EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Recent experiences with the centralised procedure

Opportunities for development

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Presented by Teresa Potter on 17 March 2017
Scientific Administrator, Development and Evaluation of Medicines

Content

- Aim – to share some experiences and provide some feedback on the centralised procedure
- Observations – from recent years with the centralised procedure (mainly new applications and extensions)
- Relevant to applicants/marketing authorisation holders, ASMF holders, manufacturers, CVMP, CMDv, rapporteurs, EMA
- What do we intend to do with it?
  - Today
  - Draft Best Practice Guide on adherence to timetables
  - Business process improvements

Veterinary Division Business process streamlining project

- Aim to rationalise and streamline administrative processes for main veterinary procedures to maximise efficiency and generate capacity
- Started Q1/2 2016: implementation mainly Q1/2 2017
- Supported by an informal advisory group of CVMP
- Industry was consulted (survey, interviews)
- Adapt and adopt best practice to align the Veterinary Division with human procedures
- Adjust roles and responsibilities within Division to support revised processes
- Scope did not cover: scientific quality; IT; fees
- Some administrative changes started 1 February e.g., no signatures on opinions, electronic sign off and transmission of all CVMP outcomes, etc
- Other administrative simplifications to follow

Communication - throughout all stages of the procedure

- Mostly good between applicants and EMA
- ASMF holders – communication between ASMF holders/applicants/EMA – presubmission re ASMF number, use of CTD and not eCTD, their use of Eudralink, etc; then also at day 70/85; day 120; during 1st clock stop; day 150; day 180; during 2nd clock stop
- Inspections – to avoid delays to applications – ensure all relevant sites are ideally authorised/inspected before submission; any sites authorised only for the production of Human medicinal products - ensure necessary changes are made ASAP before submission
- Communication between applicants and rapporteurs – (no longer at pre-submission meetings; EMA secretariat only); draft Best Practice Guide; clarification meetings

Prior to submission

- Draft Best Practice Guide on adherence to timetables
- Letter of intent - 7 months prior to submission; confirm submission date approx. 3 months before
- New (EDQM) Standard Terms process
- Product information
- Queries relating to submission process – EMA guidance; if issues encountered with eSubmission Gateway contact EMA IT service desk (training materials on eSubmission website)
- Fully updated dossiers at end of the procedure are not wanted
- Avoid delays with validation – ask any queries well in advance:
  - vet.applications@ema.europa.eu in relation to a specific submission
  - 'AskEMA' can be used for more general regulatory queries (bottom of EMA website, 'Send a question')

Product information (SPC, labelling, package leaflet)

- New QRD templates, etc
- Product information
  - some good draft product information at time of initial submission, but too often of poor quality
    - compliance with templates and guidance
    - content
    - readability
    - English
  - consider labelling early, and then again before day 180
    - check proposed texts will fit onto the labels in 3(+) or worst case languages

During clock stops

- At day 120: default is 6 m. clock stop – inform EMA well in advance (even if unsure if month x or x+1) – rapporteurs need to be informed ASAP
- At day 180: default is typically 2–3 m. clock stop. Difficulties appear to arise when applicants try to submit too quickly (for the next month) especially when there is an oral explanation with CVMP. Applicants advised to take time to ensure their best written responses and then their presentation are submitted in the appropriate timeframes.
- Delays in submission of responses: 1 m. = OK, inform EMA; CVMP approval needed for >1 m.
- New guidance on oral explanations
- Inspections - no changes to manufacturing sites with the responses to the List of Questions (LoQ) or List of Outstanding Issues (LoOI)

Clarification meetings

- Encouraged! (especially after receipt of List of Questions)
- Only for seeking clarification of (major) question(s) in the LoQ or LoOI
- Applicants need to identify well in advance which questions need clarification (and why)
- Not to be used for applicants to present their proposed responses and seek pre-assessment
- Ideally within 2 weeks after LoQ or LoOI
- Benefits – increased clarity for applicants; aim to reduce LoOI
- Note: only the views of the rapporteurs (not all CVMP members)

Conclusions

- Overall the communication works well
- Some opportunities for improvement have been identified and are being addressed
- Future - we look forward to continued exchanges with applicants

Thank you for your attention

Further information

Contact: teresa.potter@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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