DELIVERABLE

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Project Title: openMedicine

D3.1 Assessment of the WP2 solution for ‘other’ medicinal products

Version: 1.0 after ATR
Status: final

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## Revision History

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This document presents the definition of alternative and complementary use case where unambiguous identification of a medicinal or pharmaceutical product is needed.

Keywords
Unambiguous identification of medicinal products, alternative and complementary use cases
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Executive Summary D3.1

Relationship to overall goal of the project, to other work in this WP/other WPs:

WP2 has developed a generic solution for the identification and the description of medicinal and pharmaceutical products for human use considering commonly prescribed regulated medicinal products for humans.

WP3 is focused on assessing WP2 options for other than pre-packed medicinal products and identify possible gaps in the WP2 approach regarding identification and description of the product(s) and their content.

Task 3.1, reflected in this document, is focused on listing ‘other’ medicinal product types, identification of EU regulatory requirements and other relevant documents in order to highlight the reason for additional or separate regulations towards these products and in order to determine whether there is a potential need for any identifiers or attributes not foreseen in WP2. Moreover, this task is focused on determination of identification concepts developed in WP2 as applicable for ‘other’ medicinal products as well as identification of gaps and any limitations that occur. Conclusions of task 3.1 will be a starting point for task 3.2. This task in turn will focus on modification of the WP2 model so that ‘other’ medicinal products can be identified and described in a cross-border environment. Within the scope of task 3.2 the WP2 model will be extended and various scenarios will be provided in order to illustrate specific identification needs of individual medicinal products.

Objective:

The main goal of WP3 is to assess WP2 options for other than pre-packaged medicinal products (branded and not branded) and identify possible gaps in the WP2 approach regarding identification and description of the product(s) and their content. The scope of this deliverable is that of identifying – based on the WP2 solution - potential gaps and additional needs for the identification and the description of medicinal and pharmaceutical products when applied to ‘other’ medicinal products. This objective of this document is the analysis of the challenges. D3.2 handles the synthesis and solution description. This separation is deliberate: There was an initial risk (confirmed by the work during WP2 and during this analysis), that if the problems were analysed and solved immediately, without a design consolidation, there could be different identification approaches for different product types, or different solutions for regulatory and clinical aspects, which is an obstacle for practical implementation.

Approach/methods applied:

Various documents, predominantly legal ones, have been taken into consideration and analysed in order to determine product types for consideration in WP3 as well as any possible identification needs to be addressed.
Work process:

The development of the document was led by the Task Leader and supported actively by project members in accordance with individual competences. Numerous internal reviews took place in order to design and develop the report. Finally, an external review took place according to the adopted quality assurance methods.

Results:

The following types of products have been identified for consideration of this deliverable:

- non-pre-packaged medicinal products (branded and not branded),
- pre-packaged medicinal products towards which there occur additional identification needs (e.g. additionally regulated).

Discussion/Conclusions/Recommendations:

Analysis performed for this deliverable allowed to develop an inventory of other products that are not included in WP2. As a result of this analysis, it is observed that these can be aggregated them into two groups (pre-packaged and non-pre-packaged). After verifying what identification concepts and data-sets developed in WP2 are applicable, it was possible to finally determine any additional needs regarding identification of ‘other’ medicinal products.

It has been found that the WP2 solution is applicable for the majority of ‘other’ medicinal products groups identified for the sake of WP3 and especially D3.1. However, there are some examples of products (e.g. magistral formulas – also known as extemporaneous preparations, officinal formulas and radionuclides in the form of sealed sources) that need some additional guidance and extension of the WP2 model. This issue will be addressed in T3.2 and D3.2 will include further information regarding possible identification and description methods with respect to these products for the sake of e-prescription (but also patient summary, etc.) in the cross-border context this information will include, among others: a prescription for each of these products as well as an extract of an Electronic Health Record documenting a treatment with these products.
1.1. Introduction

1.1. Scope of the WP

The main goal of WP3 is to assess WP2 options for other than pre-packaged medicinal products and identify possible gaps in the WP2 approach regarding identification and description of the product(s) and their content. WP2 has adopted a generic solution for the identification and the description of medicinal and pharmaceutical products for human use considering commonly prescribed regulated medicinal products for humans. The main focus of this WP is to:

- list ‘other’ products that are not included in WP2, aggregating them into two groups (pre-packaged and non-pre-packaged),
- verify if identification concepts and data-sets developed in WP2 are applicable,
- determine if there are any additional needs regarding identification of ‘other’ medicinal products,
- develop an appropriate solution to be able to cover all ‘other’ medicinal products for human use (if needed).

WP2 was focused on branded pre-packaged medicinal products including all products authorised in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC of the community code relating to medicinal products for human use by a medicines regulator in a pre-packaged form and includes both innovator and generic products.

Apart from those products, drugs prescription, preparation and dispensation processes may be related to a larger class of products for which the product identification and description is also required. In this particular deliverable an analysis of the different types of products will be conducted in order to identify which products may be included in WP3. Then, for a selection of them the appropriateness of the WP2 solution will be verified, identifying possible gaps and any additional needs.

The following types of products are in scope of this deliverable:

- non-pre-packaged medicinal products, branded as well as not branded
- pre-packaged medicinal products towards which there occur additional identification needs (e.g. additionally regulated).

The following types of products are not in scope of this deliverable and will be addressed in WP4:
• products obtained via a compounding process (e.g. cytostatics, parenteral foods for special medical purposes),
• clusters (group of medicinal products which have been preselected by a Regulatory Agency or by the Health Ministry or other similar organization, following predefined criteria).

1.2. Goal of D3.1
Deliverable D3.1 “Assessment of the WP2 solution for ‘other’ medicinal products” has two goals to achieve:

• list ‘other’ medicinal products including non-pre-packaged branded medicinal products or pre-packaged medicinal products towards which there occur additional identification needs,
• identify any potential gaps in the WP2 model.

The goal of the deliverable is NOT to develop a classification of medicinal products but to analyse various references in order to spot any possible medicinal product types that need additional identifiers, not foreseen in WP2 or new attributes not included in the ISO IDMP standards.

1.3. Adopted approach and methodology
In order to achieve the goals of the task and deliver the final material the following approach and methodology has been adopted; WP3 is divided into two major steps:

Step 1 (corresponding to deliverable D3.1):

a) identification of EU regulatory requirements and other relevant documents regarding identification and description of other medicinal product types,
b) analysis of relevant EU regulatory aspects in order to highlight the reason for additional or separate regulations towards these products and in order to determine whether there is a potential need for any identifiers\(^1\) or identifying attributes\(^2\) not foreseen in WP2 or in the IDMP,
c) listing of ‘other’ medicinal product types,

\(^1\) an attribute that unequivocally specifies an entity - in this case a product. Each unique identifier identifies one unique product
\(^2\) identifying or descriptive attributes; identifying attributes are attributes whose unique combination of values enables to identify a unique product; descriptive attributes are attributes that describe certain aspects of the product
d) confirmation of identifying concepts out of WP2 as applicable for ‘other’ medicinal products,

e) identification of gaps and any limitations that occur.

