

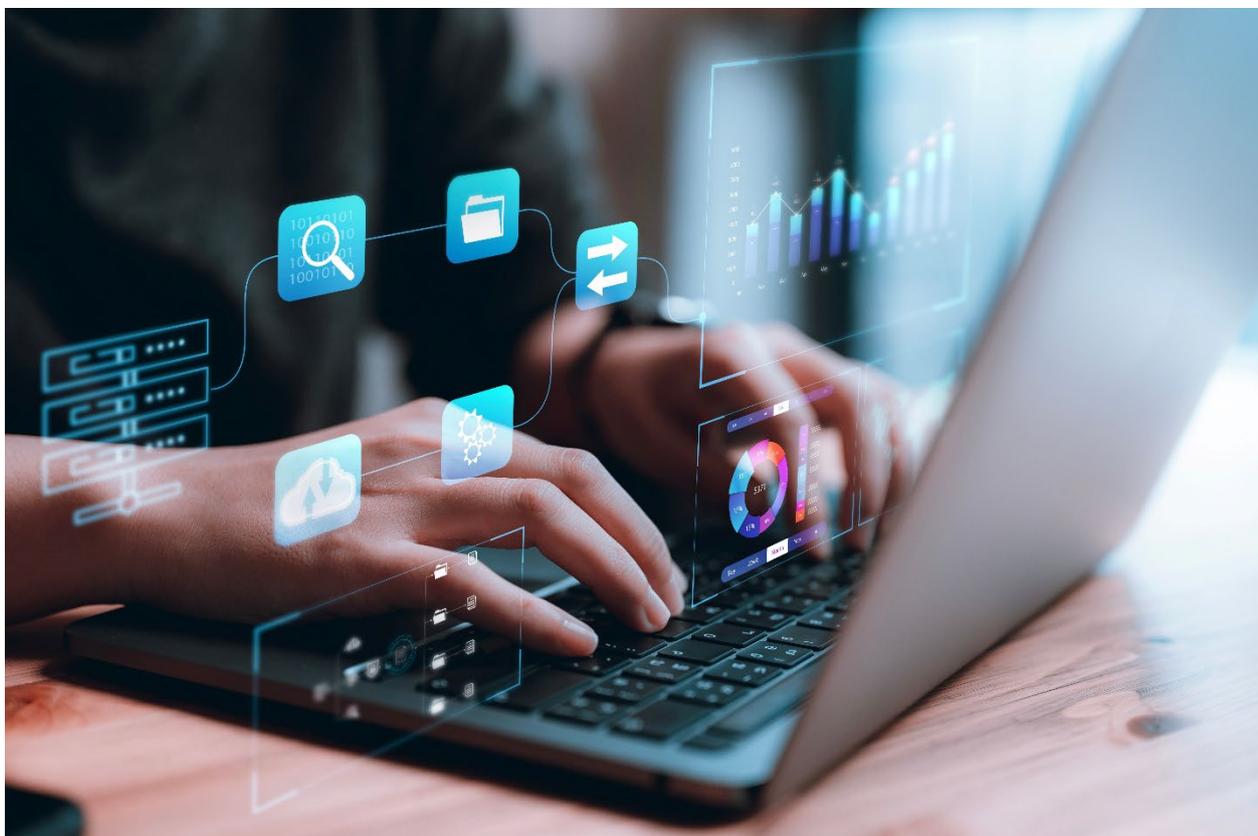


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

March 2026
EMA/392051/2025
Veterinary Medicines Division & Information Technology Division

Antimicrobial Sales and Use (ASU) Platform User Guide

User guide for National Competent Authority users



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1. Introduction

The Antimicrobial Sales and Use (ASU) Platform is a web interface developed by the European Medicines Agency ('the Agency'), to allow Member States (MSs)¹ to report their collated data on the volume of sales of antimicrobial veterinary medicinal products (VMPs), their data on the use of antimicrobial medicinal products in animals and the relevant animal population data, as per Article 57 of Regulation (EU) 2019/6², and related delegated³ and implementing acts⁴. The ASU Platform enables the storage, management and analysis of these data that are published in the European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance reports⁵ and in Power BI public dashboards⁶.

Each Member State must designate a national contact point and at least one data manager to liaise with the Agency on all matters related to data reporting. These individuals are granted access to the ASU Platform as National Competent Authority (NCA) users (also referred to as 'users' in this guide). Likewise, the Agency appoints staff members as Administrators ('Admin users') to manage the ASU Platform and to provide support to NCA users throughout the reporting process.

The ASU Platform has two components:

- The web portal: accessed via the Union Product Database (UPD), it enables users to submit their sales, use and animal population data by providing downloadable templates prefilled with veterinary medicinal product data from the UPD, and animal population data from Eurostat and TRACES. Use data templates can also be extended with human medicinal product data from the Product Management Services (PMS). NCA users must complete these templates offline with the necessary data and upload them to the ASU Platform.
- The Microsoft Power BI application: accessed by NCA users via the ASU web portal, allowing validation and analysis of the uploaded data through dedicated ASU Data Validation reports.

The aim of this user guide is to provide clear instructions for NCA users on how to use the different components and functionalities of the ASU web portal.

For more information on the:

- ASU Power BI application, please refer to the [Antimicrobial Sales and Use \(ASU\) Power BI Application - User guide for National Competent Authority users](#).
- Data variables mentioned in this user guide, please see the [Antimicrobial Sales and Use \(ASU\) technical implementation protocol](#).

2. Request for access

Before accessing the ASU Platform for the first time, NCA users must have an **EMA account** and request the '**UPD-ASU-NCA-User**' role in the **EMA Account Management** portal. To do so, NCA users must follow these steps:

¹ 27 EU Member States, Iceland and Norway.

² Regulation (EU) 2019/6: <https://eur-lex.europa.eu/eli/reg/2019/6/oj>

³ Commission Delegated Regulation (EU) 2021/578: http://data.europa.eu/eli/reg_del/2021/578/oj

⁴ Commission Implementing Regulation (EU) 2022/209: http://data.europa.eu/eli/reg_impl/2022/209/oj

⁵ More information available on the European Medicines Agency website [here](#).

⁶ These are the [ESUAvet Power BI public dashboard](#) and the [ESVAC Power BI public dashboard](#).

1. Create an **EMA account** (if they do not have one already) at <https://register.ema.europa.eu/identityiq/home.html> and select *Create an EMA account (Self-register)*⁷.
2. Request the user role '**UPD-ASU-NCA-User**':
 - a) Go to <https://register.ema.europa.eu/identityiq/home.html>
 - b) Sign in with the EMA username and password.
 - c) In the menu on the left, navigate to *Manage Access* → *Request Access for organisation*.
 - d) Search for your organisation (e.g. national competent authority) and click *Next*.
 - e) Select your organisation: select the relevant addresses returned by the search and click *Next*⁸.
 - f) Search for the '**UPD-ASU-NCA-User**' role in the search field, select it and click *Next*.
 - g) In the additional information field please attach the e-mail inviting you to use the ASU platform in PDF format, using the 'Drop here or browse' box and then click *Next*.
 - h) Submit the request and wait for approval from an Admin user.
 - i) Once your request has been approved, you will receive a confirmation e-mail.

3. Access to the ASU Platform and configuration settings

3.1. Log in and user rights

To access the ASU Platform:

1. Go to the UPD portal (<https://upd-portal-prod.azurewebsites.net/updwebui/home>).
2. Click on the *Login* button on the UPD homepage (see [Figure 1](#)).
3. Fill in your user credentials (username and password) in the successive pop-up windows.

Figure 1. Login button



⁷ Further instructions are available here: <https://register.ema.europa.eu/identityiq/help/selfregister.html>.

⁸ In case you cannot find your organisation from the list, send an email to asu.delivery@ema.europa.eu.

Once logged in, the UPD navigation menu will update to show only the components users have permission to access. Specifically:

- All users will see their username in the top right corner, a Home button to return to the main screen, a Logout button to exit the application and a logout timer indicating how much time remains before automatic logout. (These elements are highlighted with orange boxes in [Figure 2](#)).
- Users with UPD-specific roles can access the UPD menu items (highlighted with a red box in [Figure 2](#)).
- Users with ASU-specific roles can access the ASU menu item (highlighted with a green box in [Figure 2](#)).
- Users with both ASU and UPD roles can access both sets of menu items.

Figure 2. Navigation menu items per access rights



3.2. ASU roles

Two types of users can access the ASU Platform (see [Figure 3](#)): NCA users and Admin users. This guide focuses on the features available to NCA users. For the full list of permissions for each role, see [Annex 1](#).

Figure 3. ASU Platform User roles

	Access	Responsibilities
Admin Users	<p>Have full administration rights and can access all system pages, including those visible to NCA users and all pages under the specific Admin tasks menu.</p> <p>Can view data from <u>all</u> countries by selecting them in any of the dropdown <i>Country</i> menus across the ASU Platform.</p>	<p>Start and manage data calls.</p> <p>Help NCA users to submit data.</p> <p>Approve data for publication.</p> <p>Publish approved data.</p>
NCAs Users	<p>Have access to all pages under the Sales, Use, Animal population and Error reports sections of the ASU menu.</p> <p>Can only view data for their own country, which is automatically selected in all dropdown <i>Country</i> menus.</p>	<p>Upload their country's sales, use and animal population data to the ASU Platform.</p> <p>Validate these data in the Power BI application and formally submit these data on the ASU Platform.</p>

3.3. Configuration

Before downloading any ASU templates, users should check that their **Windows and/or Excel settings** match the following ASU Platform requirements:

- **semicolon (;) as list separator;**
- **comma (,) as a decimal symbol.**

If these requirements are not met, users may encounter issues when completing ASU templates offline and uploading them to the ASU Platform. To work with these settings, users should:

1. **For system-wide configuration in Windows regional settings:**

- 1.1. Open the Control Panel and click on *Clock and Region*.
- 1.2. Select *Region* and click *Additional Settings*.
- 1.3. Ensure the list separator is set to ';' (semicolon) and set the decimal symbol to ',' (comma).

2. **For Excel-specific configuration in Excel Advanced Options:**

- 2.1. Open a blank Excel file and go to *File*.
- 2.2. Select *Options* and click on *Advanced*.
- 2.3. Choose between:
 - a) Using Windows settings in Excel by ticking the *Use system separator* checkbox. If users choose this option, they should follow the instructions above on changing their Windows settings.
 - b) Using Excel's own settings by unticking the *Use system separator* checkbox and enter ',' (comma) as the decimal separator. If users choose this option, they can skip the Windows settings instructions for setting the decimal separator.

4. ASU Platform workflow overview

To comply with Article 57 of Regulation (EU) 2019/6, NCA users must submit three types of datasets each year to the Agency via the ASU Platform:

- **Sales dataset:** containing data on the volume of sales of veterinary antimicrobial medicinal products (VMPs). One sales dataset must be submitted per country and year.
- **Use dataset:** containing data on the use of both veterinary and human antimicrobial medicinal products in animals. One use dataset must be submitted per country, per year for each animal species, following the stepwise approach described in Article 15 of Commission Delegated Regulation (EU) 2021/578.
- **Animal population dataset:** containing data on relevant animal population statistics needed for analysing antimicrobial sales and use data. One animal population dataset must be submitted per country and year.

For each dataset type, a **prefilled template** can be downloaded from the ASU Platform:

- Sales and use templates are prefilled with all the relevant antimicrobial VMP information from the UPD and NCA users must fill in the number of packs sold or used for each product presentation. Before downloading these templates, NCA users can choose to extend them with additional antimicrobial medicinal products, including human medicinal products (HMPs) for use data.

- Animal population templates are prefilled with animal population statistics from Eurostat and TRACES, which NCA users must confirm or update as needed.

Every year, NCA users must submit data for the previous reporting year during the annual **data call** which has two phases:

1. **Data call preparation phase:** during which Admin users prepare the ASU platform by:
 - 1.1. Synchronising UPD product data so that it appears in the ASU sales and use templates.
 - 1.2. Preparing the sales, use and animal population questionnaires.
 - 1.3. Upload the reference animal population data from Eurostat and TRACES.

