EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 December 2022
EMA/258839/2022
Veterinary Medicines Division

# Antimicrobial Sales and Use (ASU) data reporting protocol Part 1 Reporting volume of sales

# Implementation of the requirements of Regulation (EU) 2019/6 for the collection of data on antimicrobial medicinal products used in animals

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

# Contents

# 1. Introduction

This document provides guidance to Member States (MSs)[1] on the process of reporting data on the volume of sales of antimicrobial veterinary medicinal products (VMPs) to the European Medicines Agency ('the Agency'), as referred to in Article 57 of Regulation (EU) 2019/6, by applying the format of the data established in Article 1 of the Commission Implementing Regulation (EU) 2022/209.

The reporting requirement applies to VMPs referred to in Articles 1 to 2 of Commission Delegated Regulation (EU) 2021/578.

Each MS shall appoint their 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 ASU system and database as Antimicrobial Sales and Use Data National Competent Authority User(s) ('the user'), as per Article 7(2) of the Commission Delegated Regulation (EU) 2021/578.

Member States are responsible for the data quality of their submission, including the accuracy of the information in prefilled data fields in the templates, in line with Article 6 of Delegated Regulation (EU) 2021/578.

The aim of this protocol is to inform data managers on tasks that need to be completed for reporting data on the volume of sales of antimicrobial VMPs to the Agency and developers in the MSs that are setting up national data collection systems or supporting data managers with the reporting of the data.

# 2. Acronyms

ASU – Antimicrobial Sales and Use system

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

CAP – Centralised Marketing Authorisation

CSV – Comma-separated values

DCP – Decentralised Procedure

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

PMS – Product Management Services

RMS – Referentials Management Services

SMS – Substance Management Services

SPC – Summary of Product Characteristics

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

SRP – Subsequent Recognition Procedure

[1] EEA countries, i.e. EU Member States and participating EFTA countries

UPD – Union Product Database

VMP - Veterinary Medicinal Product

# 3. Definitions

**Active moiety** – is the part of the active substance that has the actual therapeutic effect. For the purpose of this protocol, it represents the part of the substance that has antimicrobial activity, including when it is in the form of a derivative, compound or salt.

**Active substance** – means 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 ASU system and database as super user, with permission to access all data and perform all tasks.

**Antimicrobial VMP presentation** – a packaged veterinary antimicrobial medicinal product (i.e. name, strength, form, pack size and package material) approved for marketing as provided in the relevant section of the corresponding Summary of Product Characteristics (SPC). It takes into consideration not only the pack size but also the material of the packaging.

**Derivative or compound** – for the purpose of this protocol, these terms refer to related active substances which expose the animal to the same therapeutic active moiety. These could include derivatives, esters, hydrates, salts or other forms of an antimicrobial active moiety. From the technical point of view, in ASU where the strength of a derivative or compound is referred to, it is always expressed in mass, and a conversation factor can be applicable to convert the mass of the derivative or compound to mass of the antimicrobial active moiety.

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

**NCA User** – National contact point and/or data manager for liaison with the Agency with regards to the reporting of data, who has access to ASU system and database as Data National Competent (NCA) Authority user, with limited access to the system pages. Also referred to as **the user** in the text.

**Non-editable fields** – fields that cannot be edited by the user. When changed, an error validation report is generated.

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

**Package Identifier** – unique and permanent identification assigned to each package in the Union Product Database (UPD), where it corresponds to ID Level 3.

**Permanent Identifier** – unique and permanent identifier of the medicinal product in the UPD. 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.

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

[2] As per Article 4(3) of the 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

**Salt** – for the purpose of this protocol, it represents a specific form of salt in which an antimicrobial active substance is presented in a medicinal product. From the technical point of view, in ASU the strength for these salts is always expressed in International Units (IU) and a conversation factor is applicable to convert the IU of the salt to mass of the antimicrobial active substance.

**Subject to validation** – fields that are validated by the ASU system to confirm if the data uploaded 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.

# 4. Volume of Sales (overview of instructions)

This section provides an overview of the tasks that a data manager needs to perform, step-by-step, to successfully submit a dataset to the Agency.

The NCA user on behalf of each MS shall perform several sequential operations for the yearly reporting of volume of sales to the Agency. At the same time, it is also expected that the Agency (as Admin user) would perform few tasks to ensure the publication of the data. The tasks that are expected from the NCA user and Admin user are shown in Figure 1 below:

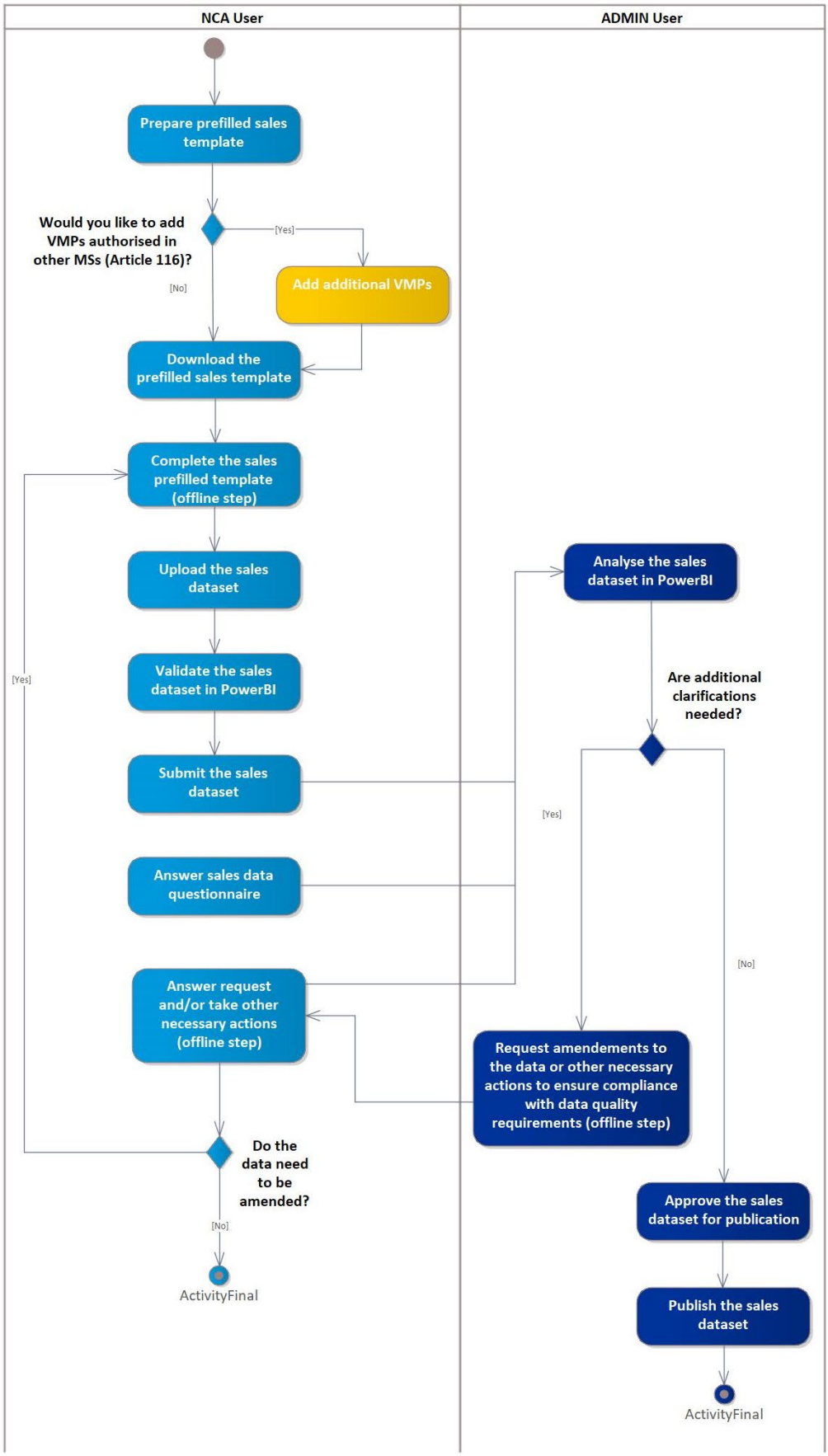


*Figure 1 – Overview of tasks for national contact point or data managers (NCA User) and EMA (ADMIN User)*

1. **Prepare and download the prefilled sales template (CSV file)**: The user shall download the CSV file for the reporting year and for the user's country from the 'Download Sales Data template' page on the ASU web application. This file will be prefilled with VMPs that comply with the criteria below:

    a. VMPs with an ATCvet code included in points 1 and 2 of the Annex of the Commission Delegated Regulation (EU) 2021/578.

    b. VMPs with a Marketing Authorisation status that was valid at least once during the reporting year or during the 4 previous years (5 years marketing coverage):

        - national marketing authorisations, such as MRP, DCP, SRP or purely National Authorisation Procedure (NAP);
        - Centralised Marketing Authorisation (CAP).

    c. Parallel traded products that comply with criteria a and b, with the involved MS as their Destination Country and were traded during the reporting year (details of the authorised product in the destination MS will be used).

    For countries with sales of antimicrobial VMPs authorised in another MS, the user will be able to add these VMPs using the 'Add other veterinary medicinal products' toggle button in the ASU interface, before generating the template by following these steps:

        1. On the 'Download Sales Data template' page of the ASU web application, the user can access a VMP search tool linked with UPD by clicking on the 'Add other veterinary medicinal products' toggle button.
        2. By using the different search criteria, the user can then search for the relevant VMPs and add them to the 'Selected products' section by selecting these products and clicking on 'add'.
        3. After identifying and adding all relevant VMPs authorised in other MSs to this section, the user should click on the "Generate prefilled template" button.
        4. The prefilled template is generated and automatically downloaded.

    The next time the user generates the prefilled template, the system will ask the user if those additional VMPs that have been selected previously should be included again in the template. If the user answers yes, it will be redirected again to the page indicated above and previously added VMPs will automatically appear in the 'Selected products' section, so that the user can opt to include them or not in the prefilled template again. To remove previously added VMPs from the template, the user should select them and then click on 'remove'.

    For all the VMPs present in the CSV file, there will be prefilled medicinal product information at the package level that originates or derives from the UPD. If available in the UPD, the data on the volume of sales (number of packages sold) reported by the Marketing Authorisation Holder (MAH) will also be provided for reference.

2. **Completing the sales prefilled template (offline action)**: The user can only change editable or partially editable fields (i.e., reference number, Article 116, product form for oral powder and intramammary products, companion animals and the number of packages sold), and validate the correctness of the remaining non-editable fields prefilled with medicinal product information (changes in these fields can only be processed via the UPD)[3]. Detailed

[3] Please view section 6.2. for further details.

information on how to complete the prefilled sales template file is provided in the following sections. Users are also advised to consult Table 1.

3. **Upload the sales dataset**: After completing the sales template with the number of packages sold for each VMP presentation for that reporting year, and, if necessary, changing data in some of the other editable fields, the user shall upload the sales dataset to the 'Upload Sales Data File' page on the ASU web application.

4. **Submit the sales dataset**: After reviewing the quality of the data and confirming that the quality, accuracy, completeness and consistency requirements are met, using the Power BI sales data validation reports made available by the Agency, the user should submit the dataset to the Agency via the 'Check Sales Data submission status' page on the ASU web application. Legal deadlines for submitting the data should be respected. Only submitted datasets will be considered for approval for publication by the Agency.

5. **Answer the sales data questionnaire**: The national contact point or data manager shall complete this questionnaire with additional data variables for that reporting year, to allow for an accurate analysis and interpretation of the data.

**Table 1.** Overview of tasks for NCA users completing the sales prefilled template (offline action)

| Reference no., Annex I, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| 1 | Country | A | No action – prefilled and non-editable |
| 2 | Year | B | No action – prefilled and non-editable |
| Not included, for information only | Permanent Identifier | C | No action – prefilled and non-editable. Included in the template for information only |
| 3 | Package Identifier | D | No action – prefilled and non-editable |
| 4 | Reference Number | E | **Action** – Editable and optional – the national ID (corresponding to the previous presentation ID or Marketing Authorisation number, as applicable, used previously for voluntary submission of veterinary antimicrobial sales data in the ESVAC project). Field can be left empty and will not be validated by the Agency.<br><br>After the user confirms the data for the first time, the changes made will persist in the database associated with the corresponding package identifiers and will appear in the prefilled template the next time the user generates it. |
| 5 | VMPs allowed for use under Article 116 | F | Partially editable: prefilled as 'N' (No) and non-editable for all VMPs authorised in the user's own country, either nationally (MRP, DCP, SRP, purely NAP), via the centralised procedure or parallel- |

| Reference no., Annex I, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| | | | trade products that have the user's own country as 'Destination Country'.<br><br>**Action** – If the user had added antimicrobial VMPs that are authorised in other MSs during the generation of the template, for these VMPs the field ARTICLE_116 will be empty and user should complete it with:<br><br>a. 'Y' (Yes) if the VMP was allowed for use under Article 116 of Regulation (EU) 2019/6;<br><br>b. 'N' (No) if the VMP was authorised for use in the user's own country under other legislative framework. |
| 6 | Veterinary medicinal product name | G | No action – prefilled and non-editable |
| 7 | Product form | H | Prefilled and partially editable: non-editable for all product forms, except oral powders and intramammary products.<br><br>**Action** – For oral powders only, the user should confirm from the information in the relevant section of the SPC if the VMP is to be administered in feed or in water and then edit this field following these rules:<br><br>• VMP only to be administered in feed: keep ORAL POWD<br>• VMP only to be administered in water, milk or milk replacer: change to ORAL SOLU<br>• VMP to be administered in both in feed and in water: keep ORAL POWD<br>• VMP authorised for use in finfish only: change to PREMIX<br><br>**Action** – For intramammary products only, the user should edit the form INTRAMAM by adding the initials '-LC' or '-DO' to indicate if the VMP is used for the treatment of lactating animals or animals during the drying-off period:<br><br>• VMP indicated only for lactating animals: INTRAMAM-LC |

| Reference no., Annex I, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| | | | • VMP indicated only for drying-off animals: INTRAMAM-DO<br>• VMP indicated for both lactation and drying-off animals: INTRAMAM-LC<br>After the user confirms the data for the first time, the changes made will persist in the database associated with the corresponding package identifiers and will appear in the prefilled template the next time the user generates it. |
| 8 | ASU pack size | I | No action – prefilled and non-editable |
| 9 | ASU pack size unit | J | No action – prefilled and non-editable |
| 10 | ATCvet code | K | No action – prefilled and non-editable |
| Not included, for information only | Scope | L | No action – prefilled and non-editable. Included in the template for information only.<br>Please note that VMPs within the mandatory scope cannot be deleted from the template, while VMPs within the voluntary scope can be manually deleted. |
| 11 | Authorised for companion animals only | M | Prefilled and partially editable field: prefilled as 'N' (No) and non-editable for VMPs with a withdrawal period registered in the UPD and prefilled as 'Y' and editable for VMPs without a withdrawal period registered in the UPD.<br>**Action** – For VMPs without a withdrawal period registered in the UPD, the user should confirm from the information in the relevant section of the SPC if the VMP is authorised for companion animals only or not and do the following:<br>• If the VMP is authorised for companion animals only: keep 'Y'<br>• If the VMP is not authorised for companion animals only (e.g., it is also or only authorised for fur animals): change to 'N'.<br>After the user confirms the data for the first time, the changes made will persist in the database associated with the corresponding package |

| Reference no., Annex I, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| | | | identifier and will appear in the prefilled template the next time the user generates it. |
| 12 | Number of packages sold | N | **Action** – The number of packages sold per VMP presentation should be provided as zero or positive values (decimals are accepted and comma should be used as decimal separator) following these rules:<br>• VMPs that fall within the mandatory scope: it is mandatory to report sales. If there are no sales of these VMPs in the reporting year, the user should report '0' (zero);<br>• VMPs that fall within the voluntary scope: it is optional to report sales. If there are no sales of these VMPs in the reporting year, the user can report '0' (zero) to keep the trend analysis, if applicable. If the user chooses not to report it, the corresponding rows should be deleted from the template;<br>• For both types of VMPs (mandatory and voluntary), the number of packages sold should be corrected and/or completed with Intra-Community movements of VMPs, i.e., with sales of antimicrobials brought from other MSs and excluding sales of antimicrobials sent to other MSs.<br>• The user should put in place measures to avoid double reporting, e.g., excluding sales between wholesalers nationally.<br>When a Marketing Authorisation Holder (MAH) has provided the volume of sales for an antimicrobial VMP presentation in the UPD for that specific country and year, this value will appear in the prefilled template for reference only. MSs can choose to use MAHs as data providers or not. If not, the number of packages sold made available in the prefilled template can be disregarded and changed accordingly. |
| Not included, for information only | Substance ID | O | No action – prefilled and non-editable. Included in the template for information only |

| Reference no., Annex I, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| 13 | Name of the antimicrobial active substance | P | No action – prefilled and non-editable |
| 14 | Name of the salt of the antimicrobial active substance | Q | No action – prefilled and non-editable |
| 15 | Name of the derivative or compound of the antimicrobial active substance | R | No action – prefilled and non-editable |
| 16 | Strength | S | No action – prefilled and non-editable |
| 17 | Unit of measurement of strength | T | No action – prefilled and non-editable |

# 5. Volume of Sales template data fields (detailed instructions)

This section describes all template data fields related to the submission of volume of sales data. It provides detailed information to data managers and developers of national data collection systems.

Please note that for most variables, alphanumeric values will be prefilled in the CSV file, as provided by the corresponding information available in relevant EMA databases, such as UPD and SPOR. For further information on these alphanumeric values, please consult the respective implementation guides.

Please note that the data types indicated in the tables below do not refer to the data type in the CSV files, which is always a string of characters, but to the data types that are going to be subjected to validation as per section 6.2.

When compared to the 'Antimicrobial Sales and Use (ASU) data reporting protocol Part 2 Reporting use data' (EMA/683217/2022):

- the following variables are specific of sales data: VMPs allowed for use under Article 116, authorised for companion animals only and number of packages sold;
- the following variables are slightly different than use for sales data: Package Identifier, veterinary medicinal product name and ATCvet code;
- the following variables are the same for both use and sales data: country, year, permanent identifier, reference number, product form, ASU pack size, ASU pack size unit, scope, substance ID, name of the antimicrobial active substance, name of the salt of the antimicrobial active

substance (when applicable), name of the derivative or compound of the antimicrobial active substance (when applicable), strength and unit of measurement of strength.

## 5.1. Country

This field specifies the country where the package of the medicinal product was sold for the reporting year.

| Tag | Description |
|---|---|
| User Guidance | Code of the country for which the volume of sales 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), according to the International Standard for country codes (ISO, 2013); XI for Northern Ireland, as listed in the Country list (List Identifier 100000000002), for all EEA countries. |

**Example(s):** AT, BG, BE, XI.

## 5.2. Year

This field indicates the period of time (calendar year) for which the volume of sales of antimicrobial VMPs at package level is reported.

| Tag | Description |
|---|---|
| User Guidance | Year for which the data on the volume of sales is 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.

## 5.3. Permanent Identifier

The Permanent Identifier (or Permanent ID) is a unique identifier of the antimicrobial VMP in the UPD.

| Tag | Description |
|---|---|
| User Guidance | The Permanent Identifier is unique to each VMP in the UPD, differentiating VMPs that are authorised in different MSs from the same MRP/DCP or SRP. In the UPD it corresponds to UPD ID Level 2. This field is included for user information only. |

| Tag | Description |
|---|---|
| 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 section *1.4 Permanent Identifier* of the UPD[4]. |

**Example:** 600000064201, 600000037969

## *5.4. Package Identifier*

Volume of Sales are to be submitted at product presentation level, which are identified by their unique Package identifier in the UPD.

| Tag | Description |
|---|---|
| User Guidance | The package identifier is a structured data field that indicates the permanent and unique identification assigned to each package/product presentation in the UPD. In the UPD it corresponds to UPD ID Level 3.<br><br>The system verifies that the package identifier is not changed or repeated in the prefilled sales 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 section *5.3 Package Identifier* of the UPD[5]. |

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

## *5.5. Reference number*

In addition to the package identifier, a reference number can be submitted as a supplementary identifier of a specific antimicrobial VMP presentation. This reference number can come from other relevant databases such as national databases. This field is optional.

| Tag | Description |
|---|---|
| User Guidance | This open-text field can be filled with the reference number or identifier of the antimicrobial VMP presentation from other relevant databases, such as national databases. Optional for MSs. The presentation ID previously used for ESVAC is an example of a reference number that can be included in this field. |

[4] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 1.4
[5] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 5.3

| Tag | Description |
|---|---|
| | After the first submission, the reference number will persist associated with the product in the database associated with the corresponding package identifier and will be included in the prefilled template the next time it is generated. It can be edited by the user before any template submission.<br><br>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. |
| Variable name in the template | REF_NUMBER |
| Editability | Blank (not prefilled), editable field |
| Conformance | Optional to report |
| Data Type | String of characters (max. 255 characters) |
| Value | Open text-field with the reference number from other database for a specific antimicrobial VMP presentation. |