**Step 2 (corresponding to deliverable D3.2):**

a) modification of the WP2 model so that ‘other’ medicinal products can be identified and described in a cross-border environment

b) examples of a prescription for each of these products as well as an extract of an Electronic Health Record documenting a treatment with these products.

Step 2 will be undertaken in Task 3.2 and the two tasks are closely related to each other D3.1 and D3.2 shall therefore be treated and analysed as complementary deliverables.
2. References

In order to develop the D3.1 the following materials and documents have been analysed and are referenced to:

- **project deliverables:**
  - D.2.1
  - D.2.2

- **ISO standards:**
  - Standard ISO11615:2012(E)
  - Standard ISO11238:2012(E)

- **EU legal framework:**
  - COMMISSION REGULATION (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for

- **JUDGMENT OF THE COURT (Third Chamber) 16 July 2015:**
  [http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxiLc3gMb40Rch0SaxuQbNj0?text=&docid=165910&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=387522](http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxiLc3gMb40Rch0SaxuQbNj0?text=&docid=165910&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=387522)

- **other sources:**
  - ‘International Non-proprietary Names (INN) for Pharmaceutical Substances’, WHO:
3. Terms and definitions

The definitions in this document are derived from, and maintained in, the online glossary:

http://www.openmedicine.ramit.be/dictionary/

The glossary will be completed progressively and intends to list the medication related concepts and their definitions in different EN/ISO standards as well as in European Directives and Guidelines.
4. **Current and future identification and description methods**

Medicinal products identification and description methods vary between countries in the European Union and also globally. This is mainly due to different legal, economic and organizational issues. Countries do store data in an electronic format in national databases but as in the majority of instances product identifiers and identifying attributes are understood nationally, data matching between countries is cumbersome and not always successful, even when implementing the full epSOS approach.

However, some steps are being taken in order to make medicinal products data available centrally for specific reasons. As an example, it is worth mentioning that all marketing-authorisation holders (MAHs) of medicines authorised in the European Union (EU) and European Economic Area (EEA) must submit information on these medicines to the European Medicines Agency (EMA) and must keep this information up-to-date. MAHs are also required to submit information concerning all medicinal products for which they hold a marketing authorisation in EEA countries outside the EU (i.e. Iceland, Liechtenstein and Norway). This is done mainly in response to the pharmacovigilance legislation. The programme is aimed at providing robust, high quality and sustainable systems and services to gather and analyse data and information for pharmacovigilance. The Article 57 project deliverables have been achieved in different phases over the past four years and the ongoing collaboration of MAHs will be vital to maximise the utility of this information for pharmacovigilance.

The EMA is in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). The move to ISO IDMP is to standardize data formats outside EU and to improve the common format. ISO IDMP includes a set of common global standards for data elements, formats and terminologies for the unique identification of and the exchange of information on medicines. Following a phased implementation process, pharmaceutical companies will be required to submit data on medicines to EMA in accordance with these formats and terminologies. With the development and adoption of the ISO IDMP standards by the European Medicines Regulatory Network (EMRN), there is an opportunity to bring together common terminologies and data structures to provide a single source of European medicinal product information.

WP2 solution was built upon the ISO IDMP standards and in accordance with the EMA implementation activities regarding this particular concept of standardized medicinal products identification as well as legal basis with respect to ISO IDMP. It is therefore important to underline that in the proposed solution it is assumed that the ISO IDMP approach is implemented in order to streamline e-prescribing and e-dispensing processes in the cross-border context. WP3 work, being a continuation of the WP2 achievements, is based on the same foundation and the same assumption. Whenever WP2 identification concepts are found to be applicable for ‘other’ medicinal products in D.3.1, it means that there is a theoretical possibility to use them in practice. However, some additional guidance is needed with reference of selected medicinal products or even the extension of the EMA scope of activities. This guidance and recommendations will be provided in D3.2.
5. Summary of approach and model developed in WP2

As defined in D2.1, the foremost goal is to enable safe dispensation of a medicinal product by correctly identifying the product prescribed. The main focus of D2.1 is the identification of a medicinal product, as defined in ISO IDMP. IDMP uses the concepts of Medicinal Product, Pharmaceutical Product, and Package, including levels within these concepts. These concepts are recommended for identification of medicinal products and constitute the basis for the identification model developed in WP2. These concepts can be illustrated in the way shown in figure 1.

![Diagram of IDMP-based identification concepts]

Figure 1. IDMP-based identification concepts

The main characteristics that are associated with the MPID, PCID, BAID_1 and BAID_2 are:

- name of the Medicinal Product;
- legal status of supply;
- terms of the marketing authorization;
- marketing authorization (licence) holder;
- manufacturer(s);
- authorizing Medicines Regulatory Agency;
- qualitative and quantitative composition;
- ingredients, strength, pharmaceutical form, route of administration;
- device(s) as part of a Medicinal Product;
- clinical particulars;
- product classification(s);
- package description [e.g. container, administration device(s) and package quantity];
- regulated product information and documentation.

The main characteristics that are associated with the PHPID are:

- Administrable Dose Form
- Unit of Measurement
- Strength

Sample Core Dataset regarding Substance includes the following descriptive attribute elements deriving from the ISO IDMP:

- Substance Name (ISO 11238 3.4 Naming of substances)
- Substance ID (ISO 11238 3.5 Requirements for unique identifiers)
- Substance Type (ISO 11238 3.6 Types of substances)

Sample Core Dataset regarding Clinical Particulars includes the following attribute elements deriving from the ISO IDMP:

- Therapeutic Indication
- Contra-Indication
- Population specifics
- Other therapy specifics
- Interactions
- Interactant
Sample Core Dataset regarding Authorisation includes the following attribute elements deriving from the ISO IDMP:

- Marketing Authorisation Number
- Country
- Legal Status of Supply
- Authorisation Status
- Authorisation Status Date
- Validity Period
- Procedure Identifier/Number (e.g. MRP number)
- Marketing Authorisation Holder Identifier
- Medicines Regulatory Agency
- Marketing authorization procedure
- Procedure identifier/number
- Procedure type

The following standards are part of IDMP and are used for the description of Pharmaceutical Products and Medicinal Product:

- EN/ISO 11238:2012(E), Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated information on substances
- EN/ISO 11239:2012(E), Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- EN/ISO 11240:2012(E), Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of units of measurement

The above enumerated product attributes have been analysed in D2.2 and grouped into the three sections, presented in table 2. Additionally, the attributes that are in the clinical documents (e.g. prescriptions) are also analysed and listed in table 3.
Table 2. openMedicine Collection of identifiers - Product characteristics

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<th>Concept</th>
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Source: D2.2
Table 3. openMedicine Collection of identifiers - information in care context

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<th>Attributes in Care Context</th>
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Source: D2.2

At the product characteristics level it is expected that all the products will have a unique ID. In order to identify in an unequivocal way it is needed to know the identifier; it is also useful to dispose of a sufficient set of identifying attributes. Identifications have always to be considered in their context. If the context is unclear, the use of an ID may not be sufficient as it is essential to know what the ID refers to. Use of any coded term (for example the product specified in a prescription) is understood only if both parties (in the example, the prescribing and dispensing systems) understand what the code refers to and can find the code value itself.

