# Making best use of the PSUR Repository

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# Agenda

- Implementation Background
  - Original Requirements
  - Timelines
  - Feedback
- The PSUR process
- The Assembly and Delivery process
  - The PSUR portal
  - The delivery file
- Concrete experience
- Key points
- Thanks, Credits and References

# Background – Original requirements

- Submission
  - All PSUR related submissions by MAH without file naming convention
  - MAH to include metadata delivery file in the PSUR zip
  - ARs and PRAC comments directly into repository
- Storage
  - All PSURs, ARs, PRAC recommendations and CHMP opinions  stored and linked via Procedure Number
- Search & Retrieval
  - Relevant stakeholders can search for documents using the metadata in delivery file

# Background - Timelines

- PRAG kick-off in March 2014
- UAT started in November 2014
- Go-live in January 2015
  - Together with Pilot Phase
  - Allow testing of the various versions
- Mandatory use on 13-Jun-2016
  - File naming conventions no longer accepted
  - No backup procedure
    - Submissions no longer done locally

# Background - Feedback on the implementation phase

- UAT
  - Included PRAG industry representatives involved in the requirements
    - Meaningful and of value
  - EMA representatives very supportive
    - Questions and concerns addressed quickly and with transparency
  - Long periods of time to run scripts
- Pilot
  - Live experience allowed to identify gaps and further requirements
  - Excellent collaboration between EMA, NCAs and Industry representatives
  - Clear and complete documentation available on the EMA Website

