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SMS Business rules

Version 1.0

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1. Introduction

This document describes the business rules applied in SMS.

This is a living document and is expected to be reviewed and updated over the coming quarters with business rules for additional substance types. Some business rules have been reviewed and endorsed by the Substance Validation Group (SVG), while others are interim SMS rules pending SVG review. For each substance type or group, the status of the applicable business rules and related cleansing status is provided.

This document should be read in conjunction with the SMS Guidance for External Users.

2. General naming rules

A substance record may reference different name types which, based on concerned regulatory procedure, will impact the selection of the preferred term and influence the confidentiality selection:

- **Systematic (chemical) names** follow a set of rules that are defined by an international body, such as the International Union of Pure and Applied Chemistry (IUPAC). Systematic names are based on the structure and composition of the chemical, and they uniquely identify one chemical. This name type can be either public or restricted and can therefore be set either as the preferred term or as an alias.
- **Common names** are names that are widely used, but do not follow the systematic naming convention. This name type can be either public or restricted and can therefore be set either as the preferred term or as an alias.
- **Official names** are names that are referenced in an official public source (e.g. Ph. Eur., INN, USAN, JAN). This name type will always be public and can therefore be set as the preferred term (for recommended INNs) or as an alias (for proposed INNs, USAN, etc.).
- **Company or laboratory codes** are combinations of letters and numbers given by companies developing a substance and are used to identify the substance while it is in development. This name type can be either public or restricted and can therefore be set either as the preferred term or as an alias.

The preferred term of a substance should be selected according to the priority ranking of the following reference sources and name types:

1. European Pharmacopoeia name[1]
2. (Modified) Recommended International Non-Proprietary Name
3. Other official name type with EU/EEA jurisdiction (e.g. INCI)
4. Common name mentioned in the SmPC or package leaflet
5. Systematic/scientific name
6. Company code

In addition to the sources/name types used for preferred terms, the following sources can also be used for aliases:

- Proposed INN
- United States Approved Name
- United States Pharmacopoeia

[1] Some older Ph. Eur. monographs have a mismatch between the name and its definition, leading to ambiguous substance records. These situations are exceptions and are being discussed between the SVG and EDQM. Further information is provided in chapter 8.3 Data Cleansing – Section 3.

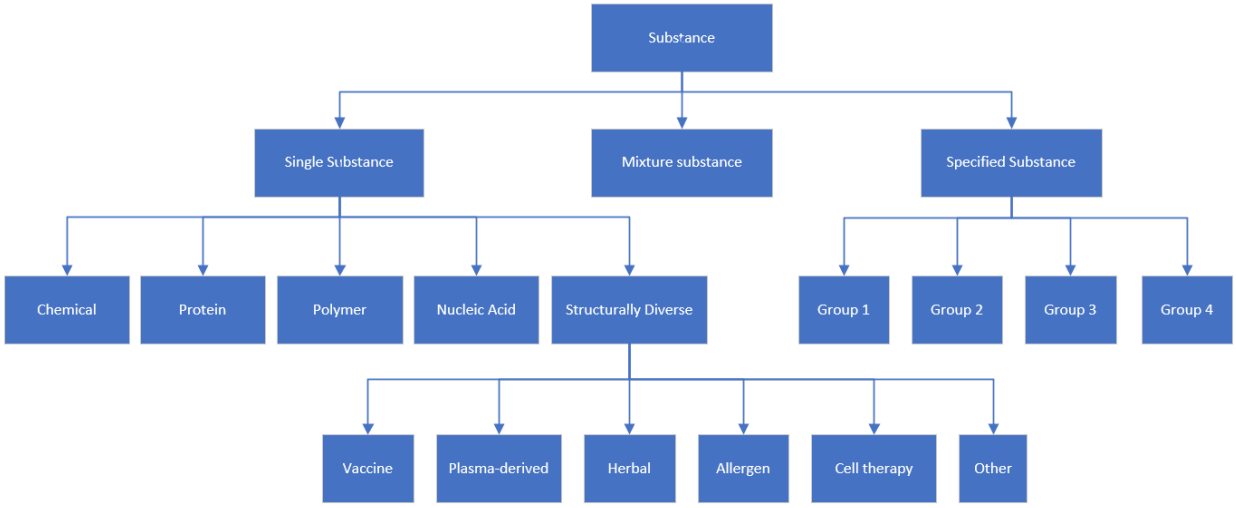
- Japanese Approved Name
- Official name in other jurisdictions (e.g. BAN, AAN)

If a salt/solvate is requested, the active moiety (free base or free acid or anhydrous substance) will also be registered for the purposes of grouping/hierarchy, if missing. If only a company code is provided (e.g. ABC-123) for a substance with a sodium salt, then "ABC-123" will be used for the free base and "ABC-123 sodium" will be used for the salt. If different company codes are provided, then they will be used accordingly. Similarly, when a radioactive substance is requested, the unlabelled substances will also be registered, if missing.

3. Substance type-specific naming rules

The substance type is defined by SMS data stewards, and it is only used for data management purposes in SMS and has no impact in any regulatory procedure. The substance types in SMS are a controlled vocabulary list from RMS, which are listed in Annex 4 of the SMS Guidance for External Users.

Figure 1. Substance type values in SMS



3.1. Chemicals

Chemicals are single substances with a discrete molecular structure.

Table 1. Status of business rules and data quality activities for chemical substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Completed
Quality review process implemented for new substances	In place for all records

3.1.1. Key principles

- Molecular formula, molecular weight and InChIKey will be generated based on systematic name and registered in SMS, in accordance with the confidentially rules defined in section 3.2 of the SMS Guidance for External Users
- All chemical substances are registered with the domain "Human use", as the domain cannot be determined reliably from the substance structure alone.
- A systematic name is always required unless an official name, CAS number or UNII is provided.
    - When an official name, CAS number or UNII are available, the molecular formula, molecular weight and InChIKey may be obtained from the corresponding database record. The systematic name is then not required for generating these data.
    - When neither a CAS number nor a UNII is available, a systematic name must be provided so that the molecular formula, molecular weight and InChIKey can be generated.
    - The molecular formula, molecular weight and InChIKey will be registered in SMS in accordance with the confidentiality rules in Section 3.2 of the SMS Guidance for External Users.
- Any UNII available at the time of registration will be added as an external code.
- All information must be handled in accordance with the confidentiality rules in Section 3.2 of the SMS Guidance for External Users.

Table 2. Data fields for chemicals

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Chemical
Preferred term	Mandatory	In accordance with General naming rules in section 2 above and confidentiality rules in the SMS Guidance for External Users
Alias*	Mandatory	Systematic name, if not used as the substance preferred term, in accordance with the confidentiality rules in the SMS Guidance for External Users
Alias*	Optional	Other company codes or common name or official names (i.e. pINN and USAN), if not used as the substance preferred term, in accordance with the confidentiality rules in the SMS Guidance for External Users
Molecular formula	Mandatory	Generated from systematic name, or external sources or supporting documentation

Data field	Conformance	Details
Molecular weight	Mandatory	Generated from systematic name, or external sources or supporting documentation
InChiKey	Mandatory	Generated from systematic name, or external sources or supporting documentation
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Conditional	If available in FDA
SVG flag	Mandatory	1

*Alias is a repeatable field. A substance record can have multiple aliases, with substance names registered as "public" or "restricted", as applicable

Examples:

Table 3. Chemical in the public domain with a recommended INN

SMS ID	100000174650
Domain	Human Use
Substance type	Chemical
Preferred term	Nirogacestat*
Alias	(2S)-2-{[(2S)-6,8-difluoro-1,2,3,4-tetrahydronaphthalen2-yl]amino}-N-(1-{1-[(2,2-dimethylpropyl)amino]-2-methylpropan-2-yl}-1H-imidazol-4-yl)pentanamide
Alias	PF-03084014
Molecular formula	C27H41F2N5O
Molecular weight	489.65
InChiKey	VFCRKLWBYMDAED-REWPJTCUSA-N
Comments	*Null*
EV Code	SUB188628
UNII	QZ62892OFJ
SVG flag	1

*The substance name "Nirogacestat" is a rINN, so it can be used as the substance preferred term.

Table 4. Chemical in the public domain with a proposed INN

SMS ID	300000005220
Domain	Human Use
Substance type	Chemical
Preferred term	N-((3S,4S)-1-(cyclopropylmethyl)-3-((1-(pyrimidin-2-yl)cyclopropyl)carbamoyl)piperidin-4-yl)-5-(2,4-difluorophenyl)isoxazole-3-carboxamide
Alias	Canverixin*
Alias	ACT-1004-1239
Molecular formula	C27H28F2N6O3
Molecular weight	522.55
InChiKey	IIDSHAJKXPUYSL-FPOVZHCZSA-N
Comments	*Null*
EV Code	SUB201601
UNII	122Q610M3R
SVG flag	1

*While the substance name "Canverixin" is an INN, it is a proposed INN, so it cannot be used as the substance preferred term.

Table 5. Chemical not in the public domain (restricted)

SMS ID	100000174986
Domain	Human Use
Substance type	Chemical
Preferred term	BI 113823
Alias	*Restricted**
Molecular formula	*Restricted**
Molecular weight	*Restricted**
InChiKey	*Restricted**
Comments	*Null*
EV Code	SUB189190
UNII	*Null*
SVG flag	1

*These data fields are still registered in SMS, but they are not publicly visibile in any consuming system.

3.1.2. Unspecified chemicals

Unspecified chemicals refer to substance records that are known to be chemicals but are missing mandatory data fields such as systematic name, molecular formula, molecular weight and/or InChiKey. These records can only be created in the two scenarios below:

- Change requests raised for pharmacovigilance purposes (i.e. directly from a SUSAR/ICSR) for which the systematic name is not available in any reliable source
- Change requests for other regulatory procedures with a systematic name not parsable (i.e. not possible to generate an InChiKey)

Table 6. Data fields for Unspecified chemicals

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Chemical
Preferred term	Mandatory	Company code
Alias	Optional	Other company codes, if available
Molecular formula	Not applicable	Not available
Molecular weight	Not applicable	Not available
InChiKey	Not applicable	Not available
Comment	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	Not available
SVG flag	Mandatory	0

Once additional information is available in the public domain or provided on in a future change request, the missing data fields will be populated and then the comment "Unspecified" and SVG flag 0 will be removed.