A number of requirements to be met have been identified in T2.2 in order to enable cross-border e-prescription and dispensation. They include the following elements:

- a central repository of common medicinal product information exists, but yet not sufficiently structured to be interactive,
- the prescription must specify the medicinal product but is not expected to convey all the product characteristics,
• the identifying information in the prescription must be sufficient by itself or complemented by additional data to identify the product,
• besides the specification of the product the receiving system must have the information available to retrieve the product to be dispensed,
• the product information may be checked by the prescribing and dispensing systems,
• it happens that the dispenser needs additional information about a product outside their local range of dispensable products,
• the substitution rules are typically built in the prescribing and dispensing systems so they are considered harmonized within the scope of prescription and dispense in the same country,
• the marketing authorization holders submit information updates to the regulators to keep the product information accurate and up to date,
• local product characteristics (e.g. local classification) may also be needed to be shared.

The overall recommendations include specifying a product by referring to one or more of the possible identifiers, namely: PhPID, MPID and PCID. The prerequisite for such recommendations is as follows: both sending and receiving party understand the concepts by using harmonised Object Identifiers (OIDs). Detailed information regarding the concept is included in WP2 deliverables.

In order to have a clear overview over the types of identifiers and differences between them, the following concepts should be borne in mind:

• PhPID – **Pharmaceutical Product Identifier**, unique identifier and uniform representation of the pharmaceutical product using the substance(s)/specified substance(s), their (reference) strength(s), the administrable dose form and, where applicable, the integral device\(^3\),

• MPID – **Medicinal Product Identifier**, unique identifier allocated to a medicinal product supplementary to any existing authorisation number as ascribed by a Medicines Regulatory Agency in a jurisdiction\(^4\),

• PCID – **Package Identifier**, unique identifier for the packaged Medicinal Product\(^5\).

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\(^3\) ISO IDMP, Standard ISO11615:2012(E)

\(^4\) ibid.

\(^5\) ibid. and ISO IDMP, Standard ISO11238:2012(E)
Another pivotal role in the whole identification process is played by the central EMA database, the Article 57 database or the future database which is going to be ISO IDMP Compliant. The database will be held for all possible regulatory processes related to medicinal products. In order to enter product data into the database, the MAH is asked to provide comprehensive product information by using a standard reporting form. This medicinal product information should be made available by the EMA, and become the important central source of information to be used across Europe.
6. Inventory of ‘other’ medicinal products

In article 1 of Directive 2001/83/EC a medicine is defined as “Any substance or combination of substances being presented as having properties for treating or preventing disease in human beings; Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”

Medicinal products can be divided into many groups with regards to various criteria. The approach that has been adopted in the project led to dividing medicinal products into: ‘pre-packaged branded medicinal products’ and ‘other’ medicinal products. WP2 deals with pre-packaged medicinal products to which Directive 2001/83/EC refers to.

The aim of the analysis undertaken for the sake of this particular deliverable is to determine:

- if there are any other examples of products that occur in a different form from a pre-packaged branded form as this mean that some other identifiers and attributes are needed in order to identify and describe the product,
- if there are any other examples of products that ARE pre-packaged and branded but require special identifiers and attributes due to additional regulations,

and

- if the attributes available in the EMA database (Article 57 now, and ISO IDMP database later on) cover additional information that is needed to describe ‘other’ medicinal products.

As a starting point for the development of an inventory to be considered for the WP3, WP2 references have been analysed, namely:

- **REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency and

Directive 2001/83 refers to a number of products that are either in scope of this directive or administrative data is that of this directive. Such as:

- advanced therapy medicinal products,
- biologic medicinal products,
- investigational medicinal products,
- radiopharmaceuticals,
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

Regulation (EC) No 726/2004, among many other information, includes an Annex in which medicinal products to be authorised by the community are included. This is the list of products that have to be authorised in a central procedure by the EMA and it embraces the following examples:

1. “Medicinal products developed by means of one of the following biotechnological processes:
   - recombinant DNA technology,
   - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including
   - transformed mammalian cells,
   - hybridoma and monoclonal antibody methods.
2. Medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.\(^6\)
3. Medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community
4. Medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.”

The list includes among others:

---

\(^6\) which are out of scope of the project as it concentrates on products for human use only
• products whose manufacturing or development process is special (e.g. medicinal products developed by means of particular biotechnological processes),
• products of innovative character (e.g. medicinal products with a new active substance that has not been referred to in any prior application whose exceptional qualities justify a ‘fast track’ procedure for authorisation),
• products for rare diseases.

The above mentioned products characteristics does not require any special attributes or identifiers not foreseen in the WP2 solution as all information regarding these medicinal products is contained in Art. 57 (a mandatory requirement towards all medicinal products authorised in Europe). Attributes, such as special manufacturing processes, development stage of the product or substance origin are products attributes that are covered with the ISO IDMP standards. These products do not need any additional identifiers either. These special pieces of data are not explicitly included either in a prescription in country A nor in an IT pharmacy system in country B because these are attributes linked to identifiers, e.g. PhPID, MPID and PCID. On that basis the matching can be done (one way or another as described in various scenarios in D2.2).

6.2. Products excluded from Directive 2001/83

Directive 2001/83 applies to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

Among other information, the directive includes a list of products that are excluded from the document. Among these products there is a subgroup that will be analysed furtherly for the sake of the WP3, e.g.:

• magistral formula,
• officinal formula,
• any radionuclides in the form of sealed sources,
• whole blood, plasma or blood cells of human origin,
• any advanced therapy medicinal product, as defined in Regulation (EC) No 1394/2007, which is prepared on a nonroutine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.
These products will be included in the inventory of ‘other’ medicinal products and analysed furtherly. However, whole blood, plasma or blood cells of human origin are not reprocessed products and will not be analysed, being out of scope of the project.

6.3. Products in scope of Directive 2001/83 and additionally regulated

The analysis of relevant documents has shown that there is a subgroup of products that are in scope of Directive 2001/83 but are additionally regulated. This subgroup includes the following products:

- homoeopathic medicines,
- herbal products,
- orphan products,
- products for paediatric use.

These products will be included in the inventory of ‘other’ medicinal products and analysed furtherly.

