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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) 2019/6 [1], and related delegated [2] and implementing acts [3].

Each MS must appoint their own National Contact Point (NCP) and the Data Manager(s) (DMs) for liaison with the Agency with regards to the reporting of data, and who will be granted access to the ASU Platform as National Competent Authority User(s) ('NCA user'). Similarly, the Agency will nominate Administrators ('Admin user') to help run the ASU Platform and to assist the NCA users to report their data via the Platform.

The ASU Platform has two components: the web portal and the Microsoft Power BI application. The web portal is part of and is accessed via the Union Product Database (UPD). It enables NCA users to submit their data on sales and use of antimicrobials in animals and on animal population statistics by providing downloadable templates (in CSV format) prefilled with medicinal product package data from the UPD, and animal population data from Eurostat and TRACES. NCA users are expected to complete these templates with the necessary data and upload them to the ASU Platform. The Microsoft Power BI application is accessed through the ASU Platform web portal and allows users to validate and analyse their 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 of ASU Platform and their functionalities.

2. Request for access

Before accessing the ASU Platform for the first time, a NCA user will require an **EMA account** with which to request the 'UPD-ASU-NCA-User' role in the **EMA Account Management (EAM)** platform. To do so, the NCA user will need to complete the following steps:

1. Request an EMA account (if they do not have one already) by going to: <https://register.ema.europa.eu/identityiq/home.html> and selecting *Create an EMA account (Self-register)*. Please follow the instructions available here: <https://register.ema.europa.eu/identityiq/help/selfregister.html>.
2. Request the user role 'UPD-ASU-NCA-User':
 - a. Go to <https://register.ema.europa.eu/identityiq/home.html> and sign in with your EMA username and password.
 - b. Navigate to *Manage Access* → *Request Access* for organisation via the menu on the left.
 - c. Enter the search criteria for the organisation on whose behalf you are requesting access (e.g., national competent authority) and click *Next*.
 - d. Select your organisation: select one of the addresses returned by the search and click *Next*.
 - e. In case you cannot find your organisation from the list, send an email to asu.delivery@ema.europa.eu.

¹ EU and EEA countries.

- f. Select your role by typing ASU in the search field, tick the ASU Role 'UPD-ASU-NCA-User' and click *Next*.
 - g. Additional information: please attach the e-mail inviting you to use the ASU platform in PDF format, using the 'Drop here or browse' box and click *Next*.
 - h. Once your request has been submitted, you will have to wait until the corresponding Admin user approves it.
 - i. Once the Admin user has approved your request, you will receive a confirmation e-mail.
3. Go to the UPD portal (<https://upd-portal-prod.azurewebsites.net/updwebui/home>) and use your user credentials to access the ASU Platform.

3. Access to the ASU Platform and configuration settings

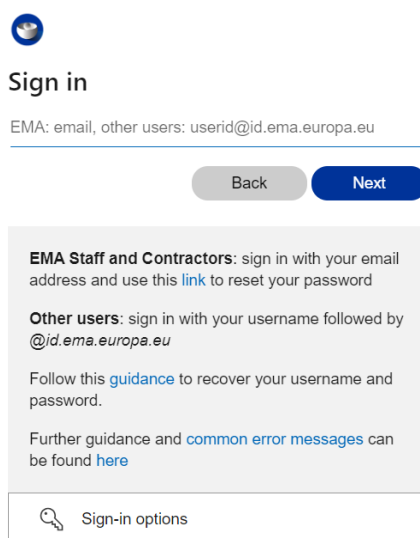
3.1. Log in and user rights

To access the ASU Platform, click on the 'Login' button on the UPD homepage (Figure 1) and fill in your user credentials (username and password) in the successive pop-up windows (Figure 2).

Figure 1. Login button



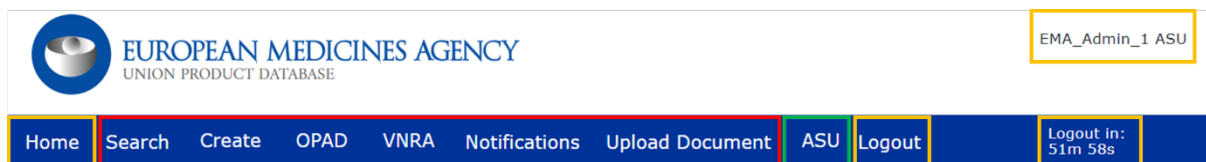
Figure 2. Sign in window



Once the user is successfully logged in, the navigation menu of the UPD web interface is updated and displays only the menu items to which the logged in user has access permission for. More specifically:

- All logged in users can see their username in the top righthand corner, the 'Home' button as the first item of the navigation menu to navigate to the home screen, the 'Logout' button to log out from the application and as the last element on the navigation menu a logout timer that indicates how much time is left before the user is automatically logged out by the system. (All these elements are indicated with orange boxes in Figure 3).
- Users with UPD roles and rights can navigate to the corresponding UPD menu items (indicated with the red box in Figure 3).
- Users with ASU roles and rights can navigate to the ASU menu item (indicated with the green box in Figure 3).
- Users with roles and rights both for ASU and UPD can navigate to both sets of menu items.