## *5.6. VMPs allowed for use under Article 116*

This section describes how to identify antimicrobial VMPs that are allowed for use in the MS under Article 116 of Regulation (EU) 2019/6.

| Tag | Description |
|---|---|
| User Guidance | If during the reporting year there are sales of antimicrobial VMPs that are authorised in a MS different from the reporting country, the user can add these VMPs to the prefilled template via the 'extended download' functionality.<br><br>Once the prefilled template has been downloaded, the user needs to manually edit this field by adding 'Y' (Yes) if these antimicrobial VMPs were allowed for use under Article 116 of Regulation (EU) 2019/6 and 'N' (No) when this is not applicable. For antimicrobial VMPs authorised in the user's own country, either nationally (MRP, DCP, SRP, purely NAP), via the centralised procedure or parallel-trade products that have the user's own country as 'Destination Country', this field will be prefilled by the system as 'N' in the template.<br><br>The next time the user generates the prefilled template using the 'extended download' functionality, any previously added VMPs authorised in other MSs will appear in the 'Selected products' section, so that the user can opt to include them in the prefilled template again or not. |
| Variable name in the template | ARTICLE_116 |
| Editability | Partially editable field:<br><br>- For NAPs, DCPs, MRPs, SRPs or CAPs: prefilled as 'N', non-editable field |

| Tag | Description |
|---|---|
| | - - For added VMPs authorised in other MSs: blank (not prefilled), editable field |
| 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 the product to the template, to indicate whether the product is allowed for use in the relevant Member State under Article 116 of Regulation (EU) 2019/6. |

**Example:** Y, N.

## *5.7. Veterinary medicinal product name*

This field is used to identify the antimicrobial VMP for which sales are being reported in a Member State per reporting year by using the full name available in the product information. Different languages can apply.

| Tag | Description |
|---|---|
| User Guidance | The veterinary 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 purely NAP). For CAPs or products authorised via MRP, DCP or SRP the name is expressed by default in English. |
| Variable name in the template | NAME |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | String |
| Value(s) | As available in section *1.8.1 Veterinary medicinal product name* (full VMP name) in the UPD[6]. |

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

## *5.8. Product form*

The product form allows for the analysis of the data per groups of pharmaceutical forms taking into consideration the route of administration and the intended site of action.

| Tag | Description |
|---|---|
| User Guidance | The product forms that can be indicated in this field are specific groupings of authorised pharmaceutical forms and are assigned automatically by the system to each VMP presentation. The 13 product forms, which are only relevant for ASU analysis, are:<br>- INJ (Injectable products) |

[6] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 1.8.1

| Tag | Description |
|---|---|
| | - INTRAMAM (intramammary products)<br>- ORAL SOLU (Oral solutions and powders to be administered with drinking water/milk/milk replacer)<br>- ORAL PASTE (Oral pastes)<br>- ORAL POWD (Oral powders to be administered in feed or in drinking water and feed)<br>- PREMIX (Premixes)<br>- TABL (Capsules, tablets, boluses and other similar oral pharmaceutical forms)<br>- INTRAUT (Intrauterine products)<br>- TOPICAL_DERM (Topical dermatological products)<br>- TOPICAL_OPHTHALM (Topical ophthalmological products)<br>- TOPICAL_OTOLOG (Topical otological products)<br>- TOPICAL_NASAL (Topical nasal products)<br>- OTHER (Other forms when none of the previous product forms are suitable)<br><br>This field is prepopulated by the system when the user generates the prefilled sales template for that specific year.<br><br>For oral powders only, the user should confirm from the information 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 or milk replacer the user should change ORAL POWD to ORAL SOLU; if the oral powder is to be administered in both feed and water, the user should keep ORAL POWD. Finally, if the oral powder is only authorised for use in finfish, the user should change ORAL POWD to PREMIX for the purpose of the analysis only, in order to harmonize the reporting across MSs.<br><br>For intramammary products only, the user should edit the form INTRAMAM by adding the initials '-LC' or '-DO' to indicate if the VMP is authorised for the treatment of lactating animals or animals during the drying-off period. If the VMP is indicated only for the treatment of lactating animals or for both the treatment of lactating animals and drying-off animals, the initials '-LC' should be added to INTRAMAM. If the VMP is only indicated for the treatment of drying-off animals, the initials '-DO' should be added.<br><br>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. If the information in the UPD changes, these changes will supersede the user updates during the next generation of the template. |

| Tag | Description |
|---|---|
| Variable name in the template | FORM |
| Editability | Partially editable field:<br>- For ORAL POWD: prefilled, editable field (to ORAL SOLU or PREMIX)<br>- For INTRAMAM: prefilled, editable field (to INTRAMAM-LC or INTRAMAM-DO)<br>- For all other forms: prefilled, non-editable field |
| Conformance | Mandatory, editable and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | As derived from the UPD section *1.5 (Authorised) Pharmaceutical form*[7] and re-codable against the applicable product, as listed in the ASU Product Form list (List Identifier 200000027138).<br>The relevant ASU product form ID term is included as one of the attributes for English terms in the following lists:<br>Pharmaceutical Dose Form List Identifier 200000000004<br>Combined Pharmaceutical Dose Form List Identifier 200000000006<br>Combined Term List Identifier 200000000007<br>Combination Package List Identifier 200000000008 |

**Example**: INJ, ORAL POWD, ORAL SOLU.

## *5.9. ASU Pack size*

The ASU pack size is a numerical value that indicates the content quantity per antimicrobial VMP presentation.

| Tag | Description |
|---|---|
| User Guidance | The ASU pack size can be defined as the total number of units in the package after reconstitution or as the quantity (number or volume) of the manufactured item(s) in the VMP presentation (based on the information included in the relevant section of the SPC).<br><br>The ASU pack size field will be automatically prefilled by the system following these rules:<br><br>1. When the VMP includes one manufactured item:<br><br>1.1 When the strength of the VMP is provided by concentration, the pack size field will be prefilled with the value resulting from the multiplication of the pack size numerical value (as available in section *5.2 Pack size* of the UPD) by the manufactured item quantity numerical value (as available in section *5.6.2 Manufactured Item Quantity* of the UPD).<br><br>1.2 When the strength of the VMP is provided by presentation, the pack size will be prefilled with the numerical value of the pack size (as available in section *5.2 Pack size* of the UPD). If the pack size is not |

[7] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 1.5

| Tag | Description |
|---|---|
| | available in section *5.2 Pack size* of the UPD, the information in section *5.6.2 Manufactured Item Quantity* will be used alternatively.<br><br>2. When the VMP includes multiple manufactured items (e.g., powder for reconstitution and solvent), the pack size will be prefilled with the pack size numerical value (as available in section *5.2 Pack size* of the UPD). |
| Variables name in the template | PACKSIZE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | Numeric value |
| Value(s) | Numerical value, as available or derived from sections *5.2 Pack size* and/or *5.6.2 Manufactured Item Quantity* of the UPD[8], following the rules described above. |

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

## *5.10. ASU pack size unit*

Field used to indicate the unit of measurement of the ASU pack size content.