6.4. Other sources of information

Another source of information, e.g. the document: ‘Boundary for the “Pharmaceutical and Biological Products” Hierarchy in the International Release of SNOMED CT® vs. National Extension Content’, revealed other possibilities regarding the extension of the list, including some other types of products not mentioned in previous chapters. They include:

- Food Supplements and OTC Medicines,
- nutritional Products,
- medical devices,
- nanotechnology products.

6.4.1. Health Supplements

Food Supplements – as a rule – are not considered as medicinal products. They are regulated separately and are included in DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Food supplements means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.
Food supplements that are used for special medical purpose are regulated separately and are treated as medicinal products.

6.4.2. Over-The-Counter products

Over-The-Counter products are pre-packaged medicinal products and are included in the WP2 solution, since the majority of OTC products are pre-packed branded medicinal products. However, OTC medicinal products include products that are not always pre-packed and branded, e.g. magistral formulas. In that case, they have different identification needs as explained in chapter 7.

6.4.3. Medical devices

Medical devices are articles intended to diagnose, cure, treat, prevent, or mitigate a disease or condition, or to affect a function or structure of the body, that do not achieve their primary effect through a chemical action and are not metabolized. Medical devices are separately regulated and are in scope of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices. Some medication devices are in two categories that are relevant for this work: reusable drug delivery systems or non-reusable devices with an active substance. The first type of medical devices is out of scope of the project. The other type is treated as a pre-packaged branded medicinal product – a medicinal product that includes the device for administration, which is covered by the ISO IDMP standards. As such, it is handled within WP2.

6.4.4. Prescription dental products

As far as Prescription dental products are concerned, they are regulated differently in different European countries. In some countries, there are no prescription dental products (e.g. products that need a prescription and are only applicable for dental treatment) in some other countries dental products are not considered as medicinal products but as cosmetics (e.g. in Spain). For that reason, these products will not be separately analysed.

6.4.5. Leeches

As far as leeches are concerned, in Europe there are no regulations regarding them. However, in the U.S. the Food and Drug Administration has approved medicinal leeches for commercial marketing, not as drugs, but as medical devices. According to an FDA Talk Paper, the agency announced that leeches meet the definition of a device because they are considered to be articles intended to diagnose, cure, treat, prevent, or mitigate a disease or condition, or to affect a function or structure of the body, that do not achieve their primary effect through a chemical action and are not metabolized. Leeches’ primary mode of action is the eating of blood, which is a mechanical process. Being classified as medical devices, or simply because they are not a medicinal product that requires cross-border identification, leeches are out of scope of the project.
Taking into the consideration the above mentioned legal context, the following products will be furtherly analysed:

- foods for special medical purpose,
- nanotechnology medicinal products.

6.5. Inventory of ‘other’ medicinal products

The analysis of the above included sources and the conclusions formulated in sections 5.1, 5.2 and 5.3, led to the development of the inventory included in table 4:
Table 4. Identified products with respect to WP in which they are discussed

<table>
<thead>
<tr>
<th>Information source</th>
<th>In scope of WP2</th>
<th>In scope of WP3</th>
<th>In scope of WP4</th>
<th>Out of scope of the project</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mentioned by name in the Directive 2001/83 and included in Regulation 726/2004</strong></td>
<td>biologic medicinal products</td>
<td>none</td>
<td>none</td>
<td>medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals</td>
</tr>
<tr>
<td></td>
<td>investigational medicinal products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>radiopharmaceuticals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>medicinal products for human use containing a new active substance which, on the date of entry into force of this</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>reprocessed plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Excluded from the Directive 2001/83</strong></td>
<td>none</td>
<td>magistral formula</td>
<td>none</td>
<td>whole blood, plasma or blood cells of human origin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>officinal formula</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>radionuclides in the form of sealed sources</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>advanced therapy medicinal product, which is prepared on a nonroutine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient

<table>
<thead>
<tr>
<th>Mentioned by name in the Directive 2001/83 and Regulation 726/2004 AND additionally regulated</th>
<th>none</th>
<th>• advanced therapy medicinal products</th>
<th>none</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>• homoeopathic products</td>
<td></td>
<td>• herbal medicinal products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• orphan medicinal products</td>
<td></td>
<td>• product for paediatric use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mentioned in other references</th>
<th>• non-reusable drug delivery systems</th>
<th>• nanotechnology medicinal products</th>
<th>• parenteral foods for special medical purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• OTC products</td>
<td>• enteral foods for special medical purposes</td>
<td>• cytotoxic compounds</td>
<td></td>
</tr>
<tr>
<td>• allergen diagnostic products</td>
<td></td>
<td></td>
<td>• leeches</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Rx dental products</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• health supplements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• reusable drug delivery systems</td>
</tr>
</tbody>
</table>

Source: own
Table 5 summarizes products that are considered in scope for WP3.

Table 5. Inventory of ‘other’ medicinal products in scope of WP3

<table>
<thead>
<tr>
<th>Non-pre-packaged medicinal products</th>
<th>Pre-packaged medicinal products</th>
</tr>
</thead>
<tbody>
<tr>
<td>magistral formula</td>
<td>advanced therapy medicinal products</td>
</tr>
<tr>
<td>officinal formula</td>
<td>foods for special medical purposes</td>
</tr>
<tr>
<td>radionuclides in the form of sealed sources</td>
<td>homoeopathic medicines</td>
</tr>
<tr>
<td>advanced therapy MP prepared on a nonroutine basis</td>
<td>herbal medicinal products</td>
</tr>
<tr>
<td></td>
<td>orphan medicinal products</td>
</tr>
<tr>
<td></td>
<td>medicinal products for paediatric use</td>
</tr>
<tr>
<td></td>
<td>nanotechnology medicinal products</td>
</tr>
</tbody>
</table>

Source: own

The list above includes both products that can be prescribed and dispensed in hospital environment only and products that are also available in community pharmacies. The overall goal of the project is to enable cross-border identification of products. E-prescription aspects are key for the analysis. However, identification issues occur also in many other use-cases, e.g. keeping record of medicinal products dispensed to a patient in his or her patient summary is also very important. That is why all products listed above will be analysed with respect to any possible identification concepts that go beyond the WP2 solution.

The developed inventory includes both products that are pre-packaged and non-pre-packaged. The overall recommendations deriving from WP2 include specifying a product by referring to one or more of the possible identifiers, namely: PhPID, MPID or PCID. The analysis will be focused on determining the product identification level to be used in order to identify and describe a product belonging to ‘other’ medicinal products in cross-border settings for different scenarios, e.g. prescribing and dispensing, developing patient summary, patient safety issues, etc.
Table 6. List of products to be considered for D3.1 and legal conditionings

<table>
<thead>
<tr>
<th>Name of product</th>
<th>Definition (or explanation)</th>
<th>Legal aspects</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) magistral formula</td>
<td>A pharmaceutical compound, prepared by the pharmacist or someone under his direction, for a given patient according to a prescription and following the technical and scientific standards of the pharmaceutical art. The product is sold at the pharmacy to the patient who is given the appropriate information about the product</td>
<td>Judgment of the Court (Third Chamber), 16 July 2015, in Joined Cases C-544/13 and C-545/13, ECLI:EU:C:2015:481.</td>
<td><a href="http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxILc3qMb40Rch0SaxuQbNj0?text=&amp;docid=165910&amp;pageIndex=0&amp;doclang=EN&amp;mode=lst&amp;dir=&amp;occ=first&amp;part=1&amp;cid=387522">http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxILc3qMb40Rch0SaxuQbNj0?text=&amp;docid=165910&amp;pageIndex=0&amp;doclang=EN&amp;mode=lst&amp;dir=&amp;occ=first&amp;part=1&amp;cid=387522</a></td>
</tr>
<tr>
<td>b) officinal formula</td>
<td>A pharmaceutical compound, developed or prepared by a pharmacist or someone under his direction, which is listed and described by the national formulary, sold at the pharmacy directly to its patients</td>
<td>Judgment of the Court (Third Chamber), 16 July 2015, in Joined Cases C-544/13 and C-545/13, ECLI:EU:C:2015:481.</td>
<td><a href="http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxILc3qMb40Rch0SaxuQbNj0?text=&amp;docid=165910&amp;pageIndex=0&amp;doclang=EN&amp;mode=lst&amp;dir=&amp;occ=first&amp;part=1&amp;cid=387522">http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d544b0894445c44c8a9230ebfa9d15c6e0.e34KaxILc3qMb40Rch0SaxuQbNj0?text=&amp;docid=165910&amp;pageIndex=0&amp;doclang=EN&amp;mode=lst&amp;dir=&amp;occ=first&amp;part=1&amp;cid=387522</a></td>
</tr>
<tr>
<td>c) radionuclides in the form of sealed sources</td>
<td>Radioactive isotopes for medical purposes that is permanently sealed in a capsule or closely bonded and in a solid form.</td>
<td>Good Radiopharmaceutical Practice</td>
<td><a href="http://www.eanm.org/publications/guidelines/index.php?navId=37">http://www.eanm.org/publications/guidelines/index.php?navId=37</a></td>
</tr>
</tbody>
</table>
| **products** | defined in Part IV of Annex I to Directive 2001/83/EC,  
-a somatic cell therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC,  
-a tissue engineered product as defined in point (b) of Reg (EC) |  |
| --- | --- | --- |
| **e) foods for special medical purposes** | Product intended to provide nutrients that may otherwise not be consumed in sufficient quantities | COMMISSION REGULATION (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses and  
![Link](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0021&from=EN) |
| **f) homoeopathic products** | Medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. | Directive 2001/83/EC and  
<table>
<thead>
<tr>
<th>g) herbal medicinal products</th>
<th>Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.</th>
<th>Directive 2001/83/EC and Directive 2004/24/EC of the European Parliament and of the Council, amending, as regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the European Union Code relating to Medicinal Products for Human Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>h) orphan medicinal products</td>
<td>A pharmaceutical agent that has been developed specifically to treat a rare medical condition</td>
<td>Directive 2001/83/EC and REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products</td>
</tr>
</tbody>
</table>


Source: own
7. Analysis of chosen products with reference to the WP2 solution

Herewith is an analysis of the products that are in scope, and how they can be related to the WP2 solution. In order to validate the WP2 ISO IDMP-based solution for the identification and description needs of other products the following approach has been adopted:

All available legal documents and other relevant materials included in Table 4 have been analysed in order to find out which identification concepts developed in the WP2 are applicable and if there are any other attributes / identifiers missing to uniquely identify and describe ‘other’ medicinal products.

7.1. Non-pre-packaged medicinal products

a) magistral formula

Description and use:

Magistral formula is a pharmaceutical compound, prepared by the pharmacist or someone under his/her direction, for a given patient according to a prescription and following the technical and scientific standards of the pharmaceutical art\(^7\).

Process overview:

A doctor prescribes a medication that the pharmacist must prepare in-pharmacy. It is a medicine aimed at an individual patient and responds to the requirements of a medical prescription which includes the specifications of the active substances to use. It will be prepared according to the scientific and technical requirements of the pharmaceutical good practice. Magistral formulas will be prepared following good manufacturing practices\(^8\) and quality control. Some formulas also include the name of the pharmacist who prepare them and all the necessary information to allow the correct identification, correct storage, as well as safe use. It could be of an authorised or not authorised active substance or medicinal product.

The pharmacist, along with his/her team of technicians, combines, according to these precise instructions, the necessary ingredients to obtain the medication. This may consist of creams, ointments, liquids, capsules, etc. The magistral preparation of products is a practical way for a doctor to personalize patient treatment according to his/her needs. It also makes medications available in formulations that do not exist commercially.

Information requirements

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\(^7\) Several definitions were found, for example in the ISO SKMT glossary, but were suited for specific scopes or purposes. This definition comprehends the relevant found definitions.

\(^8\) Good practices are usually described in local pharmacopoeias.
Magistral formulas are dispensed on the basis of compounded prescriptions. A compounded prescription is an order that requires mixing of one or more ingredients (active medicaments) with one or more pharmaceutical necessities (vehicle, suspending agent). The physician selects ingredients that he/she desires and the pharmacist prepares the medication accordingly. The name of each drug may be placed on a separate line right under the preceding one.

- **Remedium cardinale (basis).** The basis is the principal drug and gives the prescription its chief action.
- **Remedium adjuvans (adjuvant).** As the name suggests, the adjuvant is a drug that aids or increases the action of the principal ingredient.
- **Remedium corrigens (corrective).** The corrective modifies or corrects undesirable effects of the basic or adjuvant.
- **Remedium constituens (vehicle).** The vehicle is the agent used as a solvent in the solution, to increase the size and volume, or to dilute the mixture.

The most potent or principal drug is written first, the other ingredient second, and the vehicle last, as shown in the example.

Since the formulas are uniquely defined by the composition, the availability of one or the other is equivalent: Either the components, or the identifier

**Example:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natrii bromati (bromatis)</td>
<td>6,0</td>
<td>Rem. basis</td>
</tr>
<tr>
<td>Phenobarbitali</td>
<td>0,6</td>
<td>Rem. adjuvans</td>
</tr>
<tr>
<td>Sirupi Menthae</td>
<td>60,0</td>
<td>Rem. corrigens</td>
</tr>
<tr>
<td>Aquae destillatae ad</td>
<td>300,0</td>
<td>Rem. constituens</td>
</tr>
</tbody>
</table>

*Misce fiat mixture (Mix to obtain mixture)*

**Identification and description data needs:**

A magistral formula such as the one shown above is described with the following attributes:

1. Identification (Name) of the substance or product
2. Quantity of the substance or product that MAY be stated in the prescription itself (already covered) or perhaps a new attribute (to be analysed in D3.2)
3. Role of the substance or product that requires a new attribute
4. Instructions for preparation that can be present in the prescription or perhaps a new attribute (to be analysed in D3.2)
**WP2 identification concept applicable:** PhP and Substance dataset

**New identification concept applicable, not yet in the WP2 solution:** Formulary ID to be added to the list of identifiers and role of the substance or products as a new attribute

**b) officinal formula**

Officinal formula is a pharmaceutical compound, developed or prepared by a pharmacist or someone under his/her direction, which is listed and described by a formulary, sold at the pharmacy directly to its patients. The main difference between magistral and officinal formula is the fact that the latter is not a personalized treatment method and may be sold to any patient. Moreover, an officinal formula is a formula contained in the Pharmacopoeia. They must be numbered and described by the national formulary. They have to be prescribed under the generic name but never under commercial name. They must also include the name of the pharmacist who prepared them and all the necessary information to allow correct identification, correct storage, as well as safe use.