Figure 3. Navigation menu items per access rights



3.2. ASU roles

There are two types of user roles that can access the ASU Platform (Figure 4). This user guide will focus only on the ASU Platform functionalities for which the NCA user has access. Nevertheless, all the existing functionalities that users can perform and access depending on their role are listed in [Annex 1](#).

Figure 4. ASU Platform User roles

	Access	Responsibility
Admin Users	<p>Administration rights and access to all system page, including those that the NCA user can see as well as those that fall under the specific admin submenu item.</p> <p>View data from all Countries and select any country in any of the 'Country' dropdown menus of the ASU Platform.</p>	<p>Start and manage data calls.</p> <p>Asist NCA users to submit their data.</p> <p>Approve data for publication.</p> <p>Publish approved data.</p>
NCA Users	<p>Access to all the pages from the sales, use, animal population and Error reports sub-menu items of the ASU menu.</p> <p>Only view data from their own country, which is selected by default in all the 'Country'.</p>	<p>Submit data on sales and use of antimicrobial products in animals and on relevant animal population statistics for their country.</p>

3.3. Configuration

Before consulting the next chapters, please ensure that your windows settings are in line with the ASU Platform configuration with regards to semicolon and decimal points. The ASU system uses ';' (semicolon) as list separator and ',' (comma) as decimal symbol. If your windows system settings are different, you may encounter difficulties when uploading previously downloaded templates to the ASU Platform after completing them offline. To work with these settings, you need to follow the steps below:

1. Set the list separator as ';' on the Windows regional settings.
2. Set the decimal symbol as ','. This can be done on Windows regional settings (Windows level) or Excel advanced options (Excel level). In the Excel advanced options, you may indicate which settings should lead. The ones configured at Windows level or the ones configured at Excel level.

To set the list separator as ';' on Windows Regional Settings:

1. Go to Control Panel.
2. Click on Clock and Region.
3. Click on Region.
4. Click on Additional Settings.
5. Check that list separator is ';' (semi-colon).
6. If you want to set your decimal symbol at windows level, check the decimal symbol is ',' (comma).

To set the Decimal Symbol as ',' in Excel:

1. Open an empty excel file.
2. Go to File -> Options.
3. Click on Advanced.
4. If you want windows settings to overrule the excel settings, tick the check box *Use system separator*. Should you opt for this option, please consider the instructions on how to change your Windows settings in the previous section.
5. If you want excel settings to overrule the windows settings untick the check box 'Use system separator' and add ',' (comma) as decimal separator. Should you opt for this option, please skip the instructions on how to change your Windows settings in the previous section.

4. Use of the ASU Platform

4.1. Overview of the workflow

To comply with the legal obligations referred to in Article 57 of Regulation (EU) 2019/6 [1], NCA users are expected to submit the following datasets to the Agency via the ASU Platform:

- **Sales dataset:** containing data on the volume of sales of veterinary antimicrobial medicinal products. One sales dataset must be submitted per country and reporting year.
- **Use dataset:** containing data on the use of antimicrobial medicinal products in animals. One use dataset must be submitted per country and reporting year for each animal species. The reporting of use data per animal species and categories will follow the stepwise approach indicated in Article 15 of Commission Delegated Regulation (EU) 2021/578 [2].
- **Animal Population dataset:** containing data on relevant animal population statistics necessary for the analysis of antimicrobial sales and use data. One Animal Population dataset must be submitted per country and reporting year.

For each type of dataset, a prefilled template will be available to download from the ASU Platform. The Sales and Use templates will be prefilled with medicinal product package information available for each country, year and animal species (in the case of use data) in the UPD, and NCA users must indicate the number of packs sold/used of each medicinal package available in the template. The Animal Population dataset will be prefilled with animal population statistics from Eurostat or TRACES which the NCA user must confirm or update, if necessary.

