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# Antimicrobial Sales and Use (ASU) data reporting protocol Part 2 Reporting use data

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

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# Contents

# 1. Introduction

This document provides guidance to Member States (MSs)[1] on the process of reporting data on the use of antimicrobial medicinal products, including veterinary medicinal products (VMPs) and human medicinal products (HMPs) 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 2 of the Commission Implementing Regulation (EU) 2022/209.

The reporting requirement applies to both antimicrobial VMPs and HMPs referred to in Articles 3 to 4 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 use of antimicrobial medicinal products (AMPs) in animals 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

AMP – Antimicrobial Medicinal Product, including veterinary medicinal products and human medicinal products

ASU – Antimicrobial Sales and Use system

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 Marketing Authorisation

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

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

NCA – National Competent Authority

PCID – Packaged Medicinal Product Identifier of the PMS

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

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/HMP presentation** – a packaged 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 Authority (NCA) 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.

[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

**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.

**Packaged Medicinal Product Identifier** (PCID) – unique and permanent identification assigned to each package in the Product Management Services (PMS), where it corresponds to ID Level 3.

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

**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 and PMS it corresponds to ID Level 2.

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

**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. Use Data (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 data on the use of antimicrobials to the Agency. Please note that these operations need to be repeated for reporting the data per each animal species, for which data on the use shall be reported. 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:

