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Pre-release

EU-SRS

Homoeopathic Substances EU-SRS User Guide

Guidance on naming and building homoeopathic substance records in EU-SRS

Disclaimer

This document is created as part of deliverable D2.8 EU-SRS Data Management Plan of Unicom Work Package 2: Implement IDMP – Substance Management in Europe.

This guide will be a living document, used by the Substances Validation Group (SVG) for creation and maintenance of substances in EU-SRS.

The current version is a pre-release. Your feedback, if any, is welcomed by **8 December 2022.** Comments can be sent to Steven de Wit (e-mail: s.d.wit@cbg-meb.nl).

Your feedback will be considered when preparing the official release which will be submitted as Unicom deliverable to the European Commission in January 2023.

Document control

This document is subject to a regular review by the Substance Validation Group (SVG). It is a living document; changes will be captured in the version history section.

Document ownership

This document is owned by the SVG.

Revision history

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List of abbreviations

Abbreviation	Complete Form
eAF	Electronic Application Form
EMA	European Medicines Agency
EU-SRS	European Substance Registration System
FDA	Food and Drug Administration
G-SRS	Global Substance Registration System
HAB/GHP	Homöopathisches Arzneibuch/German Homoeopathic Pharmacopoeia
INN	International Nonproprietary Name
ISO IDMP	ISO Identification of Medicinal Products
Ph. Eur.	European Pharmacopoeia
Ph. Fr.	French Pharmacopoeia
PT	Preferred Term
SMS	Substance Management Service
SPOR	Substances, Products, Organisations & Referentials (EMA)
SVG	Substance Validation Group

1 Introduction

The EU Network is currently implementing the ISO IDMP standards in a phased programme based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (collectively referred to as “SPOR”) master data. ISO IDMP compliant business services for the central management and supervision of data in each of the four SPOR areas will be established through an iterative and incremental delivery approach. Through the Substance Management Services (SMS) of the SPOR programme EMA will provide the EU network centralised substance data management services.

EU-SRS will become the scientifically rigorous back-end for the Substance Management Services of SPOR. EU-SRS will be accessible to the EU regulatory network, enabling the unambiguous identification of substances used in medicinal products based on their scientific properties in accordance with ISO IDMP standard 11238 and ISO IDMP technical specification standard 19844. EU-SRS allows the unique identification of substances, which will support various purposes including the enhancement of traceability of pharmacovigilance, non-clinical, clinical and quality findings with a high degree of precision to substances by their scientific identity.

The Substance Validation Group is responsible for building substance records in EU-SRS. In addition, the SVG defines guidance and best practices for substances management in EU-SRS (per substance type). Lastly, the SVG provides EMA with cleansing feedback on substance records in SMS; the EMA SMS team will process this feedback in SMS.

1.1 Purpose

The purpose of this document is to provide practical guidance for the registration of homoeopathic substances in EU-SRS.

This document has been written to serve as a reference for the SVG and EMA SMS team during handling of homoeopathic substances records, including defining the preferred term and aliases of the homoeopathic substances, as well as when building homoeopathic substances in EU-SRS. It aims to provide practical guidance and examples to handle homoeopathic substances.

1.2 Scope

Registration of human and veterinary homoeopathic substances are in scope of this document.

This document is to be used together with the overall EU-SRS Substance Maintenance Process which describes in detail the workflow between EMA and SVG.

2 Defining a homoeopathic substance

In order to ensure good quality homoeopathic substances records, which are built in a well-organized, and harmonised way, rules have been established and agreed upon within the SVG together with relevant partners, including representation from industry. References to external documentation are made where necessary. This chapter provides general guidance on how to define homoeopathic substances.

The concepts required for the unique identification and description of substances are described in the ISO 11238 IDMP standard on substances. Guidelines for implementing ISO 11238 are provided in the technical specification ISO/TS 19844. Although ISO 11238 does not provide any guidance on substance nomenclature, it does provide a structure for the capture of names and codes that are used to refer to a substance. This section aims to provide supplementary guidance and should be read in conjunction with the standard and technical specification.