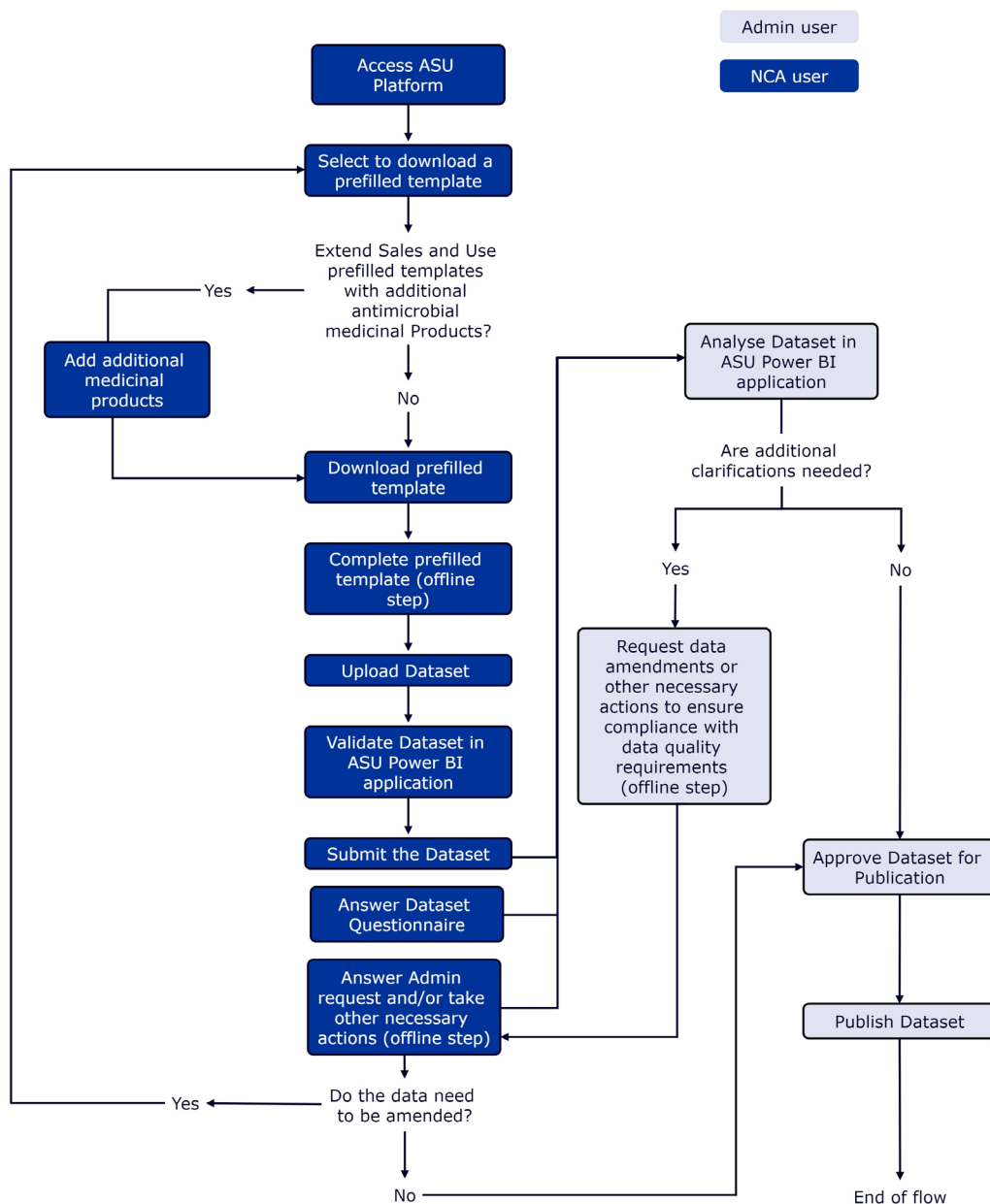
For each dataset type, the following actions are expected from the NCA user (Figure 5):

1. Download the prefilled template from the *Download data template* page available for each dataset type.
2. Complete the prefilled template offline.
3. Upload the completed dataset to the *Upload dataset* page available for each dataset type.
4. Validate the uploaded datasets in the ASU Power BI application.
5. Submit the validated datasets on the *Check dataset submission status* page available for each dataset type.

- Submit the corresponding data questionnaires available for each dataset type. The submission of questionnaires is not dependent on the submission of datasets.

Once the NCA user has completed their required actions, the Admin user will validate the reported data in the Power BI application. If data do not fulfil the data quality requirements listed in Article 6 of Commission Delegated Regulation (EU) 2021/578 [2], or further clarifications are needed, the Admin user will notify the NCA user via email. If the NCA user needs to amend a dataset, they can re-download it from the *Download data template* page and their previously submitted data will appear in the prefilled template. Once the datasets meet the necessary data quality requirements, the Admin user can change the status of the dataset from 'Submitted' to 'Approved for publication' and finally to 'Published' on the *Check dataset submission status* page.

Figure 5. ASU Platform workflow for data managers (NCA User) and EMA staff (Admin user)



4.2. Overview pages

For all three types of data, NCA users can monitor which of the expected actions are completed and which are pending. This is done through the *Data Overview* pages which are accessible by clicking on the *ASU* menu item, expanding the *Sales*, *Use* or *Animal Population Data* submenus and clicking on the *Sales data overview*, *Use data overview* or *Animal population data overview* items (Figure 6).

