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Antimicrobial Sales and Use (ASU) technical implementation protocol

Implementation of the requirements of Regulation (EU) 2019/6 for the collection of data on volume of sales of veterinary antimicrobials and use of antimicrobial medicinal products animals

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1. Introduction

This document provides guidance on the data elements and associated business rules for the reporting of data on the volume of sales of antimicrobial veterinary medicinal products (VMPs), on the use of antimicrobial medicinal products in animals and on animal population statistics to the European Medicines Agency ('the Agency'), as referred to in Article 57 of Regulation (EU) 2019/6 [1] and related Delegated and Implementing acts [2, 3].

The reporting requirement applies to both antimicrobial VMPs and human medicinal products (HMPs) referred to in Articles 1 to 4 of Commission Delegated Regulation (EU) 2021/578 and to animal population statistics referred to in Article 16 of the same regulation [2]. The data to be reported per product presentation and its format are established in Commission Implementing Regulation (EU) 2022/209 [3].

Each Member State (MSs)[1] must appoint their own national contact point and the data manager(s) for liaison with the Agency with regards to the reporting of data, and who will be granted access to the Antimicrobial Sales and Use (ASU) Platform as National Competent Authority User(s) ('NCA user'), as per Article 7(2) of Commission Delegated Regulation (EU) 2021/578 [2]. Member States are responsible for the data quality of their submission, including the accuracy of the information in prefilled data fields in the templates, as per Article 6 of Delegated Regulation (EU) 2021/578 [2].

The aim of this protocol is to describe in detail the data fields and the technical specifications for the reporting of antimicrobial sales and use data to the Agency via the ASU Platform.

2. Acronyms

ASU – Antimicrobial Sales and Use

ATC – Anatomical Therapeutical Chemical classification for human medicines developed by the WHO Collaborating Centre for Drug Statistics Methodology

ATCvet – Anatomical Therapeutical Chemical classification for veterinary medicines developed by the WHO Collaborating Centre for Drug Statistics Methodology

CAP – Centralised Authorisation Procedure

CSV – Comma-separated values

DCP – Decentralised Procedure

DCDvet – Defined Course Dose for animals

DDDvet – Defined Daily Dose for animals

HMP – Human Medicinal Product

MRP – Mutual Recognition Procedure

MS – Member State of the EU, also applicable to the other EEA countries.

NAP – National Authorisation Procedure

NCA – National Competent Authority

PCID – Packaged Medicinal Product Identifier of the PMS

[1] EU and EEA participating countries.

PMS – Product Management Services

RMS – Referentials Management Services

SMS – Substance Management System

SPC – Summary of Product Characteristics

SPOR - Substances, Products, Organisations and Referentials (SPOR) data management services, including PMS, RMS and SMS

SRP – Subsequent Recognition Procedure

UPD – Union Product Database

VMP - Veterinary Medicinal Product

3. Definitions

Active moiety – for the purpose of this protocol, it represents the part of the antimicrobial active substance that has antimicrobial activity.

Active substance –any substance or mixture of substances intended to be used in the manufacture of a veterinary medicinal product that, when used in its production, becomes an active ingredient of that product[2].

Admin User – EMA staff who has access to the ASU Platform as a super user, with permission to access all data and perform all tasks.

Antimicrobial VMP/HMP presentation – a packaged veterinary or human antimicrobial medicinal product approved for marketing as provided in the relevant section of the corresponding Summary of Product Characteristics (SPC). Each product presentation is distinguished by the name, package ID, strength, form, pack size and packaging material.

ASU derivative or compound – for the purpose of this protocol, any antimicrobial active substance that is not directly an antimicrobial active moiety and that is not defined as an ASU salt. From the technical point of view, in ASU if only the strength of the ASU derivative/compound and not that of the active moiety is known, then specific conversion factors, if available, are applied to calculate the mass of antimicrobial active moiety.

ASU Platform – web interface developed by the Agency to allow MSs to report, validate, verify and amend their data on volume of sales of VMPs, use of antimicrobial medicinal products in animals and animal population data by electronic means and in a timely manner.

ASU salt – for the purpose of this protocol, those antimicrobial active substances in salt form, that have their strength expressed in International Units (IU) and for which there is a defined conversion factor to convert the IU of the salt to the mass of the antimicrobial active substance. Currently, only colistin sulfate and colistin methane sulfonate are identified as salts in ASU.

Biomass denominator – for the purpose of this document, proxy for the animal population likely to be treated with antimicrobials within a reporting year, expressed as animal biomass (kg) per year and calculated based on a combination of the number of animals slaughtered during the data collection period and of the number of live animals present in a Member State at a given point during the data collection period, multiplied by standardised animal weights.

[2] As per Article 4(3) of the of Regulation (EU) 2019/6 [1]

Conversion factor: for the purpose of this protocol and from a technical perspective, a factor from a pre-defined list applied to either convert the mass of a derivative/compound to mass of the antimicrobial active moiety; or, when strength is expressed in International Units (IU), to convert the IU of the salt to mass of the antimicrobial active substance (currently only applies to colistin sulfate and colistin methane sulfonate).

Editable fields – fields that can be edited by the user.

NCA User – National contact point and/or data manager that will liaise with the Agency for the reporting of antimicrobial sales and use data and who can request access to the ASU Platform as a National Competent Authority user, with limited access to the system pages.

Non-editable fields – fields that cannot be edited by the user in the downloaded template. When changed, the edited information is not saved in the ASU Platform and an error validation report may be generated.

Partially editable fields – fields that are partially editable by the user in the downloaded template, i.e., the information is editable only for specific antimicrobial medicinal product presentations and according with the rules described in the protocol.

Package Identifier – unique and permanent identification assigned to each package that corresponds to Package ID in the UPD and to the PCID in PMS. In the UPD it corresponds to ID Level 3.

Parallel distribution - distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing-authorisation holder.

Permanent Identifier – unique and permanent identifier of the medicinal product in the UPD or PMS. This identifier differentiates between the medicinal products that are authorised in different MSs from the same Mutual Recognition Procedure (MRP), Decentralised Procedure (DCP), or Subsequent Recognition Procedure (SRP). In the UPD it corresponds to ID Level 2[3].

PCU – Population Correction Unit, established as a denominator for the sales data in the ESVAC project to normalise the total quantities of antibiotic active substance sold in each country by the animal population that could be potentially treated with these in each country. The PCU only includes food-producing animals, including horses and farmed fish and 1 PCU unit is equivalent to 1 kg of animal biomass.

Reference number - identifier of the antimicrobial VMP/HMP presentation from other relevant databases, such as national databases.

Subject to validation – ASU template data fields that are validated by the ASU Platform to confirm if the uploaded data were edited and reported in accordance with the rules described in the protocol.

Toggle button – A button in the ASU system that allows the user to change a setting between two states.

TRACES – Trade Control and Expert System, the European Commission's online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products.

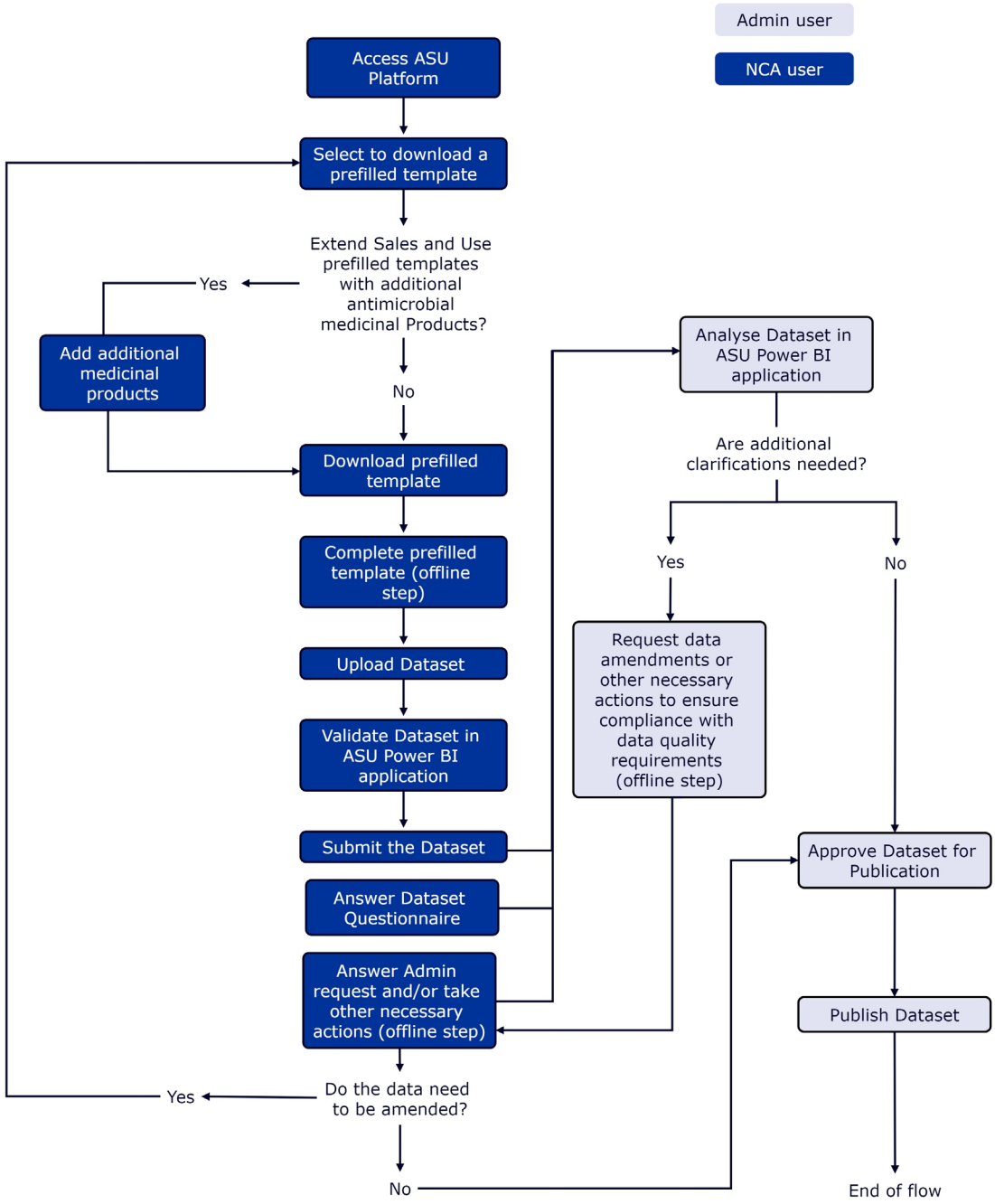
[3] In UPD, ID Level 1 corresponds to the Product Identifier (or Product ID) which acts as to a Unique identifier for the same veterinary medicinal products across Member States to enable grouping of veterinary medicinal products authorised under the decentralised, mutual recognition, or subsequent recognition procedures or which underwent harmonisation of their summaries of product characteristics. This ID is not used in the ASU Platform.

4. Overview of the ASU templates

This section provides an overview of the ASU templates which can be downloaded from the ASU Platform in csv format and which NCA users must complete to successfully submit data on volume of sales, use of antimicrobials in animals and animal population statistics to the Agency.

The NCA user on behalf of each MS must perform several sequential operations for the yearly reporting of data. In this manner, it is also expected that the Agency (as Admin user) will perform tasks to ensure the publication of the data. The tasks that are expected from the NCA user and the Admin user are shown in Figure 1. For more detailed instructions on how to perform the different tasks in the ASU Platform, please refer to the ASU Platform User Guide for NCA Users [4].

Figure 1. Overview of ASU tasks for data managers (NCA User) and EMA staff (Admin user).



The NCA user will be able to download three types of templates from the ASU Platform: the sales data template, the use data templates (one template per each of the animal species for which use data must be reported) and the animal population data template. The sales and use data templates will be prefilled with VMPs so that each row corresponds to an antimicrobial medicinal product presentation and each column to one of the different data fields that will either need to be completed by the NCA user or that will provide reference information on the medicinal product presentations that comes from the UPD (for VMPs) or from PMS (for HMPs, in the use template only). The animal population data template will be prefilled with animal statistics from reference data sources such as Eurostat or

TRACES, if available. In this template, each row will correspond to one of the different animal population categories for which animal statistics need to be reported and each column to one of the different data fields that will either need to be completed by the NCA user or which will provide reference information. For further details on the different data fields present in the ASU templates, please refer to section 5 of this protocol.

