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/Michigan/45/2015 (H1N1)pdm09-like viruses:

- reassortant virus IVR-180, which is derived from A/Singapore/GP1908/2015
- reassortant virus IVR-180A, which is derived from A/Singapore/GP1908/2015

[1] Further to the recommendation dated 15 March 2017, this amended document includes a recommendation for a suitable A/Michigan/45/2015 (H1N1)pdm09-like candidate vaccine virus for live attenuated influenza vaccines.

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- reassortant virus NYMC X-275, which is derived from A/Michigan/45/2015

As A/Hong Kong/4801/2014 (H3N2)-like viruses:

- reassortant virus NYMC X-263B, which is derived from A/Hong Kong/4801/2014
- reassortant virus NYMC X-257A, which is derived from A/New Caledonia/71/2014

As B/Brisbane/60/2008-like 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
- B/Brisbane/46/2015 (wild type)

As B/Phuket/3073/2013-like viruses (for quadrivalent vaccines including two influenza B viruses):

- B/Phuket/3073/2013 (wild type)
- B/Brisbane/9/2014 (wild type)
- B/Utah/9/2014 (wild type)

Furthermore, for manufacture of **live attenuated influenza vaccines**, the group agreed that the following strains be accepted:

As A/Michigan/45/2015 (H1N1)pdm09-like virus:

- Virus MEDI279432, which is derived from A/Slovenia/2903/2015[2]

As A/Hong Kong/4801/2014 (H3N2)-like virus:

- Virus MEDI263122, which is derived from A/New Caledonia/71/2014

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

- Virus MEDI228030, which is derived from B/Brisbane/60/2008

As B/Phuket/3073/2013-like virus:

- Virus MEDI254977, which is derived from B/Phuket/3073/2013

Reagents for vaccine standardisation may be obtained from any WHO Essential Regulatory Laboratory (ERL). It is anticipated that reagents are/ will be available from NIBSC, UK and TGA, Australia (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[3]: 12 June 2017.

[2] Updated strain

[3] See: Guideline on influenza vaccines – submission and procedural requirements

Note on labelling requirements

NCAs and manufacturers are requested to follow the labelling examples (strain descriptions) given in the updated Guideline on influenza vaccines – submission and procedural requirements.[4] This labelling guidance should be followed for the product information of all EU authorised influenza vaccines.

Regulatory and procedural requirements module
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500223481.pdf

[4] See: Guideline on influenza vaccines – submission and procedural requirements
Regulatory and procedural requirements module
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500223481.pdf

ANNEX I

Reagents for vaccine standardisation[5,6]

Available from NIBSC, UK and TGA, Australia.[7]

H1N1

A/Singapore/GP1908/2015 (IVR-180) egg derived antigen is available (NIBSC 16/292)
A/Singapore/GP1908/2015 (IVR-180A) egg derived antigen is not yet available
A/Michigan/45/2015 (X-275) egg derived antigen is available (NIBSC 16/298)
A/Michigan/45/2015-like antiserum is available (NIBSC 16/304)

H3N2

A/Hong Kong/4801/2014 (NYMC X-263B) egg derived antigen is available (NIBSC 16/286))
A/New Caledonia/71/2014 (NYMC X-257A) egg derived antigen is available (NIBSC 15/238)
A/Hong Kong/4801/2014-like antiserum is available (NIBSC 16/182)

B/Victoria/2/87 lineage

B/Brisbane/60/2008 egg derived antigen is available (NIBSC 13/234)
B/Brisbane/60/2008 (NYMC BX-35) egg derived antigen (NIBSC 16/118)
B/Brisbane/46/2015 (wild type) egg derived antigen (TGA 2016/111B)
B/Brisbane/60/2008-like antiserum is available (NIBSC 15/312) [limited availability, replacement is available 16/192]

B/Yamagata/16/88 lineage (for quadrivalent vaccines including two influenza B strains)

B/Phuket/3073/2013 egg derived antigen is available (NIBSC 16/158)
B/Brisbane/9/2014 egg derived antigen is available (NIBSC 14/274) [limited availability].
B/Phuket/3073/2013-like antiserum is available (NIBSC 15/150)

[5] Manufacturers 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.
[6] Updated
[7] For availability and progress in development of reagents, consult the following websites:
http://www.nibsc.org/science_and_research/virology/influenza_resource_/full_reagent_update.aspx
http://www.who.int/influenza/vaccines/virus/en/