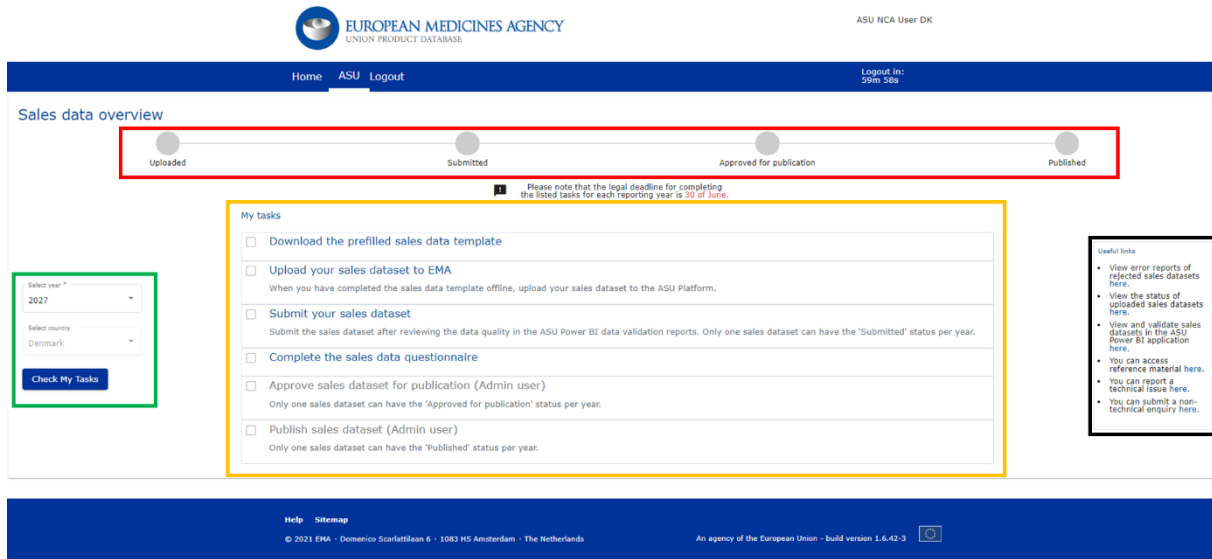
Figure 6. Navigation to *Sales data overview* page



The *Data overview* pages contain the following elements (Figure 7):

- a **progress bar** at the top which indicates the status of the data referred to in each overview page and which progresses from *Uploaded* to *Submitted* to *Approved for publication* to *Published*. (The progress bar is surrounded with a red box in Figure 7).
- a **My tasks list** which shows the actions that the user needs to perform for each type of data. The checkbox of each task is automatically updated by the system once each task is completed. The tasks include *Download the prefilled data template*, *Upload your dataset to EMA*, *Submit your dataset*, *Complete the data questionnaire*, *Approve dataset for publication* and *Publish dataset*. The NCA-user can perform all these tasks except for the last two, which can only be performed by the Admin user. The title of each task also serves as a hyperlink (by clicking on each list item) to the page where each action can be performed. (The *My tasks* list is surrounded with an orange box in Figure 7).
- On the left-hand side there are two **dropdown filters** where the users can select the reporting year and the country (only Admin users) for which they would like to see the data overview. Upon clicking the **Check My Tasks** button, the system will refresh the progress bar and tasks list. (The dropdown filters are surrounded with a green box in Figure 7).
- On the righthand side, there is a box containing **Useful links** to the [error reports](#) of datasets that have been rejected by the system during the upload process, to the [check dataset submission status](#) page, to the [ASU Power BI application](#) where datasets can be viewed and validated, to the [EMA ASU webpage](#) to access reference material (such as this user guide), to the [EMA Service Now page](#) to report a technical issue (to see how to do this please refer to [Annex 2](#)) and to the [Ask EMA page](#) to submit a non-technical enquiry. (The useful links box is surrounded with a black box in Figure 7).

Figure 7. Sales data overview page



4.3. Template download

To download a template, users should:

1. Click on the *ASU* navigation menu item.
2. Expand on one of the following submenu items, depending on the type of template they wish to download:
 - a. *Sales data*
 - b. *Use data*
 - c. *Animal population data*
3. Click on the following option, depending on the type of data selected:
 - a. *Download sales data template (Figure 8)*
 - b. *Download use data template*
 - c. *Download animal population data template*
4. On the selected *Download data template* page, the user can choose which template to download using the following dropdown menus:
 - a. Year
 - b. Country (only Admin users)
 - c. Animal species (only for use data templates)
5. Click the *Download template* button.

