EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

E-presentations
- Latest developments -

EMA/IFAH-Europe Info Day 2013

Presented by: Dr Kornelia Grein
Head of Veterinary Medicines

Content

- Status
- Developments
- Strategy on e-submission
- Update on guidance available

Status

- E-submissions in the Veterinary Sector for several years (Agency: since 2010).
- Most submissions for centralised applications are nowadays electronic.
- Survey by TIGes vet for all EU including MRP/DCP and national applications.
- Standard: PDF files, NTA structure, VNees
- TIGes vet sub group, joint meetings with industry, guidance to ensure consistency in requirements

Developments in 2012

- As adjustment was necessary for procedures for applicants and regulatory authorities to comply with e-submission requirements, the Agency accepted in first years dossier submissions not fully in line with requirements.
- Initial applications CD-ROM or DVD, later submissions often as email, different routes/addressees.
- **Changes since June 2012:** full compliance with guidelines, streamlining of procedures.
- 1st Validation step: Technical validation, 100% compliance with VNees checker
- VNees: Veterinary Nees (= **N**on **e**CTD **e**lectronic **s**ubmission), free of charge from the Belgian or French agencies' websites (links under: http://esubmission.ema.europa.eu/tiges/vetesub.htm).

Developments in 2012

Recommendations to applicants (Procedural announcement 13 April 2012):

- Check e-dossiers prior to submission, using the VNeeS checker.
- If 100% compliance is not achieved for reasons outside the influence of an applicant : justification.
- Correct labelling of any electronic submission, at least: product name, procedure number, and – as required - procedure stage (e.g. response to questions).
- Initial applications: CD or DVD
- Submissions via EudraLink/e-mail should only be addressed to vet.applications@ema.europa.eu, (copy to the product specific mailbox, if known); Not to individual staff members.
- Submit 1 week before recommended submission date.

Developments - Strategy

- **Single Agency repository** for e-applications developed, adaptation from repository for human medicines applications to veterinary applications (centralised and MRL applications).
- Will allow better product life cycle management.
- Once fully tested, change in internal business process.

- **E-Application Form** for veterinary submissions available.
- The technical issues around a defined list of veterinary substances that prevents widespread uptake is being addressed.

Developments - Strategy

- **Route for e-submissions** veterinary for the future:
- EMA Gateway is at present only to be used for human medicines submissions and not for veterinary submissions.
- The Common European Submission Platform (CESP) developed by Heads of Medicines Agencies for MRP/DCP allows submission to participating national authorities for veterinary MRP/DCP procedures or national applications.
- EMA eSubmission programme board established for strategy.
- Need to ensure alignment between the future eSubmission Gateway and CESP has been recognised and a strategy to ensure this is being developed.

Developments - Strategy

- A holistic approach is sought to the future roadmap for e-Submission across the human and veterinary areas.
- Close involvement of Heads of Agencies in agreeing future solutions.

- No plan to adopt eCTD for veterinary submissions.

- VICH: Guideline on electronic file formats (PDF files) is being developed, VICH Expert Working Group will start working shortly.

Update on guidance available

The TIGes vet has adopted several new/updated guidance documents, which are published on the TIGes vet website (see: http://esubmission.emea.europa.eu/tiges/vetesub.htm)

- Guideline on eSubmission for Veterinary Products – version 2.2
- VNees checker
- eSubmission Validation checklist - version 2.2
- Frequently asked questions
- Guidance on how to prepare a Table of contents (G-TOC Guidance)

eSubmission

VET eSubmission

- Home
- Human eSubmission
- Veterinary esubmission
- TIGes
- Documentation
- Projects:
  - Central Repository
  - eCTD
  - eAF
  - EU Module 1
  - eSubmission Gateway and eSubmission Web Client
  - eCTD NMV/RPS

The TIGes Veterinary subgroup was set up in September 2006 with the objective of developing and implementing standards for the submission of electronic information in the context of European veterinary medicines approval procedures.

Current Guidance

- Guideline on eSubmissions for Veterinary Products - version 2.2 **(Updated January 2013, effective July 2013)**
- VNeeS Checker (**Updated January 2013**)
  - National Agency for Veterinary Medicinal Products in France (ANMV)
  - Federal Agency for Medicines and Health Products in Belgium (FAGG-AFMPS)
- Templates for folder structure (2011)
  - Agencia Española de Medicamentos y Productos Sanitarios
- eSubmission Validation checklist - version 2.2 **(Updated January 2013)** Download
- Frequently Asked Questions (FAQ) **(Updated January 2013)**
- G-TOC recommendations **(January 2013)**

Useful Links

- Correlation table CTD - NtA structure
- Guidance for e-submissions to EMA

EU Change Control Process

- Change Control Process (**Updated December 2011**) Download
- Change Request Tracking table **(Updated January 2013)** Download

General TIGes Veterinary Documents

- Electronic Application Forms – For Variations and Renewals
- Terms of Reference - Download **(June 2012)**
- E-submission Roadmap - Download **(June 2012)**

Historical Documents

Conclusions

- Continued increase of e-submissions for veterinary medicines
- Familiarity with processes and standards = increased compliance with guidelines
- Streamlining for EMA procedures
- Electronic application form – remaining issues being addressed
- Development and alignment of secure EU transmission system
- TIGes vet : cooperation Member States, EMA, industry. Updated guidance

Thank you!