| Tag | Description |
|---|---|
| User Guidance | The ASU pack size unit is the measurement unit of the ASU pack size content that serves to harmonize the data. It enables the system to calculate the content of antimicrobial active substance per presentation and then to calculate the total tonnes of antimicrobial active substance sold based on the number of packages sold.<br><br>The applicable ASU pack size units are:<br><br>- ml (millilitre)<br>- l (litre)<br>- g (gram)<br>- kg (kilogram)<br>- RMS Units of Presentation terms, as applicable (e.g., vial, syringe, tablet)<br><br>The pack size unit and strength unit need to be compatible for each antimicrobial VMP presentation. The strength unit denominator should dictate the unit of measurement of the pack size. Thus both the pack size value and the unit of measurement should be converted by the system to align them with the strength unit denominator, if needed. The following links between the two apply: |

| If pack size unit is: | The substance strength unit is: |
|---|---|
| ml | mg/ml<br>IU/ml<br>g/ml<br>mg/l (conversion of the pack size unit from ml to l needed) |

[8] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 5.2 and 5.6.2

| Tag | Description |
|---|---|
| | <table><tr><td></td><td>IU/l (conversion of the pack size unit from ml to l needed)</td></tr><tr><td>l</td><td>mg/l<br>g/l<br>IU/l<br>mg/ml (conversion of the pack size unit from l to ml needed)<br>g/ml (conversion of the pack size unit from l to ml needed)<br>IU/ml (conversion of the pack size unit from l to ml needed)</td></tr><tr><td>g</td><td>mg/g<br>IU/g<br>g/g<br>g/kg (conversion of the pack size unit from g to kg needed)<br>IU/kg (conversion of the pack size unit from g to kg needed)</td></tr><tr><td>kg</td><td>g/kg<br>IU/kg<br>mg/g (conversion of the pack size unit from kg to g needed)<br>IU/g (conversion of the pack size unit from kg to g needed)<br>g/g (conversion of the pack size unit from kg to g needed)</td></tr><tr><td>RMS Unit of Presentation</td><td>mg/RMS Unit of Presentation<br>g/RMS Unit of Presentation<br>IU/RMS Unit of Presentation</td></tr></table><br>The ASU pack size unit field will be automatically prefilled by the system following these rules:<br>1. When the VMP includes one manufactured item:<br>1.1. If the strength of the VMP is provided by concentration, the unit of measurement for the ASU pack size unit will be retained as available in *5.6.2 Manufactured Item Quantity* in the UPD.<br>1.2. If the strength of the VMP is provided by presentation, the unit of measurement of the ASU pack size will be retained as available in *5.2 Pack size* in the UPD.<br>2. When the VMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the unit of measurement of the ASU pack size will be retained as available in *5.2 Pack size* in the UPD. |
| Variables name in the template | PACKSIZEU |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | Unit, as available in sections *5.2 Pack size* and/or *5.6.2 Manufactured Item Quantity* of the UPD[9], following the rules described above. The units are |

[9] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 5.2 and 5.6.2

| Tag | Description |
|---|---|
| | specified as a Term ID listed in Units of Measurement (List Identifier 100000110633) or Units of Presentation (List Identifier 200000000014), as applicable. |

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

## *5.11. ATCvet code*

The ATC vet code is the Anatomical Therapeutical Chemical classification code for VMPs.

| Tag | Description |
|---|---|
| User Guidance | This field includes the ATCvet code as indicated in the relevant section of the corresponding SPC. Data on the volume of sales only need to be reported for antimicrobial VMPs with the ATCvet codes indicated in points 1 and 2 of the Annex of the Commission Delegated Regulation (EU) 2021/578.<br>• If multiple ATCvet codes apply to the same antimicrobial VMP, then only the codes referred to in points 1 and 2 of the Annex of the Commission Delegated Regulation (EU) 2021/578 will be included in the template.<br>• Technically, all five levels of an ATCvet code can be used; however, the most granular level of information is expected to be provided if available.<br>This field is automatically prepopulated by the system when the user generates the prefilled sales template. |
| Variable name in the template | ATCVET |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | As available in section 1.7.2 *ATC vet code* of the UPD[10], if marked as antimicrobial in in Anatomical Therapeutic Chemical classification system – Veterinary (List Identifier 100000116677). |

**Examples:** QJ01CA04, QJ51AA07.

## *5.12. Scope*

The field 'Scope' informs the user on whether the collection and reporting of data on the volume of sales of an antimicrobial VMP to the Agency is mandatory or voluntary.

| Tag | Description |
|---|---|
| User Guidance | This field indicates if the collection and reporting to the Agency of data on the volume of sales of a VMP is mandatory or voluntary, based on the product ATCvet code, as per Articles 1 and 2 of the Delegated Regulation |

[10] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 1.7.2

| Tag | Description |
|---|---|
| | (EU) 2021/578. This field is automatically prepopulated by the system when the user generates the prefilled sales template. |
| Variable name in the template | SCOPE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | Boolean |
| Value | 'Mandatory' or 'voluntary' to inform the user whether collection of and reporting to the Agency of the data on the volume of sales is mandatory or voluntary, as derived from section 1.7.2 *ATC vet code* in the UPD[11].<br><br>The ATCvet codes indicated in points 1 and 2 of the Annex of the Commission Delegated Regulation (EU) 2021/578 are marked in the Anatomical Therapeutic Chemical classification system – Veterinary (List Identifier 100000116677) as antimicrobials and as either mandatory or voluntary. |

**Examples:** mandatory, voluntary.

## *5.13. Authorised for companion animals only*

This field is used to identify antimicrobial VMPs that are authorised for use in companion animals only[12].

| Tag | Description |
|---|---|
| User Guidance | To distinguish VMPs that are authorised for companion animals only from those which are not, information on withdrawal period(s) from the UPD will be used and the generated sales template will be automatically prefilled by the system following these rules:<br><br>• For antimicrobial VMPs with withdrawal period(s), this field will be automatically prefilled with 'N' (No) and the user will not be able to modify this value.<br><br>• For antimicrobial VMPs without withdrawal period(s), this field will be automatically prefilled with 'Y' (Yes). However, the user should confirm from the information in the relevant section of the corresponding SPC if the VMP is authorised for companion animals only. If this is not the case, the user should change the value from 'Y' to 'N' (e.g., the product is for use in fur animals).<br><br>For the purpose of this protocol, companion animals are considered the same animal species described in Annex I of the Regulation (EU) 2016/429 for pet animals, namely:<br><br>• dogs (*Canis lupus familiaris*); |

[11] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 1.7.2

[12] This information is important for data analysis purposes, in order to separate data on the volume of sales for companion animals from the data on the volume of sales for food-producing animals.