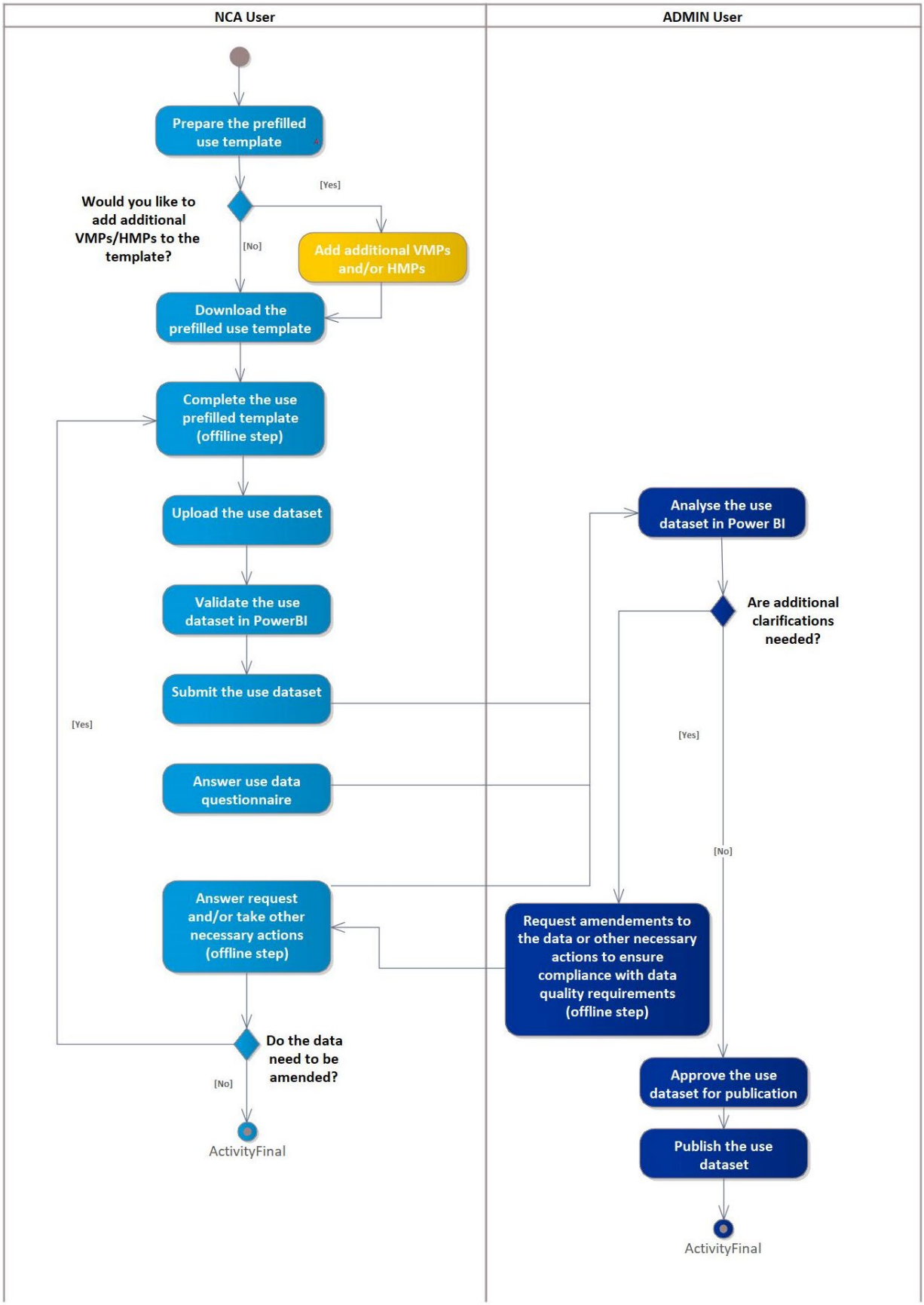


*Figure 1 – Overview of tasks for national contact point or data managers (NCA user) and EMA (ADMIN User)*

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

    a. VMPs with an ATCvet code included in point 3 and 4 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. VMPs authorised for use in the selected animal species (the target species registered in the UPD are mapped against the animal species for which data on the use shall be reported, as per Article 15 of the Commission Delegated Regulation (EU) 2021/578).

    d. Parallel traded products that comply with criteria a-c, 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 use of antimicrobial VMPs authorised in another MS, VMPs authorised for use in the MS in other animal species or HMPs both authorised for use in the MS concerned or in another MS (use outside the terms of marketing authorisation), the user will be able to add these VMPs or HMPs before generating the prefilled template by using the extended download option on the ASU interface, following these steps:

        1. On the 'Download Use Data template' page of the ASU web application, the user can access a VMP search tool linked with the 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 or authorised in the MS for use in other species to this section, the user has two options:
            a. to finalise the operation and click on the 'Generate prefilled template' button (if this option is chosen, please continue with step 4a.), or
            b. to click 'Add human medicinal products' toggle button and be redirected to another page of the ASU application (if this option is chosen, steps 4b. to 7 apply).

        4a. The prefilled template is generated and automatically downloaded.

        4b. If the user chooses option 3b., the user will be redirected to another page in the ASU web application where a search tool linked to the PMS can be accessed for searching and adding HMPs.

5. By using the different search criteria, the user can then search for the relevant HMPs and add them to the 'Selected products' section by selecting these products and clicking on 'add'.
6. After identifying and adding all relevant VMPs authorised in other MSs or authorised nationally for use in other species to this section and HMPs, the user can finalise the operation and click on the "Generate prefilled template" button.
7. 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 or HMPs that have been selected previously should be included again in the template. If the user answers yes, the user will be redirected again to the pages indicated above and previously added VMPs or HMPs 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 or HMPs from the template, the user should select them and then click on 'remove'.

For all the VMPs and HMPs present in the CSV file, there will be prefilled medicinal product information at the package level that originates or derives from the UPD or PMS.

2. **Complete the use prefilled template (offline action)**: The user can only change editable or partially editable fields (i.e., reference number, product form for oral powder products and intramammary products, long-acting and the number of packages used), and validate the correctness of the prefilled with medicinal product information of the remaining non-editable fields (changes in these fields can only be processed via the UPD or PMS)[3]. One template per animal species should be completed by the user and number of packages used should be reported in different columns for each animal population category. Detailed information on how to complete the prefilled use template file is provided in the following sections. Users are also advised to consult Table 1.
3. **Upload the use dataset**: After completing the use template for an animal species with the number of packages used for each VMP or HMP presentation for that reporting year, and, if necessary, changing the data in some of the other editable fields, the user shall upload a use dataset per animal species to the 'Upload Use Data Files' page on the ASU web application. When uploading each template, the user must select the respective animal species. One template per animal species must be uploaded by the user.
4. **Submit the use dataset**: After reviewing the quality of the data and confirming that the quality, accuracy, completeness and consistency requirements are met, using the Power BI use validation reports made available by the Agency, the user should submit one dataset per animal species to the Agency via the 'Check Use Data submission status' page on the ASU web application. Legal deadlines for submitting the data must be respected. Only submitted datasets will be considered for approval for publication by the Agency.
5. **Answer the use 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.

