IDMP Data Pilot

SPOR Task Force 24.05.2019

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Statens legemiddelverk

IDMP Data Pilot

- Work performed
- Findings
- Proposals

Why data pilot?

- Good data quality in PMS
  - Correct data
  - Consistency between similar and identical products

- Possible to generate useful PhPID
- Possible to reuse data for several purposes

What has been done?

- NCA: SE, NO, ES, EE, AT, DE, FR vet +EMA
- 40-50 products described in «IDMP excel sheet»
- Issues and questions collected
- 2 F2F meetings in 2018 (September, November)
  - NCA
  - EMA
  - IDMP experts
- Input to EU IG consultation (February 2019)
- Remaining: Finalise excel sheet, show patterns for key information

Main findings

- When people are allowed to add IDMP-information with no clear rules or description to follow – similar products look very different
  - Packaging, manufactured item, device
  - Ingredient, strength, reference strength
- It is not possible to find one pattern that fit all types of products
- The pharmaceutical product are a new concept that requires additional knowledge
- IDMP allows very detailed information, especially for packaging (containers, components, devices)
- Procedure and application: IDMP is not clear enough to be able to fill in the data
- Ingredient and strength: What to do with products not authorized according to IDMP/QRD?

Proposals

- Different patterns for different products must be described clearly in EU IG
- Level of detail needs to be decided
- Controlled enrichment – Do not add data to PMS unless clear patterns and rules are described
  - structured package information?
- IDMP/EU IG Training (NCA; EMA; Industry)