| Tag | Description |
|---|---|
| | • cats (*Felis silvestris catus*);<br>• ferrets (*Mustela putorius furo*);<br>• invertebrates (except bees, molluscs belonging to the phylum Mollusca and crustaceans belonging to the subphylum Crustacea)<br>• ornamental aquatic animals;<br>• amphibians;<br>• reptiles;<br>• birds: specimens of avian species other than fowl, turkeys, guinea fowl, ducks, geese, quails, pigeons, pheasants, partridges and ratites (*Ratitae*);<br>• mammals: rodents and rabbits other than those intended for food production.<br><br>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. If the information in the UPD changes (i.e., a new withdrawal period is defined for a VMP), 'N' will be automatically assigned to the updated VMP and will supersede the user updates during the next generation of the template. |
| Variable name in the template | COMPANION_ANIMALS |
| Editability | Partially editable:<br><br>- For VMPs with withdrawal period: prefilled as 'N', non-editable field<br><br>- For VMPs without withdrawal period: prefilled as 'Y', editable field |
| Conformance | Mandatory, editable and subject to validation |
| Data Type | Boolean |
| Value | A choice of 'Y' (yes) or 'N' (no) to indicate if the antimicrobial VMP is authorised for use in companion animals only. 'N' will apply to VMPs for which there is a withdrawal period, as available in section *3.4 Withdrawal period* of the UPD[13] and 'Y' will be the default value for VMPs without a withdrawal period. |

**Example:** Y, N.

## *5.14. Number of packages sold*

The number of packages sold indicates the volume of sales of each antimicrobial VMP presentation within the reporting Member State during the specific reporting year. MSs can choose to use MAH as data providers or not. Data sources for collecting the volume of sales shall be chosen nationally from the list of data providers indicated in Article 11(1) of the Commission Delegated Regulation (EU) 2021/578, i.e., MAH, wholesalers, retailers, feed mills, pharmacies and/or veterinarians.

[13] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 3.4

| Tag | Description |
|---|---|
| User Guidance | The number of packages sold of each antimicrobial VMP presentation is provided as zero or as a positive numerical value (decimals are accepted).<br><br>If a MAH has provided the volume of sales of an antimicrobial VMP presentation for the specific reporting country and year, this value will automatically be provided when the prefilled template is generated. These prefilled values are for reference only as it is the responsibility of MSs to report the accurate number of packages sold per antimicrobial VMP presentation.<br><br>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 shall convert any negative sales values to zero before uploading the dataset. Should correction of sales data from previous years be needed, the user should resubmit the volume of sales data for the corresponding previous years.<br><br>Number of packages 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.<br><br>The user should put in place measures to avoid double reporting, such as excluding sales between wholesalers nationally.<br><br>By default, this field will be empty when no sales are reported by the MAH or for additional antimicrobial VMP presentations added to the prefilled template (e.g., under Article 116).<br><br>Sales are 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. On the contrary, any antimicrobial VMPs that fall within the voluntary data reporting scope, as per Article 1 of the Commission Delegated Regulation (EU) 2021/578, should be deleted from the prefilled template if the MS decides not to report them. |
| Variable name in the template | NO_PACKS |
| Editability | Blank or prefilled, as applicable, editable field |
| Conformance | Mandatory, editable and subject to validation |
| Data Type | Zero or positive numerical value |
| Value | The value is zero or a positive numerical value (decimals are accepted, but not recommended to be used – 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[14]. |

**Example:** 0; 500; 45,5

[14] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 7: Submission of other post-authorisation data (EMA/717215/2021), section 2.1

## 5.15. Substance ID

The Substance ID is used to identify each specific active substance. For fixed combination VMPs, all antimicrobial active substances will appear separately in the same row of the template. Non-antimicrobial active substances, such as beta-lactamase inhibitors or anti-inflammatories, will not be included in template nor considered for the calculation of total tonnes sold. A maximum of five antimicrobial active substances per VMP is foreseen in the template.

| Tag | Description |
|---|---|
| User Guidance | This field includes a specific substance ID for each antimicrobial active substance that comes from the Substance Management System (SMS). 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 and subject to validation |
| Data Type | CodeableConcept |
| Value | As available in sections *4.3.3.1 Reference (Active) Substance* or *4.3.1. Substance* of the UPD[15]. Only substances classified as antimicrobial in the SMS are included. |

**Examples:** '100000092772, '100000147798

## 5.16. Name of the antimicrobial active substance

The name of the antimicrobial active substance identifies each relevant substance using its International Non-proprietary name (INN), as presented in the latest version of ATCvet Index.

| Tag | Description |
|---|---|
| User Guidance | The name of the antimicrobial active substance (included in the pre-defined list of antimicrobials in SMS). The INN of the antimicrobial active substance, as indicated in the latest version of ATCvet Index, is provided if available. In the cases where the name of the active substance in the UPD is the same as one of the ASU derivatives/compounds (please see the Annex, Table 3), the antimicrobial active substance name from UPD is indicated in section 5.18 (please see the section below), while the name of the respective antimicrobial active moiety is provided in this field instead. E.g., benzylpenicillin for procaine benzylpenicillin, penethamate hydriodide, benethamine penicillin and benzathine benzylpenicillin.<br><br>Every antimicrobial VMP product must have at least one antimicrobial active substance.<br><br>In the case of fixed combination products, all the antimicrobial active substances are reported individually within their corresponding section of |

[15] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 4.3.1 and 4.3.3

| Tag | Description |
|---|---|
| | 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).<br><br>This field is automatically prepopulated by the system when the user generates the prefilled sales template. |
| Variable name in the template | SUBSTANCE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | As available in section *4.3.3.1 Reference (Active) Substance* of the UPD, referring to the active moiety. Should this not be provided, as available in section *4.3.1 (Active) Substance* of the UPD[16], referring to the compound/derivative or salt.<br><br>Only for substances classified as antimicrobial in the SMS. |

**Examples**: amoxicillin, benzylpenicillin, colistin, oxytetracycline.

## *5.17. Name of the salt of the antimicrobial active substance*

This field is used to identify the specific salt form of the antimicrobial active substance when the strength is expressed in international units (IU).

| Tag | Description |
|---|---|
| User Guidance | The name of salt of the antimicrobial active substance is provided only for colistin sulfate or colistin methane sulfonate (also known as colistimethate), as applicable, when in the SPC the strength of the substance is only available in IU for the salt form.<br><br>The indication of the salt in this field will trigger the system to apply the conversion factor for the antimicrobial active substance when the strength is expressed in IU and enable the conversion from IU to mass of active substance in a standardised manner.<br><br>Please refer to Annex, Table 4, for further information on available conversion factors.<br><br>This field is automatically prepopulated by the system when the user generates the prefilled sales template. |
| Variable name in the template | SALT |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |

[16] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 4.3.1 and 4.3.3

| Tag | Description |
|---|---|
| Value(s) | As available in *4.3.1 (Active) Substance* of the UPD[17], if the substance is marked as a salt in the SMS. |

**Examples**: colistin sulfate, colistimethate.

## *5.18. Name of the derivative or compound of the antimicrobial active substance*

This field is used to identify specific derivatives or compounds of the antimicrobial active substance(s) when the strength is expressed as the mass of the compound or derivate.

| Tag | Description |
|---|---|
| User Guidance | The name of the derivative or compound of the antimicrobial active substance is provided when in the SPC only the strength of the antimicrobial active substance derivative or compound is available and the strength of the antimicrobial active moiety is not available.<br><br>The indication of the derivative or compound in this field will trigger the system to apply the conversion factor for the derivative or compound of the antimicrobial active substance and enable the calculation of the mass of the antimicrobial active moiety in a standardised manner.<br><br>If no conversion factor is available and the strength of the active substance is only provided for the derivative or salt and not for the active moiety, a conversion factor of 1 shall apply.<br><br>Please refer to the Annex, Table 4, for further information on available conversion factors.<br><br>This field is automatically prepopulated by the system when the user generates the prefilled sales template. |
| Variable name in the template | DERIVATIVE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | As available in *4.3.1 (Active) Substance* of the UPD[17], if the substance is marked as a derivative/compound in the SMS. |

**Examples**: procaine benzylpenicillin, penethamate hydriodide.

## *5.19. Strength*

The strength (quantitative composition) is a numerical value that indicates the quantity of antimicrobial active substance contained in a VMP as indicated in the relevant section of the corresponding SPC.