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

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

| Reference no., Annex II, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| 1 | Use Species | A | No action – prefilled and non-editable |
| 2 | Country | B | No action – prefilled and non-editable |
| 3 | Year | C | No action – prefilled and non-editable |
| Not included, for information only | Permanent Identifier | D | No action – prefilled and non-editable. Included in the template for information only |
| 4 | Package Identifier | E | No action – prefilled and non-editable |
| 5 | Reference Number | F | **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 identifier and will appear in the prefilled template the next time the user generates it. |
| 6 | 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>• 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 |

| Reference no., Annex II, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| | | | **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>• VMP indicated only for lactating animals: INTRAMAM-LC<br>• 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 identifier and will appear in the prefilled template the next time the user generates it. |
| 8 | Identification of long-acting parenteral products | I | **Action** – Partially editable field, applicable to parenteral products only (product form INJ). By default, this field will be empty as no reference data will be available.<br>• 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 times than that of the conventional-release dosage form administered by the same route, the user should indicate 'LA' in this field.<br>• For parenteral products that do not fulfil the above criterion (including those that have a naturally long half-life without the need of a special formulation design and/or manufacturing method), this field should be left blank.<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. |

| Reference no., Annex II, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| 9 | ASU pack size | J | No action – prefilled and non-editable |
| 10 | ASU pack size unit | K | No action – prefilled and non-editable |
| 11 | ATC/ATCvet code | L | No action – prefilled and non-editable |
| Not included, for information only | Scope | M | No action – prefilled and non-editable. Included in the template for information only.<br><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. |
| 12 | Number of packages used | N-Q (variable number linked to the number of categories per animal species | **Action** – Editable field, empty by default as no reference data will be available. The number of packages used per VMP or HMP presentation should be provided as zero or positive values (decimals are accepted and comma should be used as decimal separator) following these rules:<br>• VMP and HMPs that fall within the mandatory scope: it is mandatory to report use. If there was no use of these AMPs in the reporting year, the user should report '0' (zero);<br>• VMP and HMPs that fall within the voluntary scope: it is optional to report use. If there was no use of these AMPs 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>• The number of packages used per VMP and HMPs presentation must be reported separately for each animal species category within each animal species. Thus, the user should indicate the specific number of packages used in each animal species categories in the respective column. E.g. for cattle the number of packages used need to reported in four different columns corresponding to beef |

| Reference no., Annex II, Com. Impl. Reg. (EU) 2022/209 | Variable Name | Column in the template | Required NCA user actions |
|---|---|---|---|
| | | | cattle, beef cattle under one year of age (if applicable), dairy cattle and other cattle.<br><br>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). |
| Not included, for information only | Substance ID | O | No action – prefilled and non-editable. Included in the template for information only |
| 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. Use template data fields (detailed instructions)

This section describes all template data fields related to the submission of data on the use of antimicrobials in animals. 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 the UPD, PMS 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 1 Reporting volume of sales' (EMA/258839/2022):

- the following variables are specific of use data: animal species, long-acting parenteral products and number of packages used;
- the following variables are slightly different than sales for use data: Package Identifier/PCID, medicinal product name and ATC or 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. Animal species*

This field specifies the animal species for which data on the use of antimicrobials in animals are reported.

| Tag | Description |
|---|---|
| User Guidance | Name of the animal species for which the data on the use of antimicrobials in animals is to be submitted. |
| 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 ASU Use Species list (List Identifier 200000027170). |

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

## *5.2. Country*

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

| Tag | Description |
|---|---|
| User Guidance | Code of the country for which the data on 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 |

| Tag | Description |
|---|---|
| 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.

## *5.3. Year*

This field indicates the period of time (calendar year) for which the data on the use of antimicrobial VMP/HMPs in animals at package level are reported.

| Tag | Description |
|---|---|
| User Guidance | Year for which the data on the use of antimicrobials 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.