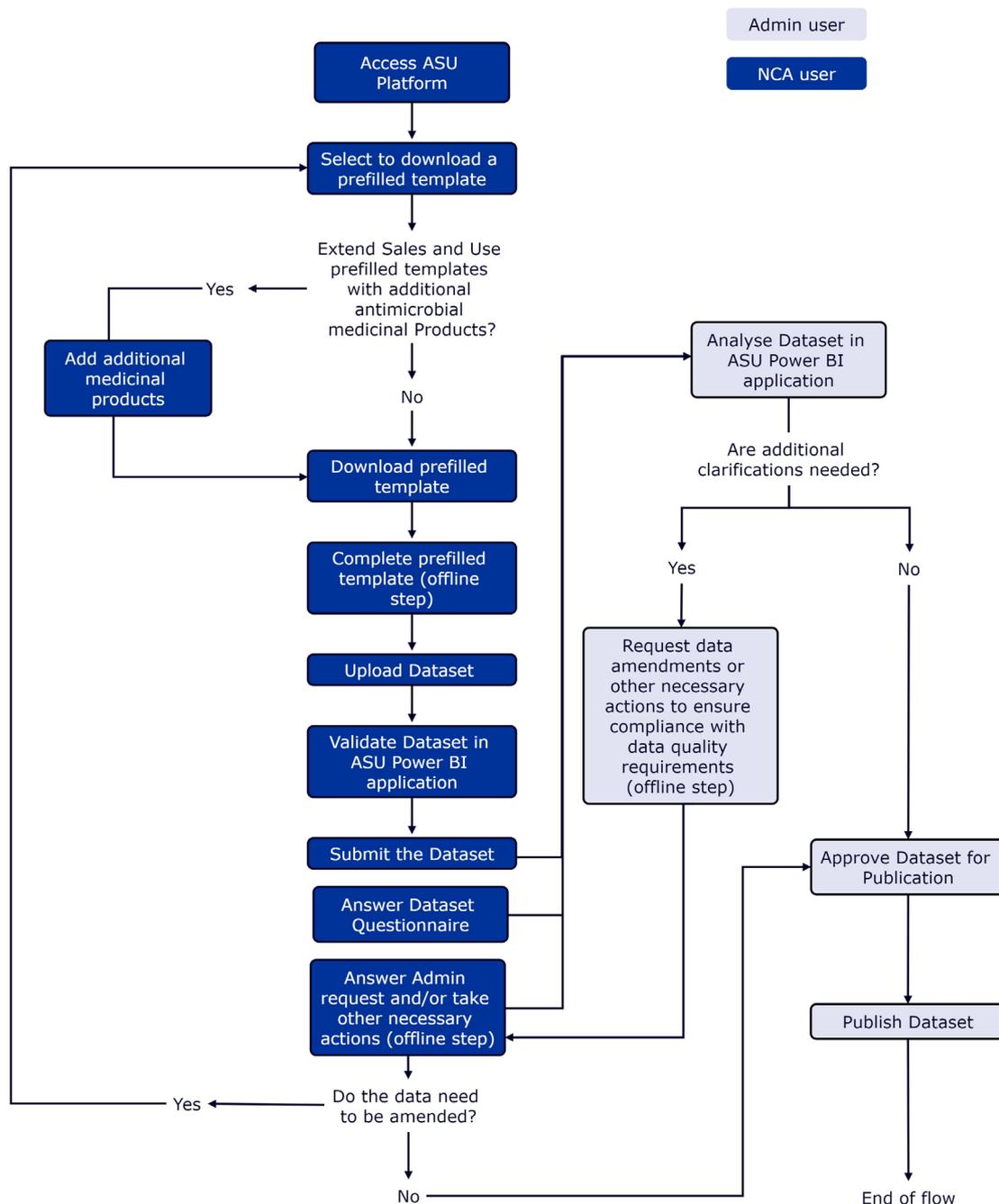
During this phase, NCA users are encouraged to revise their country's sales and use templates and consult the questionnaires to ensure everything is ready for the next phase. This may include addressing medicinal product data quality issues (see [Annex 2](#) for more details on how to resolve UPD product data quality issues).

2. **Data submission phase** (see [Figure 4](#)): for each dataset type NCA users must:
 - 2.1. Download the prefilled template from the relevant *Download data template* page.
 - 2.2. Complete the prefilled template offline.
 - 2.3. Upload the completed template/dataset to the corresponding *Upload dataset* page.
 - 2.4. Validate the uploaded dataset in the ASU Power BI application.
 - 2.5. Submit the validated dataset on the relevant *Check dataset submission status* page, confirming that it meets the legal data quality requirements.
 - 2.6. Submit the associated questionnaires available for each type of data (questionnaire submission is independent of dataset submission).

After the NCA user completes all the required steps, the Admin user reviews the submitted data in the Power BI application. If the data do not meet the data quality requirements listed in Article 6 of Commission Delegated Regulation (EU) 2021/578, or if further clarification is needed, the Admin user will notify the NCA user via email.

If amendments are required, the NCA user can download the affected template again and their previously submitted data will automatically appear prefilled. Once the dataset meets the necessary data quality requirements, the Admin user will update its status on the *Check dataset submission status* page from *Submitted* to *Approved for publication* and finally to *Published*. NCA users can use this page to monitor the progress of their datasets at any time by consulting the status displayed next to each dataset (Uploaded, Submitted, Approved for publication or Published).

Figure 4. ASU Platform workflow for data managers (NCA User) and EMA staff (Admin user)

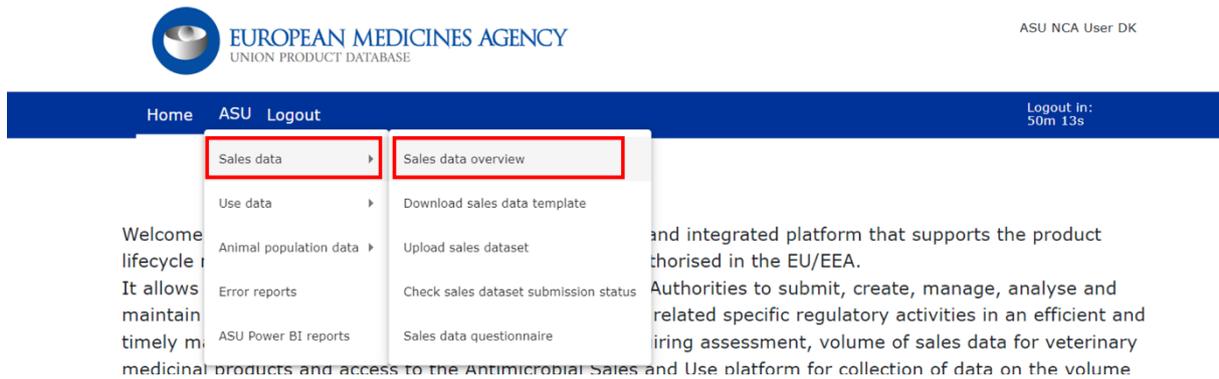


5. ASU web portal components

5.1. Overview pages

NCA users can track the progress of their Sales, Use and Animal population data submission using the *Data Overview* pages. These pages are accessible by clicking the ASU menu item, expanding the relevant data type submenu and selecting the *Sales data overview*, *Use data overview* or *Animal population data overview* page (see [Figure 5](#)).

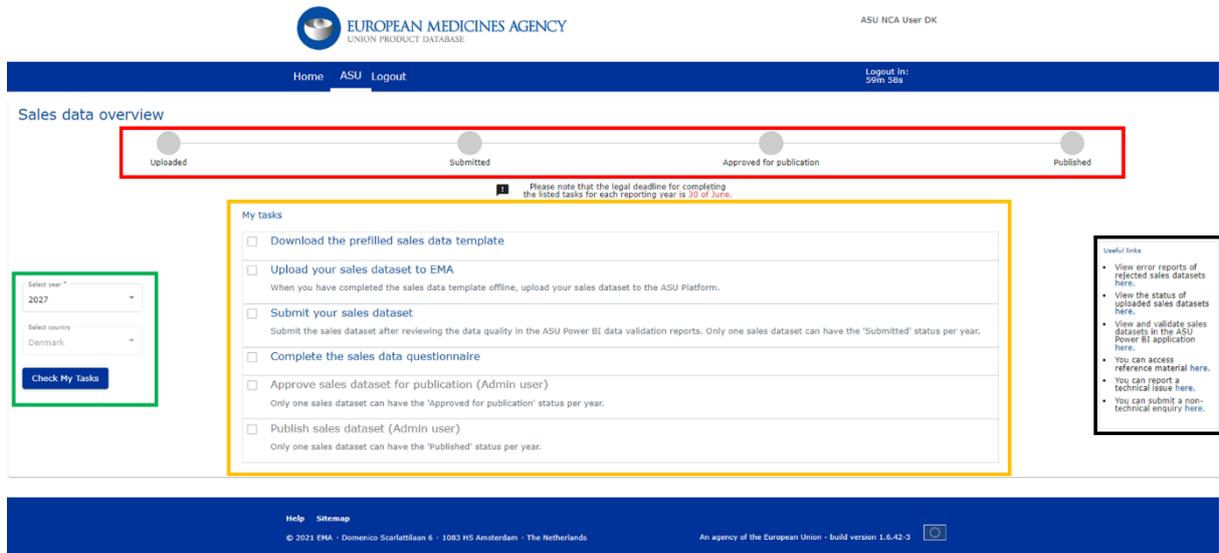
Figure 5. Navigation to *Sales data overview* page



Each *Data overview* page contains (see [Figure 6](#)):

- **Progress bar** (top): shows the status of the data as it moves from *Uploaded* → *Submitted* → *Approved for publication* → *Published* (see the red box in [Figure 6](#)).
- **My tasks list** (centre): lists of all the actions required for each data type: *Download the prefilled data template*, *Upload your dataset to EMA*, *Submit your dataset*, *Complete the data questionnaire*, *Approve dataset for publication* and *Publish dataset* (see the orange box in [Figure 6](#)). NCA users must complete all tasks except the last two, which only Admin users can do. Once a task is completed, the system automatically updates the checkbox. Each task title is a hyperlink to the relevant page where it can be performed.
- **Dropdown filters** (left): allows users to choose the reporting year (and country - Admin users only) for which they would like to see the data overview. The **Check My Tasks** button below these filters refreshes the progress bar and tasks list (see the green box in [Figure 6](#)).
- **Useful links box** (right): list of links that provide quick access to the [Error reports](#) page (see [section 5.5](#)), the [Check dataset submission status](#) page ([section 5.7](#)), the [ASU Power BI application](#), the [EMA ASU webpage](#) (with reference materials such as this user guide), the [EMA Service Now page](#) to report technical issues (see [Annex 3](#)) and the [Ask EMA page](#) for non-technical inquiries (see the black box in [Figure 6](#)).

Figure 6. *Sales data overview* page



5.2. Template download

To download a template from the ASU Platform, users should:

1. Click on the ASU navigation menu item.
2. Open the submenu for the type of template they wish to download: *Sales data*, *Use data* or *Animal population data*.
3. Select the appropriate download option: *Download sales data template* (see [Figure 7](#)), *Download use data template* or *Download animal population data template*.
4. On the selected *Download data template* page (see [Figure 8](#)), use the dropdown menus to choose the **year**, **country** (Admin users only) and **animal species** (use data templates only).
5. Click the *Download template* button.