[17] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 4.3.1

| Tag | Description |
|---|---|
| User Guidance | For each antimicrobial VMP presentation, the strength or quantity of the antimicrobial active substance(s) is specified as a numerical value based on the information included in the relevant section of the SPC.<br><br>This field will be prefilled with the strength of the active moiety when available in the UPD. In those cases when the strength of the active moiety is not available, it will be prefilled with the strength of the derivative or compound (when the strength is in mass) or salt (when the strength is in IU), as indicated in the SPC and available in the UPD, and a conversion factor will be applied, if available. If in the SPC the strength is only provided in IU, a conversion factor will be applied to convert IU to the mass of active substance in a standardised manner. Please refer to the Annex, Tables 2 and 3, for further information on available conversion factors.<br><br>The strength field will be automatically prepopulated by the system when the user generates the prefilled sales template using the information in the UPD linked with the 'Strength (presentation)', 'Strength (concentration)' or 'Manufactured item quantity'. Please see to the Annex, Table 4 below for further details. |
| Variables name in the template | STRENGTH |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | Ratio |
| Value(s) | Numerical value (strength) for which the following rules shall apply:<br><br>1. When the VMP includes one manufactured item:<br><br>1.1. If the strength of the VMP is provided by concentration, the value will be retained as available in *4.3.3.2. Reference strength (Concentration)*. If this value is not available, it will be provided using the information in *4.3.2.2. Strength (concentration)* in the UPD[18].<br><br>1.2. If the strength of the VMP is provided by presentation, the value will be retained as available in *4.3.3.1.1. Reference strength (Presentation)*. If this value is not available, it will be provided using the information in if *4.3.2.1. Strength (presentation)* in the UPD[18].<br><br>1.3. For 1.1 and 1.2, 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.<br><br>2. When the VMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the value of the strength will be retained as |

[18] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 4.3.2 and 4.3.3

| Tag | Description |
|---|---|
| | available in *5.6.2 Manufactured item quantity* in the UPD[19] for all the antimicrobial active substance(s). |

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

## *5.20. Unit of measurement of strength*

The unit of measurement of strength will consist of a numerator and a denominator, in which the denominator can be a unit of presentation (presentation strength) or a unit of measurement (concentration strength) that is compatible with the ASU pack size unit of measurement for each antimicrobial VMP presentation. This compatibility is important to harmonize 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 based on the number of packages sold.

<table>
<tr><th>Tag</th><th>Description</th></tr>
<tr><td>User Guidance</td><td>The pack size unit and strength unit must be compatible for each antimicrobial VMP presentation. The strength unit denominator should dictate the unit of measurement of the pack size. Thus both the pack size value and the unit of measurement should be converted by the system to align them with the strength unit denominator, if needed. The following links between the two apply:
<table>
<tr><th>If pack size unit is:</th><th>The substance strength unit is:</th></tr>
<tr><td>ml</td><td>mg/ml<br>IU/ml<br>g/ml<br>mg/l (conversion of the pack size unit from ml to l needed)<br>IU/l (conversion of the pack size unit from ml to l needed)</td></tr>
<tr><td>l</td><td>mg/l<br>g/l<br>IU/l<br>mg/ml (conversion of the pack size unit from l to ml needed)<br>g/ml (conversion of the pack size unit from l to ml needed)<br>IU/ml (conversion of the pack size unit from l to ml needed)</td></tr>
<tr><td>g</td><td>mg/g<br>IU/g<br>g/g<br>g/kg (conversion of the pack size unit from g to kg needed)<br>IU/kg (conversion of the pack size unit from g to kg needed)</td></tr>
<tr><td>kg</td><td>g/kg<br>IU/kg<br>mg/g (conversion of the pack size unit from kg to g needed)<br>IU/g (conversion of the pack size unit from kg to g needed)</td></tr>
</table>
</td></tr>
</table>

[19] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), section 5.6.2

| Tag | Description |
|---|---|
| | <table><tr><td></td><td>g/g (conversion of the pack size unit from kg to g needed)</td></tr><tr><td>RMS Unit of Presentation</td><td>mg/RMS Unit of Presentation<br>g/RMS Unit of Presentation<br>IU/RMS Unit of Presentation</td></tr></table><br>The unit of measurement of strength field will be automatically prepopulated by the system when the user generates the prefilled sales template using the information in the UPD linked with the 'Strength (presentation)', 'Strength (concentration)', 'Manufactured item quantity' or 'Pack size' sections depending on its compatibility with the pack size. |
| Variables name in the template | STRENGTHU |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | Unit (unit of measurement of strength). Term ID are expressed as listed in Units of Measurement (List Identifier 100000110633) or Units of Presentation (List Identifier 200000000014).<br><br>The following rules shall apply:<br><br>1. When the VMP includes one manufactured item:<br><br>1.1. When the strength of the VMP is provided by concentration, the unit of measurement will be retained as available in *4.3.3.2. Reference strength (Concentration)*. If this value is not available, it will be provided using the information in *4.3.2.2. Strength (concentration)* in the UPD[20].<br><br>1.2. When the strength of the VMP is provided by presentation, unit of measurement will be retained as available in *4.3.3.1.1. Reference strength (Presentation)*. If this value is not available, it will be provided using the information in *4.3.2.1. Strength (presentation)* in the UPD[20].<br><br>2. When the VMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the unit of measurement of the strength for all antimicrobial active substance(s) will be retained as available in *5.6.2 Manufactured item quantity* (numerator) and as available in *5.2 Pack size* (denominator) in the UPD[21]. |

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

[20] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 4.3.2 and 4.3.3

[21] Please refer to EU Implementation Guide (Vet EU IG) on veterinary medicines product data – Chapter 2: Format of the electronic submission of veterinary medicinal product information (EMA/444352/2021), sections 5.2 and 5.6.2

# 6. List of validations rules on the uploaded file

This section describes technical and business validation rules for submission of the sales template file. During the submission process, the system verifies the data provided in the CSV file generating error messages per each row if applicable.

When there are blocker errors in the file, such as wrong format, empty file, different or missing headers, the system will not verify the remaining content. For all other type of errors, no specific hierarchy exists, and all errors shall appear in the error validation report. If there are more than 20 validation errors, the errors will not be displayed in the error validation report and the user will be requested to download the prefilled template again.

