Federal agency for medicines and health products

Practical aspects of working electronically in the Network

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Agenda

- How the agency started in 2005 to work exclusively electronically (human licensing) and its rationale, lessons learned
- How the agency went mandatory electronic submissions, with own validation tool (NeeS checker) zero tolerance and later full compliance
- The performance improvements, scale economies at that time (e.g. parent and child)
- Publication of leaflets (H/V)
- The current interests and developments: veterinary esubmissions, business intelligence, working remotely
- The future focus points: connectors to portals, eCTD viewer, imports from electronic application forms, attention to long term archiving, digital signatures

Rationale to work electronically (1/2)

The drivers are :

- Reduction of the administrative burden.
- Reduction of physical archive space.
- Reduction in shipment fees both for applicants and agencies.
- Facilitation for *harmonised processing.*
- Facilitation of *automated processing* (workflow, automated mails).
- Facilitation of the review process.

Rationale to work electronically (2/2)

Continued :

- A large archive (35 TB) with response times < 2s
- Re-use of former information, economy of scale.
- Facilitates centralisation, both at applicants and agencies (platforms, portals).
- Automated reporting, Business intelligence, KPI's -> Balanced Score Card.
- Capacity or resource planning is encouraged
- Creation of authentic sources (e.g. for agency website, eHealth).
- Facilitation of dynamic offices (efficient occupation for many part time jobs).
- Facilitation of tele work, dynamic offices.

How the agency started in 2005 to work exclusively electronically

- Study 2002-2004: new back office and case management system with (i) document management and (ii) workflow.

- October 2005: MeSeA architecture (Filenet) in production. Focus on only electronic submission at the Licensing department: initially 4 different formats, currently reduced to NeeS and eCTD formats.
  - Required Change management to move from paper to electronic.
  - Agency: Training and equipment: assessors, case managers with dual screens at the office and at home.

How the agency started in 2005 to work exclusively electronically

- ICT Architecture: Integration of document management system (DMS), database and workflow. Each of these three aspects is important for the agency.
- A DMS is a generic platform to store submissions and dossiers of any type at the agency. The datamodel for medicinal products is based upon EU RDM v 1.0.
- For historical IT architectural reasons, LCM of the eCTD is partially implemented -> need to integrate with eCTD tools.
- eCTD tools in production (since 2011), trainings supplied.

How the agency started in 2005 to work exclusively electronically

- NeeS: in production since October 2005, electronic only (i.e. returning paper dossiers to the applicant)
- Starting in March 2007 with zero tolerance and rejection of dossiers, gradually. Now we see a compliance rate of 98-99 % to folder and files structure on national, MRP, DCP procedure, both with national as European applicants.

  Conclusion: Obtained by training with wonderpil structure and checker, learning phases with feedback from checker, working step by step in dialogue with applicants.
- Checker implements a subset of the EU NeeS criteria v3, this subset is updated and communicated.
- Automated handling is essential for Agency performance when dealing with huge volumes. It is essential to reduce the number of manual steps. For example, the upload procedure is fully automated (e.g. upload, checking, feedback (mail) to applicant, payment tracking).

Agency challenges

- Performance and health are paramount. Quality of submissions facilitates processing and evaluation of submissions.
- Former Introduction of parent dossier (e.g. 20 mg) and a child for the 10 mg. The child only contains the documentation specific for the 10 mg.
- Introduction of scale economies: e.g. groupings (NeeS) which are validated in a single operation.
- Problems with technical quality of submissions lead to 2 issues: e.g. life cycle mgt issues, but also to expensive communication with the applicant.
- Harmonisation within Europe: The RMS validates for the CMS in MRP/DCP.
- Alignment with legislation and new developments: e.g. Cesp. Easier to automate.

Current developments

- Veterinary licensing is now also in the Filenet system. Since 1st January 2013, Belgium is mandatory paperless for veterinary licensing.
- Publication of the SPCs and leaflets (in the three official languages in Belgium) for all medicinal products commercialised in Belgium, with automated maintenance of the versions.
- Developing business intelligence, via a data warehouse. Data warehouse is a central database in sync with production systems. Reporting: Start with office tools, to move to more efficient tools.
- Since some time we have regulation of remote working by agency staff. In practice, the agency ICT systems facilitate this extensively (vpn, ADSL lines, infrastructure at home).

The future focus points

- Automated connection to two EU systems is anticipated:
  - The first system concerns the EMA central repositories
  - The second system concerns the Cesp. First we plan a automated dispatch of the incoming messages, later an automated upload into our document management system. Possible compulsory use of Cesp by applicants.
- Future automated upload of structured application forms for licensing. Since EudraCT7, this is in production for the clinical trials authorisations.
- For one application, related to the clinical trials, we started with certificate signed outgoing PDFs for the trial authorisations. Possible scale up to all outgoing authorisations.
- With a restricted (Led by HR) sub workgroup of TIGes, the best archive practice (BAP): attention to long term archiving of the submissions.
- Integration of eCTD viewer to our document management system.

Regulator's Wish list

- Patient safety, efficacy, Cost effective processing.
- Performant submission formats and technology.
- More structured data in future – eAF is a good start.
- Efficient archiving and retrievals.
- Reduction in the number of parallel standards/systems.

- Confirmed trends in the wish list: Harmonisation and centralisation
  - EMA: Centralised procedure: large interest in central repositories: cost- effective solution for NCA's.
  - HMA: Central submissions: Cesp for MRP/DCP/NP.

- Adherence to standards by all applicants (larger and SME) and agencies.

Thank you !