Figure 7. Navigation to the *Download sales data template* page

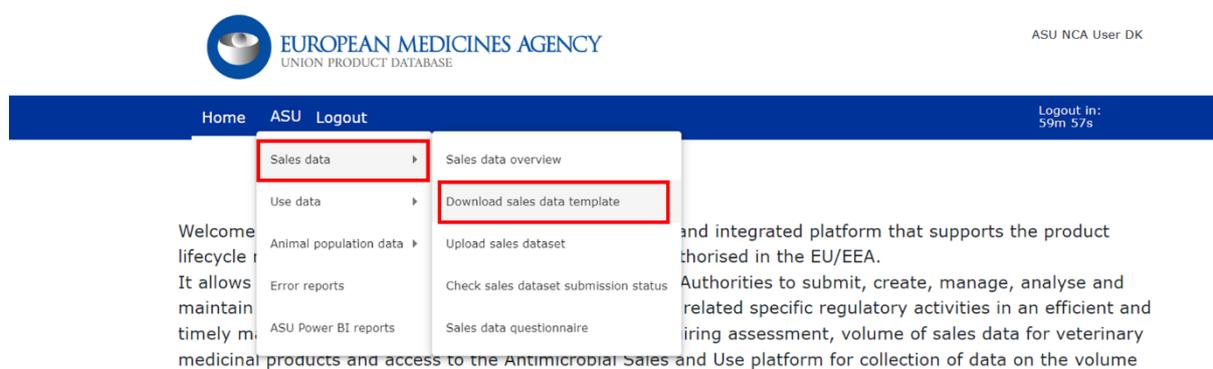
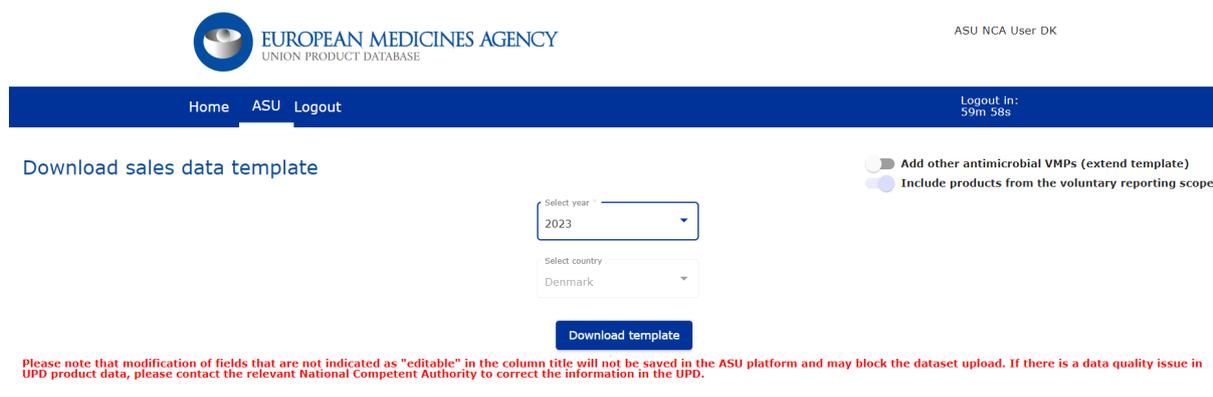


Figure 8. *Download sales data template* page.



5.2.1. Inclusion or exclusion of products from the voluntary reporting scope

All sales and use data templates are automatically prefilled with products that fall under the mandatory reporting scope⁹. Users can choose to include or exclude products from the voluntary reporting scope¹⁰ by following these steps:

⁹ Antimicrobial medicinal products for which sales and use data must be reported to the Agency based on the ATC code as per Articles 1 and 3 of Delegated Regulation (EU) 2021/578 (http://data.europa.eu/eli/reg_del/2021/578/oj).

¹⁰ antimicrobial medicinal products for which sales and use data may be reported to the Agency based on the ATC code as per Articles 2 and 4 of Delegated Regulation (EU) 2021/578 (http://data.europa.eu/eli/reg_del/2021/578/oj).

1. Go to the *Download sales/use data template* page.
2. Select the year, country (Admin users only) and animal species (for use data templates) for which they want to download a template.
3. Use the *Include products from the voluntary reporting scope* toggle button in the top right-hand corner of the page (see [Figure 8](#)) to include or exclude voluntary products. **The button is enabled by default.**
4. Click the *Download template* button.

Products under the voluntary scope can also be manually deleted from the templates offline without generating a validation error when uploading the template to the ASU Platform. This does not apply to products on the mandatory scope.

5.2.2. Extend templates with other antimicrobial medicinal products

By default, sales and use templates include only antimicrobial VMPs that are authorised for use in the user's Member State and in the relevant animal species (use templates only). Consequently, users may need to extend their templates with additional products (from either the mandatory or voluntary scope - see [section 5.2.1](#)) if they wish to report:

- sales or use of antimicrobial VMPs authorised in another Member State as foreseen in Article 116 of Regulation (EU) 2019/6;
- use of VMPs authorised in another animal species or of antimicrobial human medicinal products (HMPs) as foreseen in Articles 112-114 of the same regulation.

To **search for products** to be added to the sales and use templates, users should:

1. Go to the *Download sales/use data template* page.
2. Select the year, country (Admin user only) and animal species (for use data only) for which they want to download a template.
3. Enable the *Add other antimicrobial VMPs (extend template)* toggle button on the *Download sales data template* page (see [Figure 8](#)) or the *Add other antimicrobial VMPs or HMPs (extend template)* toggle button on the *Download use data template* page.
4. On the corresponding extend template page, search for the antimicrobial medicinal products of their interest by using a series of filters (shown in [Figure 9](#) and described in [Table 1](#)). Users must **use at least one filter** to enable the *Search* button.
5. Click on the *Search* button

Figure 9. Filters of the extend template page with the indication of the minimum number of characters per filter.

Home ASU Logout Logout in: 59m 48s

Search for antimicrobial VMPs authorised for use in other animal species, authorised in other Member States and antimicrobial HMPs Back

Domain: Veterinary Products
 Package identifier: a
 Authorisation country:
 Permanent identifier: a
 Procedure number: a
 Active substance: a

Medicinal product name: a
 ATC/ATC vet code: a
 Target species: a

Reset Search

Table 1. Filters to search for additional antimicrobial medicinal products.

Filter	Function	Type	Minimum number of characters ¹	Search result is exact match or contains ²
Domain ³	To search for human or veterinary medicinal products.	Dropdown	-	-
Package identifier	To search by UPD package ID	Free text	-	Exact match
Authorization country	To search by one of the 29 EU/EEA authorisation countries	Dropdown	-	-
Permanent Identifier	To search by UPD permanent ID	Free text	-	Exact match
Procedure number	To search by procedure number	Free text	4	Contains
Active substance	To search by active substance	Free text	4	Contains
Medicinal Product Name	To search by medicinal product name (in English or other languages)	Free text	4	Contains
ATC/ATCvet code	To search by ATC/ATCvet code	Free text	4	Contains
Target species	To search by UPD target species	Free text	3	Contains

¹ If the minimum number of characters are not provided, the corresponding filter box is highlighted in red (see [Figure 9](#)).

² Search results should be an exact match or should contain (start, middle or end) the value indicated in the filter.

³ This filter is only available on the search page for use templates.

Once the user clicks on the search button, all the products that meet the search criteria are displayed in a search results table below the filters (see red box in [Figure 10](#)). For each product, the following data are shown: *Authorization country*¹¹, *Domain* (only for use templates), *Procedure number*, *Permanent identifier*, *Package identifier*, *Medicinal product name*, *Pharmaceutical composition*, *ASU product form*, *ATC/ATCvet Code*, *Target species* and *Pack size description*.

To add products to the sales or use templates, users should:

1. Select the desired products by ticking the checkbox in the first column of the table.
2. Click the *Add* button at the top right of the table.

The selected products will appear in a separate *Selected products* table (see green box in [Figure 10](#)). This allows users to continue searching for products with different criteria while keeping track of the

¹¹ Centrally authorised products (CAPs) can only be added to use templates (never to sales templates) through the extend template functionality. This scenario should only be necessary when the CAP is authorised for a species that is different from the species of the selected use template. **When searching for CAPs to add in these cases, the authorisation country search field must be left empty.** This helps prevent incompatibility issues, as only CAPs from a user's own country should be included in the template.

products that have already been selected to be added to the templates. If users wish **to remove a product** from the *Selected products* table, they should click on the *Remove* button in the *Action* column on the far right of the table.

Once users have finished adding products, they can click the *Download template* button below the *Selected products* table on the right-hand side to **download the extended sales or use template**.

If users later decide to **re-download the sales or use data template with added products** for the same year, country and animal species (use data), the ASU system will display an *Extend template confirmation* pop up message saying: "*A previously downloaded template with additional veterinary medicinal products has been detected. Do you want to add them in the current template?*". Users have two options:

1. If users click on the *Yes* button, they will be redirected to the product search page where the previously added products will be listed in the *Selected products* table. From there they can choose whether to add new products, remove existing ones or directly download the template again.
2. If users click on the *No* button, a second pop-up message will appear warning them that: "*The previously added products will be lost. Do you want to continue?*".
 - 2.1. If users click the *No* button again, they will be redirected to the *Download Sales/Use Data Template* page without any changes being made.
 - 2.2. If users click the *Yes* button, a new sales or use data template will be generated without any of the previously added medicinal products.

Similarly, when **users download the sales or use template for a new year for the first time for the same country and animal species** (use data), the system will also display an *Extend template confirmation* pop up message saying: "*Additional veterinary medicinal products had been added in the template the previous year. Do you want to include them also in this year's template?*". Users have the same options as in the previous case.

Figure 10. Search results table (red box) and selected products table (green box) on extend template page.

The screenshot shows the ASU Platform interface. At the top, there is a search bar with various filters and a search button. Below the search bar, there are two tables. The first table, highlighted with a red box, is the 'Search result' table. The second table, highlighted with a green box, is the 'Selected products' table. Both tables have columns for Authorisation country, Domain, Procedure number, Permanent identifier, Package identifier, Medicinal product name, Pharmaceutical composition, ASU product form, ATC/ATC vet code, Target species, and Pack size description. The 'Selected products' table also includes an 'Action' column with a trash icon.

Authorisation country	Domain	Procedure number	Permanent identifier	Package identifier	Medicinal product name	Pharmaceutical composition	ASU product form	ATC/ATC vet code	Target species	Pack size description
AT	Veterinary	33 IP	600000013363	d66e20f3-f97d-49ce-a335-f64ec5d458fe			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe
AT	Veterinary	33 IP	600000013363	0e4c7926-3615-4036-8a7e-f162a203f666			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe
AT	Veterinary	33 IP	600000013363	e8f3b34-8f52-4cdf-af06-8a46a3769102			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe

Authorisation country	Domain	Procedure number	Permanent identifier	Package identifier	Medicinal product name	Pharmaceutical composition	ASU product form	ATC/ATC vet code	Target species	Pack size description	Action
AT	Veterinary	33 IP	600000013363	d66e20f3-f97d-49ce-a335-f64ec5d458fe			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe	
AT	Veterinary	33 IP	600000013363	0e4c7926-3615-4036-8a7e-f162a203f666			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe	

5.3. Content and completion of templates offline

After downloading a template from the ASU Platform, users should update or complete all the fields marked as being 'editable' in the column headers of the template. This should be done offline before uploading the file back to the ASU Platform. Detailed instructions for NCA users on completing / updating the editable fields in each type of ASU template can be found in the following sections of this user guide, in addition to a visual summary in [Annex 4](#). For more information on the contents of the ASU templates please see the [Antimicrobial Sales and Use \(ASU\) technical implementation protocol](#).

5.3.1. Sales Data template

The structure and instructions on how to complete the sales data template are provided in [Table 2](#) and [Table 3](#).

Table 2. Sales data template fields

Column	Name	Variable	Type
A	COUNTRY	Country	Prefilled and non-editable
B	YEAR	Year	Prefilled and non-editable
C	PERMANENT_IDENTIFIER	Permanent identifier	Prefilled and non-editable
D	PACKAGE_IDENTIFER	Package identifier	Prefilled and non-editable
E	AUTH_NUMBER	Authorisation number	Prefilled and non-editable
F	PROCEDURE_TYPE	Procedure type	Prefilled and non-editable
G	REFERENCE_MS	Reference member state	Prefilled and non-editable
H	REF_NUMBER(editable)	Reference number	Blank and editable (optional)

Column	Name	Variable	Type
I	ARTICLE_116(editable)	VMPs allowed for use under Article 116	Prefilled and partially editable only for those products added through the extend template functionality
J	NAME	Veterinary medicinal product name	Prefilled and non-editable
K	FORM(editable)	Product form	Prefilled and partially editable
L	ASU_PACKSIZE	ASU pack size	Prefilled and non-editable
M	ASU_PACKSIZE_UNIT	ASU pack size unit	Prefilled and non-editable
N	ATCVET	ATCvet code	Prefilled and non-editable
O	SCOPE	Scope	Prefilled and non-editable
P	COMPANION_ANIMALS (editable)	Authorised for companion animals only	Prefilled and partially editable
Q	NO_PACKS(editable)	Number of packages sold	Prefilled and editable
R, X, AD, AJ, AP	SUBST_ID (up to 5)	Substance ID	Prefilled and non-editable
S, Y, AE, AK, AQ	SUBSTANCE (up to 5)	Name of the antimicrobial active substance	Prefilled and non-editable
T, Z, AF, AL, AR	SALT (up to 5)	Name of the salt of the antimicrobial active substance	Prefilled and non-editable
U, AA, AG, AM, AS	DERIVATIVE (up to 5)	Name of the derivative or compound of the antimicrobial active substance	Prefilled and non-editable
V, AB, AH, AN, AT	STRENGTH (up to 5)	Strength	Prefilled and non-editable
W, AC, AI, AO, AU	STRENGTH_UNIT (up to 5)	Strength unit of measurement	Prefilled and non-editable

Table 3. Sales Data Template - Actions to be performed by users.

