Seasonal vaccine approval
- EUROPEAN UNION -
Jim Robertson
National Institute for Biological Standards and Control
Routes for approval

• National

• Mutual Recognition procedure
  ✓ must have already received a marketing authorisation in one Member State; compulsory for all medicinal products to be marketed in a Member State other than that in which they were first authorised

• Centralised (via EMA)
Regulations and guidance

European Commission
- Directive 2001/83 EC + amendments (mutual recognition)
- Regulation (EC) no 726/2004 (centralised procedure)

EMA website
- Pre-authorisation regulatory and procedural guidance
- Vaccine (general) specific guidance
- Influenza vaccine guidance
EU Seasonal vaccines
(not comprehensive)

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<th>National</th>
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Annual updates

National/Mutual recognition

European Commission

NOTICE TO APPLICANTS

A GUIDELINE ON FAST TRACK PROCEDURES FOR HUMAN INFLUENZA VACCINES

MAY 1999

Being revised to take into account Variations Regulations
Annual updates

Centralised

Procedural advice on the submission of variations for annual update of human influenza inactivated vaccines applications in the centralised procedure

8 November 2010
EMA/CHMP/BWP/99698/2007 Rev. 1
Committee for Medicinal Products for Human Use (CHMP)

Annex I. variation application(s) content for live attenuated influenza vaccines

21 July 2011
EMA/CHMP/BWP/577998/2010
Committee for Medicinal Products for Human Use (CHMP)

Being revised to take into account Variations Regulations
Variation regulations

COMMISSION REGULATION (EU) No 712/2012
of 3 August 2012
amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

Article 12 refers to mutual recognition/decentralised procedures
Article 13F refers to national procedures
Article 18 refers to centralised procedures

Commission guideline on the details of the various categories of variations
(2010/C 17/01)
Variations Regulations

• The Regulations define a Type-II variation as a major variation that may have a significant impact on the quality, safety or efficacy of a medicinal product.

• The Regulations and the Classification guideline set out a list of changes to be considered as Type-II variations.
New influenza guidelines

22 September 2011
EMA/CHMP/VWP/734330/2011

Committee for Medicinal Products for Human Use (CHMP)
Concept paper on the revision of guidelines for influenza vaccines

New guidance will replace:
• Pandemic guidelines
• Harmonisation guideline
• Cell culture guideline
• LAIV guideline, etc.
Quality issues

Guideline on Influenza Vaccines – Quality Module

DRAFT

EMA/CHMP/BWP/310834/2012 (March 2013)
Vaccine Working Party and Biologics Working Party (VWP, BWP)

Scope: vaccines for which experience exists -
• Inactivated, seasonal, pre-pandemic, pandemic
• Live attenuated, seasonal
• Annual updates
Non-clinical and Clinical

• Under development
Seasonal updates

Note for Guidance on Harmonisation of Requirements for Influenza Vaccines
(CPMP/BWP/214/96)

- Yearly choice of strain
- Labelling
- Potency
- Batch release
- Clinical trials

Small numbers of subjects (2 x 50)
Assess immunogenicity and tolerance

Under review
Novel vaccines

Guidance available

- Recombinant DNA products
- Adjuvants
- Pre-clinical assessment
- Clinical assessment
- DNA vaccines
- Viral vectored vaccines
Links for guidelines and Commission documents highlighted