2.1 Definition

In order to ensure that homoeopathic substances are cleansed or built in a harmonised way, rules and definitions have been established and agreed upon within the SVG. The concepts required for the unique identification and description of homoeopathic substances are described in Annex F in the ISO-standard ISO/TS 19844:

[The official ISO definition will be included upon approval by ISO]

2.2 EU-SRS hierarchy

EU-SRS provides the opportunity to establish relationships between the records and therefore a hierarchy can be built. Depending on (the origin of) the raw materials, different levels can be defined within the hierarchy of homoeopathic substances.

The levels for raw materials of microorganism, botanical and animal or human origin are as follows.

If “part” is applicable:

- **Level 1: organism (author)**

Example: Naja naja L., whole

- **Level 2: homoeopathic substance name + for homoeopathic preparations**

Example: Naja naja for homoeopathic preparations

- **Level 3: homoeopathic substance name + part**

Example: Naja naja, Venom

- **Level 4: homoeopathic substance name + part + manufacturing method**

Example: Naja naja, Venom, 4.1.1

Example: Naja naja, Venom, 3.1.1

- **Level 5: homoeopathic substance name + part + manufacturing method + potency**

Example: Naja naja, Venom, 4.1.1, D6

Example: Naja naja, Venom, 3.1.1, D6

An example of a hierarchy of related homoeopathic substances from botanical and animal or human origin and their relationships is depicted in Figure 1.

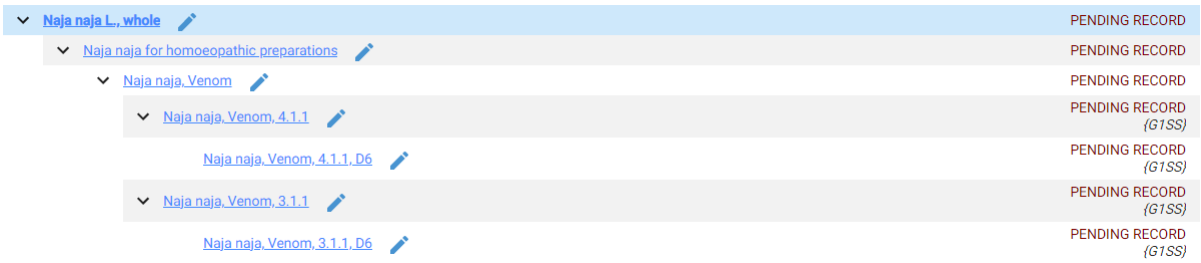

Figure 1. Example of a hierarchy that demonstrates the relationship between individual homoeopathic substances. Example shown: Naja naja.

If “part” is not applicable:

- **Level 1: organism (author)**
- **Level 2: homoeopathic substance name + for homoeopathic preparations**
- **Level 3: homoeopathic substance name + manufacturing method**
- **Level 4: homoeopathic substance name + manufacturing method + potency**

The levels for raw materials for chemicals or minerals are as follows:

- **Level 1: substance level**
- **Level 2: homoeopathic substance name + for homoeopathic preparation**
- **Level 3: homoeopathic substance name + manufacturing method**
- **Level 4: homoeopathic substance name + manufacturing method + potency**

2.3 Legislation and regulatory requirements

Human

According to Article 1(5) of Directive 2001/83/EC on the Community code relating to medicinal products for human use homoeopathic medicinal product is any medicinal product prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the national pharmacopoeias currently used officially in the Member States. A homoeopathic medicinal product may contain a number of principles.

Veterinary

Article 4(10) of Regulation (EU) 2019/6 on veterinary medicinal products provides an almost identical definition of veterinary medicinal products. Accordingly, a homoeopathic veterinary medicinal product means a veterinary medicinal product prepared from homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the national pharmacopoeias used officially in Member States.

3 Naming of homoeopathic substances

This chapter provides details around naming of homoeopathic substances in EU-SRS and SMS.

3.1 Name types

Every record in EU-SRS (independently of the level) has a preferred term, which is characterised as 'Display Name' in the system. EU-SRS contains name type information. ISO 11238 list several name types. Within the EU-SRS, examples of name types are:

- **Official name:** reflects the organization that assigns or recognizes the name associated with the substance. These names are typically non-proprietary names that are used in the labelling of pharmaceuticals. The domains and jurisdictions in which the official name is used are also captured, tracked and maintained within the terminology.
- **Systematic name:** reflects the systematic botanical name of biological substances. Alternatively, '**scientific name**' may be used as name type with this purpose.
- **Common name:** used if the name is neither an official name nor a systematic name.

3.2 Naming convention

Each unique substance receives an SMSID from SMS, and each SMSID has Preferred Term, which is characterised as 'Display Name' in the system. The Preferred Term is the name most accurately describing the substance at a given time and could change during the lifetime of a substance.

The Preferred Term is used in several forms visible to industry. Going forward, it is planned that these forms (such as eAF) will also display the aliases.

Veterinary homoeopathics are treated like human homoeopathics and follow the rules outlined in this document. Official organization to be followed for human homoeopathics apply for veterinary homoeopathics.

When adding a new Substance in SMS / EU-SRS, only the first letter of the substance should be capitalized and no dots are used within names, e.g. "*Arnica montana".*

Company own-monographs can be considered to define the names if available.

3.2.1 Preferred term

Every record in EU-SRS (independently of the level) has a preferred term (PT).

The naming of homoeopathic substances is regulated nationally in the Member States of the EU and is not uniform. In addition, monographs do not exist in a pharmacopoeia for all substances used in homoeopathic therapy. Most monographs also list several official names to choose from. In addition, in some countries manufacturing methods are also part of the substance names. Therefore, there are often several names for the same substances and it is not immediately obvious at first glance that they are identical substances.

Homoeopathic substances may have multiple traditional names, which is unique for this substance type. Most of the homoeopathic substances will not have a Ph. Eur. name mentioned in the homoeopathic monograph, but some will have a monograph in the Homöopathisches Arzneibuch (HAB) or in the Pharmacopée française (Ph. Fr.). In the HAB and in the Ph. Fr. there are often two and sometimes three titles. All names mentioned in the HAB and Ph. Fr. should be included in the record (as aliases). PTs and aliases are equally valid. To define the PT, the **main** title of a pharmacopoeia's monograph should be considered and all alternative names in Ph. Eur, in the HAB and/or in the Fr. Ph., where available, should be included as aliases.

The order of priority of homoeopathic substance PT in EU-SRS is established as follows:

1. European Pharmacopoeia Monograph *English* main title (traditional name, listed as PT).

   Whereas it is acknowledged that Latin *sub*titles used in Ph. Eur. monographs are systematically identical in the English and French version of the respective monograph [scientific names], priority is nevertheless given – for the definition of the PT – to the [traditional] name as indicated in the respective Ph. Eur. **main** titles (English/French).
2. Homöopathisches Arzneibuch (HAB) (German Homoeopathic Pharmacopoeia) monograph main title (usually scientific name, listed as PT)

   It is acknowledged that – historically justified – the title of a HAB monograph [main title: scientific name / subtitle(s): traditional name (s)], follows a different line of reasoning compared to the title of a Ph. Eur. monograph for a homoeopathic substance [main title: traditional name / subtitle(s): scientific name]. Nevertheless, and for the purpose of consistency, priority is systematically given – for the definition of the PT – to the **main** title of a pharmacopoeia's monograph. This rule also applies to other officially used pharmacopoeias (see also e.g. following item 3).
3. La Pharmacopée française (French Pharmacopoeia)
4. Official sources for scientific names (e.g. Materia Medica on homoeopathics)
5. Other relevant national Pharmacopoeias
6. INN for chemicals (as additional name to the traditional homoeopathic name)
7. Anthroposophic Pharmaceutical Codex (APC)
8. German Commission C, D & E Monographs
9. Hagers Handbuch der Drogen und Arzneistoffe

3.2.2 Aliases

Aliases (also known as synonyms) are equally valid alternative names for a PT, according to valid reference sources.