Examples:

Table 7. Chemical for pharmacovigilance without systematic name available

SMS ID	300000059006
Domain	Human Use
Substance type	Chemical
Preferred term	GS-9911
Alias	*Null*
Molecular formula	*Null*
Molecular weight	*Null*
InChiKey	*Null*
Comments	Unspecified
EV Code	SUB427493
UNII	*Null*
SVG flag	0

3.2. Proteins

Proteins are single substances with a structure based on a sequence of amino acids. Small proteins (peptides) can also be scientifically described as a chemical. According to the SMS business rules, any peptide with more than 3 amino acids will be registered as a protein. Proteins modified with a polymer or a chemical will also be registered as a protein.

Table 8. Status of business rules and data quality activities for protein substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not completed
Quality review process implemented for new substances	Not yet in place

3.2.1. Peptide

Peptides can be registered as proteins or chemicals. Peptides with three or less amino acids are to be considered chemicals, while peptides with four or more are to be considered proteins.

- Amino acid sequence must be provided.

3.2.2. Antibody

The following data elements must be provided:

- Source of the immunoglobulin (e.g. Human, Humanised, etc.)
- Immunoglobulin type (e.g. IgG1, IgG4, etc.)
- Immunoglobulin modifications (if applicable)
- Target(s)

In case of antibody-drug conjugates, information on the payload (usually a chemical) must also be provided. The payload might also be registered as a separate substance record, taking into account the business rules for the concerned substance type.

3.2.3. Fusion protein

Individual protein components must be provided.

3.3. Polymers

Polymers are substances with a multiple repeating unit. Substances composed of a chemical covalently linked to a polymer will be registered as a polymer.

Table 9. Status of business rules and data quality activities for polymer substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed for 6 polymer groups
Data cleansing completed	Completed for 6 polymer groups
Quality review process implemented for new substances	Not yet in place

3.3.1. Polymers defined by Ph. Eur.

Table 10. Polymers defined by a Ph. Eur. monograph definition

Ph. Eur. monograph	PT Examples	Aliases Examples	Invalid names Examples
Hydroxypropylcellulose	Hydroxypropelcellullose, low-substituted	Hyprolose (5-16%) L-HPC	Hydroxypropyelcellose LH-21 Hydroxypropyelcellose type JF

3.3.2. Polymers defined by property

Table 11. Data fields for Polymers

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Polymer
Preferred term	Mandatory	Polymer group + applicable property
Alias	Optional	
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Conditional	If available in FDA
SVG flag	Mandatory	1

Table 12. Polymers defined by a Ph. Eur. monograph property

Polymer group	Property to be included in PT	PT Examples	Aliases Examples	Invalid names Examples
Macrogol	Molecular weight	Macrogol 400	PEG 400 Polyethylene glycol 400 Polyoxyethylene glycol 400 PEG-8	Macrogol (PEG 400) Macrogol 400 (PEG 400)
Dimeticone	Nominal kinematic viscosity	Dimeticone 1000	Dimeticone (1000 cSt) Dimethicone 1000 Polydimethylsiloxane 1000	
Hypromellose	Substitution type, viscosity	Hypromellose 2208, 100000 mPa.s	Hydroxypropylmethylcellulose 2208, 100000 CPS Methocel K100M premium Benecel HMPC K100M	Hypromellose 100000 CP Hypromellose 2208/100000

Polymer group	Property to be included in PT	PT Examples	Aliases Examples	Invalid names Examples
			Methlose SR 90SH 100000SR (100000 mPa.S)	
Povidone	Viscosity (K-value)	Povidone K30	Kollidon 30 Povidone K28-30 Povidone K21-31	Povidone K29/31
Hydroxypropylcellulose (not Ph. Eur.)	Content of hydroxypropoxy groups	Hyprolose (71.0-76.9%)	Hydroxypropelcellullose (71.0-76.9%)	Hydroxypropelcellullose 240 mPa.S
Crospovidone	type A or type b	Crospovidone type A	Crospovidone type A (E 1202) Crospovidone (type A) Kollidon Cl	Crospovidone (E1201) Crospovidone XL Crospovidone (Kollidone Cl)

Poleymers that do not include the mandatory properity mentioned in table 12 are available as unspecified polymers and further described in section 3.3.3.

3.3.3. Unspecified polymers

Unspecified polymers refer to substance records that are polymers but are missing the respective mandatory property mentioned in the section 3.3.2.

These records have comment "Unspecified" and SVG flag 0, and they can only be used in legacy products that were approved without the respective property in the SmPC.

Table 13. Data fields for Unspecified polymers

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Polymer
Preferred term	Mandatory	Polymer group without property
Comment	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	Not available
SVG flag	Mandatory	0

Examples:

Table 14. Unspecified polymers

SMS ID	100000115769
Domain	Human Use
Substance type	Polymer
Preferred term	Macrogol
Comments	Unspecified
EV Code	SUB31091
UNII	3WJQ0SDW1A
SVG flag	0

3.4. Nucleic acid

Nucleic acids are single substances with a structure based on a sequence of nucleotides.

Table 15. Status of business rules and data quality activities for nucleic acid substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not completed
Quality review process implemented for new substances	Not yet in place

3.5. Structurally Diverse - Herbal

In accordance with Directive 2004/24/EC, herbal substances are "all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form, but sometimes fresh".

For the purposes of SMS maintenance, herbal substances are divided in five subgroups, each with different business rules:

- Genus-only
- Whole
- Part – Ph. Eur. – Single Species
- Part – Ph. Eur. – Multiple Species
- Part – Not Ph. Eur.

These records are registered in SMS with the substance type "Structurally Diverse – Herbal" if only one species is present. If multiple species are/can be present, then the substance type would be considered a "Mixture".

The business rules described in this section do not apply to herbal extracts and homeopathic substances.

The figure below describes the five herbal groups in SMS.

Figure 2. Herbal groups in SMS

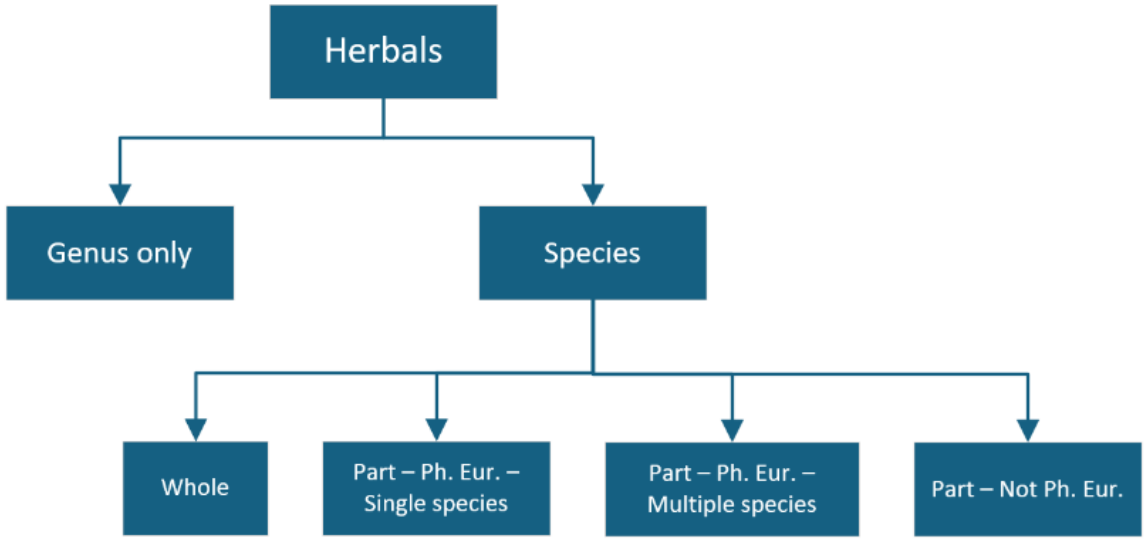


Table 16. Status of business rules and data quality activities for herbal substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Completed
Quality review process implemented for new substances	In place for all records

Reference sources for SMS Preferred term of herbal substances:

1. European Pharmacopoeia (if Ph. Eur. monograph available)
2. Taxonomic Databases (if Ph. Eur. monograph not available):
   - Plants: Plants of the World Online (Kew Gardens)
   - Fungi: Index Fungorum
   - Algae: AlgaeBase

3.5.1. Genus-only records

Context
Only to be created if both conditions below apply simultaneously:
- Request for pharmacovigilance purposes
- Reported substance name does not include species nor is it possible to infer it

Table 17. Data fields for herbals – genus only

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse - Herbal
Preferred term	Mandatory	<Taxonomic name of the Genus (without Author) in accordance with the respective taxonomic database>
Alias	Not applicable	Aliases not registered for this group of substances
Comment	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	Not available for this group of substances
SVG flag	Mandatory	0

Examples:

SMS ID	100000153626
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Carlina
Alias	*Null*
Comments	Unspecified
EV Code	SUB127785
UNII	*Null*
SVG flag	0

SMS ID	100000138865
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Alternaria
Alias	*Null*
Comments	Unspecified
EV Code	SUB79219
UNII	*Null*
SVG flag	0

3.5.2. Whole

Context
Only to be created if all conditions below apply simultaneously:
- Request for pharmacovigilance purposes
- Reported substance name includes species
- Reported substance name does not include part

Table 18. Data fields for herbals – whole

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse - Herbal
Preferred term	Mandatory	<Taxonomic name of the Species (with Author*) in accordance with the respective taxonomic database>, whole
Alias	Optional	<Common name>, "whole"
Comment	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	If available in FDA
SVG flag	Mandatory	0

*Some plant varieties do not include author in Plants of the World Online. In that case, the taxonomic name will be exceptionally registered without author.