Before opening a data call, the EMA Admin user will perform a product synchronisation between the UPD and the ASU Platform, so that antimicrobial VMPs are automatically added to the ASU sales and use templates. The VMPs that appear prefilled in the sales and use templates for each country, year and species (for use data only) are those that comply with all of the following criteria:

- VMPs with an ATCvet code included in points 1 and 2 (for sales) or 3 and 4 (for use) of the Annex of the Commission Delegated Regulation (EU) 2021/578 [2].
- VMPs that have a 'current' product status in the UPD, as derived from UPD section *1.2. Product record status* [5]. VMPs with the status 'nullified' or 'provisional' are excluded[4].
- VMPs with a Marketing Authorisation status that was valid at least once during the reporting year or during the 4 previous years (5-year marketing coverage) in the country indicated in the template, as derived from UPD sections *2.5 Authorisation status and 2.6 Date of authorisation status change* [5].
- VMPs that were granted marketing authorisation through one of the following types of procedure: Centralised Authorisation Procedure (CAP), Decentralised Procedure (DCP), National Authorisation Procedure (NAP), Mutual Recognition Procedure (MRP), Subsequent Recognition Procedure (SRP) or Parallel traded procedure (PTP) for which the country indicated in the template is the destination country.
- (For use only) VMPs authorised for use in the selected animal species that is indicated in the corresponding use template. In this manner, the target species indicated in UPD section *3.3 Target species* [5] are mapped against the animal species for which data on the use must be reported, as per Article 15 of the Commission Delegated Regulation (EU) 2021/578) [2].

NCA users can search for additional antimicrobial medicinal products and add them to the template using the extend template functionality, if they need to report:

- Sales of antimicrobial VMPs authorised in another MS (e.g. under Article 116 of Regulation (EU) 2019/6 [1]).
- Use of antimicrobial VMPs authorised for the same species in another MS; use of VMPs authorised for use in other animal species in the concerned MS or in another MS; or use of HMPs authorised for use in the concerned MS or in another MS (use outside the terms of the marketing authorisation).

[4] Once an antimicrobial VMP presentation has been added from UPD to the ASU Platform, it can only be removed by completely clearing the ASU database. In this manner, if a product's status is changed to nullified after it has been added to the ASU Platform it will continue to appear in the corresponding ASU templates of the reporting year for which it was synchronised. The same applies to packages that were subsequently deleted from the UPD after they were synchronised to the ASU Platform.

In all the ASU templates, the data fields that appear in the different columns can be of one of the following types:

- Non-editable: these fields provide reference information on the antimicrobial medicinal product (sales and use templates) or on the animal population category (animal population template) and cannot be edited by NCA users. Changes made to these fields will either not be registered in the ASU Platform or will stop the template from being successfully uploaded to the ASU Platform, generating an error validation report.
- Partially editable: these fields can be updated by the NCA user only in some cases. If they are mandatory to complete and the NCA user does not update them, this will stop the templates from being successfully uploaded to the ASU Platform, generating an error validation report.
- Editable: these fields can always be updated by the user. If they are mandatory to complete and the NCA user does not update them, this will stop the template from being successfully uploaded to the ASU Platform, generating an error validation report.

5. ASU template data fields (detailed description)

This section describes in detail all the data fields that appear in the ASU templates. In the sales data template, all antimicrobial medicinal product information refers to VMPs. In the use data template, antimicrobial medicinal product information can refer to either VMPs or HMPs.

Please note that for most data fields, alphanumeric values will be prefilled in the ASU template CSV file, as provided by the corresponding information available in relevant EMA databases, such as UPD, PMS and Substances, Products, Organisations and Referentials data management services (SPOR). For further information on these alphanumeric values, please consult the respective implementation guides [5, 6, 7]. Please note that the data types indicated in the tables below do not refer to the data type in the CSV files, but to the data types that are going to be subjected to validation by the ASU Platform.

This section distinguishes between:

- data fields that appear in both sales and use data templates: Country, Year, Permanent identifier, Package identifier, Authorisation number, Procedure type, Reference Member State, Reference number, Medicinal product name, Product form, ASU pack size, ASU pack size unit, ATC or ATCvet code, Scope, Substance ID, Name of the antimicrobial active substance, Name of the salt of the antimicrobial active substance, Name of the derivative or compound of the antimicrobial active substance, Strength and Strength unit of measurement.
- data fields that only appear in the sales data template: VMPs allowed for use under Article 116, Authorised for companion animals only and Number of packages sold.
- data fields that only appear in the use data template: Animal species, Antimicrobial medicinal products added to the template by the user, Long-acting parenteral products and Number of packages used per animal category[5].

[5] In the use templates, there is a separate column to report the number of used packages for each animal category defined per animal species. For example, in the cattle use template there are four columns to report the number of used packages – one for dairy cattle, one for beef cattle, one for beef cattle under one year of age and one for other cattle. On the contrary, in the sheep use template there is only one column to report the number of used packages as for this animal species there are not any defined animal categories. For further information on the reporting of antimicrobial use data per animal categories, please view the document: 'Antimicrobial use data reporting per animal categories (numerator) – Manual for reporting the data to the Agency' (EMA/757638/2021) [8]

- data fields that appear in the animal population data template: Country, Year, Animal species, Animal population category, Animal population measurement, Reference animal population data, Reported animal population data, Source of the reported animal population data, Source URL of the reported animal population data and Justification of the reported animal population data.

5.1. Data fields common to sales and use data templates

5.1.1. Country

Tag	Description
Definition	Code of the country for which the volume of sales or the use of antimicrobials in animals is to be submitted.
Variable name in the template	COUNTRY
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	Two-letter code (alpha-2 code), largely based on the International Standard for country codes (ISO 3166), as listed in the *Country* RMS list (RMS list ID 100000000002) [7], for all EEA countries.

Example(s): AT, BG, BE.

5.1.2. Year

Tag	Description
Definition	Calendar year for which the data on the volume of sales or the use of antimicrobials in animals are to be submitted.
Variable name in the template	YEAR
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	DateTime
Value	Four-digit number indicating the year as per the ISO 8601 date format (i.e., YYYY).

Examples: 2023, 2024.

5.1.3. Permanent Identifier

Tag	Description
Definition	The Permanent Identifier (or Permanent ID) is a unique identifier of each VMP in the UPD or of each HMP in the PMS, differentiating medicinal products that are authorised in different MSs from the same MRP, DCP or SRP. In the UPD and PMS it corresponds to ID Level 2.

Tag	Description
	Please note that an apostrophe is added in front of the Permanent ID when the template is generated and removed upon dataset submission to avoid the automatic conversion of this numerical value to scientific notation when opening the CSV file in Excel.
Variable name in the template	PERMANENT_IDENTIFIER
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	Identifier
Value	As available in UPD section *1.4 Permanent Identifier* [5] or PMS section *1.1 Product Management Service Identifier (PMS ID)* [6].

Example: 600000064201, 600000037969

5.1.4. Package Identifier/Packaged Medicinal Product Identifier

Tag	Description
Definition	The Package Identifier in the UPD or the PCID in PMS is a structured data field that indicates the permanent and unique identification assigned to each medicinal product package presentation. It can be shared by equivalent packages authorised in different MSs from the same MRP, DCP or SRP that have a different Permanent ID. In the UPD it corresponds to ID Level 3. The system verifies that there are not VMP/HMP presentations with the same permanent identifier and package identifier in the same sales or use template to avoid double reporting for the same product presentation.
Variable name in the template	PACKAGE_IDENTIFIER
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	Identifier
Value	As available in UPD section *5.3 Package Identifier* [5] or PMS section *4.1. Packaged Medicinal Product Identifier* [6].

Example: 53a00fc8-36aa-4b5e-a93e-9a62405f435e, c04cf980-18f1-4b96-bfe7-7dd0130f3b22

5.1.5. Authorisation number

Tag	Description
Definition	Marketing authorisation number assigned by the competent authority at package level or, if not available, at product level.
Variable name in the template	AUTH_NUMBER
Editability	Prefilled, non-editable field

Tag	Description
Conformance	Mandatory
Data Type	Identifier
Value	As derived from UPD sections *5.5.1 Marketing authorisation number (package level)* or *2.2. Authorisation/registration/entitlement number* [5] or from PMS sections *4.7.2 Marketing authorisation number (Package level)* or *2.2 Marketing authorisation number* [6].

Example: 9743/2016/01-02-03-07, EU/2/13/016/001, 9743/2016, EU/2/13/016

5.1.6. Procedure type

Tag	Description
Definition	Type of procedure (EU medicinal marketing authorisation approval routes) through which the initial marketing authorisation was granted by the regulatory authority for the antimicrobial VMP or HMP. The procedure types are: • Centralised procedure (CP) • Decentralised procedure (DCP) • Mutual recognition procedure (MRP) • Subsequent recognition procedure (SRP) • National procedure (NP) • Parallel trade procedure (PTP)
Variable name in the template	PROCEDURE_TYPE
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value	As derived from the UPD section *2.13.2. Procedure type* [5] or from PMS section *2.10.2. Procedure type – Medicines approval system* [6]. The ASU templates are prefilled with the short name of the different procedure types as specified in the *EU Regulatory Authorisation/Registration Procedure* RMS list (RMS list ID 100000154442) [7].

Example: CP, DCP, MRP, SRP, NP.

5.1.7. Reference Member State

Tag	Description
Definition	Name of the Reference Member State or organisation responsible for the product data of the antimicrobial VMP in the UPD: • For CAPs: EMA will be indicated. • For NAPs and PTPs: the country of the template will be indicated. • For DCPs, SRPs and MRPs: the reference member state indicated in UPD will be indicated.

Tag	Description
Variable name in the template	REFERENCE_MS
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value	As derived from the UPD section *2.11. Reference member state* [5]. When a country is indicated, the ASU templates will be populated with the two-letter code (alpha-2 code), largely based on the International Standard for country codes (ISO 3166), as listed in the *Country* RMS list (RMS list ID 100000000002) [7].

Example: EMA, AT, BG.

5.1.8. Reference number

Tag	Description
Definition	This optional open-text field can be filled with a reference number or supplementary identifier of the antimicrobial VMP/HMP presentation from other relevant databases, such as national databases. As the reporting of the data is done per product presentation (i.e., at pack size and pack material level), only one reference number per package identifier should be included. However, this field is not validated in any way by the ASU Platform. After the first time a NCA user provides a reference number for a product presentation in any of the templates (either sales or use) and successfully uploads it to the system (without generating an error validation report), the changes will be saved and will persist in the database associated with the corresponding package identifiers. From that moment onwards, the saved reference numbers will appear in all the sales and use templates the user generates in the future that contain the same package identifiers.
Variable name in the template	REF_NUMBER(editable)
Editability	Blank (not prefilled), editable field
Conformance	Optional to report
Data Type	String of characters (max. 255 characters)
Value	Open text-field to indicate a supplementary reference number for a specific antimicrobial VMP/HMP presentation. The following types of characters are permitted: letters, digits, dashes, underscores and slashes.

5.1.9. Medicinal product name

Tag	Description
Definition	The full antimicrobial medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC and specified in line with the local language of the country where the product is authorised. For CAPs the name is expressed by default in English. For products authorised under other procedures the local translation is used.
Variable name in the template	NAME
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	String
Value(s)	As available in UPD section *1.8.1 Veterinary medicinal product name* [5] or PMS section *1.14 Medicinal product name* [6].