Variable	Required user action
REF_NUMBER	Field that can be used to provide an alternative or supplementary identifier for the different VMP presentations. It is optional and may be left empty.
ARTICLE_116	For VMPs authorized in a user's own country and included by default in the template, this field is prefilled as 'N' and is not editable. For VMPs added through the extend template functionality, this field is editable and should be completed with: 'Y' if the VMP was allowed for use under Article 116 of Regulation (EU) 2019/6 ¹ . 'N' if the VMP was authorised for use in the NCA users' own country under another legislative framework.
FORM	This field is non-editable for all product forms except <u>oral powders</u> and <u>intramammary products</u> . Upon confirming the information in the relevant section of the SPC, users should: For Oral powders : Keep 'ORAL POWD' if the VMP is only to be administered in feed or in either feed or water. Change to 'ORAL SOLU' if the VMP is only to be administered in water, milk or milk replacer.

Variable	Required user action
	<p>Change to 'PREMIX' if the VMP is authorised for use in finfish only.</p> <p>For Intramammary products update the form INTRAMAM to: 'INTRAMAM-LC' if the VMP is indicated only for lactating animals or for both lactating animals and those in the drying-off period. 'INTRAMAM-DO' if the VMP is indicated only for animals in the drying-off period.</p>
COMPANION_ANIMALS	<p>This field is prefilled as 'N' and non-editable for VMPs <u>with</u> a withdrawal period registered in the UPD. It is prefilled as 'Y' and editable for VMPs without a withdrawal period registered in the UPD. In these cases, upon confirming the information in the relevant section of the SPC, users should:</p> <p>Keep 'Y' if the VMP is only authorised for other animals bred and kept (companion animals and fur animals).</p> <p>Change to 'N' if the VMP is also authorised for use in food-producing species, <u>including all horses</u>.</p>
NO_PACKS	<p>This editable field must be completed with the number of packages sold per VMP presentation using either a zero or a positive value (decimals are accepted and comma should be used as decimal separator) and following these rules:</p> <p>Reporting is required for VMPs that fall within the mandatory scope. If there are no sales, users should report '0' (zero).</p> <p>Reporting is optional for VMPs that fall within the voluntary scope. If there are no sales, users can report '0' (zero) or directly delete the corresponding rows from the template.</p> <p>For all VMPs (mandatory and voluntary), the number of packages sold should be adjusted to account for intra-community movements of VMPs (i.e. include sales brought from other MSs and exclude sales sent to other MSs).</p> <p>Take care to avoid double reporting, such as sales between wholesalers within the same country.</p> <p>If a Marketing Authorisation Holder (MAH) has provided the volume of sales (VoS) for an antimicrobial VMP in the UPD for a specific country and year, this value will appear prefilled in the corresponding sales template for those products that are included by default². VoS data is provided for reference only and MSs can choose to disregard or confirm it depending on their selected sales data providers.</p>

¹Article 116: '...a competent authority may allow the use in its territory of veterinary medicinal products not authorised in that Member State, where the situation of animal or public health so requires, and the marketing of those veterinary medicinal products is authorised in another Member State.'

²Please note that for confidentiality reasons, UPD volume of sales data will not be displayed in the sales template for the products added through the extend template functionality.

To prevent users from having to repeatedly complete or update the same fields (within the same reporting year as well as in future years), **the ASU system automatically saves certain changes when a sales template is successfully uploaded without generating an error report:**

- REF_NUMBER, ARTICLE_116, FORM and COMPANION_ANIMALS: the changes made in these editable fields are saved in the ASU Platform linked to the relevant package identifiers and will appear automatically in all future sales templates generated for the same country that include the same package identifiers. Please note that changes made in the REF NUMBER and FORM fields will also appear in the use data templates that contain the same product presentation (or vice versa, whichever is dataset type is uploaded first).
- NO_PACKS: if this field has been completed in a sales data template that has been uploaded to the system without generating an error report, when a user redownloads the sales template for the

same year and country, the template will be prefilled with these previously uploaded values.

Please note, that if new VoS data from MAHs in UPD becomes available in the ASU Platform and a user has already successfully uploaded a sales template, when the user redownloads this template the previously uploaded values and not the new VOS data will be displayed in the NO_PACKS field.

- ARTICLE_116: if a user has completed this field for a product added through the extend template functionality, this value will appear prefilled in the template of the following year if users add the same product again.

5.3.2. Use Data template

Users must download a use data template per use species. The structure and instructions on how to complete the use data template are provided in [Table 4](#) and [Table 5](#).

Table 4. Use data template fields

Column	Name	Variable	Type
A	SPECIES	Animal species	Prefilled and non-editable
B	COUNTRY	Country	Prefilled and non-editable
C	YEAR	Year	Prefilled and non-editable
D	PERMANENT_IDENTIFIER	Permanent identifier	Prefilled and non-editable
E	PACKAGE_IDENTIFIER	Package identifier	Prefilled and non-editable
F	AUTH_NUMBER	Authorisation number	Prefilled and non-editable
G	PROCEDURE_TYPE	Procedure type	Prefilled and non-editable
H	REFERENCE_MS	Reference member state	Prefilled and non-editable
I	REF_NUMBER	Reference number	Blank and editable (optional)
J	ADDED_AMPS	Medicinal product added through the extend template functionality.	Prefilled and non-editable
K	NAME	Medicinal product name	Prefilled and non-editable
L	FORM	Product form	Prefilled and partially editable
M	LONG_ACTING	Identification of long-acting parenteral products	Blank and partially editable
N	ASU_PACKSIZE	ASU pack size	Prefilled and non-editable
O	ASU_PACKSIZE_UNIT	ASU pack size unit	Prefilled and non-editable
P	ATCVET	ATC/ATCvet code	Prefilled and non-editable
Q	SCOPE	Scope	Prefilled and non-editable
R	NO_PACKS (one column per animal category) ¹	Number of packages used	Blank and editable
S	SUBST_ID (up to 5)	Substance ID	Prefilled and non-editable
T	SUBSTANCE (up to 5)	Name of the antimicrobial active substance	Prefilled and non-editable
U	SALT (up to 5)	Name of the salt of the antimicrobial active substance	Prefilled and non-editable
V	DERIVATIVE (up to 5)	Name of the derivative or compound of the antimicrobial active substance	Prefilled and non-editable
W	STRENGTH (up to 5)	Strength	Prefilled and non-editable

Column	Name	Variable	Type
X	STRENGTH_UNIT (up to 5)	Strength unit of measurement	Prefilled and non-editable

¹Variable number of columns linked to the number of use categories per animal species (each category will have a separate column to report the number of packages used in that category).

Table 5. Use Data Template - Actions to be performed by users.

Variable	Required user action
REF_NUMBER	Field that can be used to provide an alternative or supplementary identifier for the different VMP/HMP presentations. It is optional and may be left empty.
FORM	This field is non-editable for all product forms except <u>oral powders</u> and <u>intramammary products</u> . Upon confirming the information in the relevant section of the SPC, users should: For Oral powders : Keep 'ORAL POWD' if the VMP is only to be administered in feed or in either feed or water. Change to 'ORAL SOLU' if the VMP is only to be administered in water, milk or milk replacer. Change to 'PREMIX' if the VMP is authorised for use in finfish only. For Intramammary products update the form INTRAMAM to: 'INTRAMAM-LC' if the VMP is indicated only for lactating animals or for both lactating animals and those in the drying-off period. 'INTRAMAM-DO' if the VMP is indicated only for animals in the drying-off period.
LONG_ACTING	Partially editable field that only applies to parenteral products (product form INJ). By default, it will be empty and users should do the following: For parenteral products with long-acting/prolonged-release dosage forms that have been achieved through special formulation design and/or manufacturing method), and whose modified release dosage forms show slower release times than that of the conventional-release dosage form administered by the same route, users should indicate 'LA' in this field. Currently, it only applies to ceftiofur. For parenteral products that do not meet this 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 .
NO_PACKS	This editable field must be completed with the number of packages used per VMP or HMP presentation using either a zero or a positive value (decimals are accepted and a comma should be used as decimal separator) and following these rules: Reporting is required for VMPs and HMPs that fall within the mandatory scope. If there is no use, users should report '0' (zero). Reporting is optional for VMPs and HMPs that fall within the voluntary scope. If there is no use, users can report '0' (zero) or directly delete the corresponding rows from the template. For each VMP and HMP presentation, the number of packages used must be reported separately for the different animal categories of each animal species, using the respective column. For example, when reporting data for pigs, the number of packages used must be indicated in two different columns: one for fattening pigs and another for other pigs.

¹This field is Used to assign the correct DDDvet and DCDvet value from the [EMA published list](#). Currently only ceftiofur has different DDDvet and DCDvet value depending on whether it is in a long-acting product or not. Out of all the currently available products containing ceftiofur, only the centrally authorised product Naxcel shall be considered long acting for ASU purposes (permanent IDs 600000003432 and 600000003436) and should have this field updated accordingly.

To prevent users from having to repeatedly complete or update the same fields (within the same reporting year as well as in future years), **the ASU system automatically saves certain changes when a use template is successfully uploaded without generating an error report:**

- REF_NUMBER, FORM and LONG_ACTING: the changes made in these editable fields are saved in the ASU database linked to the relevant package identifiers and will appear automatically in all future use templates generated for the same country that include the same package identifiers. Please note that changes made in the REF_NUMBER and FORM fields will also appear in the sales data templates that contain the same product presentation (or vice versa, whichever is dataset type is uploaded first).
- NO_PACKS: if this field has been completed in a use data template that has been uploaded to the system without generating an error report, when a user redownloads the use template for the same year, country and animal species, the template will be prefilled with the previously uploaded values for each of the animal categories.

5.3.3. Animal Population Data template

The structure and instructions on how to complete the prefilled animal population data template are provided in [Table 6](#) and [Table 7](#).

Table 6. Animal Population data fields

Column	Name	Variable	Type
A	COUNTRY	Country	Prefilled and non-editable
B	YEAR	Reporting year	Prefilled and non-editable
C	ANIMAL_SPECIES	Animal species	Prefilled and non-editable
D	POP_CATEGORY	Animal population category	Prefilled and non-editable
E	POP_MEASUREMENT	Animal population unit of measurement	Prefilled and non-editable
F	REFERENCE_DATA	Reference animal population data	Prefilled and non-editable
G	VALUE	Reported animal population data	Blank and editable
H	SOURCE	Source of reported animal population data	Blank and editable*
I	SOURCE_URL	Source URL of reported animal population data	Blank and editable*
J	JUSTIFICATION	Justification of reported animal population data	Blank and editable*

*Only when the reference and reported animal population figures in the VALUE field are different.

Table 7. Animal Population Data Template - Actions to be performed by users.

Variable	Required user action
VALUE	Users can choose to complete this field with: the value provided in the REFERENCE_DATA field (if available), if it is correct for their country and that reporting year. a different value from that provided in the REFERENCE_DATA field, if reference data are not available or do not meet data quality requirements. In these cases, users must provide data from another source (i.e. national statistics). This field has a 15-digit limit.
SOURCE	If users follow option A in the VALUE field, the SOURCE field can remain empty . If users follow option B , they must use the SOURCE field to indicate the source of the reported data (free text with limit of 255 characters).
SOURCE_URL	If users follow option A in the VALUE field, the SOURCE_URL field can remain empty. If users follow option B , they must use the SOURCE_URL field to indicate the URL of the source of the reported data . The URL must start with http:// or https://) and be no longer than 255 characters.