Examples:

SMS ID	100000090721
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Artemisia vulgaris L., whole
Alias	Mugwort, whole
Comments	Unspecified
EV Code	SUB29266
UNII	JDR81QW9ZQ
SVG flag	0

SMS ID	300000057904
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Angelica dahurica var. formosana (H.Boissieu) Yen, whole
Alias	*Null*
Comments	Unspecified
EV Code	SUB414673
UNII	247A107296
SVG flag	0

SMS ID	100000093281
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Aspergillus fumigatus Fresen, whole
Alias	*Null*
Comments	Unspecified
EV Code	SUB29591
UNII	X88DF51T48
SVG flag	0

3.5.3. Part - Ph. Eur. – Single species

Context

- To be created upon publication of a new herbal Ph. Eur. herbal monograph for a single species

Table 19. Data fields for herbals – Part - Ph. Eur. – Single species

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse - Herbal
Preferred term	Mandatory	<Ph. Eur. monograph title in English>
Alias	Mandatory	<Ph. Eur. monograph title in Latin>
Alias	Mandatory	<Taxonomic name of the Species (with Author) in accordance with the respective taxonomic database>, <part>
Alias	Optional	<Common name>, <part>
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	If available in FDA
SVG flag	Mandatory	1

Examples:

SMS ID	100000076681
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Arnica flower
Alias	Arnicae flos
Alias	Arnica montana L., flower
Comments	*Null*
EV Code	SUB29266
UNII	OZ0E5Y15PZ
SVG flag	1

SMS ID	100000076326
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Iceland moss
Alias	Lichen islandicus
Alias	Cetraria islandica (L.) Ach., thallus
Comments	*Null*
EV Code	SUB13301MIG
UNII	*Null*
SVG flag	1

3.5.4. Part - Ph. Eur. – Multiple species

Context

- To be created upon publication of a new herbal Ph. Eur. herbal monograph for multiple species

Table 20. Data fields for herbals – Part - Ph. Eur. – Multiple species

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Mixture
Preferred term	Mandatory	<Ph. Eur. monograph title in English>
Alias	Mandatory	<Ph. Eur. monograph title in Latin>
Alias	Mandatory	<Taxonomic name of the Species 1 (with Author) in accordance with the respective taxonomic database> and/or <Taxonomic name of the Species 2 (with Author)> and/or <Taxonomic name of the Species 3 (with Author)> and/or <Taxonomic name of the Species 4 (with Author)>, <part>
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	To be added, if available
SVG flag	Mandatory	1

Examples:

SMS ID	100000176006
Domain	Human Use
Substance type	Mixture
Preferred term	Pelargonium root
Alias	Pelargonii radix
Alias	Pelargonium sidoides DC. and/or Pelargonium reniforme (Andrews) Curtis, root
Comments	*Null*
EV Code	SUB190791
UNII	*Null*
SVG flag	1

SMS ID	100000077047
Domain	Human Use
Substance type	Mixture
Preferred term	Kelp
Alias	Fucus vel Ascophyllum
Alias	Fucus vesiculosus Linnaeus or Fucus serratus Linnaeus or Ascophyllum nodosum (Linnaeus) Le Jolis, thallus
Comments	*Null*
EV Code	SUB14298MIG
UNII	*Null*
SVG flag	1

3.5.5. Part – Not Ph. Eur.

Context
- Can be created for any request type

Table 21. Data fields for herbals – Part - Not Ph. Eur.

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse – Herbal
Preferred term	Mandatory	<Taxonomic name of the Species (with Author) in accordance with the respective taxonomic database>, <part>
Alias	Optional	<Common name>, <part>
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	To be added, if available
SVG flag	Mandatory	1

Examples:

SMS ID	100000158141
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Corylus americana Walter, leaf
Alias	Hazelnut, leaf
Comments	*Null*
EV Code	SUB167510
UNII	KT0L68561O
SVG flag	1

SMS ID	100000176945
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Tremella fuciformis Berk., fruiting body
Alias	*Null*
Comments	*Null*
EV Code	SUB192019
UNII	GG8N28393G
SVG flag	1

SMS ID	300000057682
Domain	Human Use
Substance type	Structurally Diverse – Herbal
Preferred term	Fucus vesiculosus Linnaeus, thallus
Alias	*Null*
Comments	*Null*
EV Code	SUB413045
UNII	*Null*
SVG flag	1

3.6. Structurally Diverse – Vaccine (Human)

These are substance records with multiple unknown molecular entities, that are used to stimulate the body's immune response against one or more microorganisms, that can affect humans and animals. Vaccines based on a protein antigen are also registered as Structurally Diverse – Vaccine.

Table 22. Status of business rules and data quality activities for human vaccines substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not yet cleansed
Quality review process implemented for new substances	Not yet in place

3.7. Structurally Diverse – Vaccine (Veterinary)

These are substance records with multiple unknown molecular entities, that are used to stimulate the body's immune response against one or more microorganisms, that only affect animals. Vaccines based on a protein antigen are also registered as Structurally Diverse – Vaccine.

Table 23. Status of business rules and data quality activities for veterinary vaccines substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Fully cleansed
Quality review process implemented for new substances	In place

Key principles
All new veterinary vaccines must be registered with a strain unless they belong to one of the identified exceptions:
3.8.2 Vaccines for Scientific Advice
3.8.3 Recombinant protein vaccines
3.8.4 Legacy products without strain

Some vaccine records might have multiple strains and be registered as Specified Substance Group 1
3.8.5 Vaccines with multiple strains but only one potency test

Additionally, certain microorganisms have a different set of rules:
3.8.6 Influenza vaccines
3.8.7 Vector vaccines
3.8.8 Infectious bursal disease virus (intermediate strains)
3.8.9 Escherichia coli
3.8.10 Leptospira
3.8.11 Foot-and-mouth disease virus
3.8.12 Toxin-producing microorganisms

3.7.1. General rules

- Preferred term syntax: <Microorganism>, <taxonomic levels>, <strain>, <vaccine status> or <antigen>
- Alias(es) syntax: <Microorganism>, <taxonomic levels>, <strain>, <vaccine status> or <antigen>

Table 24. Veterinary vaccines name parts – general rules

Name part	Conformance	Details
Microorganism	Mandatory	Microorganism preferred term, as defined by the SVG
Taxonomic levels	Conditional	Taxonomic levels (e.g. serotype, serogroup, serovar) applicable for the given microorganism, as defined by the SVG
Strain	Mandatory*	Strain used in the given vaccine
Vaccine status or Antigen	Mandatory	"Live" or "Inactivated" or <antigen> used. Live attenuated vaccines are registered as "Live".

*with the exceptions in the Key principles mentioned above

Examples:

SMS ID	300000040441
Preferred term	Bovine viral diarrhoea virus, strain BK-1/B-1, Live
Alias	BVDV-1, strain BK-1/B-1, Live
Alias	Pestivirus A, strain BK-1/B-1, Live

SMS ID	300000028537
Preferred term	Bordetella bronchiseptica, strain Bb7 92932, fimbriae
Alias	*Null*

3.7.2. Vaccines for Scientific Advice

Preferred term syntax: Usually just a company code
Alias(es) syntax: <Microorganism>, <taxonomic levels>, <strain>, <vaccine status or antigen>

Table 25. Veterinary vaccines name parts – scientific advice

Name part	Conformance	Details
Microorganism	Mandatory	Microorganism preferred term, as defined by the SVG
Taxonomic levels	Conditional	Taxonomic levels applicable for the given microorganism, as defined by the SVG
Strain	Optional	Strain used in the given vaccine, if already known
Vaccine status or Antigen	Mandatory	"Live" or "Inactivated" or antigen used in the given vaccine

If the strain is not present, then the substance should be registered with the following data fields populated:

- Comments: Unspecified
- SVG flag: 0

Once/if information on strain becomes available, the substance preferred term/aliases will be updated in accordance with the general rules and the comment/SVG flag 0 will be removed.

Examples:

SMS ID	300000018122
Preferred term	PB-133
Alias	*Restricted*
Comments	Unspecified
SVG flag	0

SMS ID	300000039789
Preferred term	FEC-1
Alias	*Restricted*
Comments	*Null*
SVG flag	1

3.7.3. Recombinant protein vaccines

Preferred term syntax: <Microorganism>, <taxonomic levels>, <antigen> (recombinant, Virus-like particle*)
*if applicable

Table 26. Veterinary vaccines name parts – recombinant protein vaccines

Name part	Conformance	Details
Microorganism	Mandatory	Microorganism taxonomic name
Taxonomic levels	Conditional	Taxonomic levels (e.g. serotype, serogroup, serovar) applicable for the given microorganism, as defined by the SVG
Antigen	Mandatory	Antigen used in the given vaccine
(recombinant)	Mandatory	The word recombinant added in brackets without comma in the end
(recombinant, Virus-like particle)	Conditional	Proteins that self-assemble into a particle are considered a VLP (stronger immunity than without self-assembling)

Examples:

SMS ID	300000017891
Preferred term	Bovine viral diarrhoea virus 1, protein E2 (recombinant)

SMS ID	300000008531
Preferred term	Escherichia coli, shiga toxin 2e (recombinant)

3.7.4. Legacy products without strain

Some existing vaccine records without strain are kept in SMS with status current but can only be used for already approved veterinary products. They have the comment "Unspecified" and SVG flag 0, so they are not visible in the eAF and not usable in UPD for new products. When required for a variation in the eAF and, upon a substance change request, the SVG flag 0 is temporarily removed and added manually again later.

In the long term, these unspecified records should be replaced by new vaccine records with strain in conformity with the current naming rules.