Example: Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats

5.1.10. Product form

Tag	Description
Definition	The product forms that can be indicated in this field are specific groupings of authorised pharmaceutical forms that are assigned automatically by the system to each VMP/HMP presentation. The product form allows to analyse the data per groups of pharmaceutical forms taking into consideration the route of administration and the intended site of action. The 13 product forms used for ASU analysis purposes are: - INJ (Injectable products) - INTRAMAM (Intramammary products) - ORAL SOLU (Oral solutions and powders to be administered with drinking water/milk/milk replacer) - ORAL PASTE (Oral pastes) - ORAL POWD (Oral powders to be administered in feed or in drinking water and feed) - PREMIX (Premixes) - TABL (Capsules, tablets, boluses and other similar oral pharmaceutical forms) - INTRAUT (Intrauterine products) - TOPICAL_DERM (Topical dermatological products) - TOPICAL_OPHTHALM (Topical ophthalmological products)

Tag	Description
	- TOPICAL_OTOLOG (Topical otological products) - TOPICAL_NASAL (Topical nasal products) - OTHER (Other forms when none of the previous product forms apply) This field is non-editable except when the product form is ORAL POWD or INTRAMAM. For **oral powders**, to harmonise reporting across MSs, the user must confirm using the information provided in the relevant section of the SPC if the VMP is to be administered in feed or in water: • If the oral powder is to be administered only in feed, no changes are required. • If the oral powder is to be administered only in drinking water/milk/milk replacer the user must change ORAL POWD to ORAL SOLU. • If the oral powder is to be administered in both feed and water, the user must keep ORAL POWD. • If the oral powder is only authorised for use in finfish, the user must change ORAL POWD to PREMIX. For **intramammary products**, the user must update INTRAMAM to: • INTRAMAM-LC: if in the SPC the VMP is indicated only for the treatment of lactating animals or for both the treatment of lactating animals and drying-off animals. • INTRAMAM-DO: if in the SPC the VMP is only indicated for the treatment of drying-off animals. Once the user has confirmed this information, it will persist in the database associated with the corresponding package identifier and it will appear in the prefilled template the next time the user generates it.
Variable name in the template	FORM(editable)
Editability	Prefilled, partially editable field: - ORAL POWD can be edited to ORAL SOLU or PREMIX. - INTRAMAM must be edited to INTRAMAM-LC or INTRAMAM-DO. - All other forms are non-editable.
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value(s)	As derived from the UPD section *1.5 (Authorised) Pharmaceutical form* [5] or the PMS section *1.5. (Authorised) pharmaceutical form* [6] and re-codable against the applicable product form listed in the *ASU Product Form* RMS list (RMS list ID 200000027138) [7]. Each ASU product form is mapped as an attribute to the pharmaceutical forms available in the following RMS lists: - *Pharmaceutical Dose Form* (RMS list ID 200000000004)

Tag	Description
	- *Combined Pharmaceutical Dose Form* (RMS list ID 200000000006) - *Combined Term* (RMS list ID 200000000007) - *Combination Package* (RMS list ID 200000000008)

Example: INJ, ORAL POWD, ORAL SOLU, INTRAMAM-LC.

5.1.11. ASU Pack size

Tag	Description
Definition	The ASU pack size is the total number of units in a package after reconstitution or the quantity (number or volume) of the manufactured item(s) in the VMP/HMP presentation based on the information provided in the relevant section of the SPC. The ASU pack size field is automatically prefilled by the system following these rules: 1. When the VMP/HMP includes one manufactured item, and the strength is provided by: 1.1 Concentration: the ASU pack size field is calculated by multiplying the numerical value of the UPD/PMS Pack Size by the numerical value of the UPD/PMS Manufactured Item Quantity. 1.2 Presentation: the ASU pack size will be prefilled with the numerical value of the UPD/PMS pack size. 2. When the VMP/HMP includes multiple manufactured items (e.g., powder for reconstitution and solvent), the ASU pack size will be prefilled with the numerical value of the UPD/PMS pack size. For a summary of ASU pack size and strength rules, please refer to Annex 2.
Variables name in the template	ASU_PACKSIZE
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	Numeric value
Value(s)	Numerical value, as available in UPD sections *5.2 Pack size* and/or *5.6.2 Manufactured Item Quantity* [5] or PMS sections *4.4 Pack size* or *4.11.2 Manufactured item quantity* [6], following the rules described above.

Examples: 10 (syringes), 10 (ml), 2 (kg)

5.1.12. ASU pack size unit

Tag	Description
Definition	The ASU pack size unit is the unit of measurement of the ASU pack size content. The applicable ASU pack size units are: - millilitre(s)

Tag	Description
	- litre(s) - milligram(s) - gram(s) - kilogram (s) - RMS *Units of Presentation* terms (e.g. vial, syringe, tablet) The ASU pack size unit and strength unit must be compatible for each antimicrobial VMP/HMP presentation. The magnitude of the strength unit denominator dictates that of the ASU pack size unit. Thus, if needed, both the ASU pack size value and unit of measurement will be converted by the system to be aligned with the strength unit denominator. For example, if the pack size is expressed in millilitres and the strength unit denominator is expressed in litres, the pack size will be converted to litres. The following ASU pack size units and substance strength units are compatible:

Pack size unit	Compatible Substance strength unit
ml	mg/ml IU/ml g/ml mg/l IU/l
l	mg/l g/l IU/l mg/ml g/ml IU/ml
mg	mg/mg mg/g IU/mg
g	mg/g IU/g g/g g/kg IU/kg
kg	g/kg IU/kg mg/g IU/g g/g
RMS Unit of Presentation	mg/RMS Unit of Presentation g/RMS Unit of Presentation IU/RMS Unit of Presentation

The ASU pack size unit field will be automatically prefilled by the system following these rules:

1. When the VMP/HMP includes one manufactured item, and the strength is provided by:

    1.1. Concentration: the unit of measurement of the UPD/PMS Manufactured Item Quantity will be retained as the ASU pack size unit.

Tag	Description
	1.2. Presentation: the unit of measurement of the UPD/PMS Pack Size will be retained as the ASU pack size unit. 2. When the VMP/HMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the unit of measurement of the UPD/PMS Pack Size will be retained as the ASU pack size unit. For a summary of ASU pack size and strength rules and how this information is used to calculate the total amount of antimicrobial active substance sold or used, please refer to Annex 2.
Variables name in the template	ASU_PACKSIZE_UNIT
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	Unit, as available in UPD sections *5.2 Pack size* and/or *5.6.2 Manufactured Item Quantity* [5] or PMS sections *4.4 Pack size* or *4.11.2 Manufactured item quantity* [6], following the rules described above. The units are specified as a Term ID listed in RMS list *Units of Measurement* (RMS list ID 100000110633) or RMS list *Units of Presentation* (RMS list ID 200000000014), as applicable [7].

Examples: (10) syringes, (10) ml, (2) kg.

5.1.13. ATC or ATCvet code

Tag	Description
Definition	This field includes the Anatomical Therapeutic Chemical veterinary (ATCvet) classification system code (VMPs) or the Anatomical Therapeutic Chemical (ATC) classification system code (HMPs) as indicated in the relevant section of the SPC. Data on the volume of sales must be reported for antimicrobial VMPs with the ATCvet codes listed in points 1 and 2 of the Annex to Commission Delegated Regulation (EU) 2021/578 and data on the use of antimicrobials in animals must be reported for VMP and HMPs for which the ATC/ATCvet codes are listed in points 3 and 4 of the same Annex [2]. If multiple ATCvet/ATC codes apply to the same antimicrobial VMP/HMP, then only the codes referred to in points 1 to 4 of the Annex to Commission Delegated Regulation (EU) 2021/578 will be listed (separated by commas) in the ASU templates. Technically, all five levels of an ATCvet/ATC code can be used; however, the most granular level of information available will be used. **ATTENTION** Please note that the ATCvet code QG51AG has been included in the ASU Platform as mandatory to be reported both for sales and use data, as recommended in the scientific advice provided by EMA [9].

Tag	Description
Variable name in the template	ATC/ATCVET
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	As available in UPD section 1.7.2 *ATC vet code* [5] or PMS section *1.13.3. ATC code(s)* [6], and if marked as antimicrobial in the RMS list *Anatomical Therapeutic Chemical classification system – Veterinary* (RMS list ID 100000116677) or in the RMS list *Anatomical Therapeutic Chemical classification system – Human* (list ID 100000093533) [7].

Examples: QJ01CA04, QJ51AA07.

5.1.14. Scope

Tag	Description
Definition	This field indicates if the reporting to the Agency of data on the volume of sales of a VMP or on the use of a VMP/HMP is mandatory or voluntary, based on the product ATCvet/ATC code, as per Articles 1 to 4 of Commission Delegated Regulation (EU) 2021/578 [2].
Variable name in the template	SCOPE
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	Boolean
Value	'Mandatory' or 'voluntary' to inform the user whether reporting data on the volume of sales or on the use of antimicrobials in animals to the Agency is mandatory or voluntary, as derived from UPD section 1.7.2 *ATC vet code* [5] or PMS section *1.13.3. ATC code(s)* [6], in combination with the RMS list *Anatomical Therapeutic Chemical classification system – Veterinary* (RMS list ID 100000116677) and the RMS list *Anatomical Therapeutic Chemical classification system – Human RMS list* (List Identifier 100000093533) where ATCvet and ATC codes indicated in points 1 to 4 of the Annex to Commission Delegated Regulation (EU) 2021/578 are marked as antimicrobials and as either mandatory or voluntary for reporting [7]. For further information, please refer to Table 5 of Annex 4.

Examples: mandatory, voluntary.

5.1.15. Substance ID

Tag	Description
Definition	This field includes a specific substance ID for each antimicrobial active substance that comes from the Substance Management System (SMS).

Tag	Description
	Please note that an apostrophe is added in front of the SMS ID when the template is generated and removed upon dataset submission to avoid the automatic conversion of this numerical value to scientific notation when opening the CSV file in Excel.
Variable name in the template	SUBST_ID
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value	As available in UPD sections *4.3.3.1 Reference (Active) Substance* or *4.3.1. Substance* [5], or in PMS sections *5.5.3.1. Reference substance* or *5.5.1. Substance* [6].

Examples: '100000092772, '100000147798

5.1.16. Name of the antimicrobial active substance

Tag	Description
Definition	Name of the antimicrobial active substance corresponding to its International Non-proprietary name (INN), as presented in the latest version of the ATC or ATCvet Index and as available in SMS. Every antimicrobial VMP/HMP product must have at least one antimicrobial active substance. In the case of fixed combination products, all the antimicrobial active substances will be listed individually within their corresponding section of the prefilled sales template. If fixed combination products include any non-antimicrobial active substances (e.g., anti-inflammatory substances), these will not be reported in the template. This is also applicable to beta-lactamase or other enzyme inhibitors (e.g., clavulanic acid). If in UPD/PMS, the provided antimicrobial active substance is an ASU derivative/compound or an ASU salt (with its strength expressed in IU) and information on the antimicrobial active moiety is not available, this field will be prefilled with the name of the mapped antimicrobial active moiety. The name of the provided antimicrobial active substance will appear in the SALT or DERIVATIVE field of the ASU templates depending on whether it has been classified as an ASU salt or an ASU derivative (see sections 5.1.17 and 5.1.18 for more information). E.g. If the antimicrobial active substance provided in UPD/PMS is *procaine benzylpenicillin*, the mapped antimicrobial active moiety *benzylpenicillin* will appear in the SUBSTANCE field and *procaine benzylpenicillin* in the DERIVATIVE field. For more information on how the substance information is prefilled in the ASU templates, please refer to Annex 1.
Variable name in the template	SUBSTANCE
Editability	Prefilled, non-editable field

Tag	Description
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	As available in UPD section *4.3.3.1 Reference (Active) Substance* or, should this not be provided, in section *4.3.1 (Active) Substance* [5]; or as available in PMS section *5.5.3.1. Reference substance* or, should this not be provided, in section *5.5.1. Substance* [6][6]. Only for substances classified as antimicrobial in SMS.

Examples: amoxicillin, benzylpenicillin, colistin, oxytetracycline.

5.1.17. Name of the salt of the antimicrobial active substance

Tag	Description
Definition	This field is prefilled only when the antimicrobial active substance provided in UPD/PMS is classified as an ASU salt in SMS and when its strength is only expressed in IU. Currently, there are only two substances marked as ASU salts in SMS: colistin sulfate and colistin methane sulfonate. The indication of the salt in this field will trigger the system to apply a conversion factor to convert the IU of the salt to mass of the antimicrobial active substance. Please refer to Annex 1 and Annex 3 for further information on how ASU salt information is displayed in the ASU templates and on the available IU conversion factors and the rules used to apply them.
Variable name in the template	SALT
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	As available in UPD section *4.3.1 (Active) Substance* [5] or PMS section *5.5.1. Substance* [6], if the substance is marked as an ASU salt in the SMS and when the substance strength is only expressed in IU for the salt form.