## *5.4. Permanent Identifier*

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

| Tag | Description |
|---|---|
| User Guidance | The Permanent Identifier is unique to each VMP in the UPD or 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. This field is included for user information only. |
| 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] or section *1.1 Product Management Service Identifier (PMS ID)* of the PMS[5]. |

**Example:** 600000064201, 600000037969

[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 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), section 1.1

## 5.5. Package Identifier/Packaged Medicinal Product Identifier

Use data are to be submitted at product presentation level, which are identified by their unique Package identifier in UPD or PCID in PMS.

| Tag | Description |
|---|---|
| User Guidance | The package identifier/PCID is a structured data field that indicates the permanent and unique identification assigned to each package/product presentation in the UPD/PMS. In the UPD/PMS it corresponds to 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[6] or *4.1. Packaged Medicinal Product Identifier* of the PMS[7]. |

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

## 5.6. Reference number

In addition to the package identifier, a reference number can be submitted as a supplementary identifier of a specific antimicrobial VMP/HMP 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/HMP presentation from other relevant databases, such as national databases. Optional for MSs. The presentation ID for VMPs previously used for ESVAC is an example of a reference number that can be included in this field.<br><br>After the first submission, the reference number will persist associated with the product in the database 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 future 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 |

[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 5.3
[7] Please refer to 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), section 4.1

| Tag | Description |
|---|---|
| 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/HMP presentation. |

## 5.7. Medicinal product name

This field is used to identify the antimicrobial VMP/HMP for which data on the use of antimicrobials in animals are being reported by using the full name available in the product information. Different languages can apply.

| Tag | Description |
|---|---|
| User Guidance | The 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 name) in the UPD[8] or section *1.14 Medicinal product name* (full name) of the PMS[9]. |

**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/HMP presentation. The 13 product forms, which are only relevant for ASU analysis, are:<br>- INJ (Injectable products)<br>- INTRAMAM (intramammary products) |

[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), section 1.8.1
[9] Please refer to 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), section 1.14

| Tag | Description |
|---|---|
| | - 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 products forms are suitable)<br><br>This field is prepopulated by the system when the user generates the prefilled use template per animal species 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/PMS section *1.5 (Authorised) Pharmaceutical form*[10,11] and re-codable against the applicable product forms, 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, INTRAMAM-LC.

## *5.9. Long-acting parenteral products*

The long-acting parenteral products field allows for the identification of AMP with long-acting/prolonged-release dosage forms that are different from the conventional release dosage form. This information is used to assign the correct DDDvet and DCDvet value to the active substance and route of administration of each AMP.

| Tag | Description |
|---|---|
| User Guidance | 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.<br><br>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), this field should be left blank. 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 |

[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 1.5
[11] Please refer to 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), section 1.5

| Tag | Description |
|---|---|
| Conformance | Partially editable field: editable only for parenteral products (should be left blank for non-relevant products and edited for relevant parenteral products) |
| Data Type | String of characters |
| Value | Two-letter code to indicate parenteral products with long acting/prolonged release dosage forms. |

**Example:** LA

## *5.10. ASU Pack size*

The ASU pack size is a numerical value that indicates the content quantity per VMP/HMP 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/HMP 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/HMP includes one manufactured item:<br><br>1.1. If the strength of the VMP/HMP 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 or *4.4 Pack size* of the PMS) by the manufactured item quantity numerical value (as available in section *5.6.2 Manufactured Item Quantity* of the UPD or *4.11.2 Manufactured item quantity* of the PMS).<br><br>1.2. If the strength of the VMP/HMP 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 or *4.4 Pack size* of the PMS. If the pack size is not 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/HMP 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 or *4.4 Pack size* of the PMS. |
| Variables name in the template | PACKSIZE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | Numeric value |

| Tag | Description |
|---|---|
| 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[12] or from sections *4.4 Pack size* or *4.11.2 Manufactured item quantity* of the PMS[13], following the rules described above. |

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

## *5.11. 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 used based on the number of packages used.<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 AMP 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)<br>IU/l (conversion of the pack size unit from ml to l needed) |
| l | 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) |