Figure 8. Navigation to the *Download sales data template* page

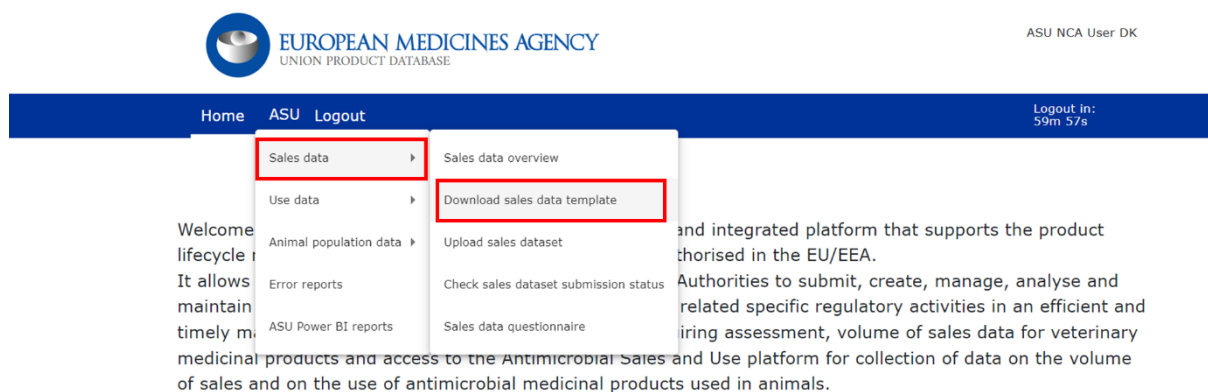
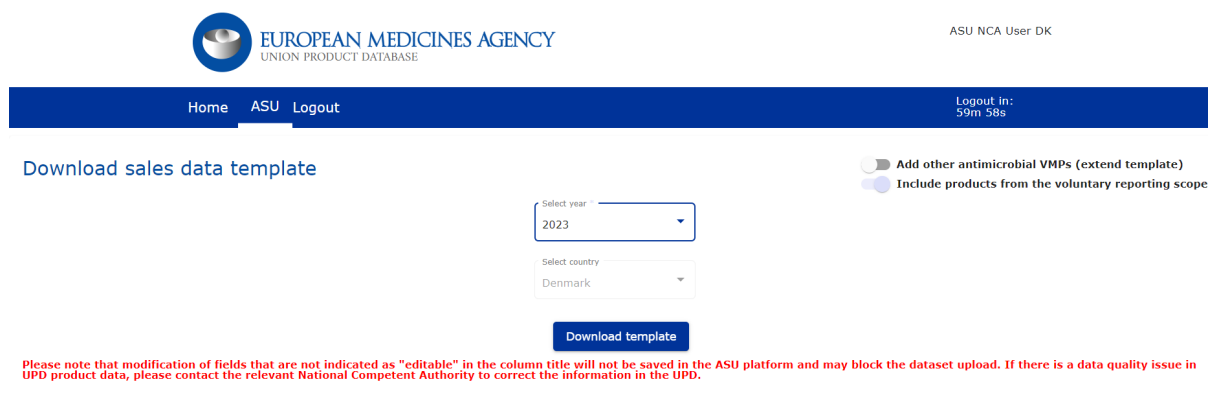


Figure 9. *Download sales data template* page.



4.3.1. Inclusion or exclusion of voluntary data

The inclusion or exclusion of voluntary data only applies to sales and use data templates. Antimicrobial medicinal products that fall under the mandatory scope, are the products for which sales and use data must be reported to the Agency based on product ATC code as per Articles 1 and 3 of the Delegated Regulation (EU) 2021/578 [2]. Antimicrobial medicinal products that fall under the voluntary scope, are the products for which sales and use data may be reported to the Agency based on product ATC code as per Articles 2 and 4 of the same regulation.

All sales and use data templates are automatically prefilled with products that fall under the mandatory reporting scope and users can choose whether to include or not products that fall under the voluntary scope by doing the following:

1. Go to the *Download sales/use data template* page.
2. Select the year, country (only Admin user) and animal species (only for use data templates) for which they would like to download a template.
3. Select to include or exclude products that fall under the voluntary scope by enabling or disabling the *Include products from the voluntary reporting scope* toggle button in the top right-hand corner of the page (see Figure 9). **The button is enabled by default.**
4. Proceed to download the template by clicking on the *Download template* button.

Please note that antimicrobial medicinal products within the mandatory scope cannot be deleted from the sales and use data templates, while those within the voluntary scope can be manually deleted from the templates without generating a validation error.