Examples: colistin sulfate, colistin methane sulfonate.

5.1.18. Name of the derivative or compound of the antimicrobial active substance

Tag	Description
Definition	Name of the ASU derivative/compound that corresponds to the antimicrobial active substance provided in UPD/PMS. The ASU derivative is only shown when the strength of the antimicrobial active moiety is not available in UPD/PMS or

[6] Please note that information on the antimicrobial active moiety can be provided in either the *Reference (Active) Substance* or the *(Active) Substance* fields of UPD/PMS, depending on the information available in the SPC. For example, if both active moiety and active substance are provided in the SPC, the active moiety should be provided in the *Reference (Active) Substance* field and the active substance in the *(Active) Substance* field. However, if only information of the active moiety is provided in the SPC, this will be directly indicated in the *(Active) Substance* field.

Tag	Description
	when the VMP/HMP has multiple manufactured items and the VMP/HMP has information for both the antimicrobial active substance and the antimicrobial active moiety (this is because of how the strength is calculated for these cases, as explained in section 5.1.19). The indication of the ASU derivative/compound in this field will trigger the system to apply a conversion factor to convert the mass of the derivative to the mass of the antimicrobial active moiety. If no conversion factor is available, a conversion factor of 1 will apply. Please refer to Annex 1 and Annex 3 for further information on how ASU derivative/compound information is displayed in the ASU templates and on the available derivative conversion factors and the rules used to apply them.
Variable name in the template	DERIVATIVE
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	As available in UPD section *4.3.1 (Active) Substance* [5] or PMS section *5.5.1. Substance* [6] if the substance is marked as an ASU derivative in the SMS.

Examples: procaine benzylpenicillin, penethamate hydriodide.

5.1.19. Strength

Tag	Description
Definition	The strength (quantitative composition) is a numerical value that indicates the quantity of antimicrobial active substance contained in a VMP/HMP presentation as indicated in the relevant section of the SPC. This field will be prefilled with the strength of the antimicrobial active moiety when available in the UPD or PMS. When the strength of the active moiety is not available, this field will be prefilled with either: • the strength of the ASU derivative/compound • the strength of the ASU salt in those cases where the antimicrobial active substance is classified as an ASU salt and the strength is expressed in IU, as indicated in the SPC and available in the UPD or PMS. The ASU strength field will be automatically prefilled by the system following these rules: 1. When the VMP/HMP includes **one manufactured item**, the strength will be provided as either a concentration or presentation strength (depending on the product presentation) of: a. The antimicrobial active moiety if available in either the UPD/PMS Reference Strength or Strength fields.

Tag	Description
	b. The ASU derivative/compound if strength of the antimicrobial active moiety is not provided in UPD/PMS (as available in the UPD/PMS Strength field). c. The ASU salt when the antimicrobial active substance is a defined ASU salt and the strength is expressed in IU (as available in the UPD/PMS Strength field). Currently only applicable to colistin sulfate and colistin methane sulfonate. In all these cases, when the denominator of the strength is different from 1, the fraction is calculated by the system and the strength denominator is converted to 1. 2. When the VMP/HMP includes **multiple manufactured items** (e.g., powders for reconstitution and solvent), the numerical value of the UPD/PMS Manufactured Item Quantity (containing the antimicrobial active substance, e.g. powder for reconstitution) is retained as the ASU strength value. If in UPD/PMS both the antimicrobial active substance and the antimicrobial active moiety are available, the strength value will be attributed to the antimicrobial active substance as this is what the manufactured item quantity corresponds to. For a further information on the substance information used in ASU, a summary of the pack size and strength rules and the conversion factors used in ASU, please refer to Annex 1, Annex 2 and Annex 3.
Variables name in the template	STRENGTH
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	Ratio
Value(s)	Numerical value, as available in UPD sections *4.3.3.2. Reference strength (Concentration)*, *4.3.2.2. Strength (concentration), 4.3.3.1.1. Reference strength (Presentation), 4.3.2.1. Strength (presentation) or 5.6.2 Manufactured item quantity* [5]; or in PMS sections *5.5.3.4. Reference strength (Concentration)* or *5.5.2.3. Strength (concentration), 5.5.3.3. Reference strength (Presentation), 5.5.2.2. Strength (presentation) or 4.11.2 Manufactured item quantity* [6], following the rules described above[7].

Examples: 50 (mg/ml), 10000 (IU/syringe).

[7] Please note that strength information on the antimicrobial active moiety can be provided in either the *Reference Strength* or the *Strength* fields of UPD/PMS, depending on the information available in the SPC. For example, if both active moiety and active substance are provided in the SPC, the active moiety strength should be provided in the *Reference Strength* field and the active substance strength in the *Strength* field. However, if only information of the active moiety is provided in the SPC, the strength will be directly indicated in the *Strength* field.

5.1.20. Strength unit of measurement

Tag	Description
Definition	The strength unit of measurement consists of a numerator and a denominator. The denominator strength unit can either be a unit of presentation (presentation strength) or a unit of measurement (concentration strength) and it must be compatible with the ASU pack size unit for each antimicrobial VMP/HMP presentation. This compatibility is important to harmonise the data and enable the system to calculate the content of antimicrobial active substance per presentation, used to calculate the total tonnes of antimicrobial active substance sold and used (based on the number of packages sold and used). For further information on the compatibility between pack size and strength units, please refer to subsection 5.1.12. The ASU strength unit of measurement field will be automatically prefilled by the system following these rules: 1. When the VMP/HMP includes one manufactured item the strength unit of measurement will be that of the corresponding selected strength value as per the rules in section 5.1.19. 2. When the VMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the UPD/PMS Manufactured Item Quantity unit will be retained as the ASU strength numerator unit and the UPD/PMS Pack Size unit will be retained as the ASU strength denominator unit. For more information on ASU strength rules, please refer to Annex 2.
Variables name in the template	STRENGTH_UNIT
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	CodeableConcept
Value(s)	Numerical value, as available in UPD sections *4.3.3.2. Reference strength (Concentration)*, *4.3.2.2. Strength (concentration)*, *4.3.3.1.1. Reference strength (Presentation)*, *4.3.2.1. Strength (presentation)* or *5.6.2 Manufactured item quantity* [5]; or in PMS sections *5.5.3.4. Reference strength (Concentration)* or *5.5.2.3. Strength (concentration)*, *5.5.3.3. Reference strength (Presentation)*, *5.5.2.2. Strength (presentation)* or *4.11.2 Manufactured item quantity* [6], following the rules described above[8]. The units are specified as a Term ID listed in RMS list *Units of Measurement* (RMS list ID 100000110633) or RMS list *Units of Presentation* (RMS list ID 200000000014), as applicable [7].

Examples: (50) mg/ml, (10000) IU/syringe.

[8] Please note that strength information on the antimicrobial active moiety can be provided in either the *Reference Strength* or the *Strength* fields of UPD/PMS, depending on the information available in the SPC. For example, if both active moiety and active substance are provided in the SPC, the active moiety strength should be provided in the *Reference Strength* field and the active substance strength in the *Strength* field. However, if only information of the active moiety is provided in the SPC, the strength will be directly indicated in the *Strength* field.

5.2. Data fields specific to the sales data template

5.2.1. VMPs allowed for use under Article 116

Tag	Description
Definition	This field serves to identify antimicrobial VMPs that are authorised for use in a MS under Article 116 of Regulation (EU) 2019/6 [1][9]. If during the reporting year there are sales of antimicrobial VMPs that are authorised in a MS different from the reporting country, the user must add them to the prefilled template via the extend template functionality. For these VMPs, this field will appear blank in the downloaded sales template and the user must manually edit this field by adding 'Y' (Yes) if the VMP was allowed for use under Article 116 of Regulation (EU) 2019/6 or 'N' (No) if the VMP was authorised for use in the NCA user's country under another legislative framework. For all the antimicrobial VMPs that appear automatically prefilled in the sales template this field will be prefilled by the system as 'N', and it will not be editable.
Variable name in the template	ARTICLE_116
Editability	Prefilled, non-editable for all VMPs that are automatically included in the sales template. Blank and editable for all VMPs added to the template by the user via the extend template functionality.
Conformance	Mandatory and subject to validation
Data Type	Boolean
Value	A choice of 'Y' (yes) or 'N' (no) to be inserted by the user after adding a product to the template via the extend template functionality.

Example: Y, N.

5.2.2. Authorised for companion animals only

Tag	Description
Definition	As per Article 16(6) of Commission Delegated Regulation (EU) 2021/578 [2], the volume of sales of antimicrobial VMPs for food-producing animals and for other animals kept or bred must be reported separately, in accordance with the format of the data in Commission Implementing Regulation (EU) 2022/209 [3]. The variable 'authorised for companion animals only' will enable the identification of products authorised only for 'other animals kept or bred', which include companion animals and fur animals.

[9] Article 116 - Health situation: *By way of derogation from Article 106(1), a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in another Member State*.

Tag	Description
	To distinguish VMPs that are only authorised for 'other animals kept or bred' (i.e. companion animals and fur animals) from those which are authorised exclusively or also for food-producing animals, the following rules will apply: • This field will be non-editable and prefilled with 'N' (not authorised for companion animals only) when the antimicrobial VMP has a withdrawal period(s) indicated in the UPD. • This field will be editable and prefilled with 'Y' (authorised for companion animals only) when the antimicrobial VMP does not have a withdrawal period(s) indicated in the UPD. In these cases, the user must confirm from the information in the relevant section of the SPC if the VMP is only authorised for other animals bred and kept (companion animals and fur animals). If this is not the case, the user must change the value from 'Y' to 'N' (e.g. when the product is also authorised for use in food-producing animal species, which also includes all horses). For this protocol, companion animals are considered the same animal species described in Annex I of the Regulation (EU) 2016/429 for pet animals [10], namely: • dogs (*Canis lupus familiaris*) • cats (*Felis silvestris catus*) • ferrets (*Mustela putorius furo*) • invertebrates (except bees, molluscs belonging to the phylum Mollusca and crustaceans belonging to the subphylum Crustacea) • ornamental aquatic animals • amphibians • reptiles • birds: specimens of avian species other than fowl, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges and ratites (*Ratitae*) • mammals: rodents and rabbits other than those intended for food production. Once the user has confirmed this information, it will persist in the database associated with the corresponding package identifier and it will appear in the prefilled template the next time the user generates it.
Variable name in the template	COMPANION_ANIMALS
Editability	Prefilled, partially editable: - For VMPs with withdrawal period: non-editable field - For VMPs without withdrawal period: editable field
Conformance	Mandatory, editable and subject to validation
Data Type	Boolean

Tag	Description
Value	A choice of 'Y' (yes) or 'N' (no) to indicate if the antimicrobial VMP is authorised for use in companion animals only based on the presence of a defined withdrawal in section *3.4 Withdrawal period* of the UPD [5].

Example: Y, N.

5.2.3. Number of packages sold

Tag	Description
Definition	The number of packages sold indicates the volume of sales of each antimicrobial VMP presentation within the reporting MS during the specific reporting year. **The value must be zero or a positive numerical value** (decimals are accepted and a comma should be used as a decimal separator). Data providers for volume of sales data must be chosen nationally from the list indicated in Article 11(1) of the Commission Delegated Regulation (EU) 2021/578, i.e., MAH, wholesalers, retailers, feed mills, pharmacies and/or veterinarians [2]. If a MAH has provided the volume of sales of an antimicrobial VMP presentation for the specific reporting country and year in the UPD, this value will automatically be provided when the prefilled template is generated. MSs can choose to use MAH as data providers or not. These prefilled values, if available, are for reference only. It is the responsibility of MSs to report the accurate number of packages sold per antimicrobial VMP presentation. It is possible for MAHs to report negative volume of sales values in the UPD (e.g., due to returns from previous years). In these cases, the user must convert any negative sales values to zero before uploading the dataset. By default, this field will be empty when no sales are reported by the MAH in UPD or for antimicrobial VMP presentations added to the prefilled template by the user via the extend template functionality (e.g., under Article 116). The number of packages sold should be corrected and/or completed with intra-Community movements of VMPs, i.e., with sales of antimicrobials brought in from other MSs and excluding sales of antimicrobials sent to other MSs[10]. The user should put in place measures to avoid double reporting, such as excluding sales between wholesalers nationally. Sales must be reported as either zero or positive numerical values for all antimicrobial VMPs that fall within the mandatory data reporting scope, as per Article 1 of the Commission Delegated Regulation (EU) 2021/578 [2]. On the contrary, it is optional to report volume of sales for any antimicrobial VMPs that fall within the voluntary data reporting scope, as also mentioned in the same Article. If there were no sales of these VMPs in the reporting year, the user can report '0' (zero) to keep the trend analysis if sales were reported for these

[10] For those VMPs that are authorised under both a parallel trade procedure and a national procedure (including DCP, SPR, MRP) in the same MS, two separate rows will be available in the ASU Sales template to report the sales corresponding to each procedure type separately (these rows will have the same product information but different permanent ID and procedure type). However, if sales of a product sold under parallel distribution are to be reported, they should be aggregated with the sales of the corresponding centrally authorised product in the ASU Sales template.