Examples:

SMS ID	100000151371
Preferred term	Canine parvovirus, Live

SMS ID	100000151421
Preferred term	Feline calicivirus, Live

3.7.5. Vaccines with multiple strains but only one potency test

Preferred term syntax: <Microorganism>, <taxonomic levels>, strains <strain 1> and <strain 2>, <vaccine status or antigen>

Table 27. Veterinary vaccines name parts – vaccines with multiple strains

Name part	Conformance	Details
Microorganism	Mandatory	Microorganism preferred term, as defined by the SVG
Taxonomic levels	Conditional	Taxonomic levels required for the given microorganism, as defined by the SVG in the Microorganisms file
Strains	Mandatory	Strains used in the given vaccine
Vaccine status or Antigen	Mandatory	"Live" or "Inactivated" or antigen(s) used in the given vaccine

Examples:

SMS ID	300000038470
Preferred term	Avian reovirus, strains 1733 and 2408, Inactivated

SMS ID	300000038464
Preferred term	Mannheimia haemolytica, serotype A1, strains 43270 and S 10R, leucotoxoid

3.7.6. Influenza vaccines

Preferred term syntax: Influenza A virus, <subtype>, <lineage*>, <sublineage*>, <strain>, <vaccine status>
*if applicable
Alias syntax: Not applicable

Table 28. Veterinary vaccines name parts – influenza vaccines

Name part	Conformance	Details
Microorganism	Mandatory	Influenza A virus
Subtype	Mandatory	H<number>N<number>
Lineage	Conditional	Only applicable to H3N8. Not yet in use in SMS.
Sublineage	Conditional	Only applicable to H3N8. Not yet in use in SMS.
Strain	Mandatory	Strain used in the given vaccine
Vaccine status	Mandatory	"Live" or "Inactivated" or antigen used in the given vaccine

Examples:

SMS ID	300000023551
Preferred term	Influenza A virus, subtype H5N2, strain A/duck/Potsdam/1402/86, Inactivated

SMS ID	300000018465
Preferred term	Influenza A virus, subtype H7N7, strain A/equine/Newmarket/77, Inactivated

3.7.7. Vector vaccines

3.7.7.1. Vectors with efficacy claim in the SmPC

The rules in this section apply when there is an efficacy claim for the vector microorganism itself in the SmPC, as well as for the inserted microorganism.

Preferred term syntax: <Vector>, <Strain*> <(gene(s) deleted*)>, encoding <gene(s) inserted> of <Inserted microorganism> <(Strain*)>, <Status*>
*if applicable

Table 29. Veterinary vaccines name parts – vectors with efficacy claim

Name part	Conformance	Details
Vector	Mandatory	Microorganism preferred term as defined by the SVG
Vector strain	Optional	Strain of the vector used
Vector deleted genes	Optional	
Expressing or encoding	Mandatory	"Expressing" is used if the antigen is expressed by the vector itself "Encoding" is used, if the antigen is encoded by the vector but expressed by e.g. the host cell
Gene of inserted microorganism	Mandatory	Gene of interest – the encoded antigen is immunogenic, once expressed
Inserted microorganism	Mandatory	Microorganism preferred term as defined by the SVG
Inserted microorganism strain	Optional	Strain from the inserted microorganism, from which the inserted gene was taken
Vaccine status	Mandatory	Live or Inactivated

Examples:

SMS ID	300000058484
Preferred term	Turkey herpesvirus, strain rHVT-IBD-H5 (cell-associated), encoding VP2 protein gene of Infectious bursal disease virus and haemagglutinin gene of Avian influenza virus subtype H5, Live

SMS ID	300000009246
Preferred term	Mycoplasma hyopneumoniae, strain Nexhyon, expressing capsid protein of porcine circovirus type 2A, Inactivated

3.7.7.2. Vectors without efficacy claim in the SmPC

The rules in this section apply when there is no efficacy claim for the vector microorganism itself in the SmPC, only for the inserted microorganism.

Preferred term syntax: <Inserted microorganism><(Strain*)>, <Gene(s) inserted> encoded by <Vector>, <Strain*><(gene(s) deleted*)>, <Status*>
*if applicable

Table 30. Veterinary vaccines name parts – vectors without efficacy claim

Name part	Conformance	Details
Inserted microorganism	Mandatory	Microorganism preferred term as defined by the SVG
Inserted microorganism strain	Optional	Strain from the inserted microorganism, from which the inserted gene was taken
Gene of inserted microorganism	Mandatory	Gene of interest – the encoded antigen is immunogenic, once expressed
Encoding	Mandatory	
Vector	Mandatory	Microorganism preferred term as defined by the SVG
Vector strain	Optional	Strain of the vector used
Vector deleted genes	Optional	
Vaccine status	Mandatory	"Live" or "Inactivated"

Examples:

SMS ID	300000032478
Preferred term	Feline leukemia virus (strain A/Glasgow-1), gp85 gene encoded by Venezuelan equine encephalitis virus (strain TC-83), self-amplifying RNA, viral particle, replication deficient

3.7.8. Infectious bursal disease virus (intermediate strains)

Preferred term syntax: <Microorganism>, <taxonomic levels>, <strain (intermediate/ intermediate plus)>, <vaccine status>

Table 31. Veterinary vaccines name parts – Infectious bursal disease virus

Name part	Conformance	Details
Microorganism	Mandatory	Microorganism taxonomic name
Taxonomic levels	Conditional	Taxonomic levels (e.g. serotype, serogroup, serovar) applicable for the given microorganism, as defined by the SVG
Strain (intermediate) or (intermediate plus)	Mandatory	The word intermediate/ intermediate plus added in brackets without comma in the end
Vaccine status	Mandatory	Mandatory

Examples

SMS ID	300000025039
Preferred term	Infectious bursal disease virus, strain VMG 91 (intermediate), Live

SMS ID	300000018586
Preferred term	Infectious bursal disease virus, strain Winterfield 2512 (intermediate plus), Live

3.7.9. Escherichia coli

Preferred term syntax: Escherichia coli, serotype <O:K:H formula> (<antigens/virulence factors>), <strain*>, <Status> or <antigens/virulence factors>
* If available

Table 32. Veterinary vaccines name parts – Escherichia coli

Name part	Conformance	Details
Escherichia coli	Mandatory	
Serotype	Mandatory	
Strains	Optional	
Vaccine status or Antigen	Mandatory	Live or Inactivated or Antigen used in the given vaccine

Examples:

SMS ID	100000170541
Preferred term	Escherichia coli, serotype O149:K88 (fimbrial adhesin F4), Inactivated

SMS ID	300000033271
Preferred term	Escherichia coli, serotype O9:K35 (fimbrial adhesin F5), Inactivated

3.7.10. Leptospira spp.

Preferred term syntax: <species>, <serovar>, <strain>, <status>
Alias syntax: <species>, <serogroup>, <serovar>, <strain>, <status>

Table 33. Veterinary vaccines name parts – Leptospira spp.

Name part	Conformance	Details
Leptospira species	Mandatory	
Serovar	Mandatory	Serovar of the strain used in the given vaccine
Strain	Mandatory	Strain used in the given vaccine
Vaccine status or Antigen	Mandatory	"Live" or "Inactivated" or antigen(s) used in the given vaccine

Examples

SMS ID	300000058882
Preferred term	Leptospira interrogans, serovar Icterohaemorrhagiae, strain L9, Inactivated

SMS ID	300000040176
Preferred term	Leptospira borgpetersenii, serovar Tarassovi, strain MSLB 1038, Inactivated

3.7.11. Foot-and-mouth disease virus

Preferred term syntax: Foot-and-mouth disease virus, <serotype>, <strain>, <vaccine status>

Table 34. Veterinary vaccines name parts – Foot-and-mouth disease virus

Name part	Conformance	Details
Foot-and-mouth disease virus	Mandatory	
Serotype	Mandatory	Serotype of the strain used in the given vaccine
Strain	Mandatory	Including topotype and lineage
Vaccine status	Mandatory	"Live" or "Inactivated" or <antigen(s)> used in the given vaccine

Examples:

SMS ID	300000033342
Preferred term	Foot-and-mouth disease virus, serotype A, strain A/Castellanos/81/87, Inactivated

SMS ID	300000009090
Preferred term	Foot-and-mouth disease virus, serotype A, strain O/Taiwan/3/97, Inactivated

Important note: Due to multistrain dossiers, the serotype-specific Foot-and-mouth disease virus vaccine records without strain (e.g. serotype O, A, C, Asia 1, SAT 1, SAT 2, SAT 3) remain with status "current" in SMS and SVG flag 0. If required for a new application, the SVG flag 0 can be temporarily removed to enable the selection of these records in the eAF.

3.7.12. Toxin-producing microorganisms

3.7.12.1. Actinobacillus pleuropneumoniae

3.7.12.1.1. Whole organism

Preferred term: Actinobacillus pleuropneumoniae, <serovar>, <strain>, <vaccine status>

Table 35. Veterinary vaccines name parts – Actinobacillus pleuropneumoniae - whole

Name part	Conformance	Details
Actinobacillus pleuropneumoniae	Mandatory	
Serovar	Mandatory	Serovar of the strain used in the given vaccine – biovar not needed and not sufficient
Strain	Mandatory	Strain used in the given vaccine
Vaccine status	Mandatory	"Live" or "Inactivated"

Example

SMS ID	300000056732
Preferred term	Actinobacillus pleuropneumoniae, serovar 2, strain Act 9, Inactivated

3.7.12.1.2. Toxins

Preferred term: Actinobacillus pleuropneumoniae, <serovar>, <toxoid>

Table 36. Veterinary vaccines name parts – Actinobacillus pleuropneumoniae - toxins

Name part	Conformance	Details
Actinobacillus pleuropneumoniae	Mandatory	
Serovar	Mandatory	Serovar of the strain used to produce the toxin in the given vaccine
Toxoid	Mandatory	ApxI/ApxII/ApxIII/ApxIV toxoid (inactivated toxin)

Example

SMS ID	Currently no SMS ID
Preferred term	Actinobacillus pleuropneumoniae, serovar 2, ApxIII toxoid

3.7.12.1.3. Outer membrane virulence factors

Preferred term: Actinobacillus pleuropneumoniae, <serovar>*, <antigen>
*depending on serovar-specificity of the antigen

Table 37. Veterinary vaccines name parts – Actinobacillus pleuropneumoniae – outer membrane virulence factors

Name part	Conformance	Details
Actinobacillus pleuropneumoniae	Mandatory	
Serovar	Conditional	Only needed, if the antigen is serovar-specific (does not provide serovar independent cross-protection), e.g. capsular polysaccharide
Antigen	Mandatory	Outer membrane virulence factor used in the given strain (e.g. outer membrane protein)

Example

SMS ID	300000018353
Preferred term	Actinobacillus pleuropneumoniae, outer membrane protein

3.7.12.2. Clostridium chauvoei

Speciality: According to Ph. Eur. 0361 inactivated liquid culture of one or more strains should be used to prepare a vaccine. So, there will always be inactivated bacterial cells and equivalent toxoid (inactivated toxin) in each vaccine.