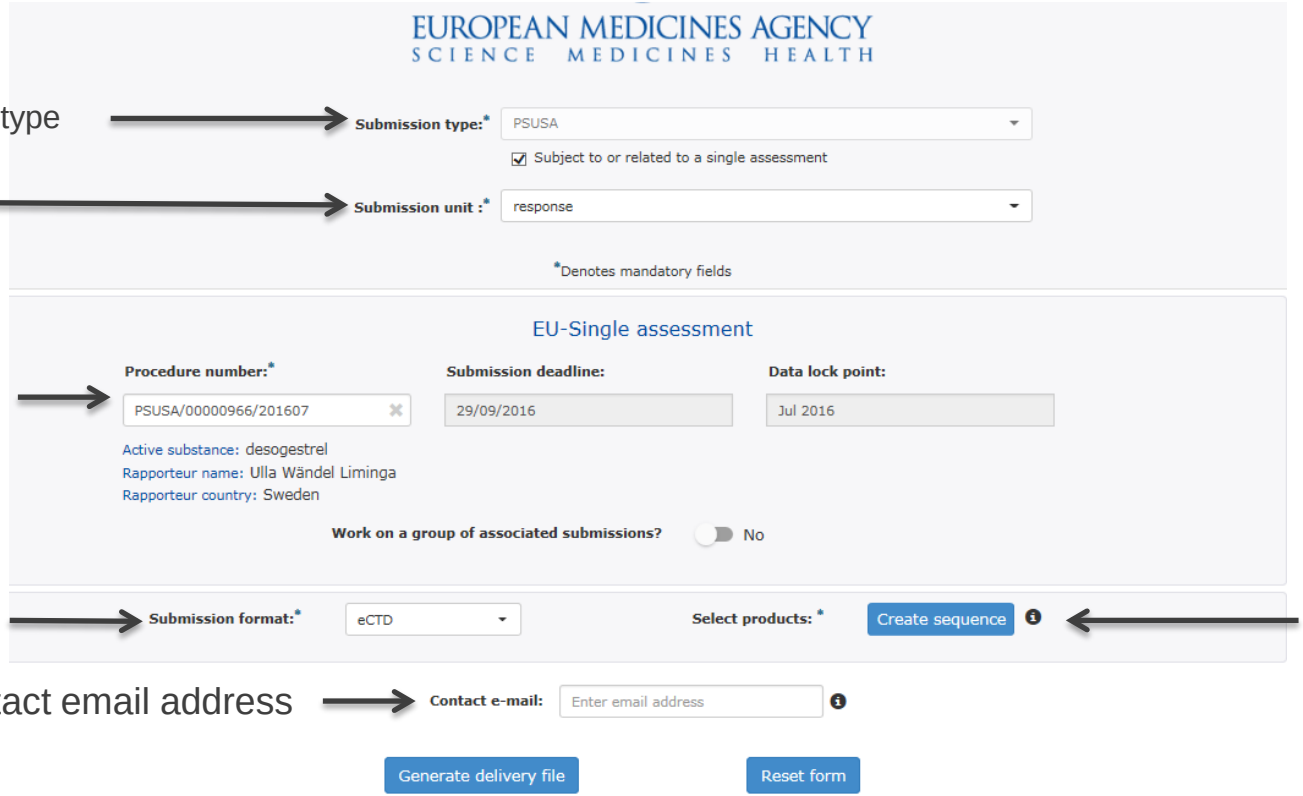
# PSUR Process – MSD

- The PSUR process is owned by the Global Safety group
  - Most other types of Submission are owned by the Regulatory Affairs groups
  - Started internally and with the EMA notifications to the EU QPPV
    - The overall process starts several months before submission date
- Planning aspect
  - Based on DLP and Submission date from the EURD list
  - Works on alerts to the various involved authoring groups
  - Will eventually trigger the Assembly and Delivery process
- Content aspect
  - Involves all authoring groups working in parallel to author PSUR content
  - Interacts closely with the planning
  - Includes QC and signoff

# The Assembly and Delivery process

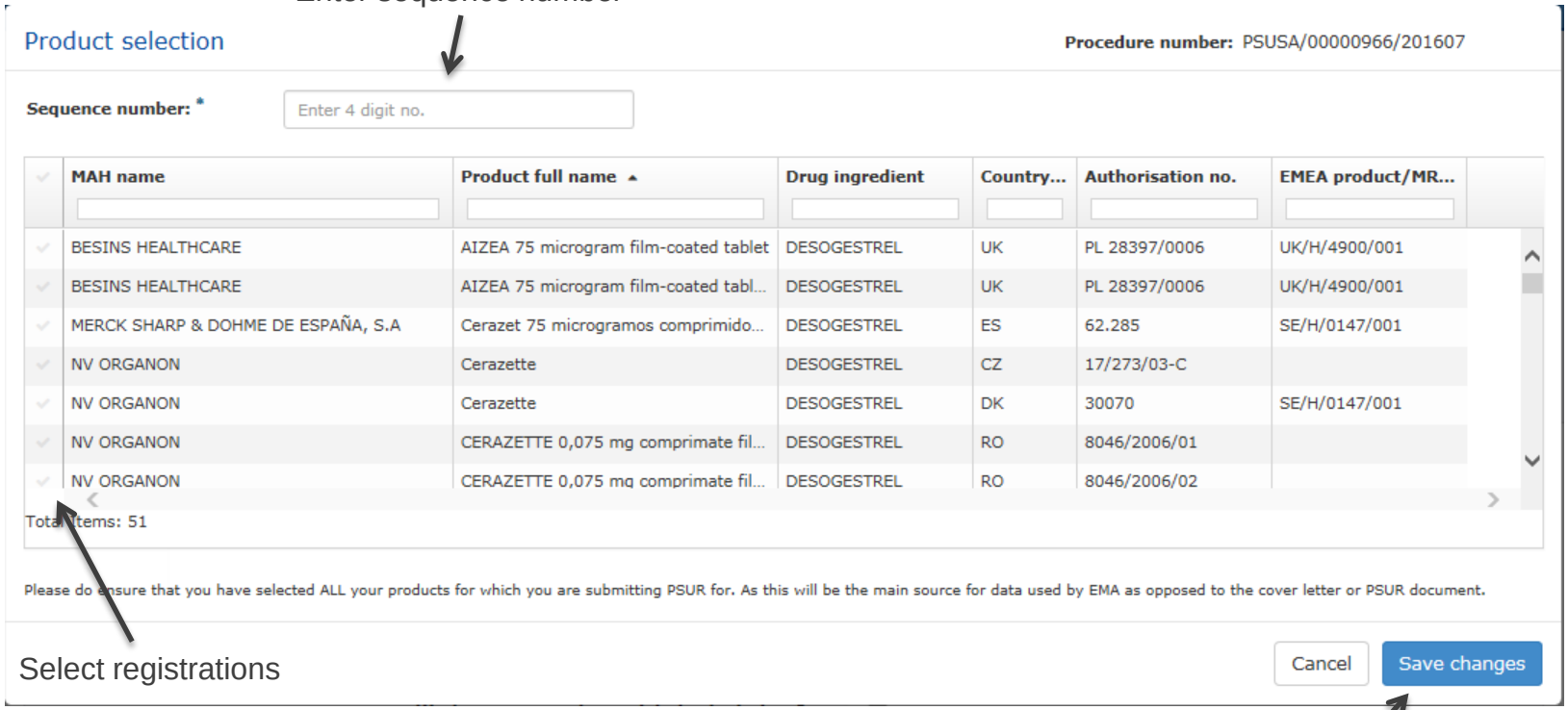
- Retrieve documents
- Build the assembly
- Create the delivery file
  - XML format
  - Contains all the metadata about the submission
    - MAH, Product Name, Substance name, PRD EV Codes, …
  - Implemented in June 2016 (for PSURs)
  - Goes along with the sequence(s)
- Send the package
  - Zip format

# The Delivery process – The PSUR Interface



# The Delivery process – The PSUR Interface

Enter sequence number




Select registrations

Save the changes

# The Delivery process – The PSUR Interface

- Available registrations are coming from the XEVMPD database
  - Only products in-scope of the procedure are displayed
  - LATEST version of the EV Codes
- Data is refreshed based on the following schema
  - 88% of the EURD entries are refreshed overnight between the DLP and the Start date of the procedure
  - 12% of the EURD entries are refreshed on DLP and on Start date. Between those 2 dates, on demand
    - Specific scope (paediatric, plasma derived substances, …)
  - Refresh stops after the Start date
    - After that, latest version of the product at Start date will be available
- Filters on Active Substance and Legal Basis
  - Other filters: Indication(s), Pharmaceutical dose, …

# The Delivery process – The delivery file

- Major changes compared to before
  - Before
    - Concerned registrations were provided via Annex1 to the Cover Letter that was part of the submission
    - NCAs relied on that information
    - Applicant could technically submit any time
  - Today
    - Concerned registrations are provided in the delivery file
    - Applicant is responsible for data accuracy
    - Applicant is restricted to submit before the Submission date
    - GSP is now directly involved

# The Delivery process – Creating the delivery file

- The biggest challenge
  - Get the right information from Regulatory Affairs
  - Make sure it matches the registrations available in the pick list
- How do we achieve that goal?
  - MSD still creates and uses the Annex1 document
  - Regulatory Affairs populate Annex1 with Authorisation numbers coming from the XEVMPD database
  - Annex1 is checked by the GSP team prior to the Submission date
    - Available 2 to 3 weeks prior to submission date

# The Delivery process – Experiences and concrete exemple

- For some products the MAH is not the «Submitter»
  - XEVMPD might not be accurate
  - Impact: Registrations not available in the pick list
  - Solution: Communication with MAH
- Some products don’t require a PSUR (Well established use)
  - EMA decision might require a PSUR submission (Referral)
  - Impact: Registrations not available in the pick list
  - Solution: Communication with EMA
- Some countries have a new Authorisation number at each variation
  - XEVMPD DB contains the number from the last renewal
  - Impact: Discrepancy between data from RA and XEVMPD DB
  - Solution: Good communication and training to RA

# Key points

- PSUR repository implementation impacted the Publishing Teams mainly
  - Delivery file process
  - XEVMPD data
  - Interaction between XEVMPD and PSUR Repository Portal
  - Bigger Interactions with the EMA
- Main challenges
  - Encountered issues require interaction with previous stages
    - RA, XEVMPD, EMA
  - Respect due dates
    - Publishing time is usually short (less than 3 days)

# Thanks, Credits and References

- Marjan Jagt-Smook – Regulatory Affairs Europe
- Elly Metcalf – Global Safety
- Guy Demol – EU QPPV
- Brenda Vanslembrouck - Regulatory Submissions Management
- http://esubmission.ema.europa.eu/psur/psur_repository.html

# Ask