Tag	Description
	product presentations in previous years or directly delete the corresponding rows from the template. Once the user has successfully uploaded a sales data template to the ASU Platform, the number of packages sold will persist in the database associated with the corresponding permanent ID, package identifier, country and year. The next time the user downloads the template for the same country and year, the previously submitted values will automatically appear in the prefilled template. If both volume of sales data from UPD and previously submitted values by the user are available, then the previously submitted values overrule the UPD data. If sales of VMPs from third countries (non-EU/EEA VMPs that are not registered in the UPD) need to be reported, the NCA user must report these sales to the Agency directly via email.
Variable name in the template	NO_PACKS
Editability	Blank or prefilled, as applicable, editable field
Conformance	Mandatory, and subject to validation
Data Type	Zero or positive numerical value
Value	The value must be zero or a positive numerical value (decimals are accepted and a comma should be used as a decimal separator). When there are values of sales reported by the MAH in the UPD, this field will be prepopulated with sales values as available in section *2.1.1 Volume of sales* and *2.1.2 Year-Month* of the UPD [5].

Example: 0; 500; 45,5

5.3. Data fields specific to the use data template

5.3.1. Animal species

Tag	Description
Definition	Name of the animal species for which the data on the use of antimicrobials in animals is to be submitted. Data on the use of antimicrobial medicinal products must be reported for the animal species, categories or stages, in a stepwise approach, as set out in Article 15 of Commission Delegated Regulation (EU) 2021/578 [2]. Therefore, one use data template is generated per animal species.
Variable name in the template	USE_SPECIES
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	Name of the animal species as listed in the RMS list *ASU Use Species* (RMS list ID 200000027170) [7].

Example(s): cattle, pigs, chickens, turkeys

5.3.2. Antimicrobial medicinal products added to the template by the user

Tag	Description
Definition	Allows for the identification of antimicrobial medicinal products added to the use data templates by the user through the extend template functionality to report antimicrobial use outside the terms of marketing authorisation. This includes use of a) antimicrobial VMPs authorised for the same use species but in a different MS, b) antimicrobial VMPs authorised for a different use species in the same or a different MS, and c) antimicrobial HMPs authorised for use in the same or a different MS.
Variable name in the template	ADDED_AMPs
Editability	Prefilled, non-editable field
Conformance	Mandatory
Data Type	String
Value	Depending on the VMP/HMP added, this non-editable field will be prefilled with: - 'N' (No) for antimicrobial VMPs that are automatically included in the use templates. - 'Y_OTHER_MS' for antimicrobial VMPs added to the template by the user and which are authorised for use in the same use species in a different MS. - 'Y_OTHER_SPECIES' for antimicrobial VMPs added to the template by the user and which are authorised for use in a different use species in the same or in a different MS. - 'Y_HMP' for antimicrobial HMPs added to the template by the user and which are authorised for use in the same or in a different MS.

Example: N, Y_OTHER_MS, Y_OTHER_SPECIES, Y_HMP

5.3.3. Long-acting parenteral products

Tag	Description
Definition	For parenteral products with long-acting/prolonged-release dosage forms (achieved through special formulation design and/or manufacturing method), whose modified-release dosage forms show slower release time than that of the conventional-release dosage form administered by the same route, the user should indicate 'LA' in this field. For other parenteral products (including those that have a naturally long half-life without the need of a special formulation design and/or manufacturing method) and all other product forms, this field should be left blank. This information is used to assign the correct DDDvet and DCDvet value to the active substance and route of administration of each VMP/HMP.

Tag	Description
	Once the user has confirmed this information, it will persist in the database associated with the corresponding package identifier and it will appear in the prefilled template the next time the user generates it.
Variable name in the template	LONG_ACTING
Editability	Blank (not prefilled), editable field
Conformance	Mandatory and subject to validation.
Data Type	String of characters
Value	Two-letter code ('LA') to indicate parenteral products with long acting/prolonged release dosage forms. It should be left blank for non-relevant products.

Example: LA

5.3.4. Number of packages used per animal category

Tag	Description
Definition	The number of packages used indicates the use of each VMP/HMP presentation per animal species and animal species category within the reporting MS during the specific reporting year. Data providers for antimicrobial use data must be chosen nationally from the list indicated in Article 13(1)(a) of the Commission Delegated Regulation (EU) 2021/578, i.e., veterinarians, retailers, pharmacies, feed mills and end-users, including farmers or breeders. Similarly, MSs can chose from the list of specific indicated in Article 13(1)(b) of the same regulation, i.e. health records, treatment logbooks, delivery notes, invoices from farms, prescriptions, pharmacy records or veterinary practice records [2]. The number of packages used per VMP/HMPs presentation must be reported separately for each animal species category within each animal species [8]. A separate column is available to report the number of packages used for each animal species category (the name of the animal category is indicated in the column header). E.g. for cattle, the number of packages used need to be reported in four columns corresponding to beef cattle, beef cattle under one year of age, dairy cattle and other cattle. If data on the use of antimicrobials in animals at national level are collected in other units than packages used for each antimicrobial VMP or HMP presentation, the amounts used (expressed in weight or in volume) should be converted by the Member State into the number of packages used before reporting to the Agency[11]. Use data must be reported as either zero or positive numerical values for all antimicrobial VMP or HMPs that fall within the mandatory data reporting scope, as per Article 3 of the Commission Delegated Regulation (EU) 2021/578 [2]. On

[11] For those VMPs/HMPs that are authorised under both a parallel trade procedure and a national procedure (including DCP, SPR, MRP) in the same MS, two separate rows will be available in the ASU Use template to report the use corresponding to each procedure type separately (these rows will have the same product information but different permanent ID and procedure type). However, if use of a product sold under parallel distribution is to be reported, it should be aggregated with the use of the corresponding centrally authorised product in the ASU Use template.

Tag	Description
	the contrary, it is optional to report use for antimicrobial VMP/HMPs that fall within the voluntary data reporting scope, as per Article 4 of the Commission Delegated Regulation (EU) 2021/578 [2]. If there was no use of these VMPs or HMPs in the reporting year, the user can report '0' (zero) to keep the trend analysis if use has been reported for these product presentations in previous years or directly delete the corresponding rows from the template. Once the user has successfully uploaded a use data template to the ASU Platform, the number of packages used will persist in the database associated with the corresponding permanent ID, package identifier, animal category (if applicable), animal species, country and year. The next time the user downloads the use template for the same animal species, country and year, the previously submitted values will automatically appear in the prefilled template.
Variable name in the template	NO_PACKS
Editability	Blank (not prefilled), editable field
Conformance	Mandatory and subject to validation
Data Type	Zero or positive numerical value
Value	The value is zero or a positive numerical value (decimals are accepted and a comma should be used as a decimal separator).

Example: 0; 500; 45,5

5.4. Animal population data template fields

5.4.1. Country

Tag	Description
Definition	Code of the country for which the animal population data are to be submitted.
Variable name in the template	COUNTRY
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	Two-letter code (alpha-2 code), largely based on the International Standard for country codes (ISO 3166), as listed in the Country list (RMS list ID 100000000002) [7], for all EEA countries.

Example(s): AT, BG, BE.

5.4.2. Year

Tag	Description
Definition	Calendar year for which the animal population data are to be submitted.
Variable name in the template	YEAR

Tag	Description
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	DateTime
Value	Four-digit number indicating the year as per the ISO 8601 date format (i.e., YYYY).

Examples: 2023, 2024.

5.4.3. Animal species

Tag	Description
Definition	Name of the animal species to which each animal population category for which data must be submitted belongs. The animal species indicated in this field are those indicated in Article 15 of Commission Delegated Regulation 2021/578 [2].
Variable name in the template	ANIMAL_SPECIES
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	Name of the animal species as listed in the ASU Use Species list (RMS list Identifier 200000027170) and which are included as an attribute in the RMS list *Animal Population Categories - Denominator* (RMS list ID 200000028943) [7].

Example(s): cattle, pigs, chickens, turkeys

5.4.4. Animal population category

Tag	Description
Definition	Name of the animal population category for which animal population data must be submitted [11]. A list of these animal population categories can be found in Annex 6.
Variable name in the template	POP_CATEGORY
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	Name of the animal population category as listed in the RMS list *Animal Population Categories - Denominator* (RMS list ID 200000028943) [7].

Example: Slaughtered Cow (B1230), Pigs for Fattening – OUT, Atlantic salmon

5.4.5. Animal population measurement

Tag	Description
Definition	The animal population measurement indicates the unit of measurement in which the animal population data must be provided for each animal population category. This unit of measurement is 'head(s)' for all animal population categories except for those that fall under the animal species 'Finfish' for which the unit of measurement is 'tonne(s)' of biomass produced per year for farmed fish (live weight at slaughter).
Variable name in the template	POP_MEASUREMENT
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	CodeableConcept
Value	'Head(s)' or 'tonne(s)' to inform the user which unit of measurement must be used to submit the animal population data for each animal population category. The units are specified as a Term ID listed in the RMS list *Units of Measurement* (RMS list ID 100000110633) and are included as values for the attribute 'Animal Population Measurement Type' in the RMS list *Animal Population Categories - Denominator* (RMS list ID 200000028943) [7].

Example: head(s), tonne(s)

5.4.6. Reference animal population data

Tag	Description
Definition	This field will be populated with official reference data from the preferred data sources for each of the animal population categories, if available, for the reporting year. If reference data are not available this field will be prefilled with a zero. The references sources for animal population data are the *European Statistical Office (Eurostat)* for numbers of livestock and slaughtered food-producing animals and the *Trade control and Expert System (TRACES)* for numbers of animals moved between the EU countries for fattening or slaughter. These data will be made available in the ASU system for each country and reporting year before the data call for users to submit their animal population data is opened.
Variable name in the template	REFERENCE_DATA
Editability	Prefilled, non-editable field
Conformance	Mandatory and subject to validation
Data Type	Zero or positive numerical value
Value	The value must be zero or a positive numerical value (decimals are only accepted in animal population categories for which the animal population

Tag	Description
	measurement is 'tonnes(s)') as obtained from the Eurostat and TRACES official databases.

Example: 0; 50000; 628,3

5.4.7. Reported animal population data

Tag	Description
Definition	This field must be populated by the user with the animal population data on total number of heads or, for finfish population categories only, the total biomass of farmed fish produced (live weight at slaughter in tonnes). Users can choose to fill in this field with: 1. the numerical value provided in the *Reference Animal Population Data* field, corresponding to the official statistics available in the data sources Eurostat and TRACES, if available. If the user selects this value, they do not need to complete any further fields in the animal population template. 2. a different value from that in the *Reference Animal Population Data* field, if the reference data is not available or if those data dont comply with the data quality requirements and national statistics should be reported instead. In this case the user will have to complete the remaining three fields of the animal population data template. Once the user has completed this field and successfully uploaded the animal population template to the ASU Platform, it will persist in the database associated with the corresponding animal population category, country and year. The next time the user downloads the template for the same country and year, the previously reported values will automatically appear in the prefilled template.
Variable name in the template	VALUE
Editability	Blank (not prefilled), editable field
Conformance	Mandatory and subject to validation
Data Type	Zero or positive numerical value
Value	The value is zero or a positive numerical value (decimals are accepted only if the animal population measurement for the animal population category is 'tonne(s)' – comma should be used as a decimal separator).