4.3.2. Extend templates with other antimicrobial medicinal products

The Sales and Use Data templates are prefilled only with antimicrobial veterinary medicinal products (VMPs) that are authorised in the Member State and for the animal species (in the case of use data) for which the user is downloading a template and which fall under the mandatory reporting scope. If the user wishes to report sales or use of antimicrobial VMPs authorised in another Member State as foreseen in Article 116 of Regulation (EU) 2019/6 [1] or the use of VMPs authorised in another animal species or of human antimicrobial medicinal products as foreseen in Articles 112-114 of the same regulation, then they will need to extend the sales and use data templates with additional products.

To add more products to the Sales and Use Data templates, the user should:

1. Go to the *Download sales/use data template* page.
2. Select the year, country (only Admin user) and animal species (only for use data templates) for which they would like to download a template.
3. Select the *Add other antimicrobial VMPs (extend template)* toggle button on the *Download sales data template* page (see Figure 9) or the *Add other antimicrobial VMPs or HMPs (extend template)* toggle button on the *Download use data template* page (see Figure 10).

Upon the selection of the toggle button, the users are redirected to a different page where they can search for other antimicrobial medicinal products using a series of filters. Users are expected to **use at least one filter** before searching for products, otherwise the *Search* button is disabled. The different filters and their characteristics described Table 1 and displayed in Figure 10.

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 search filter box is highlighted in red.

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 Extend use data template page.

Figure 10. Filters of the extend template page with the indication of the minimum number of characters per filter.

Once the user has selected at least one filter and clicked on the search button, the ASU system displays the search results in a table underneath the filters (see red box in Figure 11). For each product that matches with the selected search criteria, the following data are displayed: *Authorization country*, *Domain* (only for the Extend Use Data template page), *Procedure number*, *Permanent identifier*, *Package identifier*, *Medicinal product name*, *Pharmaceutical composition*, *ASU product form*, *ATC/ATCvet Code*, *Target species* and *Pack size description*.

Once the search results are displayed the user can:

1. Select all the products they wish to add to the sales or use data template by clicking on the checkbox in the first column.
2. Click on the *Add* button on the top right-hand side of the search results table.

The products the user has selected to add to the sales or use data templates will appear listed in a third table called *Selected products* table (see green box in Figure 11). This way the user can search for more products with different search criteria while keeping track of the products that have already been selected to be added to the templates.

If the user wishes to remove an added product from the *Selected products* table, they should click on the *Remove* button in the *Action* column on the far right-side of the table.

Once the user has finished adding medicinal products, they can proceed to download the updated sales or use data template by clicking on the *Download template* button below the *Selected products* table on the right-hand side.

If in the future, the user decides to re-download the sales or use data template for the same year, country and animal species (use data), the ASU system will warn them with 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?* The user has two options:

1. If the user clicks on the *Yes* button, they will be redirected to the extend template page with previously added products available in the *Selected products* table. From there they can choose whether to add new products, remove previously added products or directly download the template again.
2. If the user clicks on the *No* button, another pop-up message will appear warning them that: *The previously added products will be lost. Do you want to continue?*

- If the user clicks the *No* button again, they will be redirected to the *Download Sales/Use Data Template* page without any changes being made.
- If the user clicks the *Yes* button, a new sales or use data template will be generated without any of the previously added medicinal products.

Figure 11. Search results table (red box) and selected products table (green box) on extend template page.

The screenshot displays the ASU Platform interface. At the top, the European Medicines Agency logo and 'UNION PRODUCT DATABASE' are visible, along with the user 'ASU NCA User DK' and a 'Logout' button. The search criteria are set to 'Veterinary Products' and 'Sheep'. The search results table (highlighted in red) contains three entries for AT (Austria) in the Veterinary domain, all with procedure number 33 IP and pack size 999 Syringe. The selected products table (highlighted in green) shows two of these products selected, with a 'Download Template' button at the bottom right.

Search result	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
<input type="checkbox"/>	AT	Veterinary	33 IP	600000013363	d66e20f3-f976-49ce-a335-f84ec5c458fe			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe
<input type="checkbox"/>	AT	Veterinary	33 IP	600000013363	0e4c7926-3615-4056-8a7e-f162a203f666			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe
<input type="checkbox"/>	AT	Veterinary	33 IP	600000013363	e8f3bd34-bf82-4cdf-af08-8e46a37d5102			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe

Selected products	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
<input checked="" type="checkbox"/>	AT	Veterinary	33 IP	600000013363	d66e20f3-f976-49ce-a335-f84ec5c458fe			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe	<input type="checkbox"/>
<input checked="" type="checkbox"/>	AT	Veterinary	33 IP	600000013363	0e4c7926-3615-4056-8a7e-f162a203f666			ORAL SOLU	QJ01BA90	Cattle Sheep	999 Syringe	<input type="checkbox"/>

4.4. Content and completion of templates offline

Once the user has downloaded a data template from the ASU Platform, they should update or fill in all the fields indicated as being 'editable' in the column headers of the template offline before uploading it again to the ASU Platform. Instructions on how NCA users should complete/update the editable fields of the different ASU templates can be found in the following sections of this user guide and a visual summary can be found in [Annex 3](#). For further information on the contents of the ASU templates please refer to the ASU technical implementation protocol [4].

