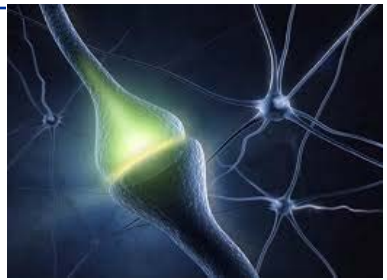
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/IFAH Europe Info Day
Procedural Update – Pre-authorisation procedures

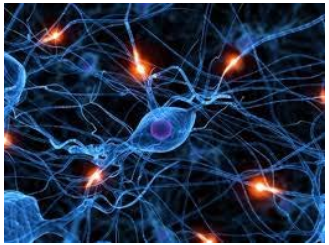


Presented by Fia Westerholm on 18 March 2016
Head of Veterinary Medicines Department

I. Overview of support during development

Upon request from company/applicant:

1. Micro-, small- and medium-sized-enterprise (SME) registration
2. Minor use minor species (MUMS)/limited market classification
   - Draft revised guidelines on reduced data requirements published on EMA website for consultation until 31 July 2016
3. Scientific support
   - Innovation Task Force (ITF) briefing meetings – early phase dialogue
   - Scientific advice - specific questions
     - Possibility for parallel scientific advice EMA -FDA/CVM



Request forms and standard procedure descriptions are available on EMA website

II. Overview of procedures in preparation for submission

1. Pre-submission meetings – Regulatory advice and scientific guidance
2. Eligibility for centralised procedure – Mandatory or optional
3. Notification of intent to submit - Appointment of rapporteurs and project manager
   - *Improved efficiency – process improvement*
   - *Better use of network expertise - multinational assessment teams*
4. Invented name check – acceptability of product name
5. Determination of need for accelerated assessment

Request forms and standard procedure descriptions are available on EMA website

Notification of intent to submit a marketing authorisation application – improved efficiency

- Request from applicant is required 7 months prior to submission
  - Applicants encouraged to identify realistic submission dates to avoid delays
  - Provided notification is received 2 weeks prior to start of next monthly CVMP meeting, EMA will process request through this CVMP meeting, else it is deferred to next month
- CVMP delegates evaluate possibilities to include application in their national work planning and to use multinational assessment team, and come forward with offers
- CVMP appoints (co)rapporteurs, EMA appoints project manager, applicant is informed of outcome in writing
  - Total time 2-4 weeks (up to recently 4-8 weeks)
  - Any delay to be communicated to vet.applications@ema.europa.eu and project manager

Multinational assessment teams – better use of network expertise

- Maximise use of available resources and expertise in EU network.
- Involve more CVMP members in assessments as (co)rapporteur.
- Lead to broader sharing of work load.
- In case of lack of specific expertise/resources required for an assessment, using (an) expert(s) from other national component authorities (NCAs) in (co)rapporteur's experts team will allow that the application can be taken on.
- Multinational assessment teams are established at time of appointment of (co)rapporteurs, on the basis of offers from CVMP delegates
  - Applicant is informed

Multinational assessment teams

III. Submission and pre-authorisation assessment procedure

1. Centralised receipt and technical validation of application in place
   - queries to vet.applications@ema.europa.eu
   - validation previously by project managers
2. Assessment milestones: list of questions, outstanding issues, oral explanation, opinion; followed by decision-making process by European Commission
   - *Quality of assessments - assessor guideline revised in December 2015*
3. Post opinion: preparation and publication of European Public Assessment Report (EPAR)
   - *Applicant's role*

New guideline for assessors – impact on centralised procedure

- Commitment to provide high quality and consistent scientific opinions
- Need to facilitate consistency and coherence in the assessment of dossiers in the European Union
- CVMP Guideline on the principles for preparing assessment reports for veterinary medicinal products (EMA/CVMP/450781/2015) completed 2015
  - Published December 2015
  - Replaces previous guideline from 2005
  - Related templates under update/implementation
  - Network assessors to be trained in 2016/2017

European Public Assessment Report (EPAR) – published for transparency

- Scope: Published for each product application on EMA website
  - Authorised products (EPAR), refused product applications (refusal EPAR, REPAR) and withdrawn applications (withdrawal EPAR, WEPAR)
- Timing: Aim to publish within 30 days after Europan Commisson Decision/withdrawal
  - Brief summary of opinion is published at opinion time on EMA website
- Content: Summary for the public (Q&A, all EU languages), product details, presentations, product information (summary of product characteristics, manufacturing authorisation holder responsible for batch release, conditions, labelling, package leaflet), and scientific discussion
- Update: Changes triggered by post-authorisation procedures

EPAR – applicant's role – focus on facts and CCI

- Summary for the public
  - Comments from applicant invited prior to translation and publication
- Scientific discussion
  - Basis is CVMP assessment report as adopted
  - Applicant invited to identify commercially confidential information (CCI), for EMA consideration and deletion in liaison with rapporteurs if needed
    - The principles to be applied for the deletion of CCI for the disclosure of EMA documents are published on the Agency website (EMEA/45422/2006)
    - Additional comments on factual inaccuracies are taken into account, however other additions, replacements or deletion of information are not accepted.
  - Endorsed by CVMP
- Applicant informed prior to publication

General queries and requests:

vet.applications@ema.europa.eu

Thank You.