Example: 0; 25000; 5435,6

5.4.8. Source of reported animal population data

Tag	Description
Definition	This open-text field must be filled in with the source of the reported animal population data when the user enters a value that is different from that

Tag	Description
	provided in the *Reference animal population data* field (if it is the same value, this field can remain blank). Once the user has completed this field and successfully uploaded the animal population template to the ASU Platform, it will persist in the database associated with the corresponding animal population category, country and year. The next time the user downloads the template for the same country and year, the previously reported values will automatically appear in the prefilled template.
Variable name in the template	SOURCE
Editability	Blank (not prefilled), partially editable. Only to be completed when the user submits a value that is different from the one provided in the *Reference animal population data* field.
Conformance	Mandatory and subject to validation.
Data Type	String of characters (max. 255 characters)
Value(s)	Open text-field to indicate which alternative data source has been used for the reported animal population data.

Example: National statistics from the Ministry of Agriculture and Livestock, National Statistical Authority

5.4.9. Source URL of reported animal population data

Tag	Description
Definition	This open-text field must be filled in with the webpage URL of the source of the reported animal population data when the user enters a value that is different from that provided in the *Reference animal population data* field (if it is the same value, this field can remain blank). Once the user has completed this field and successfully uploaded the animal population template to the ASU Platform, it will persist in the database associated with the corresponding animal population category, country and year. The next time the user downloads the template for the same country and year, the previously reported values will automatically appear in the prefilled template.
Variable name in the template	SOURCE_URL
Editability	Blank (not prefilled), partially editable. Only to be completed when the user submits a value that is different from the one provided in the *Reference animal population data* field.
Conformance	Mandatory and subject to validation.
Data Type	String of characters (max. 255 characters)

Tag	Description
Value(s)	A valid URL should be provided (e.g. URL that starts with http:// or https://) that directs to the webpage of the source used to provide the submitted animal population data[12].

Example: http://national_statistics.com, https://national_statistics.com,

5.4.10. Justification of reported animal population data

Tag	Description
Definition	This open-text field must be filled in with the justification of why an alternative data source for the reported animal population data was used when the user enters a value that is different from that provided in the *Reference animal population data* field (if it is the same value, this field can remain blank). Once the user has completed this field and successfully uploaded the animal population template to the ASU Platform, it will persist in the database associated with the corresponding animal population category, country and year. The next time the user downloads the template for the same country and year, the previously reported values will automatically appear in the prefilled template.
Variables name in the template	SOURCE
Editability	Blank (not prefilled), partially editable. Only to be completed when the user submits a value that is different from the one provided in the *Reference animal population data* field.
Conformance	Mandatory and subject to validation.
Data Type	String of characters (max. 255 characters)
Value(s)	Open text-field to indicate why an alternative data source has been used for the submitted animal population data.

Examples: Unavailability of reference data.

[12] If necessary, it is possible to provide a URL in which the data is not publicly accessible. In these cases, if the EMA Admin users have any further questions about the provided data, they will contact the NCA user directly.

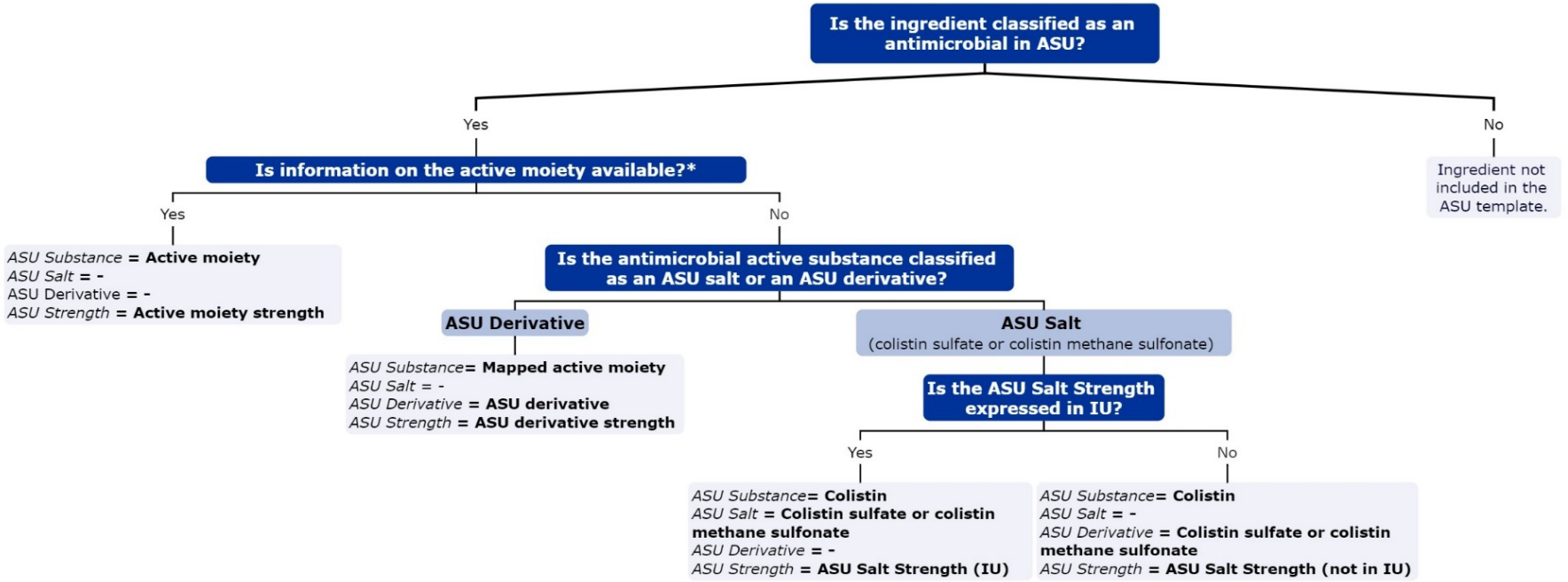
References

1. Official Journal of the European Union, Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. 2019: https://eur-lex.europa.eu/eli/reg/2019/6/oj.
2. Official Journal of the European Union, Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals 2021: http://data.europa.eu/eli/reg_del/2021/578/oj.
3. Official Journal of the European Union, Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. 2022: http://data.europa.eu/eli/reg_impl/2022/209/oj.
4. EMA, Antimicrobial Sales and Use (ASU) Platform User Guide for National Competent Authority users (EMA/27839/2024). 2024: https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinary-medicine/antimicrobial-sales-and-use-platform#ema-inpage-item-38759
5. EMA, EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/772581/2022). 2022: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eu-implementation-guide-ig-veterinary-medicines-product-data-chapter-2-format-electronic-submission_en.pdf
6. EMA, Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe – Chapter 2 (EMA/285848/2020). 2020: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf
7. EMA, Substances, Products, Organisations and Referentials data management services (SPOR): http://spor.ema.europa.eu/sporwi/
8. EMA, Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency (EMA/757638/2021). 2022: https://www.ema.europa.eu/en/documents/other/antimicrobial-use-data-reporting-animal-categories-numerator-manual-reporting-data-ema_en.pdf.
9. EMA/CMP, Advice on implementing measures under Article 57(3) of Regulation (EU) 2019/6 on veterinary medicinal products - Report on specific requirements for the collection of data on antimicrobial medicinal products used in animals (EMA/CVMP/131097/2019). 2019: Report on AM data collection requirements (europa.eu)
10. Official Journal of the European Union, Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'). 2016: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.084.01.0001.01.ENG.
11. EMA/CVMP, Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (EMA/CVMP/882931/2022). 2022: Guideline on the reporting of antimicrobial sales and use in animals at the EU level – denominators and indicators (europa.eu)

Annex 1. Substance information displayed in the ASU templates

In the Substance Management System (SMS), all antimicrobials relevant for ASU are marked as antimicrobials and classified as either an active moiety, an ASU salt or an ASU derivative/compound (please see definitions in the corresponding section of this document). In addition, all ASU salts and ASU derivatives/compounds are mapped to their corresponding antimicrobial active moiety in SMS. Depending on the information available in the UPD/PMS, the ASU templates are populated following the rules displayed in Figure 2.

Figure 2. Rules for populating the Substance, ASU salt, ASU derivative and Strength fields of the ASU Sales and Use templates based on the data available in the UPD/PMS.



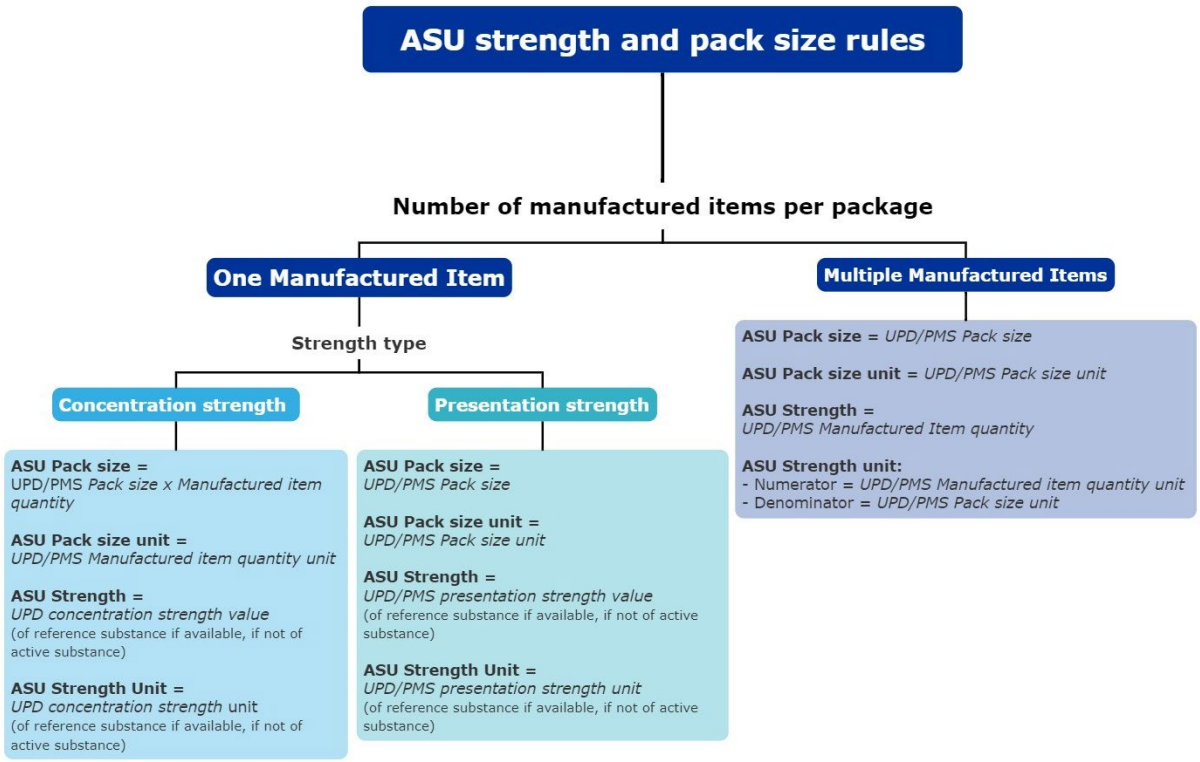
*In UPD/PMS, information on the active moiety can be found in either the *Reference (Active) Substance/Strength* or the *(Active) Substance/Strength* fields, depending on the information available in the SPC. For example, if both active moiety and active substance are provided in the SPC, the active moiety should be provided in the *Reference (Active) Substance/Strength* fields and the active substance in the *(Active) Substance/Strength* fields. However, if only information of the active moiety is provided in the SPC, this will be directly indicated in the *(Active) Substance/Strength* fields. Table 1 (below) provides some examples on what substance and strength information is shown in the ASU Sales and Use data templates based on the substance data available in the UPD.

Table 1. Examples on how substance and strength information are displayed in the UPD and ASU templates.