Preferred term syntax: Clostridium chauvoei, <strain>, cells and toxin, Inactivated

Table 38. Veterinary vaccines name parts – Clostridium chauvoei

Name part	Conformance	Details
Clostridium chauvoei	Mandatory	
Strain	Mandatory	Strain used in the given vaccine
cells and toxin, Inactivated	Mandatory	Requirement of Ph. Eur. 0361

Examples:

SMS ID	300000018471
Preferred term	Clostridium chauvoei, strain 1048, cells and toxin, Inactivated

SMS ID	300000059986
Preferred term	Clostridium chauvoei, strain F, cells and toxin, Inactivated

3.8. Structurally Diverse - Plasma derived

These are substance records with multiple unknown molecular entities that are derived from plasma. They mainly include immunoglobulins for passive immunity.

Table 39. Status of business rules and data quality activities for plasma-derived substance records

Topic	Status
Business rules reviewed by SVG	Reviewed for veterinary records only
Data cleansing completed	Cleansed for veterinary records only
Quality review process implemented for new substances	In place for veterinary records only

3.8.1. Veterinary plasma-derived

General rules
Preferred term syntax: Immunoglobulins against <Microorganism>, <taxonomic levels>, <animal source>

Table 40. Veterinary plasma-derived name parts

Name part	Conformance	Details
Immunoglobulins against	Mandatory	
Microorganism	Mandatory	Microorganism preferred term, as defined by the SVG
Taxonomic levels	Conditional	Taxonomic levels applicable for the given microorganism as defined by the SVG but without strain
Antigen	Conditional	e.g. toxin, H antigen
Animal source	Mandatory	e.g. Avian, Equine, Bovine, Canine

Examples:

SMS ID	300000033552
Preferred term	Immunoglobulins against Infectious bursal disease virus, Avian

SMS ID	300000037383
Preferred term	Immunoglobulins against Salmonella enterica subsp. enterica, serovar Abortusequi, Equine

SMS ID	300000030844
Preferred term	Immunoglobulins against Clostridium tetani toxin, Equine

3.9. Structurally Diverse - Cell therapy

These are substance records with multiple unknown molecular entities, composed of multiple cells.

Table 41. Status of business rules and data quality activities for plasma-derived substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not yet cleansed
Quality review process implemented for new substances	Not yet in place

The following data elements must be provided:
- Organism source (e.g. Autologous, Allogenic, etc.)
- Tissue source (e.g. adipose-derived)
- Cells
- Relevant modifications

3.10. Structurally Diverse - Other

3.10.1. Animal records

Animal records will be registered in SMS with the substance type "Structurally Diverse – Other". The business rules described in this section do not apply to allergens extract and homeopathic substances derived from animals.

Table 42. Status of business rules and data quality activities for animal substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Fully cleansed
Quality review process implemented for new substances	In place

They can be divided into two groups, each with different business rules:
- Whole
- Part

Reference sources
1. National Center for Biotechnology Information (NCBI) - Taxonomy Database
2. Catalogue of Life

3.10.1.1. Whole

Context
Only to be created if all conditions below apply simultaneously:
- Request for pharmacovigilance purposes
- Reported substance name includes species
- Reported substance name does not include part

Table 43. Data fields for Animals - Whole

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse - Other
Preferred term	Mandatory	<Taxonomic name of the Species with Author and year, in accordance with NCBI>, "whole"
Alias	Optional	<Common name>, "whole"
Comment	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	If available in FDA
SVG flag	Mandatory	0

Examples:

SMS ID	300000058392
Domain	Human Use
Substance type	Structurally Diverse – Other
Preferred term	Equus caballus Linnaeus, 1758, whole
Alias	Horse, whole
Comments	Unspecified
EV Code	SUB416853
UNII	R7AD7Y06PL
SVG flag	0

SMS ID	100000158256
Domain	Human Use
Substance type	Structurally Diverse – Other
Preferred term	Gallus gallus (Linnaeus, 1758), whole
Alias	Chicken, whole
Comments	Unspecified
EV Code	SUB167890
UNII	J1VH9TZH5J
SVG flag	0

3.10.1.2. Part

Context
- Can be created for any request type

Table 44. Data fields for Animals - Part

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Structurally Diverse – Other
Preferred term	Mandatory	<Taxonomic name of the Species (with Author and year) in accordance with NCBI>, <part>
Alias	Optional	<Common name>, <part>
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	To be added, if available
SVG flag	Mandatory	1

Examples:

SMS ID	100000129182
Domain	Human Use
Substance type	Structurally Diverse – Other
Preferred term	Bos taurus Linnaeus, 1758, kidney
Alias	Cow, kidney
Comments	*Null*
EV Code	Cow, kidney
UNII	5HOC10FSIC
SVG flag	1

SMS ID	300000023971
Domain	Human Use
Substance type	Structurally Diverse – Other
Preferred term	Gallus gallus (Linnaeus, 1758), liver
Alias	Chicken, liver
Comments	*Null*
EV Code	SUB216458
UNII	83GE7DVK04
SVG flag	1

3.10.2. Gene therapy

Table 45. Status of business rules and data quality activities for gene therapy substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not yet cleansed
Quality review process implemented for new substances	Not yet in place

The following data elements must be provided:
- Microorganism
- Serotype (if applicable)
- Gene encoded

3.11. Mixture

Mixtures are combinations of related single substances that are extracted/synthesised together without defined proportions.

Table 46. Status of business rules and data quality activities for mixture substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not completed
Quality review process implemented for new substances	Not yet in place

3.12. Specified Substances Group 1 (SSG1)

SSG1 includes several different groups of substances, which are listed below:

- Records related to Ph. Eur.:
  - Substances with certain physical properties defined in Ph. Eur
  - Solutions or dispersions with a defined concentration defined in Ph. Eur.
- Proprietary mixtures of excipients
  - Coatings
  - Flavours
- Veterinary vaccines with different antigens/strains
- Homoeopathic substances
- Herbal extracts
- Isophane insulins

3.12.1. SSG1 related to Ph. Eur.

This section summarises all the agreed rules on Specified Substances Group 1 (SSG1) related to European Pharmacopoeia (Ph. Eur.) monographs. The rules are described for the following subgroups:

- Property
- Solutions

The rules in this section do not apply to the following substance types:

- Radiolabelled chemicals
- Proteins
- Structurally Diverse - Plasma derived
- Herbals
- Herbals extracts
- Homeopathics

These substance groups will have different business rules, which will be published at a later date.

Table 47. Status of business rules and data quality activities for SSG1 related to Ph. Eur. substance records substance records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Completed
Quality review process implemented for new substances	Not yet in place

3.12.1.1. Property

This section refers to SSG1 records that include additional properties in the substance name. Most of the properties are not considered relevant and will not be kept. The only two properties that can be kept, if a respective Ph. Eur. monograph is present, are:

- "Form"
- "Intermix"

In the cases above, a separate SSG1 record will be kept. In all the remaining cases, a SSG1 record will not be created and, instead, users should refer to the respective parent substance.

Table 48. Business rules for SSG1 property

Property	Business rules	SMS Implementation
Form Intermix	To be kept if a Ph. Eur. monograph is available	Preferred term aligned with Ph. Eur. monograph title SVG flag 1
Amorphous Capsules Concentrate Crystalline Injection Liposomal Micronised Nanonised Powder Sterile Synthetic Tablet	Never to be kept	Comment "Duplicate of SMS ID/EV Code" of the parent substance SVG flag 0 Parent substance added as replacement

All the relevant SSG1 records related to the proprieties above are already available in SMS. New SSG1 records under this rule will be created by SMS data steward in data enrichments exercises, upon publication of new Ph. Eur. monograph relevant by EDQM and follow-up discussions with the SVG. No change requests for new SSG1 records in this scenario are expected.

Substance names with the properties not considered relevant will not be registered as aliases nor translations of the parent substance.

Examples:

Substance name	Relevant property?	Ph. Eur. monograph	SMS record
Vitamin A concentrate (oily form), synthetic	Yes	0219 - Vitamin A concentrate (oily form), synthetic	100000131318 - Vitamin A concentrate (oily form), synthetic
Acetylene intermix (1 per cent) in nitrogen	Yes	2903 - Acetylene intermix (1 per cent) in nitrogen	300000058768 - Acetylene intermix (1 per cent) in nitrogen
ADIPIC ACID, MICRONISED	No	N.A.	100000077961 - Adipic acid

The data fields of the three substance records mentioned in column A of the table below are then listed below.

SMS ID	100000131318
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Vitamin A concentrate (oily form), synthetic
Alias	*Null*
EV Code	SUB45105
UNII	*Null*
SVG flag	1

SMS ID	300000058768
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Acetylene intermix (1 per cent) in nitrogen
Alias	*Null*
EV Code	SUB419299
UNII	*Null*
SVG flag	1

SMS ID	100000166257
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	ADIPIC ACID, MICRONISED
Alias	*Null*
Comments	Duplicate of 100000077961/SUB12744MIG
EV Code	SUB180355
UNII	*Null*
SVG flag	0
Replacement ID	100000077961

3.12.1.2. Solutions

A SSG1 record will be kept for a solution, if under one the following conditions:
- An individual monograph (i.e. 4 digits) for the solution is present in the European Pharmacopoeia;
- A monograph for the solution is present in an EEA national pharmacopoeia;
- It is a SVG identified exception and is listed in this guidance document

If under one of the scenarios above, a SSG1 record for the solution will be kept in SMS:

Table 49. Business rules for SSG1 solutions

Scenario	Preferred term	Alias 1	Alias 2
Ph. Eur. monograph for SSG1 solution	Title of the monograph	Concentration range as defined in Ph. Eur.	Concentration range in an alternative unit of measure as defined in Ph. Eur. (if available)
Other EEA national monographs for SSG1 solution	Title of the monograph in English	Concentration range as defined in the national monograph	Concentration range in an alternative unit of measure as defined in national monograph (if available)
SVG exception	Parent substance + <concentration>	N. A.	N. A.

