PIM & QRD

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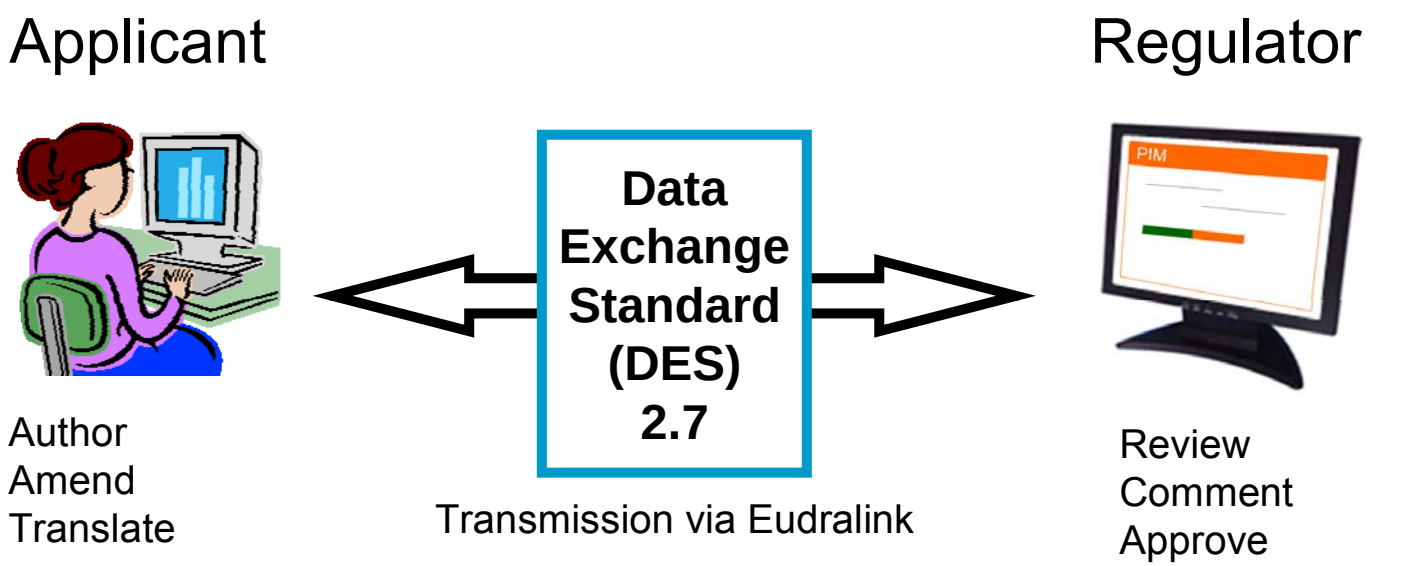
PIM - Overview

- Introduction to PIM
  - What PIM is
  - PIM Systems
- Status of PIM
  - Pilot Phase
  - Data Migration
- Plans and challenges
  - Opportunities and challenges for MAHs
  - The way forward

What is PIM

- PIM (Product Information Management) is a system for the electronic exchange of product information
- New marketing authorisation applications and post-authorisation submissions in the centralised procedure
- Compliant with the Quality Review of Documents (QRD) templates

PIM Systems



Key : LAT = Light Authoring Tool
PDVE = PIM DES Validation Engine
PRS = PIM Review System

PIM Systems

Data Exchange Standard (DES) v2.8

- Driven by regulatory and business requirements
  - Implement readability changes to the package leaflet
  - Support non-conflicting overlapping comments
- Release for testing technical changes while waiting for package leaflet text
- Will be supported by PIM Review System v6 and used for the migration exercise

PIM Review System (PRS) v6

Objective	Progress
Improve the PRS performance and scalability	• Issues identified and new architecture to remedy issues • Build started, interim load test to confirm new architecture
Improve the usability of the PRS	• New user interface being designed with user interface experts and user group • Main pages redesigned and approved by the user group
Improve the PRS document compare	New algorithm selected and being implemented with user involvement
Provide all high priority requirements	High priority requirements for PRS 6.0 being implemented

PIM Status

Pilot Phase

- 5 companies participating
- 7 products
- 4 MAAs
- 3 migrations
- 26 PAPs

Issues encountered

- Technical (DES) and systems
- Training
- Change management
- No SME involvement

Type	No.
Initial MAA	4
Migration	3
Line Extension	1
Renewal	2
Annual Reassessment	1
Variation Type Ia	1
Variation Type Ib	1
Variation Type II	20

** Data up to March'10*

PIM Status

Data Migration

Current Activity

- Conclusion of Data Analysis of all CAPs (SmPC only)
  - No changes to DES, improvement in template adherence
- Proof of Concept: Pre-Migration Quality Review
  - Reduce migration effort by resolving issues earlier
- Proof of Concept: Applicant led migration
  - Confirm: Process; Resource; Guidance
- Consolidation and publication of guidance

Planned Activity

- Proof of Concept: Agency led migration
- Migration timetable

Opportunities for MAHs

- Improved compliance with QRD guidance
- Concentration on content rather than format
- Improved quality of product information
  - Consistency through re-use
  - Improved delivery mechanisms for patients
- Improved commenting process
  - Not reliant on track changes
- Improved version control
- Long-term added value of XML-tagged information
  - Improved comparison across products