Variable	Required user action
JUSTIFICATION	<p>If users follow option A in the VALUE field, the JUSTIFICATION field can remain empty.</p> <p>If users follow option B, they must use the JUSTIFICATION field to explain why alternative data were provided (free text with limit of 255 characters).</p> <p>If the VALUE submitted is 0, users should clarify in this field whether this represents a genuine zero (meaning no animals of that category are produced in their country) or if the data are unavailable.</p>

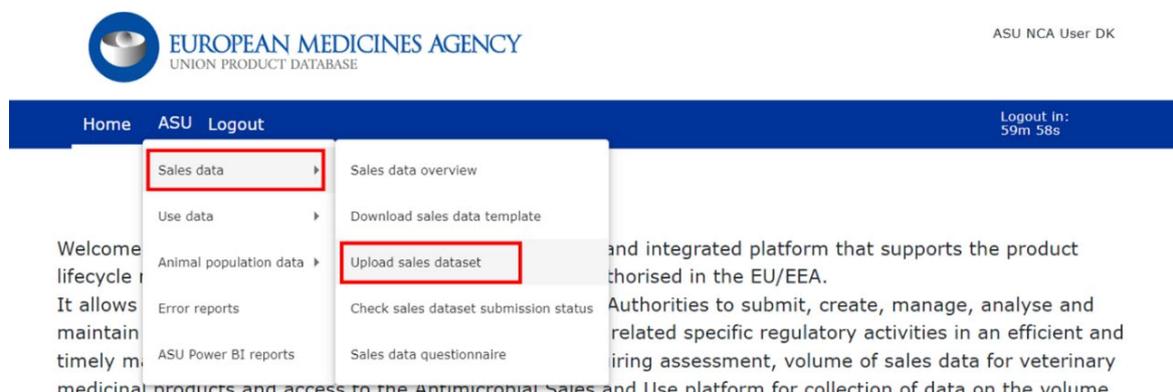
To prevent users from having to complete or update the same fields, **the ASU system automatically saves certain changes when an animal population template is successfully uploaded without generating an error report**. If the VALUE, SOURCE, SOURCE_URL or JUSTIFICATION fields have been completed in an animal population data template that has been uploaded to the system without generating an error validation report, when a user redownloads the animal population data template for the same year and country, the template will be prefilled with the previously uploaded values in each of these fields for each of the animal population categories.

5.4. Upload of datasets

To upload a dataset, users should:

1. Click on the ASU navigation menu item.
2. Expand one of the following submenu items, depending on the type of dataset they want to upload: *Sales data*, *Use data* or *Animal population data*.
3. Click on the relevant upload option for the selected dataset type: *Upload sales dataset* (see [Figure 11](#)), *Upload use dataset* or *Upload animal population dataset*.
4. On the corresponding *Upload Data File* page, select the dataset they wish to upload using the following dropdown menus (see [Figure 12](#)): **year**, **country** (only Admin users) and **animal species** (only for use dataset)¹².
5. Click on the *Select file* button and select a file from the file explorer.
6. Click on the *Upload* button to complete the process.

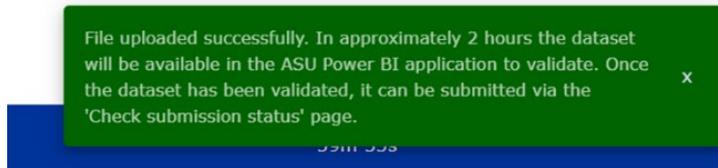
Figure 11. Navigation to the *Upload sales dataset* page



¹² The system allows users to upload use datasets for more than one use species simultaneously.

If the dataset is uploaded correctly without errors, the system displays a green notification message confirming the successful upload and informing that the dataset will be available to validate in the ASU Power BI application within the following two hours (see [Figure 12](#)).

Figure 12. Successful upload of a dataset toaster message



If the dataset contains errors and is not uploaded correctly, the system displays a red notification message that also contains a hyperlink to the generated error report (see [Figure 13](#)).

Figure 13. Unsuccessful upload of a dataset toaster message



5.5. Error reports page

When a dataset upload fails due to validation errors, the system automatically generates a report listing all the detected issues. This allows users to review and correct errors before attempting to re-upload the dataset to the ASU Platform. To access an error validation report users can either click on the hyperlink in the red notification message that appears when they try to upload the dataset (see [Figure 13](#)) or they can go to the *Error reports* page by:

1. Clicking the *ASU* navigation menu item.
2. Selecting the *Error reports* menu item.
3. Using the dropdown filters in the centre of the *Error reports* page to select the corresponding **year**, **country** (only Admin users) and **dataset type** (sales, use or animal population) (see the red box in [Figure 14](#)).
4. Clicking the *Search* button.
5. In the search results table below the filters, clicking on the *Error report* link for the dataset of interest (see the green box in [Figure 14](#)).

Figure 14. Error reports page

EUROPEAN MEDICINES AGENCY
UNION PRODUCT DATABASE

ASU_NCA User DK

Home ASU Logout Logout in: 59m 29s

Search for error reports

Select year *
2023

Select country
Denmark

Select Submission Typ...
Search

Country	Year	Rejected file	Submission date	Dataset type	Submitter	Error report
Denmark	2023	Sales Template - DK 2023 (1).csv	28/11/2024 09:17 (UTC)	Sales Data	ASU_NCA_User_DK	Error report
Denmark	2023	Sales Template - DK 2023 (1).csv	13/11/2024 16:46 (UTC)	Sales Data	ASU_NCA_User_DK	Error report

Once users open an error report, they will see a table listing the errors found in the uploaded dataset. The table includes the following columns:

- ID: error ID.
- Row with error: row number in the dataset csv file that contains the error.
- Error description: type of error detected.
- Submitted value: value entered by users.
- Prefilled value: value originally prefilled by the system (if applicable).
- Column(s): column in the dataset csv file that contains the error.

If there are blocking errors in the dataset (e.g. wrong format, empty file, missing or incorrect headers), the system will not verify the remaining content. Non-blocking errors will be listed in order of appearance in the error report without any specific hierarchy. If more than 20 validation errors are detected, an error report will not be generated and users will be asked to download the prefilled template again. A list of the validation errors the ASU system checks can be found in [Annex 5](#). Users can print or save the error report as a PDF by clicking the *Print* button in the top right corner. To return to the general *Error report* page, users should click the *Back* button next to the *Print* button (see [Figure 15](#)).

Figure 15. Error validation report example.

ASU NCA User DK

Home ASU Logout Logout In: 57m 26s

Print Back

Validated file: Sales Template - DK 2023.csv
Total errors reported: 898

Date: 28/11/2024 09:17:25 (UTC)
Year: 2023
Country: Denmark

The uploaded file contains more than 20 errors, it is strongly suggested to download a new version of the prefilled template and resubmit your sales data.

Guidelines: The sales data validation execution is prioritized according to business rule applicability. This means that generic rules (e.g. file format and secure) are executed first and in case of an error the validation process is terminated. User has to correct the reported errors (e.g. align submitted file headers with those of the downloaded sales template) and try again. Then the data quality validations are performed. If any error(s) are identified then they will be listed on the following area.

ID	Row with error	Error Description	Submitted Value	Prefilled Value	Column(s)
1	0	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 from the template. If there are no sales, please indicate '0' (zero) in the number of packs sold field.			
2	2	NO_PACKS cannot be empty. Please complete this information.			NO_PACKS(editable)
3	3	NO_PACKS cannot be empty. Please complete this information.			NO_PACKS(editable)
4	4	NO_PACKS cannot be empty. Please complete this information.			NO_PACKS(editable)

5.6. Validating uploaded datasets in the ASU Power BI application

After a dataset is successfully uploaded to the ASU Platform during an ASU data call, it may take up to two hours for the data to appear in the ASU Power BI application. This delay is due to the scheduled synchronisation between the two components, which varies depending on expected user activity¹³. Users will not receive a notification informing them that their dataset is available for analysis in the ASU Power BI application, but they can check in Power BI when the data was last refreshed.

Users can access the ASU Power BI application by using:

- The *ASU Power BI reports* item in the main *ASU* menu.
- The link provided in the *Useful links* area of the different *Data overview* pages.
- The link available in the pop-up message that appears when users submit a dataset for the first time (see [Figure 12](#)).

For more information on the ASU Power BI Data Validation reports, please refer to the [Antimicrobial Sales and Use \(ASU\) Power BI Application - User guide for National Competent Authority users](#).

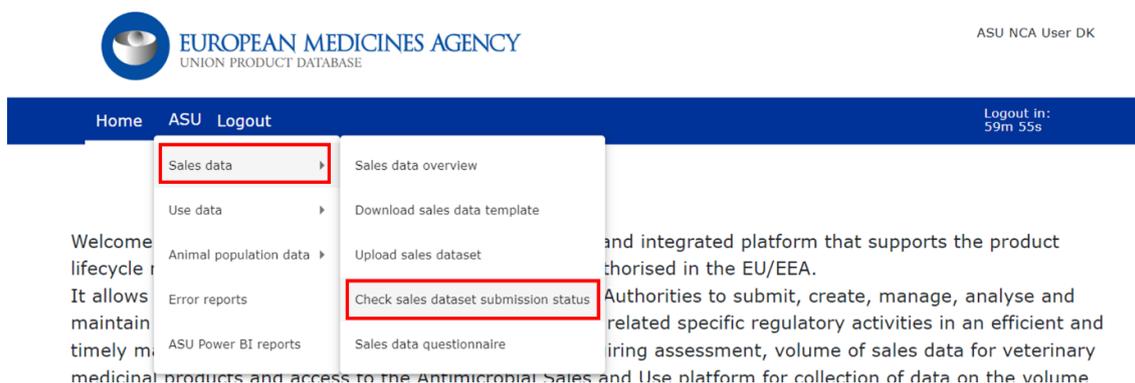
5.7. Submit data

After users successfully upload and validate their dataset in the ASU Power BI application, they must navigate to the *Check dataset submission status* page of each type of data and submit their dataset. To navigate to this page, users should:

- Click on the *ASU* navigation menu item.
- Expand on of the following submenu items, depending on the type of dataset they wish to submit: *Sales data*, *Use data* or *Animal population data*.
- Click on the relevant option for the selected data type: *Check sales dataset submission status* (see [Figure 16](#)), *Check use dataset submission status* or *Check animal population dataset submission status*.

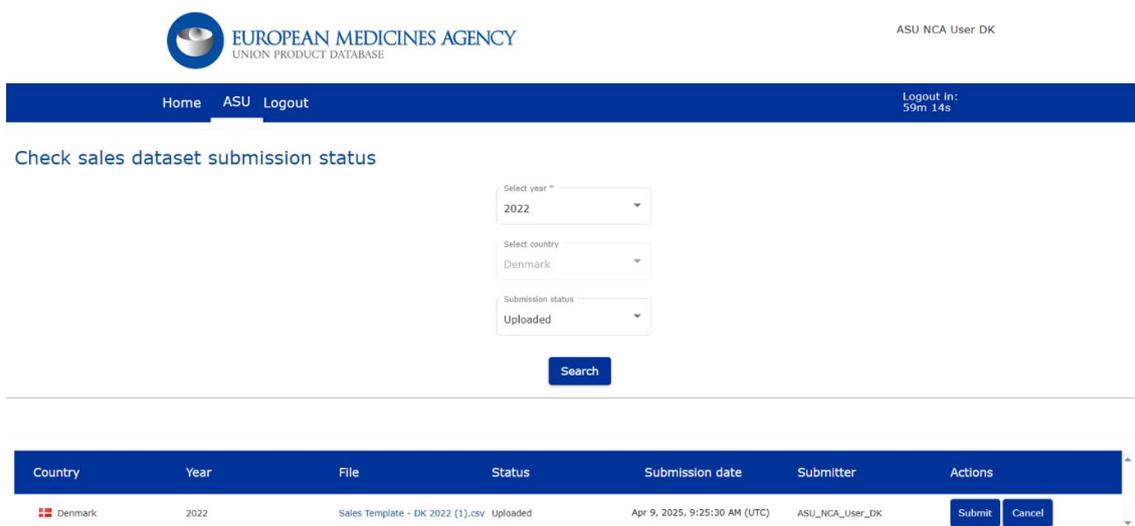
¹³ Data are refreshed in the ASU the Power BI application from 7am to 7pm CET from Monday to Friday every hour (June), every two hours (March, April, May, July, August and September) or every four hours (the remaining months of the year).

Figure 16. Navigation to the *Check sales dataset submission status* page



4. Once users are on the *Check data submission status* page, they can find the dataset they wish to submit by selecting the **year**, **country** (admin users only) and **submission status** (optional).
5. Search for the dataset of interest in the *Search results* table that will appear below the filters and click the *Submit* button next to the dataset with the status *Uploaded* that they wish to submit (see [Figure 17](#)).

Figure 17. *Check sales dataset submission status* page.



6. The system will then display a pop-up message for users to confirm that the dataset has been validated in the ASU Power BI application and that it meets the data quality requirements (see [Figure 18](#)). Users can choose to click:
 - a) The *Power BI* button if they wish to go back to the ASU Power BI application to further validate their data.
 - b) The *Submit* button if they wish to proceed with their dataset submission. This button will only be enabled once users click the checkbox next to the confirmation message.
 - c) The *Close* button if they wish to cancel the submission process.