[12] 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
[13] Please refer to 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), sections 4.4 and 4.11.2

| Tag | Description |
|---|---|
| | <table><tr><td></td><td>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/HMP includes one manufactured item:<br>1.1. If the strength of the VMP/HMP is provided by concentration, the unit of measurement for the ASU pack size unit will be retained as available in in *5.6.2 Manufactured Item Quantity* in the UPD or *4.11.2 Manufactured item quantity* in the PMS.<br>1.2. If the strength of the VMP/HMP 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 or *4.4 Pack size* in the PMS.<br>2. When the VMP/HMP 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 or *4.4 Pack size* in the PMS. |
| 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[14] or sections *4.4 Pack size* or *4.11.2 Manufactured item quantity* of the PMS[15], following the rules described above. The units are specified as a Term ID listed in Units of Measurement (List Identifier |

[14] 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
[15] Please refer to 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), sections 4.4 and 4.11.2

| Tag | Description |
|---|---|
| | 100000110633) or Units of Presentation (List Identifier 200000000014), as applicable. |

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

## *5.12. ATC or ATCvet code*

The ATC or ATCvet codes are the Anatomical Therapeutical Chemical classification codes for HMPs and VMPs respectively.

| Tag | Description |
|---|---|
| User Guidance | This field includes the ATC/ATCvet code as indicated in the relevant section of the corresponding SPC. Data on the use of antimicrobials in animals only need to be reported for VMP and HMPs for which the ATC/ATCvet codes are indicated in points 3 and 4 of the Annex the Commission Delegated Regulation (EU) 2021/578.<br>• If multiple ATC/ATCvet codes apply to the same AMP, then only the code(s) 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, any of the five levels of each ATC/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 | ATC/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[16] *or 1.13.3. ATC code(s) in the* PMS[17], if marked as antimicrobial in in Anatomical Therapeutic Chemical classification system – Veterinary (List Identifier 100000116677) and Anatomical Therapeutic Chemical classification system - Human (List Identifier 100000093533). |

**Examples:** QJ01CA04, QJ51AA07.

## *5.13. Scope*

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

[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), section 1.7.2
[17] Please refer to 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), section 1.13.3

| Tag | Description |
|---|---|
| User Guidance | This field indicates if the collection and reporting to the Agency of data on the use of an AMP is mandatory or voluntary, based on the product ATC/ATCvet code, as per Articles 3 and 4 of the Delegated Regulation (EU) 2021/578. This field is automatically prepopulated by the system when the user generates the prefilled use 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 on whether collection of and reporting to the Agency of the data on the use of antimicrobials is mandatory or voluntary, as derived from section *1.7.2 ATC vet code* in the UPD[18] or *1.13.3. ATC code(s)* in the PMS[19].<br><br>The ATCvet and ATC 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) and Anatomical Therapeutic Chemical classification system - Human (List Identifier 100000093533) as antimicrobials and as either mandatory or voluntary. |

**Examples:** mandatory, voluntary.

## *5.14. Number of packages used*

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 sources for collecting data on the use of antimicrobials shall be chosen nationally from the list of data providers 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. Data collection shall be based on specific data sources as appropriate, namely health records, treatment logbooks, delivery notes, invoices from farms, prescriptions, pharmacy records or veterinary practice records, as indicated in Article 13(1)(b) of the Commission Delegated Regulation (EU) 2021/578.

| Tag | Description |
|---|---|
| User Guidance | The number of packages used of each antimicrobial VMP/HMP presentation is provided as zero or as a positive numerical value (decimals are accepted). By default, this field will be empty as no reference data will be available.<br><br>The number of packages used per VMP/HMPs presentation is reported separately for each animal species category within each animal species. Thus, the user should indicate the specific number of packages used in |

