Europe IFAH
Representing the European Animal Health Industry

Electronic submission – Industry perspective

Dr. Michael Colmorgen, IFAH-Europe

2013 European Medicines Agency/IFAH-Europe Info Day

8 March 2013, EMA, London

Today's topics

- Status of implementation and challenges
- Change Management / Revision of TIGes guidance
- Related projects
- Lessons learnt for ICT governance
- Global e-submission?
- Vision

Status of implementation - 2013

- **VNeeS implementation – a manageable effort**:
  - Simple tools sufficient to create submission ("standard" PC software), no review tool required.
  - Overall not overly costly nor complicated.
- Benefits of e-submission as such not in question.
- Industry has invested in training, tools and hardware.
- Electronic submission has become daily praxis for many regulatory affairs professionals, **but** …

Status of implementation - 2013

Initial hurdle at times where there are fewer and fewer resources:

- Impact on **internal processes** in industry
  - authoring, archiving, IT security etc.
  - can be a major effort
- Capability and resources of **local affiliates?**
  - Dossier creation tends to be more centralised, but simple tools still allow direct input of affiliates.
  - Faster implementation for harmonised procedures.

Implementation challenges

Some challenges remain!

- **Security** - unprotected transfer of CDs/DVDs
  - ➢ Important to proceed with single portal solution.
- Often questions arising related to **dossier structure** ("Notice to Applicants" requirements)
  - ➢ Decoupling electronic transfer specification from specific dossier structure?

    These are different topics!

Implementation challenges

- The “original” is now electronic - how to **archive**?
  - ➢ Challenge of fast changing IT environment
    - o But dossier files must be readable, easily retrievable and precisely visually reproducible today and in many years time.
  - ➢ New and **synergistic** approaches to archiving are needed on industry and regulator’s sides!

Implementation challenges

- **New** set of **national requirements** (specific for e-submission)
  - Avoid national requirements.
  - No additional paper documents (at least for portal submission!)
  - Guidance on NCA submission requirements: Resolve gaps for specific NCAs, resolve inconsistencies and consolidate information.
  - Refer to harmonised TIGes veterinary guidance.

Implementation challenges

- Potential improvements of regulatory **process**
  - e.g. CMS acceptance of **RMS technical validation**?

    Does only work well for “1 identical dossier” <u>without</u> national adaptations.

    Efficiency of a standardized e-submission process strongly benefits from absence of national dossier requirements!

Implementation challenges

- Consistent **“technical validation”** of e-submissions needed
  - … seems to improve based on experience gained.
  - Clear set of common validation rules helpful.
- Still also **diverse quality of submissions by industry** – e.g. degree of navigability
  - Observe also best practices to increase efficiency of review process!
  - “Common-sense” approach helpful.

Implementation challenges

- **Mandatory** e-submission?
  - Needs monitoring of progress in e-submission.
  - Follow strategic approach across EU instead of single MS focused activities.
  - Allow transition periods.
  - Keep fall-back paper process (MA transfer, SME, MUMS?)
- **Are there other issues, that can be solved by (change of) TIGes guidance?**

E-submission Change Management

A **change process** should

- safeguard **stability** of requirements (important to ensure efficient processes),
- ensure **pragmatism** - keep formats simple and pragmatic,
- represent the interest **of all stakeholders** who may be affected by changes,
- be driven by **business needs of the veterinary sector** aiming at cost effectiveness,
- allow for appropriate **implementation periods**!

E-submission Change Management

Practice of change management?

- Any stakeholder may submit a question / change request concerning TIGes veterinary guidance documents

  For further details see
  http://esubmission.emea.europa.eu/tiges/vetesub.htm

- Seek alignment within your association / agency before submission.

E-submission Change Management

- TIGes vet **Change Control Group**

  to align positions across stakeholders,
  to prepare decisions in TIGes veterinary plenary,
  to speed up process.

  - Meets virtually

  - Representatives of regulatory authorities (NCAs, EMA) and stakeholders (AVC, EGGVP and IFAH-Europe)

2013 revision of TIGes guidance

- Next revision to be implemented by **July 2013**
- Specification has **not changed much** over about 2 years.
  - Considering **experience** gained and providing **clarification**.
  - Avoiding **technical validation issues.**
  - **Synergies** with other sectors (e.g. alignment of specific validation rules with (human) NeeS).
  - Major new “best practice” issues related to **efficient navigation** of submissions.

Related initiatives - eAF

- Electronic application form (eAF)
  - **in principle good idea**!
    - PDF forms are easy to use.
    - Structured data (XML) can be used to feed authority tracking systems and finally product databases.
- However **forced alignment to paper** is inappropriate for eAF.
  - ➢ Think out of the box of the paper world!

Related initiatives - eAF

- Too **narrow mandate for changes** to the eAF (changes without involvement of NtA group?)

- Use of **standardised terminology**
  - Do not underestimate the effort to build-up and validate complex EUTCT lists (especially substances…).
  - Many terms initially missing - Nothing can be perfect from beginning – But then keep some flexibility for data entry.
  - Change processes for standard terms need to be ready and transparent.

Related initiatives - CESP

- **Simple** mechanism
  to send information **securely** and
  simultaneously to many agencies

HMA Heads of Medicines Agencies **Common European Submission Platform**

- **Quite positive feedback** from users
- For full efficiency **broad acceptance needed** by NCAs and industry
- **One single portal** remains future target
- **No national requirements!**

European ITC governance and strategy

- **Streamlined** overall governance process needed
  - Review of process welcomed.

- Appropriate **business involvement** to be assured for **veterinary sector.**

  - Both **strategic** and **technical implementation.**
  - Need of forum with **overall process and system landscape overview for veterinary sector** (Need to ensure compatible systems.).
  - Keep in mind though **resource implications** for the veterinary sector!

European ITC governance and strategy

- Ensure **short decision-making channels** (sufficient mandate of representatives).
- **Avoid silonisation** of industry versus regulators, topic is a classical win/win.
- **Share** best practices/lessons learned.
- **Continue** current good level of cooperation!

Global e-submission?

- Still long way to go…
- IFAH-EU strongly supporting VICH initiative on **common file format requirements**
- Goal – refer to **standards** (e.g. ISO)
  - Keeps technical parts short and simple.
  - Easier to head for synergies across sectors (e.g. pesticides, and others)
- Avoid too specific tools that are not applicable across regions.

Vision?

- Efficient electronic processing of
  - ➢ **1 harmonised dossier**
  - ➢ compiled according to **1 specification**
  - ➢ uploaded via **1 secure portal**

- **Global re-use** of modules (e.g. study data)

➢ Supporting **efficiency of the overall business process!**

Thank you for your attention!

Any further thoughts?
Questions?

(Glossary on next slide…)

Glossary

CCG	Change Control Group
CESP	Common European Submission Platform
eAF	electronic Application Form
eCTD	electronic Common Technical Document
PDF	Portable Document Format
EUTCT	European Union Telematics Controlled Terms
TIGes	Telematics Implementation Group for Electronic Submission
VNeeS	veterinary NeeS (“Non-eCTD electronic Submission”)
XML	Extensible Markup Language