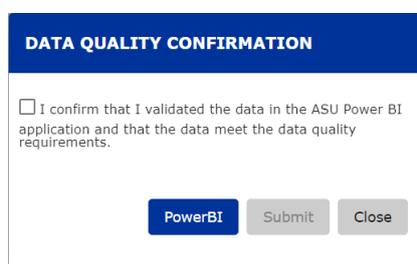
If users upload and submit a second dataset for the same year, country and animal species (use data only) for which there is already a dataset with *Submitted* status, the previously submitted dataset will automatically be cancelled by the system and its status will be changed to *Cancelled*. Users can also cancel previously uploaded, submitted or approved for publication datasets by clicking on the *Cancel*

button in the corresponding row of the *Submission Status Search Results* table. Only Admin users can cancel published datasets.

Once a template has been uploaded to the ASU Platform, it can be downloaded at any time from the corresponding *Check dataset submission status* page. If in future data calls a user needs to correct data submitted in previous years, the corresponding published dataset should be cancelled by the Admin user and the NCA user can redownload the template for the year of interest, make the necessary corrections and resubmit the dataset, following the same validation process as when the dataset was submitted for the first time.

Whenever a dataset's status changes, the *Date* column in the *Submission Status Search Results* table is automatically updated to show the exact time and date of the change. All timestamps on the ASU Platform are displayed in Coordinated Universal Time (UTC) to prevent any confusion between different time zones.

Figure 18. Data quality requirements checkbox



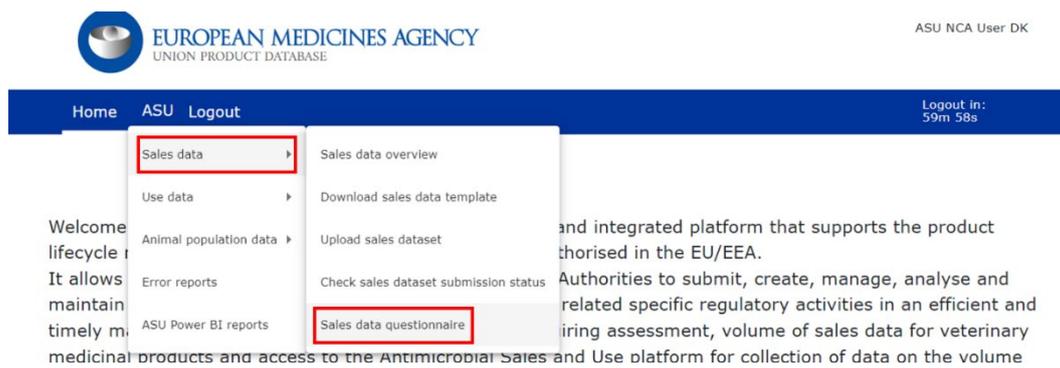
5.8. Questionnaires

In addition to submitting sales, use and animal population data, NCA users must also complete questionnaires for each data type. Questionnaires are prepared by Admin users before a data call is opened. Questionnaire submission is independent from dataset submission, so NCA users can work on their responses and save their progress, before submitting the final questionnaire at any time during the data call.

To access and complete an ASU questionnaire, users should:

1. Click the *ASU* navigation menu item.
2. Expand one of the following submenu items, depending on the type of data for which a user wishes to submit their questionnaire response: *Sales data*, *Use data* or *Animal population data*.
3. Click on the relevant option, based on the selected data type: *Sales data questionnaire* (see [Figure 19](#)), *Use data questionnaire* or *Animal population data questionnaire*.

Figure 19. Navigation to *Sales data questionnaire* page



- Once on the corresponding *Data Questionnaire* page, select the year and country (Admin users only) for which they would like to retrieve a questionnaire (see [Figure 20](#)) and click on *Search*.

Figure 20. Select sales data questionnaire page.

EUROPEAN MEDICINES AGENCY
UNION PRODUCT DATABASE

ASU NCA User DK

Home ASU Logout Logout in: 59m 58s

Select sales data questionnaire

Select year *
2022

Select country
Denmark

Search

- The system will load the questionnaire which may contain the following types of questions (see [Figure 21](#)):
 - Free-text questions:** can be answered by entering the response into a free-text field with no character limit. To see their full answer, users can simply click and drag the bottom right corner of the response box to expand it.
 - Checkbox questions:** can be answered by selecting one or multiple checkboxes.
 - Radio button questions:** can be answered by selecting only one of the available radio buttons.
 - Matrix questions:** can be answered by selecting one option per matrix row.
- Once users have finished working on a questionnaire response, they can choose to click one of three buttons at the bottom of the page:
 - Save draft:** to save a draft version of the questionnaire response before submitting it. The next time they access the same questionnaire, the draft questionnaire response will be displayed and users will be able to continue editing it.
 - Submit response:** to submit the questionnaire, only enabled once all mandatory questions marked with a red asterisk (see [Figure 21](#)) have been answered. Once a questionnaire has been submitted, it can only be updated by Admin users.
 - Print:** to print or save their draft or submitted questionnaire response in PDF format (see [Figure 22](#)).

At the top left of each questionnaire, below the *Select sales data questionnaire* filters, the following details are shown (see [Figure 22](#)):

- A 'Questionnaire edited on' timestamp, which is updated every time a user saves a questionnaire draft or if an Admin updates a submitted questionnaire.
- The questionnaire status, shown as either DRAFT or FINAL.
- A 'Submitted on' timestamp, which appears when users submit questionnaire and is updated if an Admin user subsequently makes changes to the submitted questionnaire.
- Username of users who submitted the questionnaire. If an Admin user updates a submitted questionnaire, their name will replace the original submitter's username.

All timestamps on the ASU Platform are displayed in Coordinated Universal Time (UTC) to prevent any confusion between different time zones.

Figure 21. Example of a *Data collection questionnaire* with checkbox, free text and radio button questions, some with the red asterisk indicating that providing a response is mandatory.

2 - Data collection system

2.1 Data provider(s)*

- Marketing Authorisation Holders
- Feed mills
- Pharmacies
- Wholesalers
- Retailers
- Veterinarians

2.2 Country's national distribution system for veterinary medicinal products*

3 - Data quality

3.1 Please indicate if necessary actions have been taken or not to avoid double reporting of sales:*

Yes

No

Figure 22. *Sales data questionnaire* page

ASU NCA User DK

Home Search Create OPAD VNRA Notifications Upload Document ASU Logout Logout in: 59m 57s

Select sales data questionnaire

Select year *
2023

Select country *
Austria

Search

Submitted on 10/09/2024 09:10 (UTC).
Questionnaire edited on 10/09/2024 09:10 (UTC).
Questionnaire status: **FINAL**
Submitter: ASU_EMA_Admin_1

Print

Annex 1. Overview of ASU user roles

[Table 8](#) lists all the existing functionalities that users can perform in the ASU Platform depending on their user role.

Table 8. ASU user functionalities

Menu	Functionalities	NCA user	Admin user
Sales data	View <i>Sales data overview</i> page	✓	✓
	View <i>Download sales data template</i> page	✓	✓
	View <i>Upload sales dataset</i> page	✓	✓
	View <i>Check sales dataset submission status</i> page	✓	✓
	View <i>Sales data questionnaire</i> page	✓	✓
	Expand country dropdown in any page underneath the <i>Sales data</i> menu	✗	✓
	Expand year dropdown in any page underneath the <i>Sales data</i> menu	✓	✓
	Download Sales data template	✓	✓
	Upload Sales data template	✓	✓
	Extend Sales data template with veterinary antimicrobial medicinal products authorised in other MSs	✓	✓
	Download Sales dataset from <i>Check sales dataset submission status</i> page	✓	✓
	Submit a Sales dataset	✓	✓
	Approve a Sales dataset for publication	✗	✓
	Publish a Sales dataset	✗	✓
	Cancel an uploaded, submitted or approved for publication Sales dataset	✓	✓
	Cancel a published Sales dataset	✗	✓
	Save a Sales questionnaire as draft	✓	✓
	Submit a Sales questionnaire	✓	✓
	Edit a submitted Sales questionnaire	✗	✓
	Use Data	View <i>Use data overview</i> page	✓
View <i>Download use data template</i> page		✓	✓
View <i>Upload use dataset</i> page		✓	✓
View <i>Check use dataset submission status</i> page		✓	✓
View <i>Use data questionnaire</i> page		✓	✓
Expand country dropdown in any page underneath the <i>Use data</i> menu		✗	✓
Expand year dropdown in any page underneath the <i>Use data</i> menu		✓	✓

Menu	Functionalities	NCA user	Admin user
	Expand animal species dropdown under all pages under the <i>Use data</i> menu	✓	✓
	Download Use data template	✓	✓
	Upload Use data template	✓	✓
	Extend template with VMPs authorised in other MSs, VMPs authorised for other animal species or HMPs	✓	✓
	Download Use dataset from <i>Check use dataset submission status</i> page	✓	✓
	Submit a Use dataset	✓	✓
	Approve a Use dataset for publication	✗	✓
	Publish a Use dataset	✗	✓
	Cancel an uploaded, submitted or approved for publication Use dataset	✓	✓
	Cancel a published Use dataset	✗	✓
	Save a Use questionnaire as draft	✓	✓
	Submit a Use questionnaire	✓	✓
	Edit a submitted Use questionnaire	✗	✓
Animal Population Data (APD)	View <i>Animal population data overview</i> page	✓	✓
	View <i>Download animal population data template</i> page	✓	✓
	View <i>Upload animal population dataset</i> page	✓	✓
	View <i>Check animal population dataset submission status</i> page	✓	✓
	View <i>Animal population data questionnaire</i> page	✓	✓
	Expand country dropdown in any page underneath the <i>APD data</i> menu	✗	✓
	Expand year dropdown in any page underneath <i>APD data</i> menu	✓	✓
	Download APD template	✓	✓
	Upload APD template	✓	✓
	Download APD dataset from <i>Check APD dataset submission status</i> page	✓	✓
	Submit APD dataset	✓	✓
	Approve an APD dataset for publication	✗	✓
	Publish an APD dataset	✗	✓
	Cancel an uploaded, submitted or approved for publication APD dataset	✓	✓
	Cancel a published APD dataset	✗	✓
Save an APD questionnaire as draft	✓	✓	

Menu	Functionalities	NCA user	Admin user
	Submit an APD questionnaire	✓	✓
	Edit a submitted APD questionnaire	✗	✓
Error reports	View <i>Error reports</i> page	✓	✓
	Expand country dropdown	✗	✓
	Expand year dropdown	✓	✓
	Open an Error Report Page for a specific year, country and dataset	✓	✓
ASU Power BI reports	Open ASU-BI application	✓	✓
Admin menu	Data status overview	✗	✓
	Package synchronisation	✗	✓
	Animal population reference data	✗	✓
	Data call management	✗	✓
	New questionnaire template	✗	✓
	View questionnaire templates	✗	✓
	DDDvet and DCDvet values	✗	✓

Annex 2: Medicinal product data quality issue troubleshoot guide

[Table 9](#) lists the most common medicinal product data quality issues and tips on how to resolve them. Please note that if product data is updated in UPD (VMPs) or PMS (HMPs), the product must be resynchronised by an Admin user for the updates to appear in the ASU Platform.

Table 9. Common medicinal product data quality issues and how to resolve them

ASU/UPD data quality issue	What to check
A product does not appear in the ASU sales and use templates.	<ol style="list-style-type: none"> 1. Is the product status current? 2. Does the ATCvet/ATC code fall within the ASU reporting scope? 3. Does the product have a valid marketing authorisation status or was it valid at least once in the past 5 years (including the year of the data call)? <p>The answer to all these questions must be yes for the product to appear in the ASU templates.</p>
The product appears in the templates but does not have any pack size or substance information.	<ol style="list-style-type: none"> 1. Has the package information been entered correctly? 2. Is the package information compatible with the strength information? (See the next point). 3. Is the strength a structured strength with numerator and denominator or is it a free text strength? (The latter is not accepted by ASU)
The product appears in the ASU templates, has pack size information but does not have substance or strength information.	<ol style="list-style-type: none"> 1. Is the strength unit compatible with the pack size unit? <ol style="list-style-type: none"> a. For VMPs with <u>presentation strength</u>, the pack size unit of measurement must be the same as the strength denominator unit of measurement. (E.g., Pack size = 100 tablets, strength = X mg per 1 tablet) b. For VMPs with <u>concentration strength</u>, the manufactured item quantity unit of measurement must be compatible with the strength denominator unit of measurement (both volume or mass units – e.g., millilitre(s) and millilitre(s), gram(s) and kilogram(s)). c. For VMPs with <u>more than one manufactured item</u> (e.g., powder and solvents for reconstitution), the active ingredients should only be linked to the relevant manufactured item (e.g., the powder for reconstitution)¹⁴. 2. Does the substance have a current SMS ID? 3. Is the substance mapped as an antimicrobial for ASU (only Admin users can check this)? 4. Is the ingredient linked to the package? 5. Is the strength a structured strength with numerator and denominator or is it a free text strength? (The latter is not accepted by ASU) <p>The answer to all these questions must be yes for the substance and strength information to appear in the ASU templates.</p>

¹⁴ Having active ingredients linked to the incorrect manufactured item (e.g., the solvent for reconstitution) can also cause incorrect substance/strength information to appear in the ASU templates. To correct this, the active ingredient should only be linked to the correct manufactured item.

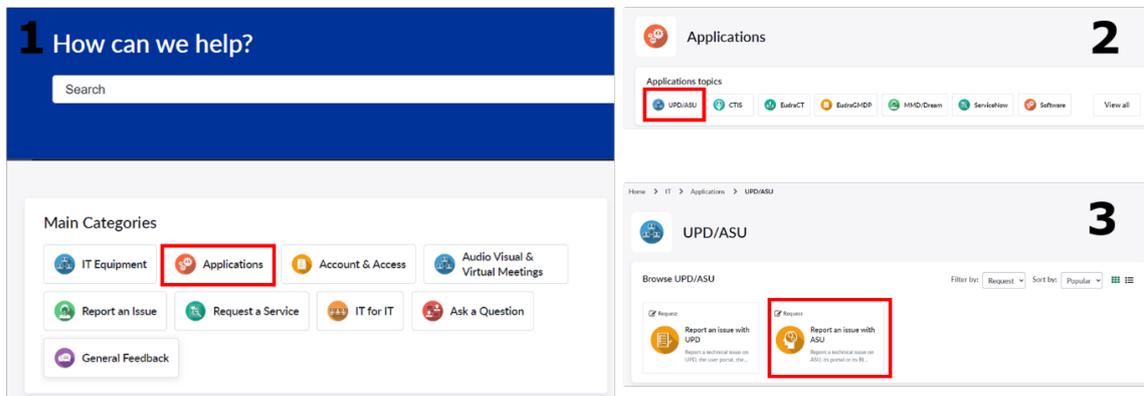
ASU/UPD data quality issue	What to check
The product appears in the ASU templates but an ingredient is missing.	<ol style="list-style-type: none"> 1. Has the ingredient been added to UPD? 2. Is the ingredient linked to the package? 3. Does the substance have a current SMS ID? 4. Is the substance mapped as an antimicrobial for ASU (only Admin users can check this)? <p>The answer to all these questions must be yes for all the ingredients to appear in the ASU templates.</p>
Updated UPD volume of sales (VoS) data does not appear in the ASU sales template	<ol style="list-style-type: none"> 1. Was the product information resynchronised after the latest VoS data was made available in UPD? 2. Was a template uploaded before the latest VoS data became available? (If yes, this will block the latest VoS data from appearing in the templates after a product resynchronisation and this cannot be undone).
In the ASU sales template, a product for non-food-producing animals has a 'N' in the COMPANION_ANIMALS field.	<ol style="list-style-type: none"> 1. Is there anything in the withdrawal period field in UPD? If so, it needs to be removed. 2. Was a N uploaded in this field for the previous reporting year? Change to a Y.
Substance information appears duplicated for the same product in the ASU templates	<ol style="list-style-type: none"> 1. Does the package have multiple manufactured items unnecessarily? If so, remove the extra ones and enter the package information correctly. 2. This can sometimes be caused by a backend issue open a ServiceNow ticket. <p>If the duplicated substance cannot be removed, this will not affect the analysis as it is automatically ignored in the ASU BI calculations.</p>
A product appears in the ASU sales template but not in the ASU use templates	Check that the product has the correct target species.
The ASU product form is incorrect	<p>Check that the UPD pharmaceutical form is correct.</p> <p>If a product's pharmaceutical form is updated in UPD and the product data is resynchronised in ASU, the corresponding product form is also updated in all the relevant ASU sales/use templates, including previously uploaded ones.</p>

Annex 3. How to submit a technical query on ASU via EMA ServiceNow

To report a technical issue or provide feedback on ASU Platform functionalities, users should open an EMA ServiceNow ticket using one of the following options in the *Main Categories* section of the [ServiceNow homepage](#):

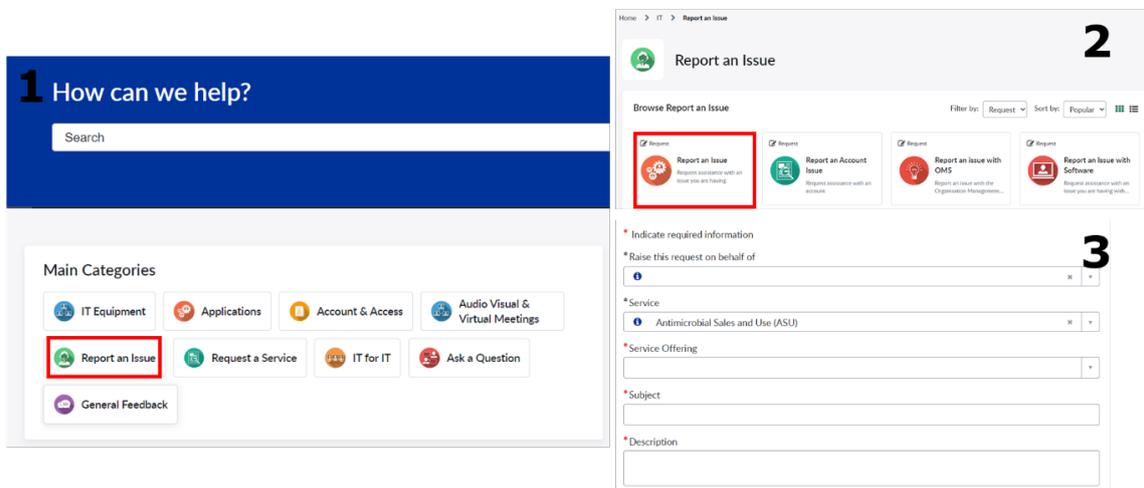
1. Applications (Figure 23 step 1):
 - 1.1. Within the *Applications* page, search for and click on the IT application *UPD/ASU* (Figure 23 step 2).
 - 1.2. Select to *Report an issue with ASU* (Figure 23 step 3).
 - 1.3. Complete the ticket (Figure 24 step 3) with a description of the issue, indicating the affected ASU Platform component (*ASU Portal* or the *ASU BI reports*) in the *Service Offering* dropdown menu.

Figure 23. Submit an ASU technical query on EMA ServiceNow via the *Applications* route



2. **Report an issue** (Figure 24 step 1):
 - 2.1. Within the *Report an issue* page, click on *Report an issue* (Figure 24 step 2).
 - 2.2. Complete the ticket (Figure 24 step 3) with a description of the issue, indicating the Service (select *Antimicrobial Sales and Use (ASU)*) and the affected ASU Platform component (*ASU Portal* or the *ASU BI reports*) in the *Service Offering* dropdown menu.

Figure 24. Submit an ASU technical query on EMA ServiceNow via the *Report an issue* route



Annex 4. ASU Visual User Guide summaries

Figure 25. Summary of NCA user tasks

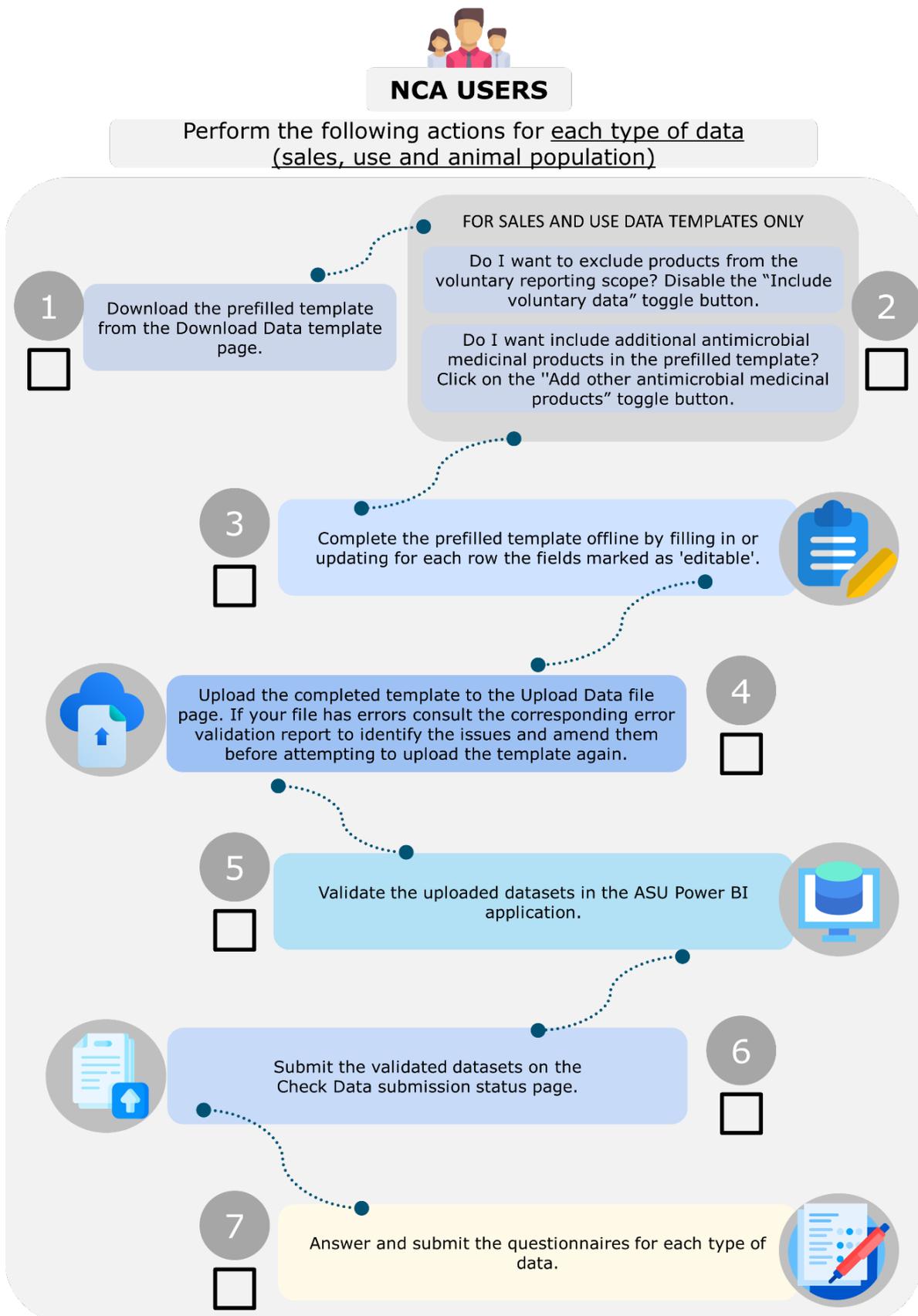


Figure 26. Summary of actions NCA users must perform on ASU sales template

RULES TO COMPLETE THE ASU SALES DATA TEMPLATE

REF_NUMBER  Can be used to provide an alternative ID for the VMP (e.g., the national ID). It can also be left empty.

ARTICLE_116  **If the VMP was added through the extend template functionality, add:**

- "Y" → if the VMP was allowed for use under Article 116 of Regulation (EU) 2019/6.
- "N" → if the VMP was authorised for use under a different legislative framework.

FORM  **If FORM= ORAL POWD:**

- Keep "ORAL POWD" → if VMP is administered only in feed or in either feed or water.
- Change to "ORAL SOLU" → if VMP is administered only in water, milk or milk replacer.
- Change to "PREMIX" → if VMP is authorised for use only in finfish.

If FORM= INTRAMAM:

- Change to "INTRAMAM-LC" → if VMP is indicated only for lactating animals or if it is indicated for both lactating and drying-off animals
- Change to "INTRAMAM-DO" → if VMP is indicated only for drying-off animals.

