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Revised to include strain IVR-153

COMMITTEE FOR HUMAN MEDICINAL PRODUCTS (CHMP)

**BIOLOGICS WORKING PARTY (BWP)
BWP AD-HOC INFLUENZA WORKING GROUP**

**EU RECOMMENDATION FOR THE EMERGENT NOVEL H1N1 INFLUENZA
VACCINE COMPOSITION**

The Biologics Working Party and its Ad hoc Influenza Working Group have endorsed the WHO recommended antigenic composition of H1N1 influenza strains (reference virus) to be used for emergent novel H1N1 vaccine development¹. The majority of the novel influenza A (H1N1) isolates are antigenically and genetically related to the A/California/7/2009 (H1N1)v virus². Should vaccines be prepared against the novel influenza A (H1N1) virus, it is therefore recommended that vaccines contain the following:

- An A/California/7/2009 (H1N1)v-like virus

WHO Collaborating Centres, Essential Regulatory Laboratories and other partners are developing high-growth reassortant A/California/7/2009 (H1N1)v-like viruses. Currently, the following A/California/7/2009 (H1N1)v-like production strains have been announced on the WHO website and are being evaluated as to their suitability for vaccine production:

- Reassortant virus X-179A, derived from A/California/7/2009 (H1N1)v virus³
- Reassortant virus NIBRG-121, derived from A/California/7/2009 (H1N1)v virus⁴
- Reassortant virus IDCDC-RG15, derived from A/Texas/5/2009 (H1N1)v virus⁵
- Reassortant virus IVR-153, derived from A/California/7/2009 (H1N1)v virus⁶

WHO, through the Global Influenza Surveillance Network, will continue to monitor the evolution of the influenza A(H1N1) virus, and will update recommendations of vaccine viruses whenever needed. Consequently, this EU recommendation is expected to be amended to take into account the suitability and availability of additional strains and the outcomes of discussions with vaccine manufacturers. Information on reagents for vaccine standardisation will be provided in due course.

This recommendation does not replace the annual recommendations for vaccine viruses for seasonal trivalent influenza vaccines⁷.

¹ http://www.who.int/csr/resources/publications/swineflu/vaccine_recommendations/en/index.html

² v: variant H1N1 viruses

³ http://www.who.int/csr/resources/publications/swineflu/candidates_X-179a/en/index.html

⁴ http://www.who.int/csr/resources/publications/swineflu/candidates_nibrg121/en/index.html

⁵ http://www.who.int/csr/resources/publications/swineflu/candidates_IDCDC_RG15/en/index.html

⁶ <http://www.who.int/csr/resources/publications/swineflu/ivr153/en/index.html>

⁷ Please see <http://www.emea.europa.eu/pdfs/human/bwp/13389509en.pdf> for the EU recommendations for the seasonal influenza vaccine composition for the season 2009/2010.