

# e-CTD Implementation in Belgium



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Medical and Pharmaceutical  
Consultancy and Applications

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## New ways of working in Belgium



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## New ways of working in Belgium

- **eSubmission Guidelines** – New ways of working at DGMP Version 1.1 27/07/2005
- Circularly letter n° 462 of 29/07/2005: e-submission of registration files for medicinal drugs
- 3/10/2005 a new integrated computer system was implemented which allows the evaluation of eCTD: FILENET

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## eSubmission Guidelines in BE Introduction (1)

- 2003-2004: Business Process Reengineering project conducted at DGMP  
Conclusion:  
Implementation of new **back-office** and **case management system** with document and workflow management capabilities

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## eSubmission Guidelines in BE Introduction (2)

- In order to:
  - Automate administrative processes and improve the operational efficiency of the BE NCA
  - Accelerate case management and decision-making processes
  - Eliminate paper handling (storage, copying, transportation, confidential shredding, etc.)
  - Increase communication and knowledge transfer

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## eSubmission Guidelines in BE Introduction (3)

- In order to:
  - Enable access to a centralized data model in line with EU legislation
  - Further improve the quality carried out by the BE NCA
  - Build an electronic interface to industry stakeholders for electronic applications and communications

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## **eSubmission Guidelines in BE**

### **The integrated IT system within DGMP**

Phase 1: Implementation of an integrated computerized management system for the Registration Department (02/05 – 10/05)

- Electronic dossier handling & management
- Documents & data management

Phase 2: Extension of the system to the other departments of DGMP (11/05 – 06/06) + access via a secure Portal

- R&D (Clinical trials)
- Vigilance
- Proper use of the Medicinal Product

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## **eSubmission Guidelines in BE**

### **Main changes in the registration process:**

5 steps:

2. Submission of “Letter of Intent” prior to submission of dossier and definition of fee
3. e-Submission according to Guidelines
4. At each step of the process, the applicant will be informed of the dossier status
5. MAD = AMM issued directly by the system
6. Portal available in 2006

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## eSubmission Guidelines in BE PORTAL

When the portal will be ready, applicant will be able to:

- Fill in online forms directly on the Portal
- Upload files and dossiers to the eSubmission system via the Portal
- Check status of submitted dossiers
- Check its portfolio of MA (AMMs)

## eSubmission Guidelines in BE Scope of the eSubmission program

- 1st run:            only HUMAN allopathic drugs
- 2nd run:           other drugs: Human homeopathic  
                         other issues: pharmacovigilance
- 3rd run:            other drugs: Veterinary ...

## **eSubmission Guidelines in BE**

### **eSubmission system went live on 10/05**

Phase A: prior to 10/05: paper + electronic (full & variations Type II)

Phase B: between 10/05 and 01/07: electronic following guidelines

Phase C: after 01/07: only eCTD

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## **eSubmission Guidelines in BE**

### **Recommendation:**

Start using eCTD first for new drug applications and capitalize on this eCTD dossier to submit variations in order to manage the product's lifecycle more easily

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## eSubmission Guidelines in BE Accepted e-dossier format

- Type 1: full eCTD
  - eAF based on eCTD specifications in XML format
  - eDocuments (PDF) in eCTD XML backbone
- Type 2: partial eCTD
  - eAF based on eCTD specifications in XML format
  - eDocuments (PDF) in eCTD directory structure
- Type 3: minimal eCTD
  - AF in MS Word or PDF
  - eDocuments (PDF) in eCTD directory structure

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## eSubmission Guidelines in BE Contents per type of application

- 1) **New submissions (EU & Nat.):**  
Type 1 (or Type 2 if not feasible)
- 3) **Variation Type I A & B, II (EU & Nat.):**  
Type 1, 2 or 3
- 5) **Renewals (EU & Nat.):**  
Type 3

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## eSubmission Guidelines in BE How to submit to DGMP?

- Send compressed documents via e-Mail ( dgg\_dispatching\_dgm@health.fgov.be) unless its size is larger than 40MB
- Burn type 1, 2 or 3 application on CD-Rom and send to DGMP Dispatching with paper cover letter

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## Industries implementation Defining key factors for success



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## Overview

- Policy and Communication
- Planning
- Resources
- Standards
- Procedures
- Infrastructure
- Training
- Legal aspects

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## Policy and Communication

- Support by top management!!!
- Adequate organisational change management
- Internal and external communication strategy promoting business benefits
- Guidance on eCTD implementation
- Successful day to day management of RA department with long term view

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## Planning

- Common policy (BE NCA & Industry) to develop a consistent strategy and implementation plan
- Common long term implementation plan
- Phased implementation approach – careful but determined steps towards electronic only environment
- Work on the pretext of: “once eCTD, always eCTD”

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## Resources

- Adequate **human** resources
- Adequate **financial** resources
- Adequate **time** frames

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## Standards

- Timely development of standards
- Adoption and implementation of EU and BE standards in own Standard Operating Procedures (RA SOPs)
- Increase structured data content of eCTD

## Procedures

- Reorganisation/restructuring of RA departments if needed
- Revision of internal RA SOPs: working procedures for validation, access, review, validation, liberation and archiving
- Integration of old paper based applications with new electronic applications
- Adequate handling of Life Cycle Management

## Infrastructure

- User friendly working environment
- hardware and software requirements
- free to low-cost tools and invest in time saving eCTD tool
- implementation and training of eCTD software
- interfaces with internal systems
- backup and storage longevity
- e-Signature

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## Training

- IT staff
- RA staff
- experimental submission

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## Legal aspects

- Appropriate legal environment
- Legal acceptance of electronic archiving
- Successful implementation of legislation

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## sprl MPCA bvba Roadmap

- Contact with IABG-LSS 22/07/05
- Purchase, installation and training in 08 & 09/05
- First dossiers uploading in eCTD Manager as per 10/05
- Submission at DGMP of 14 new submissions & several variations
- Validation at DGMP Dispatching is ongoing

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## sprl MCPA bvba Experience with eCTD Manager

- Easy to learn, user-friendly and time saving
- Overall automatic tool
- No extreme high investment costs
- **“once eCTD, always eCTD”**

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## sprl MCPA bvba Conclusion

eCTD submission is still very new in EU/ Belgium but there is no way back ...

Time moves fast and once you get used to eCTD and electronic filing in general you work in a very comfortable situation (no copies, easy archiving, ...)

**...eSubmissions is the future in worldwide pharmaceutical affairs**

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**THANK YOU FOR YOUR ATTENTION!**

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