[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), section 1.7.2
[19] Please refer to 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), section 1.13.3

| Tag | Description |
|---|---|
| | each animal species categories. 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. A column to report the number of packages used for each animal species category is available. The columns to report the number of packs used include the name of the animal species category. No further action to include these columns in the template is needed from the user, as a specific template is provided per animal species.<br><br>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).<br><br>In case any data on the use of antimicrobials in animals at national level are collected in other units than packages used for each antimicrobial VMP presentation, the number of packages used should be calculated by the Member State from the amounts used (expressed in weight or in volume) before reporting to the Agency.<br><br>Use are reported as either zero or positive numerical values for all antimicrobial VMP/HMPs that fall within the mandatory data reporting scope, as per Article 3 of the Commission Delegated Regulation (EU) 2021/578. On the contrary, any antimicrobial VMP/HMPs that fall within the voluntary data reporting scope, as per Article 4 of the Commission Delegated Regulation (EU) 2021/578, should be deleted from the prefilled template if the MS decides not to report them. When there are previous reports, zero can be reported to keep trend analysis. |
| Variable name in the template | NO_PACKS |
| Editability | Blank (not prefilled), 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). |

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

## *5.15. Substance ID*

The Substance ID is used to identify each specific active substance. For fixed-combination AMPs, 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 used. A maximum of five antimicrobial active substances per VMP or HMP 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 | For VMP, as available in sections *4.3.3.1 Reference (Active) Substance* or *4.3.1. Substance* of the UPD[20]. For HMP, as available in section *5.5.3.1. Reference substance* or *5.5.1. Substance* of the PMS[21]. For both cases, 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 by using its International Non-proprietary name (INN) as presented in the latest version of ATC or 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 or PMS is the same as one of the ASU derivatives/compounds (please see the Annex, Table 3), the antimicrobial active substance name from UPD or PMS 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 AMP must have at least one antimicrobial active substance.<br><br>In the case of fixed combination AMPs, all the antimicrobial active substances shall be reported individually within their corresponding section of the prefilled sales template. If fixed combination AMPs 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). |

[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 4.3.1 and 4.3.3
[21] Please refer to 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), sections 5.5.1 and 5.5.3

| Tag | Description |
|---|---|
| | This field is automatically prepopulated by the system when the user generates the prefilled use template. |
| Variable name in the template | SUBSTANCE |
| Editability | Prefilled, non-editable field |
| Conformance | Mandatory and subject to validation |
| Data Type | CodeableConcept |
| Value(s) | For VMP, 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[22], referring to the compound/derivative or salt. For HMP, as available in section *5.5.3.1. Reference substance*, or should this not be provided, as available in section *5.5.1. Substance* of the PMS[23].<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 |

[22] 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
[23] Please refer to 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), sections 5.5.1 and 5.5.3.1

| Tag | Description |
|---|---|
| Value(s) | As available in *section 4.3.1 (Active) Substance* of the UPD[24] or *5.5.1. Substance* of the PMS[25], 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 section *4.3.1 (Active) Substance* of the UPD[24] or *5.5.1. Substance* of the PMS[25], if the substance is marked as a derivative/compound in the SMS. |

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

[24] 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
[25] Please refer to 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), section 5.5.1

## *5.19. Strength*

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

| Tag | Description |
|---|---|
| User Guidance | For each antimicrobial VMP/HMP 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.<br><br>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.<br><br>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/PMS linked with '*Strength (presentation)*', '*Strength (concentration)*' or '*Manufactured item quantity*' sections. 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/HMP 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[26]. For HMP, sections *5.5.3.4. Reference strength (Concentration)* or *5.5.2.3. Strength (concentration)* of the PMS[27] are applied instead.<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* |

[26] 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
[27] Please refer to 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), sections 5.5.2 and 5.5.3

| Tag | Description |
|---|---|
| | *(Presentation)*. If this value is not available, it will be provided using the information in *4.3.2.1. Strength (presentation)* in the UPD[28]. For HMP, sections *5.5.3.3. Reference strength (Presentation)* or *5.5.2.2. Strength (presentation)* of the PMS[29] are applied instead.<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/HMP includes multiple manufactured items (e.g., powders for reconstitution and solvent), the value of the strength will be retained as available in *5.6.2 Manufactured item quantity* in the UPD[30] or *4.11.2 Manufactured item quantity* in the PMS[31] 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/HMP presentation. This compatibility is important to harmonize the data and enable the system to calculate the content of antimicrobial active substance per presentation, and the total tonnes of antimicrobial active substance used based on the number of packages used.