- The EU-SRS PT should be written in British English. Any US English term can however to be kept as an alias.
- Ph. Eur. Monograph *French* main title (traditional name) should be included as alias if possibly different from English main title.
- Scientific names used in Ph. Eur. monograph *sub*titles should be included as aliases.
- HAB monograph *sub*title(s) should be included as aliases.
- French Pharmacopoeia *sub*title(s) should be included as aliases.

3.2.3 Invalid substance names

Any substance name that is not an alias as described in paragraph 4.4.2 and that is not available in any valid reference source is considered invalid and should be deprecated, unless otherwise justified.

3.2.4 Reference information

All public records must have at least one public reference where the "PUBLIC_DOMAIN_RELEASE" tag is populated (otherwise the record cannot be public). The reference may be a publicly available database or an authorized naming body (please refer to the acceptable naming sources described above). In general, the product information should contain this information.

Each name (independently of the access) must have a reference (including alias, acronym, synonym etc.). References can be newly created or reused (once added to a record) by selecting the tick box. Independently of the tag mentioned above names can be marked as public using the tick box "Public Domain". This is specific for this name and has no influence on the accessibility of the whole record.

3.3 Naming Syntax

The following elements may be used for the naming syntax on the five levels in the hierarchy of related homoeopathic substances: Homoeopathic Substance Name, Delimiter(comma), Plant/Animal Part, Manufacturing Method, Potency

3.3.1 Naming Syntax elements

Homoeopathic Substance Name

The naming of homoeopathic substances depends on the availability of a monograph in the Ph. Eur. and in other national pharmacopeia names, see section 3.2.1.
The manufacturing method is stated, whereby the numbering of the methods of the Ph. Eur. has priority over the HAB and the French Pharmacopoeia. The vehicle is not given if this is evident from the production method.

If there is no monograph in a pharmacopoeia, the common homoeopathic name, the scientific name or the name according to the product information is used.

The homoeopathic substance name should be selected according to the priority ranking as mentioned above.

Delimiter (Comma)

If the homoeopathic name is followed by the element “Plant/Animal Part”, a comma is placed between the two-name elements.

Example: Arnica montana, Radix

Plant/Animal Part

For plants, the Latin description of the plant part used has to be specified.

Example: Planta tota, Radix, Flos, Herba

For animals, the Latin description of the animal part used has to be specified
Exception: If the complete animal is used, the name elements “Delimiter” and “Plant/Animal Part” have to be omitted.

Example: Cor, Hepar

Manufacturing Method

The manufacturing method shall be indicated by stating the pharmacopoeia in which the method is listed and the number of the method. See 4.3.5 for the hierarchy.

Examples: for Ph. Eur. method: 1.1.8
for HAB method: HAB 47a

Potency

The potency is given without the addition of Dil. or Trit. Only the decimal/centesimal/LM potencies are given.

For the PTs the potency is given according to the rules of Ph. Eur. Monograph “Homoeopathic preparations” (1038), section “potentisation” for example as:

D4 for D4, 4 DH, 4X

C10 for C10, 10 CH, 10C

LM1 for 1 LM, LM I.

For the Aliases the potency can also be given according to the rules of the concerned pharmacopoeias.
Examples: D4, C10, 6 DH, 10 CH, 12X, 6C, LM I, K1000

3.3.2 Level 1

The level 1 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin is included in table 1. For homoeopathic substances that are derived from raw materials of microorganism, botanical, animal or human origin the naming syntax should contain the organism name. For homoeopathic substances that are derived from raw materials of chemical or mineral origin the naming syntax should contain the substance level.

Table 1. Level 1 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin.

Origin	Naming Syntax
Microorganism, botanical and animal or human	<Organism name>
Chemical or mineral origin	<Substance level>

3.3.3 Level 2

The level 2 naming syntax for homoeopathic substances that are derived from raw materials of botanical, animal, human, chemical or mineral origin is included in table 2. For homoeopathic substances that are derived from raw materials of microorganism, botanical, animal or human origin the naming syntax should contain the homoeopathic substance name followed by the text “for homoeopathic preparations”. For homoeopathic substances that are derived from raw materials of chemical or mineral origin the naming syntax should also contain the homoeopathic substance name followed by the text “for homoeopathic preparations”

Table 2. Level 2 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin.