COMPANION_ANIMALS  **If COMPANION_ANIMALS = Y:**

- Keep "Y" → if the VMP is authorised for other animals bred and kept (companion animals and fur animals).
- Change to "N" → if the VMP is also authorised for use in food-producing species, including all horses.

NO_PACKS  Indicate the number of packages sold per VMP using **zero or positive values***

- **For VMPs in MANDATORY SCOPE:** it is mandatory to report sales. If there were no sales, report '0' (zero).
- **For VMPs in VOLUNTARY SCOPE:** it is optional to report sales. If there were no sales, report '0' (zero) or delete the corresponding row from the sales template.
- **For all VMPs:** correct/complete the number of packages sold with intra-Community movements of VMPs, i.e., add sales of VMPs brought from other Member States and exclude sales of VMPs sent to other Member States.

* Decimals are accepted and a comma should be used as decimal separator
** 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 purposes only. These data also need to be corrected with intra-Community movements of VMPs. 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.

Figure 27. Summary of actions NCA users must perform on ASU use template

RULES TO COMPLETE THE ASU USE DATA TEMPLATES

REF_NUMBER



Can be used to provide an alternative ID for the VMP (e.g., the national ID). It can also be left empty.

FORM



If FORM= ORAL POWD:

- Keep "ORAL POWD" - if VMP is administered only in feed or in either feed or water.
- Change to "ORAL SOLU" - if VMP is administered only in water, milk or milk replacer.
- Change to "PREMIX" - if VMP is authorised for use only in finfish.

If FORM= INTRAMAM:

- Change to "INTRAMAM-LC" - if VMP is indicated only for lactating animals or if it is indicated for both lactating and drying-off animals
- Change to "INTRAMAM-DO" - if VMP is indicated only for drying-off animals.

LONG_ ACTING



If FORM = INJ:

- Add "LA" - if product has long-acting/prolonged-release dosage forms.*
- Leave blank - if product does not have long-acting/prolonged-release dosage forms.

* Long-acting/prolonged-release dosage forms are achieved through special formulation design and/or manufacturing method and show slower release times than those of conventional-release dosage forms administered via the same route. They do not include parenteral products that have a naturally long half-life without the need of a special formulation design and/or manufacturing method.

NO_PACKS



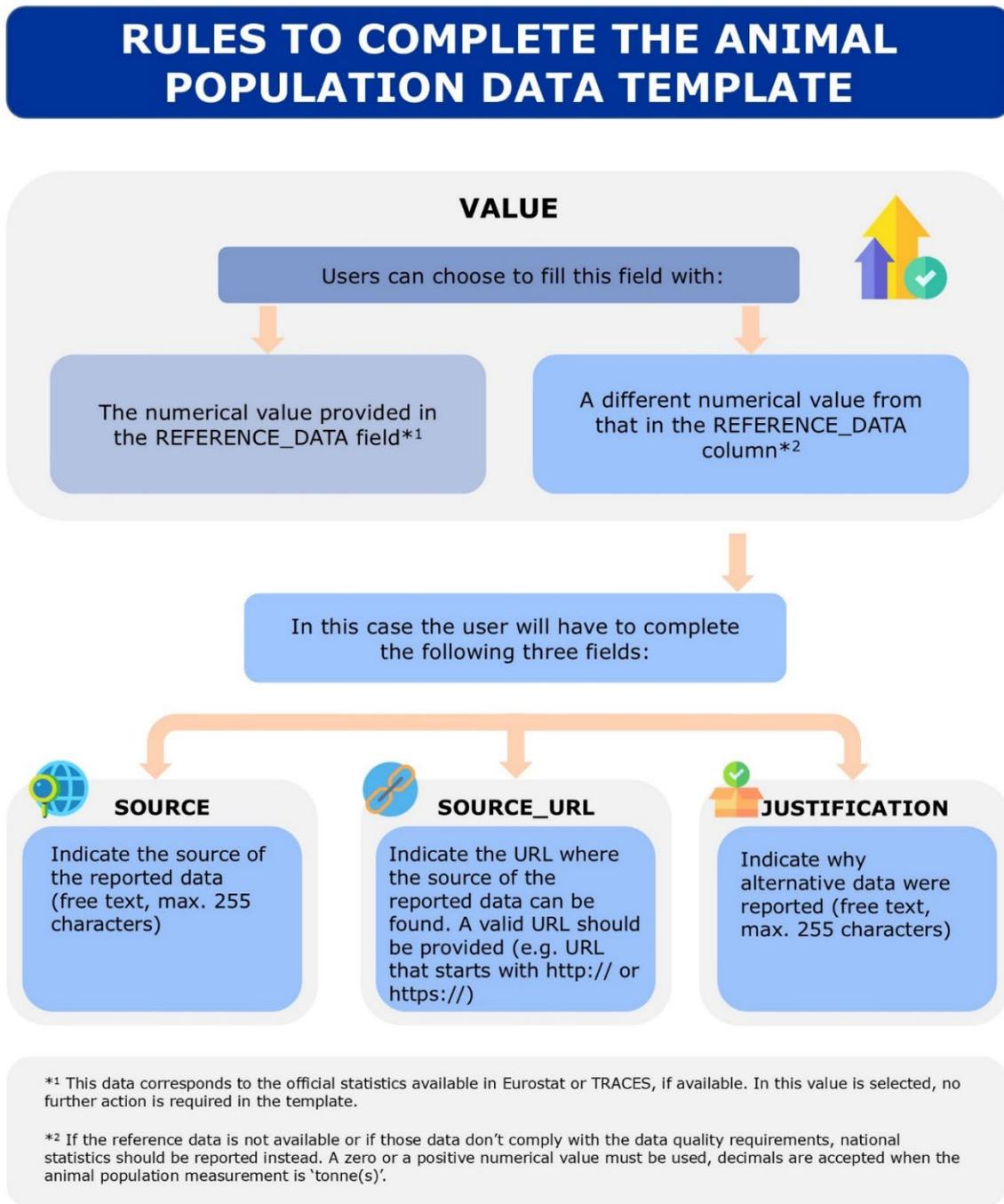
Indicate the number of packages used per product presentation and per animal category using **zero or positive values***

- **For VMPs and HMPs in MANDATORY SCOPE:** it is mandatory to report use. If there was no use, report '0' (zero).
- **For VMPs and HMPs in VOLUNTARY SCOPE:** it is optional to report use. If there was no use, report '0' (zero) or delete the corresponding row from the use template.
- The **number of packages** used per VMP and HMPs presentation must be reported separately for each animal category within each animal species, by indicating the number of packages used in the respective column.**

*Decimals are accepted and a comma should be used as decimal separator

**E.g. for cattle the number of packages used need to reported in four different columns corresponding to beef cattle, beef cattle under one year of age (if applicable), dairy cattle and other cattle.

Figure 28. Summary of actions NCA users must perform on ASU animal population template



Annex 5. ASU Platform validation errors

[Table 10](#) lists all the validation errors that the ASU Platform searches for when a dataset is uploaded.

Table 10. ASU validation errors

Affected Template	Affected field	Error
All	All	The uploaded dataset has not been previously downloaded from the ASU Platform.
All	All	The file provided is empty.
All	All	The file format must be csv.
All	COUNTRY	COUNTRY does not match the one selected for file upload.
All	COUNTRY	COUNTRY cannot be empty.
All	YEAR	YEAR format is not as expected (YYYY).
All	YEAR	YEAR does not match the one selected for file upload.
All	YEAR	YEAR cannot be empty.
Animal Population	All	Rows cannot be deleted from the template.
Animal Population	All	The column headers of the uploaded dataset do not match those of the downloaded animal population template.
Animal Population	ANIMAL_SPECIES	ANIMAL_SPECIES cannot be manually modified.
Animal Population	POP_CATEGORY	POP_CATEGORY cannot be empty.
Animal Population	POP_CATEGORY	Population categories cannot be duplicated in the template.
Animal Population	POP_MEASUREMENT	POP_MEASUREMENT cannot be empty.
Animal Population	VALUE	VALUE cannot be empty. Please complete this information.
Animal Population	VALUE	VALUE can only be zero '0' or positive values (decimals are only accepted when POP_MEASUREMENT = 'tonnes').
Animal Population	VALUE	The Reported animal population value (VALUE(editable) column G) must not exceed 15 integer digits.
Animal Population	SOURCE	If a value different from that displayed in the REFERENCE_DATA field is reported in the VALUE field, please indicate the SOURCE of this value.
Animal Population	SOURCE	The value in the SOURCE column must not exceed 255 characters.
Animal Population	SOURCE_URL	If a value different from that displayed in the REFERENCE_DATA field is reported in the VALUE field, please indicate the SOURCE_URL of this value.
Animal Population	SOURCE_URL	The value in the SOURCE_URL column must not exceed 255 characters.
Animal Population	SOURCE_URL	Please provide a valid URL that starts with http:// or https://.
Animal Population	JUSTIFICATION	If a value different from that displayed in the REFERENCE_DATA field is reported, please indicate why in the JUSTIFICATION field.
Animal Population	JUSTIFICATION	The value in the JUSTIFICATION column must not exceed 255 characters

Affected Template	Affected field	Error
Animal Population	SOURCE, SOURCE_URL, JUSTIFICATION	If a value different from that displayed in the REFERENCE_DATA field is reported in the VALUE field, please indicate the SOURCE, SOURCE-URL and JUSTIFICATION of this value.
Sales and Use	All	Package identifiers cannot be duplicated. The same PERMANENT_ID cannot have duplicated PACKAGE_IDs.
Sales and Use	All	The column headers of the uploaded dataset do not match those of the downloaded sales/use template.
Sales and Use	All	Package identifier(s) or Permanent identifier(s) not previously present in the downloaded sales/use template cannot be added manually.
Sales and Use	REF_NUMBER	REF_NUMBER can only include letters, digits, dashes, underscores and it cannot be longer than 255 characters.
Sales and Use	FORM	FORM cannot be empty.
Sales and Use	FORM	Please note that the pre-filled template includes intramammary products. The FORM 'INTRAMAM' must be manually updated to 'INTRAMAM-LC' or 'INTRAMAM-DO' depending on whether the VMP is used for lactating or drying-off animals. If the VMP is intended for use in both, please update to 'INTRAMAM-LC'.
Sales and Use	FORM	The only alternative values allowed for 'ORAL POWD' are 'ORAL SOLU' or 'PREMIX'.
Sales and Use	FORM	FORM value cannot be changed. If there is an error, please contact the relevant NCA to correct the information in UPD.
Sales	All	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 from the template. If there are no sales, please indicate '0' (zero) in the number of packs sold field.
Sales	ARTICLE_116	ARTICLE_116 cannot be empty.
Sales	ARTICLE_116	The only allowed value for VMP presentations that appear prefilled in the sales template is 'N'. For those VMP presentations added by users via the extend template functionality, this field can only be updated to 'Y' if they were authorised for use under Article 116. If not, 'N' should remain in this field.
Sales	COMPANION ANIMALS	COMPANION_ANIMALS cannot be empty. Please enter 'Y' if the VMP is authorised for other animals bred or kept (companion animals and fur animals), otherwise enter 'N'.
Sales	COMPANION ANIMALS	When the VMP has a withdrawal period registered in UPD, the COMPANION_ANIMALS field is prefilled with 'N' and cannot be changed. If there is an error, please contact the relevant NCA to correct the information in UPD.
Sales	COMPANION ANIMALS	Please enter 'Y' if the VMP is authorised for companion animals only, otherwise enter 'N'.
Sales	NO_PACKS	NO_PACKS cannot be empty. Please complete this information.
Sales	NO_PACKS	NO_PACKS can only be zero or positive values (decimals are accepted).

Affected Template	Affected field	Error
Use	All	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 from the template. If there is no use to be reported, please indicate '0' (zero) in the number of packs used field.
Use	SPECIES	SPECIES cannot be empty.
Use	SPECIES	Animal species does not match the one selected for file upload.
Use	LA	Only 'LA' can be used to identify parenteral products with long-acting/ prolonged-release dosage forms (achieved through special formulation design and/or manufacturing method).
Use	LA	The identification of products with long-acting/ prolonged-release dosage forms is only applicable to parenteral products (form = INJ).
Use	NO_PACKS	NO_PACKS cannot be empty. Please complete this information.
Use	NO_PACKS	NO_PACKS can only be zero or positive values (decimals are accepted).