E.g.	SPC ingredient information	Information displayed in UPD				Information displayed in ASU sales/use template				
		Reference (Active) Substance	***Reference Strength***	***(Active) Substance***	***Strength***	**ASU Substance**	**ASU salt**	**ASU derivative /compound**	**Strength**	**Strength UoM**
1	Amoxicillin trihydrate 10 mg/ml (corresponds to Amoxicillin 8mg/ml)	Amoxicillin	8mg/ml	Amoxicillin trihydrate	10 mg/ml	Amoxicillin	-	-	8	mg/ml
2	Amoxicillin 5mg/ml	-	-	Amoxicillin	5mg/ml	Amoxicillin	-	-	5	mg/ml
3	Amoxicillin trihydrate 10 mg/ml	-	-	Amoxicillin trihydrate	10 mg/ml	Amoxicillin	-	Amoxicillin trihydrate	10	mg/ml
4	Colistin sulphate 5.000.000 IU/ml	-	-	Colistin sulphate	5000000 IU/ml	Colistin	Colistin sulphate	-	5.000.000	IU/ml
5	Colistin sulphate 80 mg/ml	-	-	Colistin sulphate	8 mg/ml	Colistin	-	Colistin sulphate	80	mg/ml
6	Colistin sulphate 5.000.000 IU/ml (corresponds to Colistin 83.33 mg/ml)	Colistin	83.33 mg/ml	Colistin sulphate	5.000.000 IU/ml	Colistin	-	-	83.33	mg/ml

Annex 2. Use of pack size and strength in ASU

Figure 3. Rules for populating the ASU pack size and strength fields in the ASU templates.



'ASU Pack size', *'ASU Pack size unit'*, *'ASU Strength'* and *'ASU Strength Unit'* correspond to the data fields of the same name in the ASU sales and use data templates.

'UPD/PMS Pack size', *'UPD/PMS Manufactured item quantity'*, *'UPD/PMS Pack size unit'*, *'UPD/PMS Manufactured item quantity unit'*, *'UPD/PMS concentration strength'* and *'UPD/PMS presentation strength'* correspond to the information available for VMPs in the UPD sections: 5.2 Pack size, 5.6.2 Manufactured Item Quantity, 4.3.3.2. Reference strength (Concentration), 4.3.2.2. Strength (concentration), 4.3.3.1.1. Reference strength (Presentation) and 4.3.2.1. Strength (presentation) [5]. For HMPs, sections 4.4 Pack size, 4.11.2 Manufactured item quantity, 5.5.3.4. Reference strength (Concentration), 5.5.2.3. Strength (concentration), 5.5.3.3. Reference strength (Presentation) and 5.5.2.2. Strength (presentation) of the PMS apply instead [6].

Table 2. Examples on how pack size and strength information are used in ASU to calculate the total amount of antimicrobial active substance sold or used per product presentation.

E.g.	Details	Calculation
20 boxes of Amoxibactin used	- Pack size = 1 box with 1 blister of 10 tablets = 10 tablets/box - Strength = 250 mg amoxicillin / tablet	10 tablets/box x 250 mg amoxicillin/tablet x 20 boxes =50.000 mg amoxicillin used
5 boxes of Vetriclox T.S. sold	- Pack size = 1 box with 100 syringes - Strength = 1000 mg cloxacillin benzathine / syringe - Derivative conversion factor (Cloxacillin benzathine – cloxacillin) = 0.74	100 syringes x 1000 mg cloxacillin benzathine / syringe x 5 boxes x 0.74 = 370.000 mg of cloxacillin sold

Annex 3. Conversion factors used in ASU

Table 3. IU conversion factors used for the calculation from IU to mg of antimicrobial active substance.

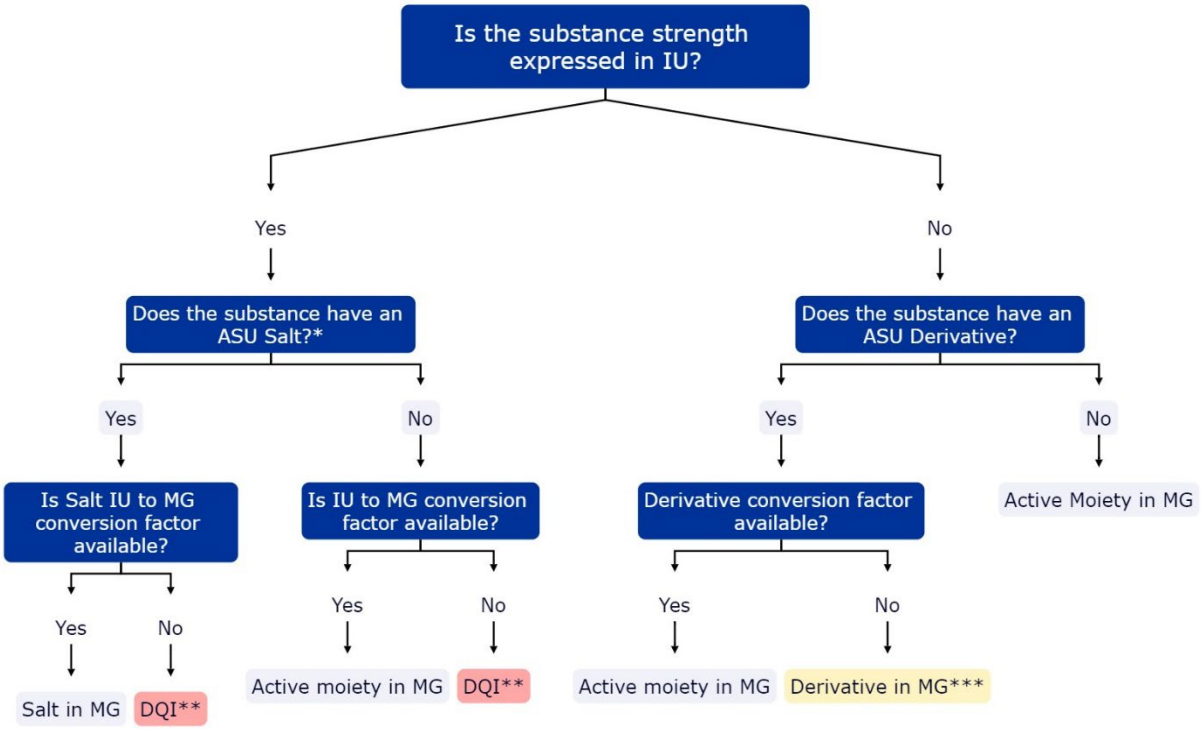
Active Substance	IU/mg	Conversion factor (mg/IU)
Apramycin	552	0.0018116
Bacitracin	74	0.013514
Benzylpenicillin (applies to all derivatives/compounds of benzylpenicillin)	1670	0.0005988
Chlortetracycline	1000	0.001
Colistin sulfate	20500	0.000049
Colistin methane sulfonate (colistimethate)	12700	0.000079
Dihydrostreptomycin	777	0.001287
Erythromycin	920	0.001087
Framycetin	706	0.0014172
Gentamicin	620	0.001613
Kanamycin	796	0.001256
Neomycin	762	0.0013123
Oxytetracycline	880	0.0011364
Paromomycin	750	0.0013333
Polymyxin B	8403	0.000119
Spiramycin	3200	0.000313
Streptomycin	760	0.0013158
Tetracycline	982	0.00101833
Tobramycin	875	0.001142857
Tylosin	1000	0.001

Table 4. Derivative conversion factors used for the calculation from mass of ASU derivative/compound to mass of antimicrobial active moiety.

Derivative or compound	Conversion factor
Benethamine penicillin	0.61
Benzathine benzylpenicillin[1]	0.68
Cefapirin benzathine	0.78
Cefalexin benzathine	0.74
Cloxacillin benzathine	0.78
Oxacillin benzathine	0.77
Penethamate hydriodide	0.60
Procaine benzylpenicillin[2]	0.57

[1] Applies also to benzathine benzylpenicillin tetrahydrate.
[2] Applies also to procaine benzylpenicillin monohydrate.

Figure 4. Rules on how IU and derivative conversion factors are applied in the ASU system based on the information displayed in the ASU templates.



* Currently, the only defined ASU Salts are colistin sulfate and colistin methane sulfonate.

** DQI = data quality issue. Whenever the system encounters a strength expressed in IU for which an IU conversion factor has not been determined, the calculation of mass of active substance in MG will not be possible and the product containing the substance will be marked as having a data quality issue so that it can be identified that a new conversion factor is needed.

*** Whenever the system encounters a derivative for which there is no available derivative conversion factor, the Admin user will be notified so that if necessary new derivative conversion factors can be defined and added to the system.

Annex 4. RMS lists used in ASU

Table 5. RMS lists used in ASU [7].

RMS list ID	RMS list name	ASU specific	Description of use in ASU
100000116677	Anatomical Therapeutic Chemical classification system – Veterinary	No	• ATCvet codes that fall in the ASU reporting scope, referred to in points 1-4 of the Annex of the Commission Delegated Regulation (EU) 2021/578 [2], are marked with the extended attribute: **'ANTIMICROBIAL_AS_PER_DA_2021/578 = Y'**. • ATCvet codes that fall in the sales data mandatory scope, referred to in point 1 of the Annex, are marked with the extended attribute: **'MANDATORY_TO_REPORT_SALES = Y'**. • ATCvet codes that fall in the use data mandatory scope, referred to in point 3 of the Annex, are marked with the extended attribute: **'MANDATORY_TO_REPORT_USE = Y'**.
100000093533	Anatomical Therapeutic Chemical classification system – Human list	No	• ATC codes that fall in the ASU reporting scope, referred to in points 3 and 4 of the Annex of the Commission Delegated Regulation (EU) 2021/578 [2], are marked with the attribute: **'ANTIMICROBIAL_AS_PER_DA_2021/578 = Y'.** • ATC codes that fall in the use data mandatory scope, referred to in point 3 of the Annex, are marked with the extended attribute: **'MANDATORY_TO_REPORT_USE = Y'.**
200000028943	Animal Population Categories - Denominator	Yes	List of animal population categories for which animal population must be reported for the calculation of PCU and biomass denominators. Each animal population category presents the following extended attributes: • Animal population group: to which each population category belongs (only for those used in PCU calculation). • Use species: to which each population category belongs. • Use category: to which each population category belongs, if applicable. • Animal Population Measurement Type: can be 'head(s)' or 'tonne(s)'to indicate in which unit of measurement the animal population data for each animal population category should be reported. • Unit of Measurement Weight: unit of measurement in which the standard weight for each animal category is expressed. For all animal categories it is 'gram(s)'. • ESVAC denominator: can be 'Y' (yes) or 'N' (no) depending on whether the animal population category is used for the calculation of the PCU denominator.

RMS list ID	RMS list name	ASU specific	Description of use in ASU
			• ASU denominator: can be 'Y' (yes) or 'N' (no) depending on whether the animal population category is used for the calculation of the biomass denominator. • ESVAC weight: standard weight of each animal population category used for the calculation of the PCU denominator. • ASU weight: standard weight of each animal population category used for the calculation of biomass denominator. • IN_OUT_FLAG: can be 'Y' (yes), 'N' (no) or null depending on whether it refers to an animal population category of animals brought in from another Member State, of animals sent out to another Member State or of animals bred and raised in the Member State in question, respectively.
200000028717	Animal Population Groups - Denominator	Yes	List of animal population groups to which the animal population categories for the PCU denominator calculation are mapped to. These are 'Cattle', 'Pigs', 'Poultry', 'Caprinae', 'Equidae', 'Rabbits' and 'Fish'.
200000028732	ASU Antimicrobial classification	Yes	Terms that belong to the 3-level classification used in the ASU system to classify antimicrobial substances. For more information see Annex 5.
200000027138	ASU product form	Yes	List of product forms used in ASU: Injectable products (INJ), Intramammary products (INTRAMAM), Intramammary products for lactating cows (INTRAMAM-LC), Intramammary products for drying-off cows (INTRAMAM-DO), Oral powders (ORAL POWD), Oral solutions (ORAL SOLU), Oral pastes (ORAL PASTE), Premixes (PREMIX), Tablets/capsules (TABL), Intrauterine or gynaecological products (INTRAUT), Dermatological products (TOPICAL_DERM), Ophthalmological products (TOPICAL_ OPHTHALM), Otological products (TOPICAL_OTOLOG), Nasal products (TOPICAL_NASAL) and Other forms (OTHER).
200000027170	ASU Use species	Yes	List of the ASU Use Species used in ASU following Article 15 of Commission Delegated Regulation 2021/578 [2]: 'Cattle', 'Pigs', 'Chickens', 'Turkeys', 'Other poultry', 'Sheep', 'Goats', 'Finfish', 'Horses', 'Rabbits', 'Other food-producing animals', 'Dogs', 'Cats' and 'Fur animals'.
200000027199	ASU Use categories	Yes	List of the ASU Use categories used in ASU as specified in the 'Antimicrobial use data reporting per animal categories (numerator) - Manual for reporting the data to the Agency' (EMA/757638/2021) [8] following Article 15 of Commission Delegated Regulation 2021/578 [2]: 'Beef cattle', 'Beef cattle for slaughter under 1 year of age', 'Dairy cattle', 'Other cattle', 'Fattening pigs', 'Other pigs', 'Broilers', 'Laying hens', 'Other chickens', 'Fattening turkeys', 'Other turkeys', 'Ducks', 'Geese', 'Atlantic salmon', 'Rainbow trout', 'Gilthead seabream', 'European seabass', 'Common carp', 'Minks' and 'Foxes'.