Challenges for MAHs

- Learning sufficient information about PIM
- Transition from Word-based to XML-based processes
- What does the Agency-led migration look like?
- Migration of authorised product information
  - Aligning with QRD and identification and correction of errors
  - Scheduling of migrations
- Maturity of PIM tools and services
  - Sufficient choice of commercial tools that are well tested
  - Robustness of the Light Authoring Tool
    - Will it be the right tool for your company/process?
  - Sufficient service providers for those MAHs
    - Needs to be in place before large-scale migration programme

The way forward

EMA committed to PIM
(SoI under revision)

Full engagement
(MoU)

Production use

Data Migration

PIM Extension

QRD – Overview

- The QRD Secretariat
  - ➢Role & Activities
- The QRD Group
  - ➢Role, Mandate & Functioning
- Product Information (PI) Quality Review
  - ➢Key milestones
  - ➢Revised PIPIT Procedure
- ➢ QRD role in PIM

The QRD Secretariat

- Part of Medical Information (MI) Sector since 2006
- Sits in MI Product Information Quality (PIQ) Section since September 2009
  - PIQ Section covers 3 main areas
    - Quality Review of Documents (QRD) activities
    - Mock-up & Specimens review
    - Name Review Group (NRG) activities
- Currently consists of a total of 11 staff
  - 6 ADs + 3 AST + 2 AST (int)

QRD Areas of activity

- Product Information (PI) Quality Review
- Secretariat of the Quality Review of Documents (QRD) Group
- Product specific or general issues
- Legislation, guidance, reference documents
- User testing
- Standard Terms
- Active involvement in the PIM Project
- Translation services (CdT)

The QRD Group

- QRD Group established in June 1996 to handle linguistic aspects of Product Information
- Composition
  - European Medicines Agency (chair & secretariat)
  - Member States (1 Human + 1 Vet)
  - European Commission
  - Norway & Iceland (as observers)
  - Translation Centre (based in Luxembourg)
- Meets at the EMA in plenary meetings 4 times per year

The QRD Group

QRD mandate (under review)

- To ensure clarity, consistency and accuracy of the medicinal product information and of its translations
- To verify the terminology used in translations
- To promote legibility of patient information
- To contribute to the development of common understanding on the implementation of legislation and guidelines

The QRD Group

QRD plenary meetings

- Topics for discussion come from legislation, PI ongoing reviews, external queries, PTLs, MSs, etc.
  - Requests for combined printed PLs (justification + SPC&PL)
  - Requests for simplification of labelling (art 63 Dir 83/2001)
  - Specific issues with regard to expression of strength
  - New standard terms
- Particicipation of PTL + QRD Secr assistance with documentation
- Outcome of the topic discussion communicated to applicant by PTL after the meeting minutes are drafted.

PI Quality Review

Key stages

- By Day 120: EN PI undergoes a preliminary "technical" check (PIQ Technical review) by EMA QRD staff (ensure template compliance, correct location of information, identify issues such as combined PLs, expression of strength, standard terms, linguistic issues, etc.)
  - ► Interaction PTL - Applicant
- + Day 121: EN PI reviewed again by EMA QRD staff + MSs QRD members + relevant patients' organisation (only PL)
  - ➢ Day 165 QRD sub-group meeting
    - At the request of the applicant
    - Not mandatory; only if major issues need discussion (otherwise, writing/TC)
    - PTL/PTM meeting chair + EMA QRD Secretariat assistance
    - 2 MSs QRD members + 2/3 representatives from applicant
  - ► Interaction QRD Secretariat (PTL) - Applicant

PI Quality Review

Key stages (cont.)

- Right before Opinion: final check of EN PI by EMA QRD Secr to ensure correct implementation of QRD comments
  - ► Interaction PTL (QRD Secr) - Applicant
- After Opinion: Review of all languages PI by MSs QRD members (with coordination and assistance from QRD Secr)
  - ► Interaction MSs QRD members & QRD Secr - Applicant

PI Quality Review

Revised PIPIT Guidance

- Impact of new Variations regulation
  - No QRD review on the EN PI for any type of Variation (Type IA/IB/II). Only when major changes are introduced, internal decision to be taken.
  - Linguistic review for Type IBs affecting annexes.
  - Grouping and worksharing arrangements.
- Generics/Hybrids/Biosimilars
  - EN review only by EMA (pre- and post- D120). For hybrids/biosimilars normal QRD pre-opinion process to apply (with MSs review).
  - EMA proactive role in transmitting final translations of originator to generic company.

PI Quality Review

Revised PIPIT Guidance (cont.)

- D110 PIQ comments sent to applicant as part of Day 120 List of Questions (no longer as a separate set of comments).

- Handling of PI for SMEs
  - Early coordination with PTL of EN PI assessment
  - Translations performed by CdT (except NO/IS)
  - Coordination with EMA SME Office throughout

QRD role in PIM

- QRD Secretariat part of the PIM DES Team since 2003
- QRD currently represented in most PIM Project Teams (via QRD Secr or QRD MSs)
- Close collaboration with EMA PM Sector with regard to the revision of the QRD templates (DES v2.8)
- PIM is a permanent topic in the QRD Plenary meetings agenda since 2004
- External EMA QRD webpage links to QRD Templates and PIM DES → synchronised publication of QRD templates and DES
- Ongoing EMA discussion on future ownership of DES

THANK YOU