Noncompounded prescription or formula officinalis (officina is the Latin word for workshop) does not require mixing of two or more ingredients to obtain a finished product. A precompounded order consists of a drug or a mixture of drugs that can be supplied by a pharmaceutical company by its official or proprietary name and, if it contains more than one substance, the specific ingredients do not have to be listed.

Whenever it happens that the formula is modified by a pharmacist due to certain reasons, then such medicinal products shall be treated and identified as magistral formula.

**Example and explanation:**

*Siropus simplex* (Saccharum 64,0, Aqua purificata 36,0)

**Identification and description needs:**

This formula is described with the following attributes:

1. Identification (Name) of the substance or product
2. Quantity of the substance or product that MAY be stated in the prescription itself (already covered) or perhaps a new attribute (to be analysed in D3.2)
3. Role of the substance or product that requires a new attribute
4. Instructions for preparation that can be present in the prescription or perhaps a new attribute (to be analysed in D3.2)
5. (local / regional / global) formula ID: analysed in D3.2

**WP2 identification concept applicable:** PhP and substance dataset can be used to identify the substance or product.
New identification concept applicable, not yet in the WP2 solution: national formula ID and role of the substance or products as a new attribute

c) radionuclides in the form of sealed sources

A radiopharmaceutical product is any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose. Radioactive materials can be permanently sealed in a capsule or is closely bonded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, also under foreseeable mishaps. Sealed-source therapy, in which the radioisotope remains in a capsule or metal wire during therapy and is never allowed to dissolve in fluids, is usually referred to as brachytherapy.

Brachytherapy contrasts with unsealed source radiotherapy in which a therapeutic radionuclide (radioisotope) is injected into the body to chemically localize to the tissue requiring destruction. Brachytherapy instead involves the precise placement of short-range radiation-sources (radioisotopes) directly at the site of the cancerous tumour. These are enclosed in a protective capsule or wire, which allows the ionizing radiation to escape to treat and kill surrounding tissue but prevents the charge of radioisotope from moving or dissolving in body fluids. The capsule may be removed later, or (with some radioisotopes) it may be allowed to remain in place.

Example:

Commonly used radiation sources (radionuclides) for brachytherapy include:

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cesium-131 (^{131}Cs)</td>
<td>Electron Capture, ε</td>
</tr>
<tr>
<td>Cesium-137 (^{137}Cs)</td>
<td>β^- particles</td>
</tr>
<tr>
<td>Cobalt-60 (^{60}Co)</td>
<td>β^- particles</td>
</tr>
<tr>
<td>Iridium-192 (^{192Ir})</td>
<td>γ-rays</td>
</tr>
<tr>
<td>Iodine-125 (^{125}I)</td>
<td>Electron Capture, ε</td>
</tr>
<tr>
<td>Palladium-103 (^{103}Pd)</td>
<td>Electron Capture, ε</td>
</tr>
<tr>
<td>Ruthenium-106 (^{106}Ru)</td>
<td>β^- particles</td>
</tr>
</tbody>
</table>

Identification and description needs:

Both capsule (or any other material used) and the radionuclide itself should be identified in a unique way. For this purpose, both the name and an identifier of a particular radionuclide and its type shall be used. Currently, these identifiers are not available and are not foreseen in the WP2 solution.

WP2 identification concept applicable: PhP dataset

New identification concept applicable, not yet in the WP2 solution: PhP for radionuclides in the form of sealed sources
7.2. Pre-packaged medicinal products additionally regulated

a) advanced therapy medicinal products

As a rule, advanced therapy medicinal products are in scope of the Directive 2001/83/EC. These products are additionally regulated by Regulation (EC) No 1394/2007. In addition to the particulars mentioned in Article 55(2) and (3) of Directive 2001/83/EC, the following particulars shall appear on the immediate packaging of advanced therapy medicinal products:

(a) the unique donation and product codes, as referred to in Article 8(2) of Directive 2004/23/EC;

(b) in the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement ‘For autologous use only’.

This requirement refers to products deriving from the same individual. In other words, one individual is both a donor and a recipient. It means that these products are not subject to the analysis as they cannot be substituted in any way and no equivalents can be found.

There are also advanced therapy medicinal products which are prepared on a nonroutine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient. In that case, the approach is similar to the one used with reference to magistral formulas regarding identification issues.

Example:

ChondroCelect is a suspension for implantation that contains cartilage cells and is a type of advanced therapy medicine called a ‘tissue-engineered product’, containing cells or tissues that have been manipulated so that they can be used to repair, regenerate or replace tissue.

Identification and description issues:

Whenever advanced therapy medicinal products are pre-packaged branded products such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

Advanced therapy medicinal products produced on nonroutine basis dispensed in hospitals shall be identified by means of PhP dataset.

WP2 identification concept applicable: PhP, MP and PC datasets (pre-packaged products) or PhP dataset (when subject to magistral rules).

b) foods for special medical purposes
The term "foods for special medical purposes" means dietary foods intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition. For this reason these products must be used under medical supervision which may be applied with the assistance of other competent health professionals. In other words, dietary foods for special medical purposes means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision.

Foods for special medical purposes can be divided into enteral and parenteral nutrition.

- PARENTERAL - Parenteral nutrition will be dealt with in WP4
- ENTERAL - With reference to enteral nutrition products that are pre-packaged branded products such products the WP2 solution should be applicable in order to meet identification needs in a cross-border setting.

Example:

CARNATION® INSTANT BREAKFAST® LACTOSE FREE PLUS, Chocolate Splash, 250 mL

Identification and description needs:

Foods for special medical purposes are pre-packaged branded products. It means that in order to meet identification needs in a cross-border setting such products should have all pre-defined identifiers appropriate for products included in the WP2 solution.

WP2 identification concept applicable: PhP, MP and PC datasets

c) homoeopathic products

Homoeopathic medicines are medicinal products prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. They are regulated by Directive 2001/83/EC. However, additionally, they are regulated by COUNCIL DIRECTIVE 92 / 73 /EEC of 22 September 1992 widening the scope of Directives 65 /65 /EEC and 75 /319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homoeopathic medicinal products. The latter does not include any additional identification needs but rather explains the nature of homoeopathic medicines. Directive 2001/83/EC underlines that homoeopathic medicines must be registered and approached in a similar manner as ‘other’ medicinal products in scope of that directive.