4.4.1. Sales Data template

Detailed information on the structure and on how to complete the prefilled sales data template is provided in the following tables.

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_IDENTIFIER	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)
I	ARTICLE_116(editable)	VMPs allowed for use under Article 116	Prefilled and partially editable
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	Blank 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 the user.

Variable	Required user action
REF_NUMBER	Field that can be used to provide an alternative or supplementary identifier for the different VMP presentations. It can also be left empty.
ARTICLE_116	<p>Prefilled as 'N' and non-editable for all VMPs authorised in the user's own country and which appear in the template by default.</p> <p>Blank and editable for all VMPs added through the extend template functionality during the generation of the template. The user should complete the field with:</p> <ul style="list-style-type: none"> a) 'Y' if the VMP was allowed for use under Article 116 of Regulation (EU) 2019/6. b) 'N' if the VMP was authorised for use in the NCA users' own country under another legislative framework.
FORM	<p>Non-editable for all product forms except:</p> <p>Oral powders - upon confirming the information in the relevant section of the SPC, the user should:</p> <ul style="list-style-type: none"> • Keep 'ORAL POWD' - if VMP is only to be administered in feed or if VMP is to be administered in either feed or water. • Change to 'ORAL SOLU' - if VMP is only to be administered in water, milk or milk replacer. • Change to 'PREMIX' - if VMP is authorised for use in finfish only. <p>Intramammary products – upon confirming the information in the relevant section of the SPC, the user should update the form INTRAMAM to:</p> <ul style="list-style-type: none"> • 'INTRAMAM-LC' - if VMP is indicated only for lactating animals or if it is indicated for both lactating and drying-off animals. • 'INTRAMAM-DO' - if VMP is indicated only for drying-off animals.
COMPANION_ANIMALS	<p>Prefilled as 'N' and non-editable for VMPs with a withdrawal period registered in the UPD and prefilled as 'Y' and editable for VMPs without a withdrawal period registered in the UPD.</p> <p>For VMPs <u>without</u> a withdrawal period registered in the UPD, upon confirming the information in the relevant section of the SPC, the user should:</p> <ul style="list-style-type: none"> • keep 'Y' if the VMP is only 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	<p>The number of packages sold per VMP presentation should be provided as zero or positive values (decimals are accepted and comma should be used as decimal separator) following these rules:</p> <ul style="list-style-type: none"> • VMPs that fall within the mandatory scope: it is mandatory to report sales. If there are no sales of these VMPs in the reporting year, the user should report '0' (zero).

Variable	Required user action
	<ul style="list-style-type: none"> VMPs that fall within the voluntary scope: it is optional to report sales. If there are no sales of these VMPs in the reporting year, the user can report '0' (zero) or directly delete the corresponding rows from the template. For both types of VMPs (mandatory and voluntary), the number of packages sold should be corrected and/or completed with Intra-Community movements of VMPs, i.e., with sales of antimicrobials brought from other MSs and excluding sales of antimicrobials sent to other MSs. The user should put in place measures to avoid double reporting, e.g., excluding sales between wholesalers nationally. <p>When a Marketing Authorisation Holder (MAH) has provided the volume of sales (VoS) for an antimicrobial VMP presentation in the UPD for that specific country and year, this value will appear in the prefilled template for reference only. MSs can choose to use MAHs as data providers or not. If not, the number of packages sold made available in the prefilled template can be disregarded and changed accordingly.</p>

After the user completes or updates the data in the editable fields REF_NUMBER, ARTICLE_116, FORM and COMPANION_ANIMALS for the first time and uploads them to the system without generating an error report, the changes made will persist in the database associated with the corresponding package identifiers and will appear in all the sales templates the user generates in the future that contain the same package identifiers. Please note that the REF_NUMBER provided for a product presentation will also appear in the use data templates that also contain that product presentation (or vice versa, whichever is dataset type is uploaded first).

With regards to the NO_PACKS data, 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 the previously reported values. If both VoS data from MAH in UPD and previously reported values by the user are available, then the previously reported values will override the VoS from the MAH.

4.4.2. Use Data template

The user shall download a use data template per use species. Detailed information on the structure and on how to complete the prefilled use data template is provided in the following tables.

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

1. Variable 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 the user.

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 can also be left empty.
FORM	Non-editable for all product forms except: Oral powders - upon confirming the information in the relevant section of the SPC, the user should: <ul style="list-style-type: none"> Keep 'ORAL POWD' - if VMP is only to be administered in feed or if VMP is to be administered in either feed or water.