## *6.1. Technical validations*

| Description | Error message while uploading the file |
|---|---|
| **Wrong file format. A CSV file is needed.** | Only CSV file format is allowed |
| **File provided is empty** | The file provided is empty |
| **Different column expected (including header names, order and number)** | The submitted file headers (columns) do not match those of the downloaded sales template |
| **Number of packs sold cannot be empty** | Number of packs cannot be empty. Please complete this information |
| **'Field' (any other field different from number of packs sold) cannot be empty** | 'Field' cannot be empty. Please download the prefilled template again |
| **Different country** | Country does not match the one selected for file upload |
| **Year is YYYY** | Year format is not as expected (YYYY) |
| **Different year** | Year does not match the one selected for file upload |
| **Reference number format not allowed** | Please ensure that reference number includes only letters, digits, dashes, underscores and is not longer than 255 characters |
| **Number of packages sold is not zero or a positive number** | The value for number of packages sold must be zero or positive values (decimals are accepted) |

## *6.2. Business validations*

| Description | Error message while submitting the file |
|---|---|
| **Package Identifier is repeated** | It is not allowed for package identifiers to be duplicated per product presentation |
| **Package Identifier does not exist in the template** | Package identifier does not exist in the prefilled template |
| **Permanent Identifier/Package Identifier/Name/Form/Packsize/PacksizeU/Scope/ATCvet/Subst_ID/Substance/Salt/Derivative/Strength/StrengthU value is different from the original value in the prefilled template** | The field's value is not allowed to be manually modified. In case there is a data quality issue in the UPD, please contact the relevant National Competent Authority to correct the information in the UPD |

| Description | Error message while submitting the file |
|---|---|
| **Article 116 is different from 'N' (no) for prefilled VMP presentations authorised nationally** | The only allowed value for prefilled VMP presentations authorised nationally is 'N' |
| **Article 116 is different from 'N' or 'Y' for VMP presentations authorised added to the template using the extended download functionality** | Please enter 'Y' if manually added VMP presentation is authorised under Article 116 of the Regulation (EU) 2019/6, otherwise enter 'N' |
| **Authorised for companion animals is different from 'N' (no) for VMPs with a withdrawal period** | The only allowed value for prefilled VMP for which a withdrawal period is registered is 'N'. In case of error, please contact the NCA and/or the MAH in order to update the information in the UPD |
| **Authorised for companion animals only is different from 'N' (no) or 'Y' (Yes) for VMPs without a withdrawal period** | Please enter 'Y' if the VMP is authorised for companion animals only, otherwise enter 'N' |
| **Product form 'ORAL POWD' was updated to a different value from 'ORAL SOLU' or 'PREMIX'** | The only alternative values allowed for 'ORAL POWD' are 'ORAL SOLU' or 'PREMIX' |
| **Product form 'INTRAMAM' was not updated or was updated to a different value from 'INTRAMAM-LC' or 'INTRAMAM-DO'** | Please note that the pre-filled template includes intramammary products. You have to manually add in the FORM column of the template for INTRAMAM the suffix '-LC' for products used for lactating animals and the suffix '-DO' for products used for drying off animals. If the product is for use in both, please add '-LC'. |
| **VMPs for which sales are mandatory to report, as per their respective ATCvet code, are deleted from the template** | Veterinary antimicrobial medicinal products with an ATCvet code that falls within the mandatory scope for the reporting of volume of sales, as per Article 1 of the Commission Delegated Regulation (EU) 2021/578, cannot be deleted. If there are no sales, please indicate '0' (zero) in the number of packs sold field. |

If the user tries to upload a file that contains errors, an error validation report will be generated and the file will not be stored in the database. The error validation report will contain the following fields: ID (of the error), Row with error (in the CSV file), Submitted value, Prefilled value, ASU variable, Permanent Identifier, Package Identifier, UPD field name, Procedure type and Reference Member State.

If the system detects any discrepancies between the prefilled alphanumeric values (from the UPD) and the submitted values (for the ASU variables Permanent Identifier, Package Identifier, Name, Form, Packsize, PacksizeU, Scope, ATCvet, Subst_ID, Substance, Salt, Derivative, Strength, StrengtU), they will be indicated as errors in the error validation report.

The user can use the error validation report to inform the respective National Competent Authority (Reference Member State) of these detected discrepancies and ask for the correction of the UPD entries.

As indicated in recital 6 of the Commission Implementing Regulation (EU) 2022/209, and in line with Article 6 of Delegated Regulation (EU) 2021/578, MSs remain responsible for fulfilling the data quality requirements with respect to the information provided on the antimicrobial medicinal products authorised at national level, including the accuracy of the information provided by the Agency in the prefilled data entry fields sourced from the UPD or other information management systems relying on information provided by Member States.

# Annex

**Table 2.** Conversion factors for calculation from IU to mg of antimicrobial active substance

| Active Substance | IU/mg | Conversion factor (mg/IU) |
|---|---|---|
| Apramycin | 552 | 0.00181 |
| Bacitracin | 74 | 0.01351 |
| Benzylpenicillin[1] | 1670 | 0.00060 |
| Chlortetracycline | 1000 | 0.001 |
| Colistin sulfate | 20500 | 0.00005 |
| Colistin methane sulfonate (colistimethate) | 12700 | 0.00008 |
| Dihydrostreptomycin | 777 | 0.00129 |
| Erythromycin | 920 | 0.00109 |
| Framycetin | 706 | 0.00142 |
| Gentamicin | 620 | 0.00161 |
| Kanamycin | 796 | 0.00126 |
| Neomycin | 762 | 0.00131 |
| Oxytetracycline | 880 | 0.00114 |
| Paromomycin | 750 | 0.00133 |
| Polymyxin B | 8403 | 0.00012 |
| Spiramycin | 3200 | 0.00031 |
| Streptomycin | 760 | 0.00132 |
| Tetracycline | 982 | 0.00102 |
| Tobramycin | 875 | 0.00114 |
| Tylosin | 1000 | 0.001 |

[1] Applies to all derivatives/compounds of benzylpenicillin.

**Table 3.** Name of derivates/compounds for which conversion factors are applied

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

In the UPD, information on the active substance and the strength can be provided using the salt/derivative in sections 4.31 (Active) Substance and 4.3.2. Strength (quantitative composition), or using the moiety in section *4.3.3.1. Reference (active) substance*. Information on the INN and moiety should be used for ASU whenever available. The following rules will apply, based on data availability in the UPD:

**Table 4.** Rules for including active substance information in the ASU template using the information available in the UPD (with examples)

| **UPD field A** | **UPD field B** | **UPD field C** | **UPD field D** | **5.16 ASU antimicrobial active substance** | **5.17/5.18 ASU derivative/salt** | **5.19 ASU strength** |
|---|---|---|---|---|---|---|
| *4.3.1 Salt/derivative Substance*<br>benzathine benzylpenicillin | *4.3.2. Salt/derivative strength*<br>100 mg | *4.3.3.1. Moiety substance*<br>benzylpenicillin | *4.3.3.1.1.* or *4.3.3.2.1 Moiety strength*<br>68 mg | | | |
| X | X | X | X | C | - | D |
| X | X | X | | C | A | B |
| | | | | C | A (ASU derivative/salt) | B (a conversion factor is applied to the substance content) |
| X | X | | | Moiety/preferred substance | A | B |
| | | | | Moiety/preferred substance | A (ASU derivative/salt available) | B (a conversion factor is applied to the substance content) |