EU Guidance on Influenza Vaccines

James S Robertson, PhD
Partners Meeting
Dubai, 2014
Previous guidance

• Harmonisation of requirements for influenza vaccines
• Cell culture inactivated influenza vaccines
• Development of live attenuated influenza vaccines
• Pandemic influenza vaccines (various)
• Procedural guidance (various)
• Isolation of candidate influenza vaccine viruses in cell culture
Concept paper on the revision of guidelines for influenza vaccines

- Quality, non-clinical, clinical
- Seasonal, pre-pandemic, pandemic
- Inactivated, live attenuated
27 February 2013  
EMA/CHMP/BWP/310834/2012  
Vaccine Working Party and Biologics Working Party (VWP, BWP)

Guideline on Influenza Vaccines – Quality Module
Draft

<table>
<thead>
<tr>
<th>Draft Agreed by VWP/BWP</th>
<th>December 2012</th>
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<tr>
<td>Adoption by CHMP for release for consultation</td>
<td>February 2013</td>
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<tr>
<td>Start of public consultation</td>
<td>08 March 2013</td>
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<td>End of consultation (deadline for comments)</td>
<td>08 August 2013</td>
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Committee for Proprietary Medicinal Products (CPMP)

Note for Guidance on Harmonisation of Requirements for Influenza Vaccines

- Annual updates, labelling, potency, batch release
- Clinical trials related to yearly licensing
3. CRITERIA FOR ASSESSMENT OF VACCINES

3.1. Serological data

a) the following serological assessments should be considered for each strain in adult subjects, aged between 18 and 60, and at least one of the assessments should meet the indicated requirements:

- number of seroconversions or significant increase in antihaemagglutinin antibody titre > 40%;
- mean geometric increase > 2.5;
- the proportion of subjects achieving an HI titre ≥40 or SRH titre > 25 mm² (*) should be > 70%.

b) the following serological assessments should be considered for each strain in adult...
Explanatory note on the withdrawal of the Note for guidance on harmonisation of requirements for influenza Vaccines and of the core SmPC/PL for inactivated seasonal influenza vaccines

- Adopted by CHMP January 2014
- Removal of annual clinical trial - 2015-2016 season
Evaluation of serological trials submitted for annual re-licensure of influenza vaccines to regulatory authorities between 1992 and 2002


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Medicines Evaluation Board, The Hague, The Netherlands
Department of Virology, Erasmus University Medical Center, Rotterdam, The Netherlands
Department of Zoology, University of Cambridge, Cambridge, UK
1. 06 March 2014
2. EMA/PRAC/135943/2014
3. Pharmacovigilance Risk Assessment Committee (PRAC)

4. **Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU**

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<tr>
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Weblinks

Concept paper:

Quality module (draft):

Harmonisation:

Withdrawal note:

Interim guidance:

Voordouw Vaccine paper: