Post registration processes – frequent questions and practical examples

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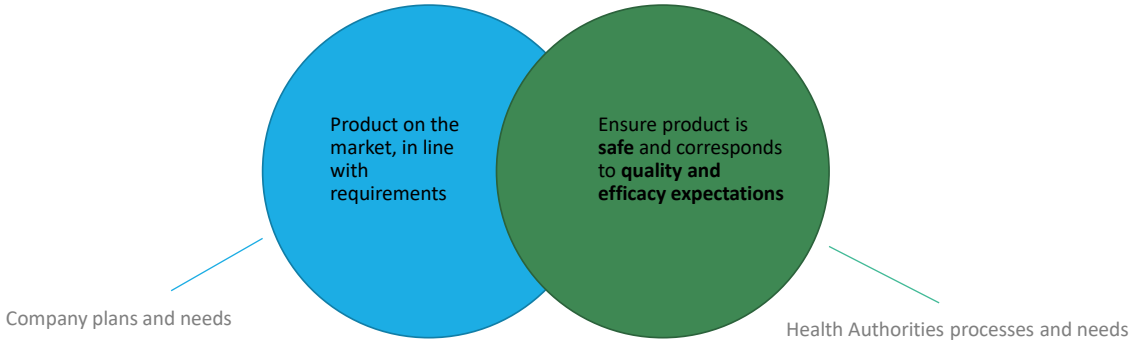
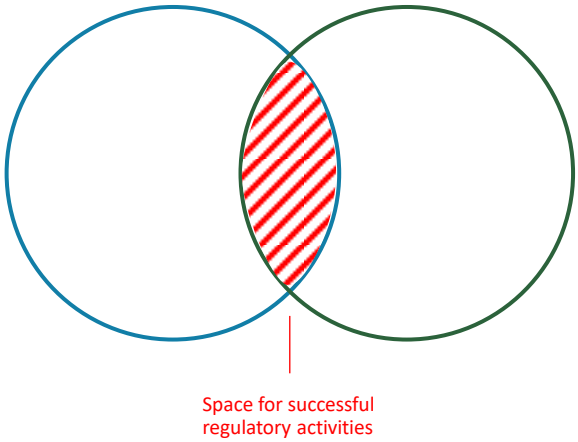
Agenda

- Strategic considerations
- Postregistration processes
- Common challenges
- Variations
- Renewal and Duplicates
- Commitments, Transfers and Withdrawals
- EMA´s IRIS
- ePI