Example:
Avenoc is a homoeopathic medicine that is used to relieve minor symptoms of hemorrhoids and similar venous conditions due to dilated blood vessels in the rectal area.

Identification and description needs:
Whenever homoeopathic medicines are pre-packaged branded products such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

WP2 identification concept applicable: PhP, MP and PC datasets
Whenever homoeopathic medicines are preparations made in a pharmacy, they should be approached as magistral formulas (see point a) of this chapter).

d) herbal medicinal products
Herbal products include any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations. Herbal products are regulated by Directive 2001/83/EC. However, additionally, they are regulated by Directive 2004/24/EC of the European Parliament and of the Council, amending, as regards Traditional Herbal Medicinal Products, Directive 2001/83/EC on the European Union Code relating to Medicinal Products for Human Use. The latter does not include any additional identification needs but rather refers to registration procedures that are simpler in case of herbal medicinal products (e.g. clinical trials are not required, etc.). This simplified registration procedure is intended for herbal medicinal products with a long tradition, which do not fulfil the requirements for a marketing authorisation, in particular those requirements whereby an applicant can demonstrate by detailed references to published scientific literature that the constituent or the constituents of the medicinal products has or have a well-established medicinal use with recognised efficacy and level of safety (so-called "well established use"). With regard to the manufacturing of these products and their quality, applications for registration of traditional herbal medicinal products have to fulfil the same requirements as applications for a marketing authorisation.

Example:
Peppermint oil is an essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant.

Identification and description needs:
Whenever herbal medicines are pre-packaged branded products such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

WP2 identification concept applicable: PhP, MP and PC datasets
Whenever herbal medicines are preparations made in a pharmacy, they should be approached as magistral formulas (see point a) of this chapter).

e) orphan medicinal products

Orphan medicinal products are products including a pharmaceutical agent that has been developed specifically to treat a rare medical condition or valuable medicinal products at risk to disappear from the market. These products are in scope of Directive 2001/83/EC. Moreover, they are additionally regulated by REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 1999 on orphan medicinal products. The purpose of this Regulation is to lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products. In particular, the regulation refers to the procedure regarding the process of obtaining the designation of a medicinal product and the procedure of handling application forms by the Agency where the application for marketing authorisation is made. The regulation does not reveal any additional identification needs with respect to these products.

Example:

\textit{Dacogen (active substance: decitabine) is an orphan medicinal product used in treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organization (WHO) classification, who are not candidates for standard induction chemotherapy}

Identification and description needs:

Orphan medicinal products are pre-packaged branded products such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

WP2 identification concept applicable: PhP, MP and PC datasets

f) products for paediatric use

Products for paediatric use include medicinal products for medical care of infants, children, and adolescents. They are regulated by Directive 2001/83/EC. However, they are additionally regulated by REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. This Regulation lays down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population. The regulations says that a ‘medicinal product authorised for a paediatric indication’ means a medicinal product which is authorised for use in part or all of the paediatric population and in respect of which the details of the authorised indication are specified in the summary of the product characteristics drawn up in accordance
with Article 11 of Directive 2001/83/EC. The regulations refer to the procedure of qualifying medicinal products as products for paediatric use. However, the regulation does not reveal any additional identification needs with respect to these products.

**Example:**

*Movicol (active substances: Macrogol 3350, Sodium chloride, Sodium bicarbonate, Potassium chloride)* is a medicinal product for paediatric use used in treatment of chronic constipation with children.

**Identification and description needs:**

Products for paediatric use are pre-packaged branded products such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

**WP2 identification concept applicable:** PhP, MP and PC datasets

- **g) narcotics**

Some products may be considered as narcotics in one country or another, or globally considered narcotics. These products are regulated and as such have an identifier that is globally recognized. They can be treated as packaged products.

The constraints that exist on narcotics are not impacting identification, but rather permissions to prescribe and dispense

**Example:**

*Product X (must see D1.1)* is a product that is considered a narcotic in country B (must see D1.1). In the prescription, the physician identifies the product from its ID in the formulary. The dispenser identifies the product and, from his local product DB, realizes that the product is a narcotic, and must check with the patient or in the prescription if additional data is provided to justify the dispense.

**Identification and description needs:**

Narcotics are pre-packaged branded products. Such products should have all pre-defined identifiers appropriate for products included in the WP2 solution in order to meet identification needs in a cross-border setting.

**WP2 identification concept applicable:** PhP, MP and PC datasets

7.3. **Identification of substances**

In some instances it is the substance that differentiates one product from another. A common approach including all types of substances will be included in the ISO IDMP solution, currently under development. It means that no matter what kind of product is taken into consideration, being it a herbal, homoeopathic, nanotechnology or advanced therapy medicinal products, the solution will provide substance
The Agency is currently developing an EMA roadmap to implement Substance, Products, Organisations and Referentials (SPOR) master data management services, which will also support the implementation of the ISO IDMP standards in consultation with the EU regulatory network and European pharmaceutical-industry associations. These include data management services for:

- substance data, describing the ingredients of a medicine,
- product data, describing the marketing and medicinal information relating to a product,
- organisation data, providing the contact details of organisations and individuals responsible for various aspects of a medicine,
- referential data, providing controlled vocabularies (e.g. dosage, pharmaceutical forms, country codes, package codes, weight codes) for a medicine, which are explicitly defined for use in Europe.

The EMA will create in collaboration with the EU Regulatory Network a target operating model that will ensure the unique identification of substances is in compliance with the ISO IDMP 11238 standard. This approach has the following goals:

- To develop and deploy an information system that can serve as a global repository for definitional, regulatory and scientific information on substances;
- To develop and distribute a global identifier for every substance in medicinal products and clinical trials;
- To distribute an information system for both regulators, companies and other interested parties to facilitate registration into the global repository.

7.4. Gap analysis regarding ‘other’ medicinal products

In the course of the analysis, it has been found that the WP2 solution is applicable for the majority of ‘other’ medicinal products groups identified for the sake of WP3 and especially D3.1. The aim of the analysis was to verify what identification concepts that have been developed in the WP2 solution are applicable for ‘other’ medicinal products. Table 7 includes the gap-analysis by showing which attributes are and / or will be available in future when the ISO IDMP approach is fully implemented and which will not be available. For the latter, the WP2 model will have to be modified in order to enable medicinal product cross-border identification.

All the cases identified so far are assuming that:

- the regulators have assigned the identifiers for the products and value sets for the attributes.
- the different national databases have incorporated these identifiers
- the clinical documents (prescriptions, patient summaries) are able to transport those identifiers and attributes (all, or a subset - that remains to be decided).
However, if a transition phase is needed between pre- and post-IDMP adoption at the European level, these assumptions may not apply, e.g.:

- the cross-border identifiers may not be available
- the identifiers conveyed in a prescription (or other document) may not be the global ones.
- the attributes may not share a value set (e.g. substance codes)

In T3.2 the impact of this situation will be analysed and various scenarios will be presented in D3.2.