Substance names with a specific concentration will not be added as aliases or translations of the replacement records.

Table 50. Change requests rules for new SSG1 solutions

Scenario	Change requests for new SSG1 accepted?	Explanation
Ph. Eur. monograph for SSG1 solution	No	As of Ph. Eur. 12.3, all the relevant SSG1 solutions are already available in SMS. New SSG1 records will be created by SMS data steward in data enrichments exercises, upon publication of new relevant Ph. Eur. monographs by EDQM and follow-up discussions with the SVG.
Other EEA national monographs for SSG1 solution	Yes, with monograph attached	Any change request will be discussed with the SVG and a new SSG1 solution might be created.
SVG exception	No	All required SSG1 solutions are already available in SMS. In the absence of a record with a specific concentration, the general solution SSG1 (if available) or the parent substance should be instead.

Examples:

SMS ID	SMS PT	Scenario	Reference	Outcome in SMS
100000076353	Ethanol (96 per cent)	Ph. Eur. monograph for SSG1 solution	Ph. Eur: 1317 Ethanol (96 per cent) Concentration range: 92.6-95.2% m/m (95.1-96.9% V/V)	The record 100000076353 - Ethanol (96 per cent) will be kept with SVG flag 1. Translations of this substance name can be added in SMS.
100000134653	ETHANOL 94% (M/M)	Ph. Eur. monograph for SSG1 solution		The ethanol concentration within the range specified in the Ph. Eur. monograph. These two records will have SVG flag 0 and, eventually, will be nullified. The substance names "ETHANOL 94% (M/M)", "Ethanol 96.6 % (V/V)" and their respective translations in other EU languages will not be kept in SMS
300000001482	Ethanol 96.6 % (V/V)	Ph. Eur. monograph for SSG1 solution		
300000061034	Potassium lactate solution	Other EEA national monographs for SSG1 solution	German Pharmacopoeia: Potassium lactate solution Concentration range: 49-51% m/m	The record 300000061034 - Potassium lactate solution will be kept with SVG flag 1. Translations of this substance name can be added in SMS

SMS ID	SMS PT	Scenario	Reference	Outcome in SMS
100000077713	Ammonia solution	SVG exception	SVG	This record is kept with SVG flag 1, since it is a SVG listed exception.
100000163031	GLYCEROL 96%	Not applicable	0497 - Glycerol (85 per cent) Concentration range: 83.5-88.5 per cent *m/m*	Outside of scope of specification for the related Ph. Eur. monograph 0497 - Glycerol (85 per cent). The SMS ID is replaced by general record: 100000092821 – Glycerol "GLYCEROL 96%" and its respective translations in other EU languages will not be kept in SMS.
100000135488	BENZYL ALCOHOL (1%)	Not applicable	None	No monograph available. The SMS ID is replaced by substance record: 100000086395 - Benzyl alcohol "Benzyl alcohol (1%)" and its respective translations in other EU languages will not be kept in SMS.

SMS ID	100000076353
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Ethanol (96 per cent)
Alias	Ethanol 92.6-95.2% m/m
Alias	Ethanol 95.1-96.9% V/V
Comments	*Null*
EV Code	SUB11946MIG
UNII	*Null*
SVG flag	1
Replacement ID	*Null*

SMS ID	100000134653
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	ETHANOL 94% (M/M)
Alias	*Null*
Alias	*Null*
Comments	Duplicate of 100000076353/SUB11946MIG
EV Code	SUB63663
UNII	*Null*
SVG flag	0
Replacement ID	100000076353

SMS ID	300000001482
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Ethanol 96.6 % (V/V)
Alias	*Null*
Alias	*Null*
Comments	Duplicate of 100000076353/SUB11946MIG
EV Code	SUB199793
UNII	*Null*
SVG flag	0
Replacement ID	100000076353

SMS ID	300000061034
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Potassium lactate solution
Alias	Potassium lactate aqueous solution 49-51% m/m
Alias	*Null*
Comments	*Null*
EV Code	SUB441615
UNII	*Null*
SVG flag	1
Replacement ID	*Null*

SMS ID	100000077713
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Ammonia solution
Alias	Ammonium hydroxide solution
Alias	Ammonium hydroxide aqueous solution
Comments	*Null*
EV Code	SUB12867MIG
UNII	*Null*
SVG flag	1
Replacement ID	*Null*

SMS ID	300000023303
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Ammonia solution 28%
Alias	*Null*
Alias	*Null*
Comments	Duplicate of 100000076694/SUB11706MIG
EV Code	SUB215803
UNII	*Null*
SVG flag	0
Replacement ID	100000076694

SMS ID	100000163031
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	GLYCEROL 96%
Alias	*Null*
Alias	*Null*
Comments	Duplicate of 100000092821/SUB07948MIG
EV Code	SUB177167

SMS ID	100000163031
UNII	*Null*
SVG flag	0
Replacement ID	100000092821

SMS ID	100000135488
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	BENZYL ALCOHOL (1%)
Alias	*Null*
Alias	*Null*
Comments	Duplicate of 100000086395/SUB05771MIG
EV Code	SUB70867
UNII	*Null*
SVG flag	0
Replacement ID	100000086395

All the relevant SSG1 solutions that will be maintained in SMS are listed on the table below.

Table 51. Valid SSG1 solution substance records

Parent record	Concentration range	Reference	SMS ID	Preferred term
Acetic acid	99.0-100.5% m/m	Ph. Eur.: 0590 - Acetic acid, glacial	100000076667	Acetic acid, glacial
Acetic acid	Any not mentioned above	SVG	100000162503	Acetic acid solution
Aluminium acetate tartrate	1.3-1.45% m/m Al, 5.3-6.3% m/m acetate	German Pharmacopoeia	100000168525	Aluminium acetate tartrate solution
Ammonia	25.0-30.0 % m/m	Ph. Eur.: 0877 - Ammonia solution, concentrated	100000076694	Ammonia solution, concentrated
Ammonia	Any not mentioned above	SVG	100000077713	Ammonia solution
Benzalkonium chloride	475-525 g/L	Ph. Eur.: 0371 - Benzalkonium chloride solution	100000076913	Benzalkonium chloride solution
Chlorhexidine digluconate	190-210 g/L	Ph. Eur.: 0658 - Chlorhexidine digluconate solution	100000091053	Chlorhexidine digluconate solution
Ethanol	92.6-95.2% m/m (95.1-96.9% V/V)	Ph. Eur.: 1317 - Ethanol (96 per cent)	100000076353	Ethanol (96 per cent)
Ethanol	Any not mentioned above	SVG	100000140938	Ethanol, diluted
Formaldehyde	34.5-38.0% m/m	Ph. Eur.: 0826 - Formaldehyde solution (35 per cent)	100000080149	Formaldehyde solution (35 per cent)
Glucose	>70.0% V/V	Ph. Eur.: 1330 - Glucose, Liquid	100000080176	Glucose, liquid
Glycerol	83.5-88.5% m/m	Ph. Eur.: 0497 - Glycerol (85 per cent)	100000078195	Glycerol (85 per cent)
Glyceryl trinitrate	1-10% m/m	Ph. Eur.: 1331 - Glyceryl trinitrate solution	100000092262	Glyceryl trinitrate solution
Hydrochloric acid	35.0-39.0% m/m	Ph. Eur.: 0002 - Hydrochloric acid, concentrated	100000075989	Hydrochloric acid, concentrated
Hydrochloric acid	9.5-10.5% m/m	Ph. Eur.: 0003 - Hydrochloric acid, dilute	100000075990	Hydrochloric acid, dilute
Hydrochloric acid	Any not mentioned above	SVG	100000078724	Hydrochloric acid
Hydrogen peroxide	2.5-3.5% m/m	Ph. Eur.: 0395 - Hydrogen peroxide solution (3 per cent)	100000075991	Hydrogen peroxide solution (3 per cent)
Hydrogen peroxide	29-31% m/m	Ph. Eur.: 0396 - Hydrogen peroxide solution (30 per cent)	100000075992	Hydrogen peroxide solution (30 per cent)
Hydrogen peroxide	Any not mentioned above	SVG	300000061030	Hydrogen peroxide solution
Iodine	2.4-2.7% m/m iodine, 2.4-2.7% m/m potassium iodide	German Pharmacopoeia	100000077357	Alcoholic iodine solution
Lactulose	Lactulose solution > 620 g/L	Ph. Eur.: 0924 - Lactulose, liquid	100000091963	Lactulose, liquid
Maltitol	68-85% m/m	Ph. Eur.: 1236 - Maltitol, liquid	100000080123	Maltitol, liquid

