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Meeting the challenge of open access to medicinal products across the Union

Identification and description other medicinal products

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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.

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Typified formulas

TYPIFIED FORMULAS - which includes all officinal and not-extended registered magistral 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

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Untypified formulas – need for extention

UNTYPIFIED FORMULAS - for those magistral formulas that are not registered or are extended

- **Specification and cross-border identification of untypified 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

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Radionuclides

- **Focus on radiopharmaceuticals**

The IDMP can cover identification of radiopharmaceuticals

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Thank you for your attention

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