| Tag | Description |
|---|---|
| User Guidance | 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: |

| 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)<br>IU/l (conversion of the pack size unit from ml to l needed) |
| l | mg/l<br>g/l |

[28] 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
[29] Please refer to 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), sections 5.5.2 and 5.5.3
[30] 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
[31] Please refer to 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), section 4.11.2

| Tag | Description |
|---|---|
| | <table><tr><td></td><td>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 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/PMS 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/HMP includes one manufactured item:<br><br>1.1 If 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[32]. For HMP, sections *5.5.3.4. Reference strength* |

[32] 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 |
|---|---|
| | *(Concentration)* or *5.5.2.3. Strength (concentration)* of the PMS[33] should apply instead.<br><br>1.2. If the strength of the VMP is provided by presentation, the 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[34]. For HMP, sections *5.5.3.3. Reference strength (Presentation)* or *5.5.2.2. Strength (presentation)* of the PMS[33] should apply instead.<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 substances(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[35]. For HMP, sections *4.11.2 Manufactured item quantity* (numerator) and *4.4 Pack size* (denominator) of the PMS[36] should apply instead. |

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

# 6. List of validations rules on the uploaded file

This section describes technical and business validation rules for submission of the use 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 use data template |

[33] Please refer to 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), sections 5.5.2 and 5.5.3
[34] 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
[35] 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
[36] Please refer to 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), section 4.11.2

| | |
|---|---|
| **Number of packs used cannot be empty** | Number of packs cannot be empty. Please complete this information |
| **'Field' (any other field different from number of packs used) cannot be empty** | 'Field' cannot be empty. Please download the prefilled template again |
| **Different use species** | Animal species does not match the one selected for file upload |
| **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 used is not zero or a positive number** | The value for number of packages used 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 for 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/Packsize U/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/PMS, please contact the relevant National Competent Authority to correct the information in the UPD/PMS |
| **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' (for the use species cattle only) 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'. |
| **VMP/HMPs for which data on the use of antimicrobials are mandatory to report, as per their respective ATCvet/ATC code, are deleted from the template** | Antimicrobial medicinal products with an ATC or ATCvet code that fall within the mandatory scope for the reporting of data on the use of antimicrobials in animals, as per Article 3 of the Commission Delegated Regulation (EU) 2021/578, cannot be deleted. If there is no use to be reported, please indicate '0' (zero) in the number of packs used field. |
| **One or more animal species use categories (when there are multiple categories) were deleted for the same package identifier** | Data on the use for all the animal species categories associated with one animal species should be reported. In case of no use, please do not delete the line, but report zero instead. |
| **Long-acting identification is different from 'LA'** | To identify parenteral products with long-acting/prolonged-release dosage forms (achieved through special formulation design and/or manufacturing method) please indicate 'LA'. |

| Description | Error message while submitting the file |
|---|---|
| **Long-acting identification is used for other product forms different from INJ** | The identification of products with long-acting/prolonged-release dosage forms is only applicable to parenteral products (INJ). |

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/PMS field name, Procedure type and Reference Member State.

If the system detects any discrepancies between the prefilled values (from the UPD or PMS) and the submitted alphanumeric values (for the ASU variables Permanent Identifier, Package Identifier, Name, Form, Packsize, PacksizeU, Scope, ATC/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 or PMS 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 AMPs 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 *4.3.1 (Active) Substance* and *4.3.2. Strength (quantitative composition)*, or using the moiety in section *4.3.3 Reference strength*. In the PMS, the same information is provided in sections *5.5.2. Substance strength (quantitative composition)* and *5.5.3. Substance reference strength (quantitative composition)*, respectively. 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/PMS:

**Table 4.** Rules for including active substance information in the ASU template using the information available in the UPD/PMS (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./5.5.1. Salt/derivative Substance* benzathine benzylpenicillin | *4.3.2./5.5.2. Salt/derivative strength* 100 mg | *4.3.3.1./5.5.3.1. Moiety substance* benzylpenicillin | *4.3.3.1.2* or *4.3.3.2.1/5.5.3.3.* or *5.5.3.4. Moiety strength* 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) |