Parent record	Concentration range	Reference	SMS ID	Preferred term
Methacrylic acid - ethyl acrylate copolymer (1:1)	No range available	Ph. Eur.: 1129 - Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent	100000079565	Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent
Nitric acid	68.0-70.0% m/m	Ph. Eur.: 1549 – Nitic acid	100000080017	Nitric acid
Nitric acid	Any not mentioned above	SVG	300000061031	Nitric acid solution
Oxygen	>96.0% V/V	Ph. Eur.: 3098 - Oxygen (98 per cent)	300000060787	Oxygen (98 per cent)
Oxygen	90.0-96.0% V/V	Ph. Eur.: 2455 - Oxygen (93 per cent)	300000060786	Oxygen (93 per cent)
Phosphoric acid	84.0-90.0% m/m	Ph. Eur.: 0004 - Phosphoric acid, concentrated	100000090950	Phosphoric acid, concentrated
Phosphoric acid	9.5-10.5% m/m	Ph. Eur.: 0005 - Phosphoric acid, dilute	100000079606	Phosphoric acid, dilute
Poly(vinyl acetate)	25.0-30.0%	Ph. Eur.: 2152 - Poly(vinyl acetate) dispersion 30 per cent	100000166436	Poly(vinyl acetate) dispersion 30 per cent
Polyacrylate	28.5-31.5%	Ph. Eur.: 0733 - Polyacrylate dispersion 30 per cent	100000079840	Polyacrylate dispersion 30 per cent
Potassium hydroxide	Any concentration	SVG	300000061033	Potassium hydroxide solution
Potassium lactate	49-51% m/m	German Pharmacopoeia	300000061034	Potassium lactate solution
Propylene glycol	Any concentration	SVG	300000061108	Propylene glycol solution
Sodium (S)-lactate	>50% m/m	Ph. Eur.: 2033 - Sodium (S)-lactate solution	100000127143	Sodium (S)-lactate solution
Sodium chloride	Any concentration	SVG	100000138605	Sodium chloride solution
Sodium hydroxide	Any concentration	SVG	100000078045	Sodium hydroxide solution
Sodium lactate	>50% m/m	Ph. Eur.: 1151 - Sodium lactate solution	100000092018	Sodium lactate solution
Sorbitol	68.0-72.0% m/m (crystallising)	Ph. Eur.: 0436 - Sorbitol, liquid (crystallising)	100000079562	Sorbitol, liquid (crystallising)
Sorbitol	68.0-72.0% m/m (non-crystallising)	Ph. Eur.: 0437 - Sorbitol, liquid (non-crystallising)	100000079582	Sorbitol, liquid (non-crystallising)
Sorbitol	68.0-85.0% m/m	Ph. Eur.: 2048 - Sorbitol, liquid, partially dehydrated	100000133229	Sorbitol, liquid, partially dehydrated
Sucrose	66.0-67.5 m/m	Ph. Eur.: 2797 - Sucrose, liquid	100000093359	Sucrose, liquid
Sulfuric acid	Any concentration	SVG	100000128795	Sulfuric acid solution
*Any other**	*Any concentration*	*N.A.*	*N.A.*	*N.A.*

*Additional SSG1 solutions records related to an EEA national pharmacopoeia can be registered upon request.

3.12.1.3. Diluted

These records are related to a Ph. Eur. Monograph of a dry mixture between an active substance and a (variable) diluent:

- Potassium clavulanate, diluted
- Pentaerythrityl tetranitrate, diluted
- Isosorbide dinitrate, diluted
- Isosorbide mononitrate, diluted

A SSG1 substance record with record matching the Ph. Eur. title will not be kept. Instead, a SSG1 record for each possible combination below will be kept:

- Active substance (present in the Ph. Eur. title and description)
- Diluent (present in the Ph. Eur. description)
- Ratio of active substance:diluent

The rule above is only applicable to SSG1 solutions related to a Ph. Eur. Monograph. For any other scenarios a SSG1 record will not be kept. Instead, users should refer to the respective parent substance.

Examples:

Ph. Eur. monograph	SMS record
Potassium clavulanate, diluted	100000168460 - Potassium clavulanate, diluted (potassium clavulanate - cellulose, microcrystalline (1:1))
	100000168461 - Potassium clavulanate, diluted (potassium clavulanate - silica, colloidal anhydrous (1:1)
	100000175209 - Potassium clavulanate, diluted (potassium clavulanate - silica, colloidal hydrated (1:1))

3.12.1.4. Denatured ethanol

The business rules below apply to ethanol solutions that were denatured with an additive.

Table 52. Business rules for SSG1 – denatured ethanol

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Specified Substance Group 1
Preferred term	Mandatory	Ethanol, denatured with <additive>
Alias	Not applicable	*Null*
Comment	Not applicable	*Null*
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	Not available
SVG flag	Mandatory	1

Examples:

SMS ID	100000172106
Preferred term	Ethanol, denatured with petroleum spirit

SMS ID	100000138296
Preferred term	Ethanol, denatured with denatonium benzoate

In addition, one single Unspecified record is present in SMS for this substance group. This record should only be used for legacy products that contain denatured ethanol without denaturing additive specified in the SmPC.

Example:

SMS ID	100000130573
Preferred term	Ethanol, denatured

3.12.1.5. Water grades

The following water grades are the only records that will be kept as SSG1 records.

Table 53. Business rules for SSG1 – water grades

Grade	Reference	Record in SMS
Water for injections	Ph. Eur.	100000078023 - Water for injection
Water, distilled	Ph. Eur.	100000130650 - Water, distilled
Water, purified	Ph. Eur.	100000132955 - Water, purified
Potable water	Swiss Pharmacopoeia (Pharmacopoeia Helvetica)	100000134781 - Potable water
Sterile water	SVG	100000090718 - Sterile water

3.12.2. Coatings

Coatings are propriety mixtures of excipients used to modify the colour or other properties of an oral pharmaceutical form of medicinal products.

Table 54. Status of business rules and data quality activities for coating substance records

Topic	Status
Business rules reviewed by SVG	Only for Colorcon® coatings
Data cleansing completed	Only for Colorcon® coatings
Quality review process implemented for new substances	Only for Colorcon® coatings

3.12.2.1. Most common coating manufacturers

The business rules described in this section cover the most prevalent coating manufacturers in SMS.

Table 55. Coatings manufacturers, brands, types and preferred term syntax

Manufacturer	Brand	Types	Preferred term syntax
Colorcon®	Opadry®	AMB, AMB II, aqueous enteric, enteric, EZ, fx, II, or *N.A.*	Opadry <type> <code> <colour>
	Opalux®	Dry, or *N.A.*	Opalux <type>, <code>, <colour>
	Opacode®	WB, or *N.A.*	Opacode <type> <code> <colour>
	Opaspray®	*N.A.*	Opaspray <type> <code> <colour>
	Opatint®	*N.A.*	Opatint <type> <code> <colour>
	Pigment blend®	*N.A.*	Pigment blend <type> <code> <colour>
	Lake blend®	*N.A.*	Lake blend <type> <code> <colour>
	Acryl-EZE®	II, or *N.A.*	Acryl-EZE <type> <code> <colour>
Seppic®	Sepifilm®	LP, PW, SC, SE, SN, TM, or *N.A.*	Sepifilm <type> <code> <colour>
	Sepisperse®	AP, AS, Dry, K, M or, *N.A.*	Sepisperse <type> <code> <colour>
	Sepitrap®	AP	Sepitrap <type> <code>
	Sepicide®	HB	Sepicide <type> <code>
	Sepineo®	*N.A.*	Sepineo <code>
Biogrund®	AquaPolish®	D, P, or *N.A.*	AquaPolish <type> <colour> <code>
Ideal cures®	Instacoat®	Aqua II, Aqua III, EHP, SFC, SOL, T2F, Universal	Instacoat <type> <code> <colour>
	Instamoistshield®	*N.A.*	Instamoistshield <code> <colour>
	Instaglow®	*N.A.*	Instaglow <code>

Table 56. Data fields for coating substance records

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Specified Substance Group 1
Preferred term	Mandatory	As per the respective syntax in the table above
Alias	Not applicable	Aliases not registered for this group of substances
EV Code	System-generated	Generated by XEVMPD
UNII	Optional	If published by FDA (currently only available for some Opadry® substance records)
SVG flag	Optional	After internal EMA review (currently only applicable to Colorcon® substance records)

Examples:

SMS ID	100000085557
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Opadry OY-S-29019 clear
Alias	*Null*
EV Code	SUB20455
UNII	WCE543V7AA
SVG flag	1

SMS ID	100000130702
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Pigment blend PB-22877 yellow
Alias	*Null*
EV Code	SUB43467
UNII	*Null*
SVG flag	1

SMS ID	300000064264
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Sepifilm LP 007 clear
Alias	*Null*
EV Code	SUB456765
UNII	*Null*
SVG flag	*Null*

SMS ID	300000047258
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Sepitrap AP 4000
Alias	*Null*
EV Code	SUB296952
UNII	*Null*
SVG flag	*Null*
SMS ID	100000175813
Domain	Human Use

SMS ID	300000047258
Substance type	Specified Substance Group 1
Preferred term	AquaPolish D grey 089.44 MS
Alias	*Null*
EV Code	SUB190336
UNII	*Null*
SVG flag	*Null*

SMS ID	300000034501
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Instacoat universal A05E00041 white
Alias	*Null*
EV Code	SUB223955
UNII	*Null*
SVG flag	*Null*

3.12.2.2. Other coating manufacturers

For less commonly used coatings in SMS, the naming syntax provided in the supporting documentation will be applied to the respective preferred terms.

Specific business rules the additional manufactures/brands might be added in later versions of this document.

Examples:

SMS ID	300000013581
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Mastercote yellow SP2152
Alias	*Null*
EV Code	SUB206582
UNII	*Null*
SVG flag	*Null*

SMS ID	300000040664
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Colorcoat MB4W-E 1 white
Alias	*Null*
EV Code	SUB258386
UNII	*Null*
SVG flag	*Null*

3.12.2.3. Unspecified coatings

SMS contains some unspecified coating substance records for medicinal products with coatings that were approved without colour and/or code. These records have comment "Unspecified" and SVG flag 0 and are normally not available in the eAF. If required for a variation or renewal, then the SVG flag 0 can be temporarily removed upon a change request, to allow the use of these records in these applications. Afterwards, the SVG flag 0 will be manually added again. These substance records cannot be used for new marketing authorisation applications.

Examples:

SMS ID	100000134621
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Opadry
Alias	*Null*
Comments	Unspecified
EV Code	SUB63310
UNII	*Null*
SVG flag	0

SMS ID	100000138124
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Sepifilm
Comments	Unspecified
Alias	*Null*
EV Code	SUB77451
UNII	*Null*
SVG flag	0

3.12.3. Flavours

Flavours are propriety mixtures of excipients used to modify the taste of oral pharmaceutical forms of medicinal products. The business rules described in this section cover the most prevalent flavour manufacturers in SMS.

In SMS, they correspond to substance records with the name parts listed below:
- Flavour (British spelling, preferred name part to be used)
- Flavor (American spelling)
- Aroma

Other related name parts (e.g. essence or perfume) are not in scope of these business rules.

Two levels of granularity are currently present in SMS:
- Specific level
- High-level (unspecified)

Table 57. Status of business rules and data quality activities for flavours records substance records

Topic	Status
Business rules reviewed by SVG	Not yet fully reviewed
Data cleansing completed	Partially cleansing (Duplicates and Unspecified only)
Quality review process implemented for new substances	Only in place for Unspecified flavours (high-level)

3.12.3.1. Specific-level

The business rules described in this section are applicable to all new flavour records used in medicinal products not yet approved.