Strategic step back – room for success

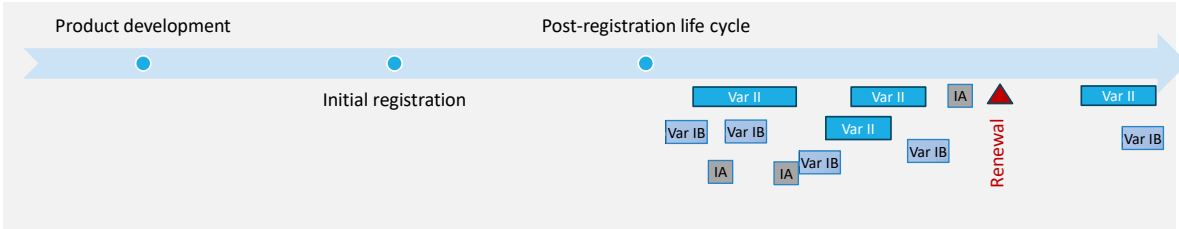


Strategic step back – room for success



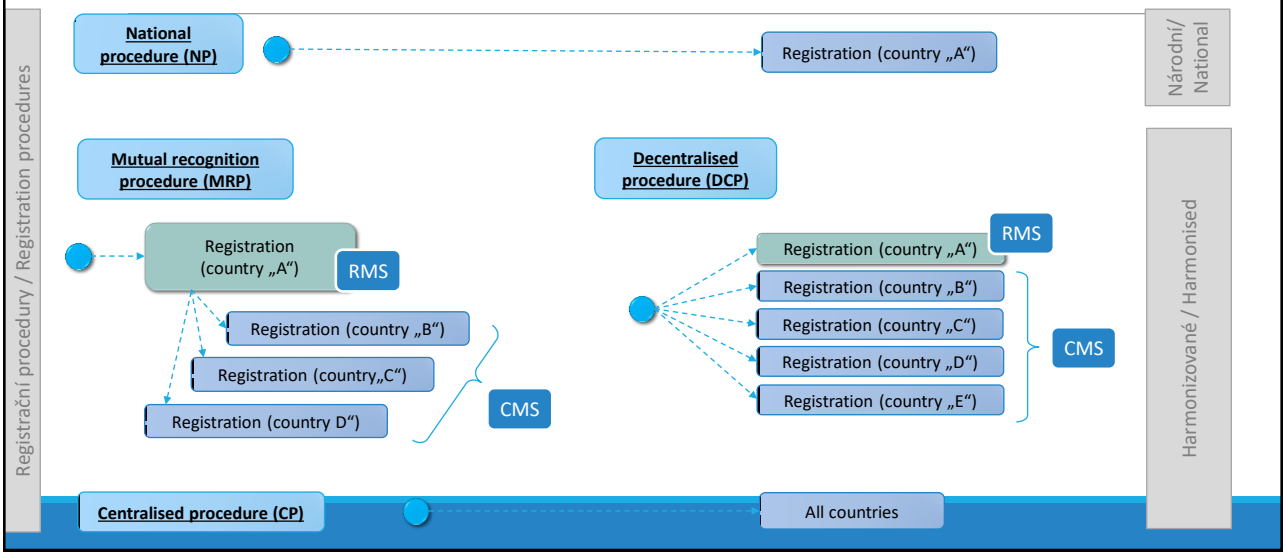
Product life cycle

Product´s life cycle (lenght) depends on many aspects – INN, product type, registrations type, commercial interest…

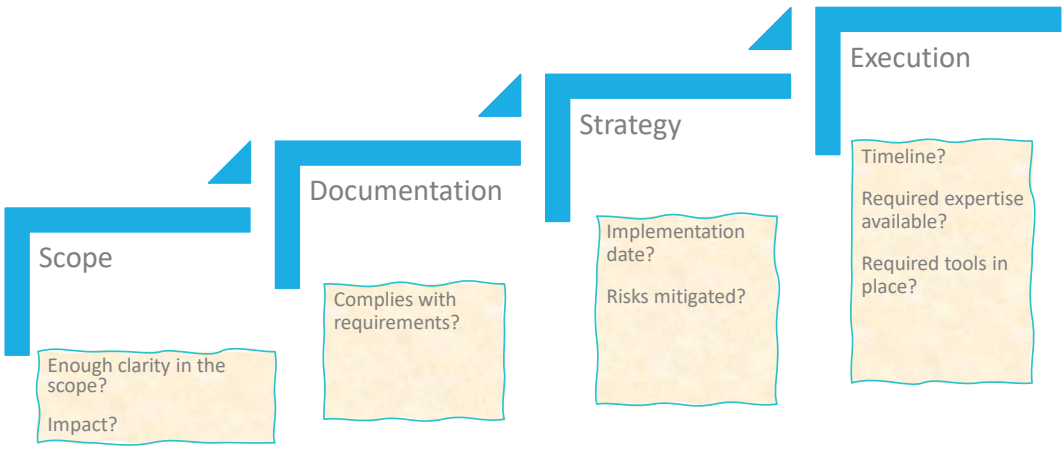


Strategic step back – stakeholder management

The initial registration and type of the product will govern the post-registration processes



Common challenges

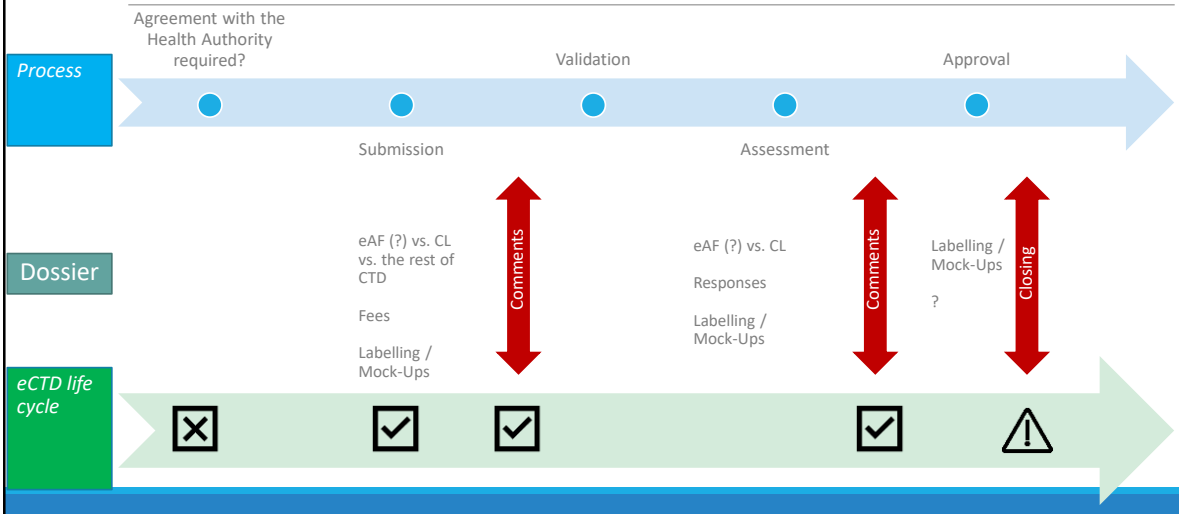


Post-registration processes

- Anything related to regulatory post MA authorisation

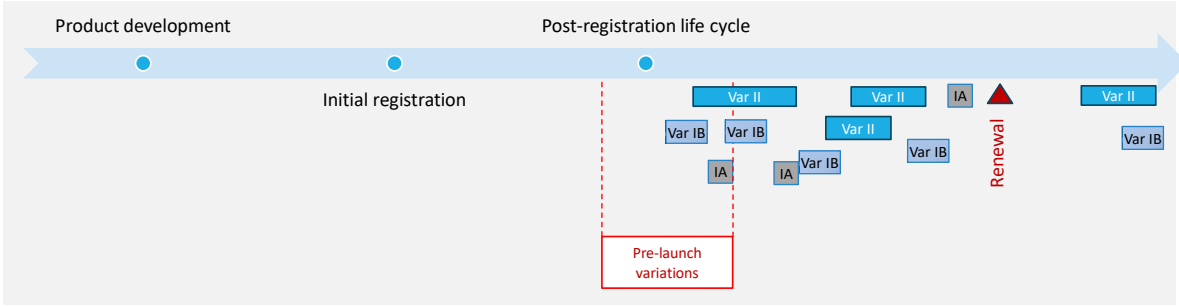
- Most frequent ones:
  - Variations
  - Renewal
  - Duplications
  - Commitments
  - MAH or RMS transfers
  - Withdrawals

Common challenges



Product life cycle

Importance of critical variations understanding



Variations

- „Do & tell“ – implemetation prior submission possible
  - Validation + 30 days assessment
  - No HA comments possible
  - Submission vs. Implementation date
    - Type IA → within 1 year
    - Type IAin → within 14 days
- „Tell, wait & do“ – requiring approval
  - Type IB – 30 days assessment with comments
  - Type II
    - Timeline depending on initial registration type
    - Comments during assessment
- With impact on packaging
  - Anything from above
  - Mock-ups changes
    - National specifics - type P in CZ, notification in PL…

- Timeline for approval
  - Standardized?
- Labelling impact?
  - IB vs. Type II **!**
- Batch release impact
  - IA vs. IB
  - IA vs. IB/II
- Grouping
  - IA groupings
  - Mixed groupings

Renewal & duplicates

Renewal

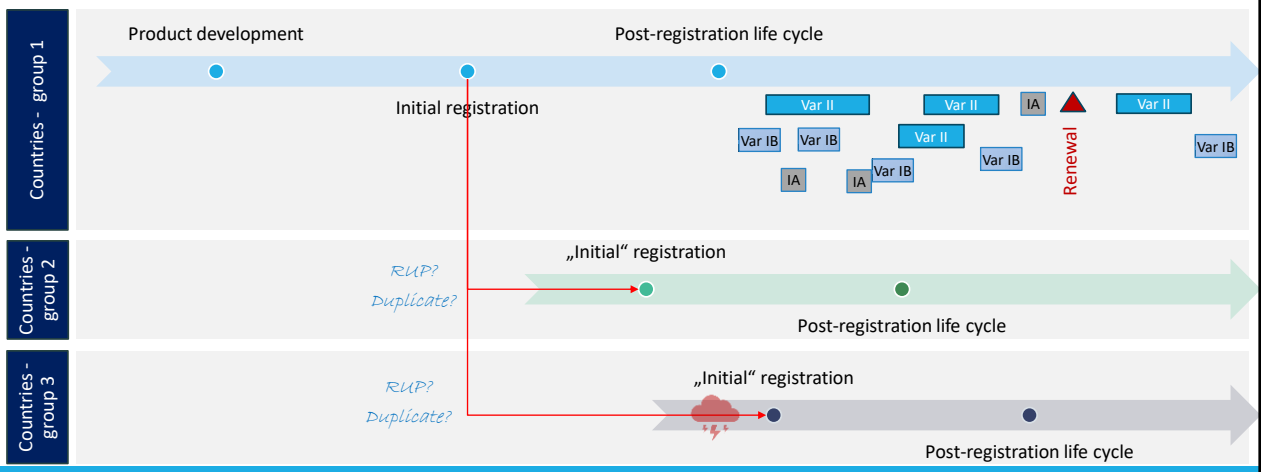
- Precise understanding of submission date
- Simplified vs. standard procedure
- Creating „breathing space“ for the renewal
  - Ongoing variations during renewal?
- Validity of the MA during an ongoing renewal

Duplicates

- This is regarded as a NEW registration (MA) application !
- Precise planning & preparation
- Timely and detailed agreement with a Health authority
  - Steps and timelines to be agreed
- Creating „breathing space“ for a duplicate

Product life cycle

Importance of preparation and risks assessment



Commitments, Transfers and MA withdrawal

Commitments

- Data promised to be delivered „post-authorisation“ (relevant to the procedure)
- Formal assessment process differs at MSs and EMA, depending on commitment type, data type, procedure etc.
- Strict deadlines for submission, delays or postponment must be negotiated with relevant HA

MAH transfer

- Administrative
- Suitability of the new MAH
- Data alignment

RMS Transfer

- Prior Agreement with the new RMS is a must!
- Approaches/willingness to become a RMS differs among EU MS HAs

Withdrawals

- Administrative process
- Variation withdrawal:
  - Variation withdrawal: careful about eCTD lifecycle → correction sequence!!!
  - Change of a variation scope (e.g. Groupings): careful about eCTD lifecycle
- MA withdrawal: careful for harmonised procedures (RMS!)

Recap: IRIS transition scope

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Procedures already available in IRIS:

- General procedures (requests for RPIs for new products, change of name and address of applicant)
- Inspections (GMP, GVP, GCP)
- Marketing status reporting
- Orphan designations
- Paediatrics procedures
- Veterinary signal management
- Scientific advice
- Parallel distribution regulatory procedures
- PRIME eligibility
- Product lifecycle procedures *
  - Variations
  - Marketing Authorisation Transfers
  - Art 61.3 notifications

New procedures on IRIS from end of Dec 2024 (date TBC)**:

- Post-authorisation measures (PAM)
- Annual reassessment
- Referrals
- Post-authorisation safety study (PASS)/ Post-marketing surveillance studies (PMSS)
- Periodic safety update reports (PSUR)
- Line extensions
- Renewals

**For a subset of Human and Veterinary Centrally Authorised Products (CAPs)*

***eCTD/VNeeS submissions will be registered in SIAMED until then

***NOTE:** Submission of all regulatory procedures of the product lifecycle will still be performed via the current systems (i.e. Gateway and PSUR repository)*

FROM: EMA Training webinar on post-authorisation procedure management in IRIS for Marketing Authorisation Holders, 12 November 2024

ePI

- electronic Product Information aims to provide European Union to digitised and up-to-date product information, for healthcare professionals and patients in future
- The ePI pilot, launched in July 2023, has successfully concluded with the publication of 23 ePIs for live regulatory procedures for centrally and nationally authorised medicines
  - UAT & 1st pilot finalized
  - 2nd pilot under discussion/consideration
  - Timelines for next steps not published
  - EMA vs. Industry pressure
- The data gathered during the pilot will inform definition of a pathway towards next steps

Thank you