Identification and description other medicinal products

Anna Gawrońska
Institute of Logistics and Warehousing
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Other medicinal products

Non-pre-packaged medicinal products
- magistral formula
- officinal formula
- radionuclides in the form of sealed sources
- advanced therapy MP prepared on a nonroutine basis

Pre-packaged medicinal products
- advanced therapy medicinal products
- foods for special medical purposes (enteral)
- homoeopathic medicines
- herbal medicinal products
- orphan medicinal products
- medicinal products for paediatric use
- nanotechnology medicinal products
Results of the analysis

- according to the results of the gap analysis there is a need to extend the general solution developed with respect to Art.57 database with reference to some products, e.g. magistral formulas, officinal formulas, radionuclides in the form of sealed sources, advanced therapy MP prepared on a nonroutine basis
- if the same approach is adopted with reference to ‘other’ medicinal products the general solution will meet their identification needs
- product additional information, e.g. attributes should cover all specific identification needs enabling distinguishing products and determining individual differences between,
- whenever there is an attribute type missing in the product description, the database should be extended in order to meet other products’ identification needs.
Typified formulas

• Typified formulas, cannot be specified and identified across jurisdictions by using an identifier, so it must be described by their attributes

The attributes for officinal formulas are:
- Formula local identifier, if any
- Ingredients
  • Identifier, if any
  • Name
  • Strength
  • Role
- Preparation instructions
Untyped formulas – need for extension

**Untyped formulas** - for those magistral formulas that are not registered or are extended

- **Specification and cross-border identification of untyped formulas** through identifiers is not possible. In order to reference such products in a clinical document, a **specification** of the formula must be made.

For that formula, the following tree needs to be sent:

*(for the Preparation: )*  
- Preparation ID if available  
- Preparation Name if available  
- Instructions for the formula

*(For each component: )*  
- Component ID (i.e. product ID)  
- Component name  
- Role  
- Component strength  
- Quantity  
- Component dose form
Radionuclides

• Focus on radiopharmaceuticals

The IDMP can cover identification of radiopharmaceuticals
Thank you for your attention