Best practise / knowledge sharing workshop
Procedural Change with IDMP
WP 04
INFARMED - National Authority of Medicines and Health Products, I.P.
2024-04-02
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INFARMED

- Human Medicinal Products – clinical trials, marketing authorisation, pharmacovigilance, inspection, availability
- Health technology assessment
- Medical devices
- OMCL laboratory
- Cosmetics

April 02, 2024

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Future system

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Working data – New marketing authorisations

- National portal
- Process management system
- Medicines database

- Manufacturers
- Active substances and excipients
- Packages
- Pharmaceutical form
- Product name
- Shelf life
- Special precautions for storage
- …

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Working data - Variations

- National portal
- Process management system
- Medicines database

- Manufacturers
- MAH transfers
- Excipients
- Packages
- Product names
- Shelf life
- Special precautions for storage

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### Working data - Organisations

<table>
<thead>
<tr>
<th>Entity</th>
<th>Address</th>
<th>Version</th>
<th>Additional Info.</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayer Bitterfeld GmbH (Fab. Bitterfeld - Wolfen)</td>
<td>Ortsteil Greppin, Salegaster Chaussee 1 - 06803 - Bitterfeld - Wolfen - DE</td>
<td>100</td>
<td></td>
<td>28-07-2010</td>
<td></td>
</tr>
</tbody>
</table>

- Historical data on organisations – Start Date and End Date
- National submission portal: currently approved
- Variations: automatic update of medicines database
Working data - Organisations

National organisations database

Organisations SOP
- New/changes also validated against OMS
- ORG ID and LOC ID in database
- Data quality

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Working data - Substances

- National submission portal: currently approved formula
- Variations: automatic update of medicines database
Working data - Substances

► National substances database

Substances SOP

 ► New/changes
 ► SMS ID
 ► Data quality

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Working data - Referentials

► New system for referentials

Medicines database

Reference data

Referentials management system

► Other systems at INFARMED

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Working data - referentials

Ingredient Role list

Active
Excipient
Flavor
Preservative
Propellant
Solvent
Coating
Reagent
Printing ink
...

Active
Excipient
Solvent / Diluent
Adjuvant
Starting material for excipient
Raw materials used in the manufacture of the product
Starting material for active substance
Overage

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Working data - referentials

Manufacturing Activity list

- Manufacturer
- Responsible for Batch Release
- Labelling
- Bulk Manufacturer

... X ...

- Manufacturer responsible for batch certification
- Primary packaging
- Processing operations for the medicinal product
Working data - referentials

Legal Status for the Supply list

Medicinal product subject to restricted medical prescription – a), b), c)

Medicinal product not subject to medical prescription - pharmacy only

Medicinal product on medical prescription renewable delivery / non-renewable delivery / renewable or non-renewable delivery / exempt for some presentations
Working data - PMS

National portal

Process management system

GiMED

- Packages
- Product names
- Shelf life
- Special precautions for storage

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Working data - PMS

MAH transfers

Approx. 2900 between 2019-2023
Procedural Change with IDMP

► As IDMP implementation spreads more in INFARMED, different departments will have to include IDMP in their procedures
► National specificity: submission portals
► Where in the flow is data being entered manually – IDMP an opportunity to automate
► Where and how to introduce right now procedural changes to start progressing as much as possible in SPOR and IDMP without having to wait for major changes in the systems or databases
► Substances, organisations and some RMS lists seem to be the best candidates
► Cultural change
Thank you for your attention.