Analysis and Outcome

The analysis (i.e. the goal of this document) is done by evaluating the identification needs against the mechanisms and attributes already defined, and mark where these mechanisms may or not be used.

The results of this systemic analysis are shown in tables 7 and 8:

Table 7 shows the detailed gap analysis – for each of the products considered in this document, it is checked whether the attributes in the WP2 solution exist, can be applied and are sufficient.
Table 7. Gap analysis regarding ‘other’ medicinal products in scope of WP3

<table>
<thead>
<tr>
<th>ISO IDMP</th>
<th>Pre-packaged branded products (WP2 products)</th>
<th>WP3 products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Magistral formulas</td>
<td>Official formulas</td>
</tr>
<tr>
<td>Concept</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Product Attributes</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Y</td>
<td>Y</td>
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</tbody>
</table>

| Concept  | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
| Product Attributes | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |
|          | Y | n/a | n/a | n/a | Y | Y | Y | Y | Y | Y |

Table continued...
<table>
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<tr>
<th>Attributes in Care Context</th>
<th>Legal Status of Supply</th>
<th>Classification</th>
<th>Package</th>
<th>Package Item Container</th>
<th>Type</th>
<th>Quantity</th>
<th>Material</th>
<th>Alternate Material</th>
<th>Manufactured Item</th>
<th>Manufactured Dose Form</th>
<th>Unit of Presentation</th>
<th>Manufactured Item Quantity</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Attributes in Care Context</th>
<th>Product identification</th>
<th>Identifier</th>
<th>Codeset</th>
<th>Product Name</th>
<th>Strength</th>
<th>Pharmaceutical Dose Form</th>
<th>Posology</th>
<th>Quantity to administer per intake</th>
<th>Frequency of intakes</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
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<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
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</tbody>
</table>

9 the field is available in the prescription and it will be shown in D3.2 what is the identifier used
10 the field is available in the prescription and if here is an identifier it can be put there, but it is a local identifier
<table>
<thead>
<tr>
<th>Patient Summary</th>
<th>Treatment</th>
<th>Quantity to administer</th>
<th>Indication</th>
<th>Route</th>
<th>Substitution handling</th>
<th>Active ingredient</th>
<th>Name</th>
<th>Code</th>
<th>Exemption: brand name</th>
<th>Strength</th>
<th>Pharmaceutical Dose Form</th>
<th>Number of units per intake</th>
<th>Frequency of intakes</th>
<th>Duration of treatment</th>
<th>Treatment Start</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment Start</td>
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<td>Y Y Y Y Y Y Y Y Y</td>
<td>Y Y Y N Y Y Y Y</td>
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<tr>
<td></td>
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</tbody>
</table>
Finally, Table 8 presents the summary of the analysis of chosen products with reference to the WP2 solution – the products that require extension or not.

Table 8. Results of the analysis of chosen products with reference to the WP2 solution

<table>
<thead>
<tr>
<th>Subgroup of products</th>
<th>Name of the product</th>
<th>WP2 identification concept applicable</th>
<th>Need for extension of WP2 model (Yes or No)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-pre-packaged medicinal products</strong></td>
<td>a) magistral formula</td>
<td>Susbtance ID</td>
<td>Yes – guidance needed</td>
</tr>
<tr>
<td></td>
<td>b) officinal formula</td>
<td>PhPID</td>
<td>Yes – guidance needed</td>
</tr>
<tr>
<td></td>
<td>c) radionuclides in the form of sealed sources</td>
<td>PhPID</td>
<td>Yes – guidance needed</td>
</tr>
<tr>
<td></td>
<td>d) advanced therapy medicinal products prepared in a hospital on a nonroutine basis</td>
<td>PhPID</td>
<td>Yes – guidance needed</td>
</tr>
<tr>
<td><strong>Pre-packaged medicinal products additionally regulated</strong></td>
<td>a) advanced therapy medicinal product$^{11}$</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>b) foods for special medical purposes</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>c) homoeopathic medicines</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>d) herbal products</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>e) orphan products</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>f) medicinal products for paediatric use</td>
<td>PhPID, MPID, PCID</td>
<td>No</td>
</tr>
</tbody>
</table>

Source: own

The results of the gap analysis show that there is a need to extend the WP2 model with reference to the following types of products:

- magistral formulas,

$^{11}$ excluding the ones prepared on nonroutine basis in a hospital
- officinal formulas (including advanced therapy medicinal products prepared on nonroutine basis in a hospital),
- radionuclides in the form of sealed sources.

Other products included in the table shall be approached in the same way as described in D2.2, chapter 10. Various scenarios can be taken into consideration. They include both products prescribed by brand name and products prescribed by generic name or INN. Due to the fact that additional legal requirements towards these products does not influence their identification process and also because all products attributes are included in ISO IDMP, no additional identification needs exist with reference to these products. **WP2 solution is fully applicable.**

The prerequisite for the solution developed in WP2 to be working with reference to the above included ‘other’ medicinal products, is meeting the requirements formulated in section 4. That means, among others, that a central repository of common product information must exist and that central repository should include identification concepts developed in WP2. Some guidance may be needed for the clinical domain, i.e. an explanation on how the clinical documents may use the attributes in WP2 to convey the necessary information. For example, conveying a magistral formula in a prescription, not using the formula's identifier but rather the components. Moreover, there should be a possibility to include other product information if needed or if new types of products appear. The logic adopted regarding data type, format and aggregation methods, should be similar to the one adopted in the WP2 solution.
7.5. Conclusions

The conducted analysis led to formulation of the following conclusions:

- The WP2 solution can meet, with eventual extensions, the identification needs for the other products considered in scope.

- For some of these products, if the same approach is adopted with reference to ‘other’ medicinal products identified for the sake of D3.1, then the WP2 solution meets their identification needs:
  - if these products, as described and analysed in this document, 1 have appropriate identifiers depending on identification needs of each product and all product additional data is included in the database, then the WP2 solution meets the identification needs of these ‘other’ medicinal products,

- For some other products, according to the results of the gap analysis there is a need to extend the WP2 solution with reference to products mentioned in 7.4 which will be presented in D3.2:
  - product additional information, e.g. attributes should cover all specific identification needs enabling distinguishing products and determining individual differences between them,
  - whenever there is an attribute type missing in the product description, the database should be extended in order to meet other products’ identification needs.
  - The gaps – i.e. the attributes that are needed - are identified in this document.

This document provides the analytical input for the next task, which is validated by the uptake of the input and description of the solution in the D3.2. Examples of various scenarios to confirm this analysis will be analysed in T3.2 and included in D3.2.