Table 58. Preferred term syntax for flavours – specific level

Data field	Conformance	Details
<Taste>	Mandatory	In case of multiple tastes, then they should be added alphabetically and separated by "-"
"flavour"	Mandatory	"Flavour" to be always used instead of "flavor"
<Manufacturer>	Mandatory	Manufacturer name as per the table below
<Brand>	Optional	Some flavours also include a brand name. No SVG decision has been taken on this name part, so it is optional for now
<code>	Mandatory	Flavour code as per manufacturer's specifications

Note: the name parts natural/artificial/special/liquid/power should not be kept in the PT or aliases

The table below lists the names of the most commonly used flavour manufacturers in substance records in SMS (around 90%).

Table 59. Most common flavour manufacturers in SMS

Manufacturer name to be used in the PT	Other names	Details
Bell	Bell Flavors & Fragrances	
Curt Georgi		
DSM-Firmenich	Firmenich	Created by the merge of the manufacturers DSM and Firmenich
Fona		
Frey + Lau	Frey & Lau, F&L	
Givaudan		This manufacturer bought Roure and Quest
IFF	International Flavors & Fragrances	This manufacturer bought Frutarom, Bush Boake Allen, Foote & Jenks
Kerry		
Mane		
Robertet		
Sensient		
Silesia		
Sterling Aromi		
Symrise		This manufacturer bought Haarmann & Reimer and Dragoco
Takasago		
Topo Pharma		
Variati		
Vioryl		
Virginia Dare		

Note: The symbol "&" can cause technical issues in some consuming systems, so it will not be included in the manufacturer's name part

Table 60. Data fields for flavours substance records (specific-level)

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Specified Substance Group 1
Preferred term	Mandatory	<Taste(s)> flavour <Manufacturer> <*Brand**> <code>
Alias	Not applicable	Aliases not registered for this group of substances
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	UNIIs not currently available for this group of substances
SVG flag	Not applicable	Quality review process not yet in place

**Optional name part within the preferred term syntax*

Examples:

SMS ID	100000161082
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Strawberry flavour Firmenich 052311 AP 0551
Alias	*Null*
EV Code	SUB174412
UNII	*Null*
SVG flag	*Null*

SMS ID	100000165997
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Honey flavour IFF SN781458
Alias	*Null*
EV Code	SUB179947
UNII	*Null*
SVG flag	*Null*

SMS ID	300000064316
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Apple-banana flavour Symrise 204244
Alias	*Null*
EV Code	SUB456988
UNII	*Null*
SVG flag	*Null*

3.12.3.2. High-level (Unspecified)

SMS contains some unspecified flavour substance records (high-level) for medicinal products with flavours listed in the SmPC without manufacturer and/or code.

These records have comment "Unspecified" and SVG flag 0 and are normally not available in the eAF. If required for a variation or renewal and, upon a substance change request, the SVG flag 0 can be temporarily removed to allow the use of these records in these specific applications. Afterwards, the SVG flag 0 will be manually added again. These substance records cannot be used for new marketing authorisation applications.

Table 61. Preferred term syntax for unspecific flavour substance records (high-level)

Data field	Conformance	Details
<Taste>	Mandatory	In case of multiple tastes, then they should be added alphabetically and separated by "-"
"flavour"	Mandatory	"flavour" to be always used instead of "flavor"

Table 62. Data fields for unspecified flavours substance records (high-level)

Data field	Conformance	Details
SMS ID	System-generated	Generated by SMS IDD, upon substance registration
Domain	Mandatory	Human Use
Substance type	Mandatory	Specified Substance Group 1
Preferred term	Mandatory	<Taste(s)> flavour
Alias	Not applicable	Aliases not registered for this group of substances
Comments	Mandatory	Unspecified
EV Code	System-generated	Generated by XEVMPD
UNII	Not applicable	UNIIs not currently available for this group of substances
SVG flag	Mandatory	SVG flag 0 added during weekly review process

Examples:

SMS ID	100000078237
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Strawberry flavour
Alias	*Null*
Comments	Unspecified
EV Code	100000078237
UNII	*Null*
SVG flag	0

SMS ID	100000157837
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Strawberry-watermelon flavour
Comments	Unspecified
Alias	*Null*
EV Code	SUB166607
UNII	*Null*
SVG flag	0

SMS ID	100000181359
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	Banana-strawberry flavour
Comments	Unspecified
Alias	*Null*
EV Code	100000181359
UNII	*Null*
SVG flag	0

3.12.4. Adjuvants

Adjuvants are substances that are used in vaccine medicinal products to enhance the body's immune response. The adjuvants covered in this section are proprietary mixtures of multiple components and are considered Specified Substances Group 1 records.

Table 63. Status of business rules and data quality activities for SSG1 adjuvant substance records

Topic	Status
Business rules reviewed by SVG	Only reviewed for Seppic®
Data cleansing completed	Only cleansed for Seppic®
Quality review process implemented for new substances	Not yet in place

The most common manufacturer of Veterinary adjuvants is Seppic® for the adjuvant Montadine®. However, since these adjuvants can also be used in human medicinal records, the substance domain will always be registered as "Human".

Table 64. Name parts for Seppic® adjuvants

Name part	Conformance	Details
<Montanide>	Mandatory	
Type	Conditional	Type, if applicable, as per Seppic® specifications (e.g. ISA, IMS, GEL)
Code	Mandatory	Code, as per Seppic® specifications

Examples:

SMS ID	100000148289
Preferred term	Montanide ISA 711

SMS ID	300000054155
Preferred term	Montanide IMS 251C VG

3.12.5. Homeopathics

Homoeopathic substances are prepared from homoeopathic stocks in accordance with a homoeopathic manufacturing procedure. They include the degree of dilution and/or potentisation and are registered as Specified Substances Group 1.

Table 65. Status of business rules and data quality activities for homeopathic substance records

Topic	Status
Business rules reviewed by SVG	Not yet reviewed
Data cleansing completed	Not yet cleansed
Quality review process implemented for new substances	Not yet in place

3.13. Specified Substances Group 2 (SSG2):

SSG2 substances refer to substances or Specified Substances Group 1 with the manufacturer in the preferred term and would contain data fields with limited manufacturing information.

SSG2 were never registered in SMS and change requests for this substance type will always be rejected. Instead, the respective parent should be used instead.

Table 66. Status of business rules and data quality activities for SSG2 records

Topic	Status
Business rules reviewed by SVG	Not applicable
Data cleansing completed	Not applicable (no records present in SMS)
Quality review process implemented for new substances	Not applicable

3.14. Specified Substances Group 3 (SSG3):

SSG3 substances refer to substances or Specified Substances Group 1 with a grade from a pharmacopoeia (e.g. "Ph. Eur.", "USP", "BP").

SSG3 are not currently in use in SMS and change requests for this substance type will always be rejected. Instead, the respective parent should be used instead.

Table 67. Status of business rules and data quality activities for SSG3 records

Topic	Status
Business rules reviewed by SVG	Fully reviewed
Data cleansing completed	Fully cleansed
Quality review process implemented for new substances	Not applicable

Examples:

SMS ID	100000152985
Domain	Human Use
Substance type	Specified Substance Group 3
Preferred term	BENZOIC ACID PH.EUR.
Alias	*Null*
Comments	Duplicate of 100000090433/SUB12469MIG
EV Code	SUB126764
UNII	*Null*
SVG flag	0
Replacement ID	100000090433

SMS ID	100000153246
Domain	Human Use
Substance type	Specified Substance Group 3
Preferred term	SODIUM FLUORIDE BP
Alias	*Null*
Comments	Duplicate of 100000091554/SUB15285MIG
EV Code	SUB127170
UNII	*Null*
SVG flag	0
Replacement ID	100000091554

SMS ID	100000133934
Domain	Human Use
Substance type	Specified Substance Group 1
Preferred term	FLUOCINONIDE USP
Alias	*Null*
Comments	Duplicate of 100000090286/SUB07715MIG
EV Code	SUB57003
UNII	*Null*
SVG flag	0
Replacement ID	100000090286

3.15. Specified Substances Group 4 (SSG4):

SSG4 substances refer to substances or Specified Substances Group 1 with a manufacturer and would contain data fields with detailed manufacturing information, constituents (e.g. impurities) and specifications.

SSG4 were never registered in SMS and change requests for this substance type will always be rejected. Instead, the respective parent should be used instead.

Table 68. Status of business rules and data quality activities for SSG4 records

Topic	Status
Business rules reviewed by SVG	Not applicable
Data cleansing completed	Not applicable (no records present in SMS)
Quality review process implemented for new substances	Not applicable

4. Document versions

A major version is considered when a new chapter is published or an existing chapter is profoundly revised, while a minor version is considered when an already existing chapter is just slightly updated.

Version	Date	Main changes
1.0	23 November 2026	First version

Annex 1: Glossary

Acronym	Name
AAN	Australian Approved Name
BAN	British Approved Name
BP	British Pharmacopoeia
CAS	Chemical Abstracts Service
eAF	Electronic Application Form
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EU	European Union
FDA	Food and Drug Administration
ICSR	Individual Case Safety Report
IDD	Informatica Data Director
InChIKey	International Chemical Identifier in “key” format
INCI	International Nomenclature Cosmetic Ingredient
INN	International Nonproprietary Name
IUPAC	International Union of Pure and Applied Chemistry
JAN	Japanese Accepted Name
NCBI	National Center for Biotechnology Information
Ph. Eur.	European Pharmacopoeia
pINN	Proposed International Non-proprietary Name
PT	Preferred Term
rINN	Recommended International Non-proprietary Name
RMS	Referential Management Service
SmPC	Summary of Product Characteristics
SMS	Substance Management Service
SSG1	Specified Substance Group 1
SSG2	Specified Substance Group 2
SSG3	Specified Substance Group 3
SSG4	Specified Substance Group 4
SUSAR	Suspected Unexpected Serious Adverse Reaction
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
UPD	Union Product Database
USAN	United States Adopted Name
USP	United States Pharmacopeia
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary