EDM Agency Update
Swissmedic
Dr. Urs Niggli
Swissmedic

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Overview

1. Look back: Implementation of eCTD
2. eSubmission Solution of Swissmedic
3. Statistics
4. Experiences with eSubmissions
5. Future Steps
   • eSubmissions
   • IT Roadmap / IT Architecture
   • Submission Process
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Look back: Implementation Steps of eSubmissions

<table>
<thead>
<tr>
<th>Initial Applications</th>
<th>Variations</th>
<th>Complete Life Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applications Types Step 1 (as of January 2010)</td>
<td>Applications Types Step 2 (as of July 2010)</td>
<td>Applications Types Step 3 (as of January 2011)</td>
</tr>
<tr>
<td>New applications:</td>
<td>1. Variations requiring a notification procedure</td>
<td>1. PSUR</td>
</tr>
<tr>
<td>1. NAS: New Active Substance</td>
<td>2. Variation requiring authorization without scientific review</td>
<td>2. Parallel Import</td>
</tr>
<tr>
<td>2. NGF: New Galenic Form</td>
<td>3. Variation requiring authorization incl. scientific review</td>
<td>3. Application for 5 years Data Protection</td>
</tr>
<tr>
<td>3. NKC: New Combination</td>
<td>4. Variations requiring authorization of the product information (SmPC, patient information)</td>
<td>4. Co-marketing</td>
</tr>
<tr>
<td>4. BMS: Known Active Substance</td>
<td>5. DMF/PMF</td>
<td>5. Prolongation, renunciation of prolongation</td>
</tr>
<tr>
<td>5. GENERIC</td>
<td>6. Applications according to Paragraph 13 TPA (pilot)</td>
<td>6. Renouncement of authorized medicinal products</td>
</tr>
<tr>
<td>6. IE: New Indication</td>
<td></td>
<td>7. Applications according to Paragraph 13 TPA</td>
</tr>
<tr>
<td>7. NDE: New Dosage Recommendation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. NDC: New Dosage Strength</td>
<td></td>
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</tr>
</tbody>
</table>

Not realised yet: eSubmissions for veterinary products
Elements of the eSubmission solution Swissmedic

- Specification and Guidelines
  - Q&A
  - Guidance for Industry
  - Swiss Module 1 Specification
  - Swiss Validation Criteria
- Technical Solution
  - Review Tool
  - Validation Tool
- Processes and Guidance
  - Step 1: Initial Applications
  - Step 2: Variations
  - Step 3: remaining Processes
  - Support concept
- Support and Training
  - eSubmission Web Site
  - Intranet Web Site
  - Introduction Events
  - Training Modules

Swissmedic eSubmissions Web Site (updated continuously):
www.swissmedic.ch > Authorisations > eSubmissions Swissmedic

Support is provided at:
esubmissions@swissmedic.ch
(Single Point of Contact, 24 hours response time)

Number of requests via the Single Point of Contact:
eSubmission Solution Swissmedic

Currently valid eCTD-specific documents

Guidelines and Specifications:
- Questions & Answers of Swissmedic eCTD Implementation V1.3
- Swiss eCTD Validation Criteria v1.1
- Swiss Module 1 specification for eCTD v1.1
- Guidance for Industry on Providing Regulatory Information in eCTD Format v1.2
- Guidance on Applications according to Paragraph 13 TPA for eCTD Applications v1.0

Forms:
- Form Technical Validation eCTD
- Check list Content Validation
- Check list Content Validation eCTD Paragraph 13 TPA

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Statistics

Number of eSubmissions (Applications) Jan to Oct 2011:

- 17% of all new applications (69 of 344) are eSubmissions
- eSubmissions are used mainly for NAS applications (new active substance) → 60% of all NAS applications are eSubmissions
- 176 eSubmissions have been submitted for variations

New Applications (NA) Jan to Oct 2011:
- NAS: new active substance
- NAS div: new dosage strength, new galenic form, new dosage recommendation, new indication
Statistics

Number of eCTD sequences received Jan 2010 to Oct 2011:

Number of companies which submitted eCTDs first time:

Total number corresponds to approx. 15% of the pharmaceutical companies for human medicinal products.

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Experience with eSubmissions

Experience with processes, tools and staff

- Paper and electronic processes have to be pursued in parallel.
- Efficiency potentials can not be fully utilised.
- Paper and electronic processes require different skills, especially at the process level of document reception and technical validation.
- More advanced tools are required to handle the electronic submissions internally (Business case management, document management).
- Technical and business validation issues are often close together. Therefore communication to the applicant should be in one step.

- More advanced tools are required to handle the electronic submissions internally (Business case management, document management).

Currently, traditional office tools and file shares are used for internal distribution of information.

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Experience with eSubmissions

General experience with eSubmissions

- Full use of eCTD can be taken only if requirements are met. This requires discipline on both sides applicant and Swissmedic. However, flexibility is granted whenever possible.
- There is a continuous learning and collecting of experience about eCTD on both sides, Swissmedic and industry.
- Many applications use eCTD without problems. Applicants new in the field of eCTD need some time and practice to meet requirements.
- Small applications (e.g. variations requiring notification procedure) require much more time for publishing (applicant) and processing (Swissmedic). Internal processes have to be further optimised to enhance efficiency.

Experience with eSubmissions: typical problems and mistakes

- Lifecycle issues
  - lifecycle operators
- Naming convention
- Hyperlinks
  - broken or missing hyperlinks
  - references not hyperlinked
- Wrong use of the "common" folder
  - M1 contains only "common" folder in case of one galenic form (dosage form)
- "Re-naming" of galenic form (dosage form) in subsequent eCTD sequences
- Large documents do not contain bookmarks

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Experience with eSubmissions

Experience with eSubmissions: typical questions via SPOC

- Placement of documents in the xml backbone
- Lifecycle issues in M1
- Way of submitting the documents (w or w/o signature, scan vs. OCR, etc.)
- How to prepare and submit baselines (currently approx. 30 baselines have been submitted to Swissmedic)
- How to use and prepare consolidation sequences
- Hyperlinking
- Interpretation of technical validation errors
- Swissmedics plans to implement the new EU technical validation criteria

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Future Steps: eSubmissions

Update of documents based on change requests and requests through SPOC

- Swiss M1 specification and Q&A
- Updates as necessary

Introduction of new EU validation criteria:

- Swissmedic will introduce the new EU validation criteria by next year
- Introduction has not been scheduled yet

Introduction of eMed for veterinary medicinal products

- Swissmedic is in touch with TIGes vet
- Introduction TBD

Introduction of NMV eCTD standard based on ICH specification v4.0

- Swissmedic is observer for EFTA at the ICH
- ICH step 4 sign-off is planned for 2014
Future Steps: IT Roadmap / IT Architecture

- eGovernment portal: Online Forms - Track & Trace
- SAP/Finance, Controlling, Procurement, Billing, HR
- Core System for Case Management and Pharmaceutical Database (SAP CRM)
- eCTD EURS or Yours (EY)
- Product Information System
- E-Collaboration

- Basic architecture elements, e.g., identity management, secure data transmission, machine to machine data gateway (Sonic), external access.

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Future Steps: IT Roadmap / IT Architecture

<table>
<thead>
<tr>
<th>Project name</th>
<th>Project description</th>
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<tbody>
<tr>
<td>DRP</td>
<td>SAP ERP implementation (finance, controlling...)</td>
</tr>
<tr>
<td>PRIME</td>
<td>Case Management, Planning, Medicinal Product Database</td>
</tr>
<tr>
<td>APS</td>
<td>Advanced Planning &amp; Scheduling</td>
</tr>
<tr>
<td>DQS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>eCTD</td>
<td>Electronic Submission (eCTD)</td>
</tr>
<tr>
<td>FPE</td>
<td>Registering of Company and of Primary Vigilance</td>
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<tr>
<td>NDS-INT</td>
<td>Control of Narcotics</td>
</tr>
<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
</tr>
<tr>
<td>MEDREG</td>
<td>Register of Health Professionals</td>
</tr>
<tr>
<td>DMS</td>
<td>Electronic Document Management System</td>
</tr>
<tr>
<td>eGov-Portal</td>
<td>E-Government Portal/ implementation</td>
</tr>
<tr>
<td>MIS</td>
<td>Management Information System</td>
</tr>
<tr>
<td>IFM</td>
<td>Medicinal Product Information System</td>
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</tbody>
</table>
Current business process model:
Business cases are managed individually in each sector (decentralised)

New process model:
Central submission process will be established for sectors Authorisation, Market Surveillance and Licensing.
The Submission Team will be placed in sector Infrastructure (outside sectors Authorisation, Market Surveillance and Licensing).

First Step (implementation 2012)
Submission Process:
• reception of application and correspondence
• start of business case or assign to business case
• technical validation
• formal (business) validation
• internal distribution

Incoming Correspondence

Second Step (implementation tbd)
Submission Process:
• finalisation and shipping of correspondence
• billing
• verification of business data
• closing of dossier and business case
• etc.
End of Presentation

Thank you for your attention!

Dr. Urs Niggli
Head Submission (Jan 2012)
niggl@swissmedic.ch

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