RMS list ID	RMS list name	ASU specific	Description of use in ASU
			Each ASU use category is mapped to their corresponding ASU use species.
200000000008	Combination Package	No	One of the four RMS lists used to populate the UPD field *1.5 (Authorised) Pharmaceutical form*. Each term has an 'ASU PRODUCT FORM' extended attribute used to indicate which ASU Product form the term is mapped to.
200000000006	Combined Pharmaceutical Dose Form	No	One of the four RMS lists used to populate the UPD field *1.5 (Authorised) Pharmaceutical form*. Each term has an 'ASU PRODUCT FORM' extended attribute used to indicate which ASU Product form the term is mapped to.
200000000007	Combined Term	No	One of the four RMS lists used to populate the UPD field *1.5 (Authorised) Pharmaceutical form*. Each term has an 'ASU PRODUCT FORM' extended attribute used to indicate which ASU Product form the term is mapped to.
200000000004	Pharmaceutical Dose Form	No	One of the four RMS lists used to populate the UPD field *1.5 (Authorised) Pharmaceutical form*. Each term has an 'ASU PRODUCT FORM' extended attribute used to indicate which ASU Product form the term is mapped to.
100000108853	Target species	No	RMS list used to populate the UPD field *3.3. Target species.* Each term has an 'ASU USE SPCIES' extended attribute used to indicate which ASU Use species the term is mapped to.

Annex 5. ASU Antimicrobial Substance Classification

Table 6. ASU three-level antimicrobial classification

Level 1	Level 2	Level 3
Antiinfectives	Antiinfectictives	Antiinfectives
		Biguanides and amidines
		Organic acids
		Other chemotherapeutics
		Quinoline derivatives
Antimycobacterials	Antimycobacterials	Aminosalicylic acid and derivatives
		Hydrazides
		Other drugs for the treatment of tuberculosis
		Thiocarbamide derivatives
Antiprotozoals	Antiprotozoals	Aminoquinolines
		Antimony compounds
		Aromatic diamidines
		Arsenic compounds
		Artemisinin and derivatives, combinations
		Artemisinin and derivatives, plain
		Biguanides
		Carbanilides
		Dichloroacetamide derivatives
		Hydroxyquinoline derivatives
		Methanolquinolines
		Nitroimidazole derivatives
		Other agents against amoebiasis and other protozoal diseases
		Other agents against leishmaniasis and trypanosomiasis
		Other antimalarials
		Other antiprotozoal agents
		Pyranes and hydropyranes
		Triazines
Antivirals	Antivirals	Antivirals for treatment of HCV infections
		Antivirals for treatment of HIV infections, combinations
		Cyclic amines
		Integrase inhibitors
		Neuraminidase inhibitors
		Non-nucleoside reverse transcriptase inhibitors
		Nucleoside and nucleotide reverse transcriptase inhibitors
		Nucleosides and nucleotides excl. reverse transcriptase inhibitors
		Other antivirals
		Phosphonic acid derivatives

Level 1	Level 2	Level 3
		Protease inhibitors
		Thiosemicarbazones
Antifungals	Azoles	Imidazole and triazole derivatives
		Triazole and tetrazole derivatives
	Other antifungals for systemic use	Antifungal for systemic use
	Other antifungals for topical use	Other antifungals for topical use
	Other antimycotics for systemic use	Other antimycotics for systemic use
Antibacterials	1-2 gen. cephalosporins	First-generation cephalosporins
		Second-generation cephalosporins
	3-4 gen. cephalosporins	Fourth-generation cephalosporins
		Third-generation cephalosporins
	Aminoglycosides	Other aminoglycosides
		Streptomycins
	Amphenicols	Amphenicols
	Carbapenems	Carbapenems
	Fluoroquinolones	Fluoroquinolones
	Glycopeptides	Glycopeptide antibacterials
	Imidazole derivatives	Imidazole derivatives
	Lincosamides	Lincosamides
	Macrolides	Macrolides
	Monobactams	Monobactams
	Nitrofuran derivatives	Nitrofuran derivatives
	Other antibacterials	Other antibacterials
	Other cephalosporins and penems	Other cephalosporins and penems
	Other quinolones	Other quinolones
	Penicillins	Beta-lactamase resistant penicillins
		Beta-lactamase sensitive penicillins
		Combinations of penicillins, incl. beta-lactamase inhibitors
		Penicillins with extended spectrum
	Pleuromutilins	Pleuromutilins
	Polymyxins	Polymyxins
	Quinoxalines	Quinoxalines
	Steroid antibacterials	Steroid antibacterials
	Streptogramins	Streptogramins
	Sulfonamides	Combinations of sulfonamides and trimethoprim, incl. derivatives
		Intermediate-acting sulfonamides
		Long-acting sulfonamides
		Short-acting sulfonamides
		Sulfonamides

Level 1	Level 2	Level 3
	Tetracyclines	Tetracyclines
	Trimethoprim	Trimethoprim

Annex 6. Overview of the animal populations categories and weights for the denominators of sales and use data and for the ESVAC denominator

Table 7. Overview of animal populations datasets, their data format and the weights that will be used to calculate the denominator for the sales and use data and used to calculate the ESVAC denominator.

Animal population data[1]		Data format	Animal population category	Animal population weight (kg)	ESVAC category	ESVAC weight (kg)
Male calves, less than 1 year old, not for slaughter (A2110C)	Livestock	Heads	Beef cattle	314	-	-
Male bovine animals, 1 to less than 2 years old (A2120)	Livestock	Heads	Beef cattle	500	-	-
Male bovine animals, 2 years old or over (A2130)	Livestock	Heads	Beef cattle	680	-	-
Non-dairy cows (A2300G)	Livestock	Heads	Beef cattle	595	-	-
Heifer, 1 year old, for slaughter (A2220B)	Livestock	Heads	Beef cattle	440	-	-
Heifer, 2 years old or over, for slaughter (A2230B)	Livestock	Heads	Beef cattle	564	-	-
Calves and young cattle (B1100)	Slaughter	Heads	Beef cattle (<1 year age)	314	Cattle	140
Heifers (B1240)	Slaughter	Heads	-	-	Cattle	200
Cows (B1230)	Slaughter	Heads	-	-	Cattle	425
Bullocks and bulls (B1210_1220)	Slaughter	Heads	-	-	Cattle	425
Dairy cows (A2300F)	Livestock	Heads	Dairy cattle	595	Cattle	425
Female calves, less than 1 year old, not for slaughter (A2210C)	Livestock	Heads	Dairy cattle	314	-	-
Heifer, 1 year old, not for slaughter (A2220C)	Livestock	Heads	Dairy cattle	440	-	-
Heifer, 2 years old or over, not for slaughter (A2230C)	Livestock	Heads	Dairy cattle	564	-	-
Pigmeat (B3100)	Slaughter	Heads	Fattening pigs	120	Pigs	65

Animal population data[1]		Data format	Animal population category	Animal population weight (kg)	ESVAC category	ESVAC weight (kg)
Breeding sows > 50 kg (A3120)	Livestock	Heads	Fattening pigs	240	Pigs	240
Chicken (B7100)	Slaughter	Heads	Broilers	2.4	Poultry	1
Laying hens producing eggs for human consumption (A5110OH)	Livestock	Heads	Laying hens	2.4	-	-
Turkey (B7300)	Slaughter	Heads	Fattening turkeys	13.2	Poultry	6.5
Duck (B7200)	Slaughter	Heads	Ducks	4.2	-	-
Goose (B7410)	Slaughter	Heads	Geese	6.7	-	-
Lamb (B4110)	Slaughter	Heads	Sheep	29	-	-
Live sheep (A4100)	Livestock	Heads	Sheep	75	Caprinae	75
Slaughtered sheep & goats (B4000)	Slaughter	Heads	-	-	Caprinae	20
Goat meat (B4200)	Slaughter	Heads	Goats	21	-	-
Live goats (A4200)	Livestock	Heads	Goats	65	-	-
Atlantic salmon ([SAL] *Salmo salar*)	Production	Biomass	Atlantic salmon	-	-	-
Rainbow trout ([TRR] *Oncorhynchus mykiss*)	Production	Biomass	Rainbow trout	-	-	-
Gilthead seabream ([SBG] *Sparus aurata*)	Production	Biomass	Gilthead seabream	-	-	-
European seabass ([BSS] *Dicentrarchus labrax*)	Production	Biomass	European seabass	-	-	-
Common carp ([FCP] *Cyprinus carpio*)	Production	Biomass	Common carp	-	-	-
Fish ([F07] Total farmed fish)	Production	Biomass	-	-	Fish	-
Living horses	Livestock	Heads	Horses	400	Equidae	400
Slaughtered rabbits	Slaughter	Heads	Rabbits	2	Rabbits	1.4
Living dogs	Living animals	Heads	Dogs	20	-	-
Living cats	Living animals	Heads	Cats	5	-	-
Minks	Breeding females	Heads	Minks	3.9	-	-
Foxes	Breeding females	Heads	Foxes	20	-	-

[1] When Eurostat dataset exists (even if data are not available), the respective label code is shown inside brackets for guidance (Eurostat codes may be subject to changes).

Table 8. Overview of the animal trade movements between Member States for fattening or slaughter, data source and standard weights that will be used in the calculation of the denominators for the sales and use data and of the ESVAC denominator

Animal population category	TRACES CN codes	Data format	Animal population category[1]	Animal population weight (kg)	ESVAC category	ESVAC weight (kg)
Cattle <1 year age for fattening	0102 29 10	Heads	Beef cattle < 1 year age	140	-	-
Cattle < 1 year age for slaughter	0102 29 21 0102 29 29 0102 02 29 41 0102 02 29 49	Heads	Beef cattle < 1 year age	314	-	-
Cattle >1 year age for fattening	0102 29 51	Heads	Beef cattle > 1 year age	500	-	-
Cattle > 1 year age for slaughter	0102 29 59 0102 29 61 0102 29 69 0102 29 91 0102 29 99	Heads	Beef cattle > 1 year age	623	-	-
Fattening bovine	0102	Heads	-	-	Cattle	140
Slaughtered bovine	0102	Heads	-	-	Cattle	425
Pigs for fattening	0103	Heads	Fattening pigs	25	Pigs	25
Pigs for slaughter	0103	Heads	Fattening pigs	120	Pigs	65
Chickens for slaughter	0105 94 00	Heads	Broilers	2.4	-	-
Turkeys for slaughter	0105 99 30	Heads	Fattening turkeys	13.2	-	-
Ducks for slaughter	0105 99 10	Heads	Ducks	4.2	-	-
Slaughtered poultry	0105	Heads	-	-	Poultry	1
Sheep for fattening	0104 10	Heads	Sheep	20	Caprinae	20
Sheep for slaughter	0104 10	Heads	Sheep	29	Caprinae	20
Goats for fattening	0104 20	Heads	Goats	20	Caprinae	20
Goats for slaughter	0104 20	Heads	Goats	21	Caprinae	20

[1] Animal categories or stages are only defined for use data. The new denominator for sales will not make such distinction as it will be calculated per species based on the same animal population data as for use.