Origin	Naming Syntax
Microorganism, botanical and animal or human	<Homoeopathic substance name> + for homoeopathic preparations
Chemical or mineral	<Homoeopathic substance name> + for homoeopathic preparations

3.3.4 Level 3

The level 3 naming syntax for homoeopathic substances that are derived from raw materials of botanical, animal, human, chemical or mineral origin is included in table 3. For homoeopathic substances that are derived from raw materials of microorganism, botanical, animal or human origin the naming syntax should contain the homoeopathic substance name followed by the part if available. If the part is not available the manufacturing method should be included instead. For homoeopathic substances that are derived from raw materials of chemical or mineral origin the naming syntax should also contain the homoeopathic substance name followed by the manufacturing method.

Table 3. Level 3 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin.

Origin	Naming Syntax
Microorganism, botanical and animal or human	When <part> is available: <Homoeopathic substance name> + <part> When <part> is not available: <Homoeopathic substance name> + <manufacturing method>
Chemical or mineral	<Homoeopathic substance name> + <manufacturing method>

3.3.5 Level 4

The level 4 naming syntax for homoeopathic substances that are derived from raw materials of botanical, animal, human, chemical or mineral origin is included in table 3. For homoeopathic substances that are derived from raw materials of microorganism, botanical, animal or human origin the naming syntax should contain the homoeopathic substance name followed by the part if available and subsequently by the manufacturing method. If the part is not available the manufacturing method should be included instead of the part, followed by the potency. For homoeopathic substances that are derived from raw materials of chemical or mineral origin the naming syntax should also contain the homoeopathic substance name followed by the manufacturing method and the potency.

Table 4. Level 4 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin.

Origin	Naming Syntax
Microorganism, botanical and animal or human	When <part> is available: <Homoeopathic substance name> + <part> + <manufacturing method> When <part> is not available: <Homoeopathic substance name> + <manufacturing method> + <potency>
Chemical or mineral	<Homoeopathic substance name> + <manufacturing method> + <potency>

3.3.6 Level 5

The level 5 naming syntax for homoeopathic substances is only applicable when the raw materials are of microorganism, botanical, animal or human origin and when the part is available. The naming syntax should contain the homoeopathic substance name, followed by the part, the manufacturing method and the potency (see table 5).

Table 5. Level 5 naming syntax for homoeopathic substances that are derived from raw materials of microorganism, botanical, animal, human, chemical or mineral origin.

Origin	Naming Syntax
Microorganism, botanical and animal or human	When <part> is available: <Homoeopathic substance name> + <part> + <manufacturing method> + <potency> When <part> is not available: Not applicable
Chemical or mineral	Not applicable

4 Appendix

4.1 Databases for all substances types

Database Name	Description
INN	The INN Programme assigns International Nonproprietary Names to medicinal substances through a broad consultative process. WHO is responsible for the INNs.
European Pharmacopoeia	The purpose of the European Pharmacopoeia is to promote public health by the provision of recognised common standards for the quality of medicines and their components. As these standards ensure that medicines reaching the market are safe for use by patients, it is essential that they are appropriate. Their existence also facilitates the free movement of medicinal products in Europe and beyond.
Medicines Complete	A site which guides on to several different publications, databases containing information about medicines.
FDA Substance Registration System	Registration system in the U.S. by FDA and the U.S. National Library of Medicine (NIH), provides UNII-codes, Unique Ingredient Identifier.
G-SRS	Database built by GiNAS, NIH. This is the basis for the EU-SRS.
International Pharmacopoeia	International Pharmacopoeia provided by WHO.

4.2 Databases specific for homoeopathic substances

Database Name	Description
French Pharmacopoeia	This is a direct link to the homoeopathic part of the French Pharmacopoeia
Materia Medica	A list of all remedies used in homoeopathic drugs; they also have the abbreviations. There is a repertory for usage.
German Homoeopathic Pharmacopoeia	Book available in English and German
Kew Garden	Medical plant names services
HagerROM	Hagers Handbuch der Drogen und Arzneistoffe