Pandemic Influenza Vaccines: Update on EU Regulatory Planning

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EU Mutual Recognition Procedure for Licensing

- First national MA by RMS — 210 days
- MRP – phase — 90 days
  - objections from CMS → day 50
  - applicants' response → day 60
  - break-out meeting → day 75
  - final position → day 85
  - end of MRP → day 90
- Licence for RMS and CMS only

EU Fast Track Procedure for Annual Update of Influenza Vaccine Licences (Mutual Recognition type II variation)

- Assessment of quality data

  → agreement between MS by day 42

- Assessment of clinical data

  → agreement between MS by day 68

- National approval within 5 working days

  i.e. day 73

Problems with EU pandemic vaccination strategies

Data from H5N3, H2N2 and H9N2 vaccine clinical trials suggest that currently - licensed vaccines and vaccination strategies are unlikely to provide adequate protection against pandemic influenza

European Community Influenza Pandemic Preparedness Plan

October 1998

"In the event of an influenza pandemic, there will be no time to review applications for MA's as it is done today ……
There is a need, in the interpandemic phase, to put in place a procedure which would permit the ongoing review of data as they become available ……. a 'rolling review' process"

EU Note for Guidance on Pandemic vaccines (in preparation)

Identification of issues

- Type of vaccine and vaccination schedule not likely to be licensed
  - –Possibilities include, monovalent, egg/cell, ± adjuvant, whole virus/split/subunit, one/two doses, different antigen content, reverse genetics seed virus
- Little time to review new licensing dossiers
- Little time to conduct clinical trials before vaccine licensing
- Little time for normal QC tests
- Vaccine potency reagents may not be available
- Little time for official batch release

EU Note for Guidance on Pandemic vaccines (in preparation)

Proposals

- A core MA dossier for a ‘mock up’ vaccine to be prepared in advance
  - –Quality
    - Validation of production processes and testing strategies
    - Data needed for virus produced by reverse genetics
  - –Pre-clinical
    - Safety profile of new adjuvant
  - –Clinical
    - Use of published or existing data
    - Development of correlates of immunity
    - Trial populations
    - Safety database

EU Note for Guidance on Pandemic vaccines (in preparation)

Proposals

- Fast track licensing and testing procedures developed in advance
  - Rolling review process for pandemic MA dossier
- A pandemic MA dossier prepared at onset of pandemic
  - Approval of quality data only?
  - Clinical data to be submitted later?