Variable	Required user action
	<ul style="list-style-type: none"> Change to 'ORAL SOLU' - if VMP is only to be administered in water, milk or milk replacer. Change to 'PREMIX' - if VMP is authorised for use in finfish only. <p>Intramammary products – upon confirming the information in the relevant section of the SPC, the user should update the form INTRAMAM to:</p> <ul style="list-style-type: none"> 'INTRAMAM-LC' - if VMP is indicated only for lactating animals or if it is indicated for both lactating and drying-off animals. 'INTRAMAM-DO' - if VMP is indicated only for drying-off animals.
LONG_ACTING	<p>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.</p> <ul style="list-style-type: none"> 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. 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.
NO_PACKS	<p>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:</p> <ul style="list-style-type: none"> 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). 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) or directly delete the corresponding rows from the template. 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 report in four different columns corresponding to beef cattle, beef cattle under one year of age (if applicable), dairy cattle and other cattle.

After the user completes or updates the data in the editable fields 'REF_NUMBER", 'FORM" and 'LONG_ACTING" for the first time and uploads them to the system without generating an error report, the changes made will persist in the database associated with the corresponding package identifiers and will appear in all the use templates the user generates in the future that contain the same package

identifiers. Please note that the REF NUMBER provided for a product presentation will also appear in the sales data templates that also contain that product presentation.

With regards to the 'NO_PACKS' data, 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 reported values for each of the animal categories.

4.4.3. Animal Population Data template

Detailed information on the structure and on how to complete the prefilled animal population data template is provided in the following tables.

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

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

Variable	Required user action
VALUE	NCA users can choose to complete this field with: a) the value provided in the REFERENCE_DATA field (if available), if the NCA user confirms that it is correct for their country and that reporting year. b) a different value from that provided in the REFERENCE_DATA field, if reference data is not available or if those data do not comply with the data quality requirements, the NCA user is required to provide or amend such data from another source (i.e., national statistics).
SOURCE	If in the VALUE field the user has provided a different value to that of the REFERENCE_DATA column, the NCA user should use this field to indicate the source of the reported data (free text).
SOURCE_URL	If in the VALUE field the user has provided a different value to that of the REFERENCE_DATA column, the NCA user should use this field to indicate the

Variable	Required user action
	URL where the source of the reported data can be found. A valid URL should be provided (e.g. URL that starts with http:// or https://).
JUSTIFICATION	If in the VALUE field the user has provided a different value to that of the REFERENCE_DATA column, the NCA user should use this field to provide a justification as to why alternative data were provided (free text).

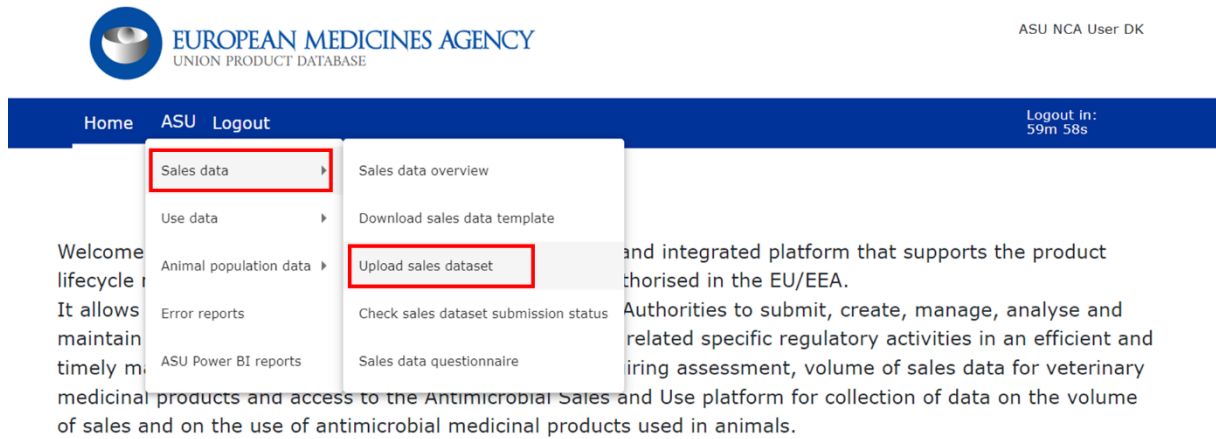
If the 'VALUE' field has been completed in an animal population data template that has been uploaded to the system without generating an error validation report, when a user redownloads the animal population data template for the same year and country, the template will be prefilled with the previously reported values for each of the animal population categories as well as the values reported in the SOURCE, SOURCE_URL and JUSTIFICATION fields, where applicable.

4.5. Upload of datasets

To upload a dataset, users should:

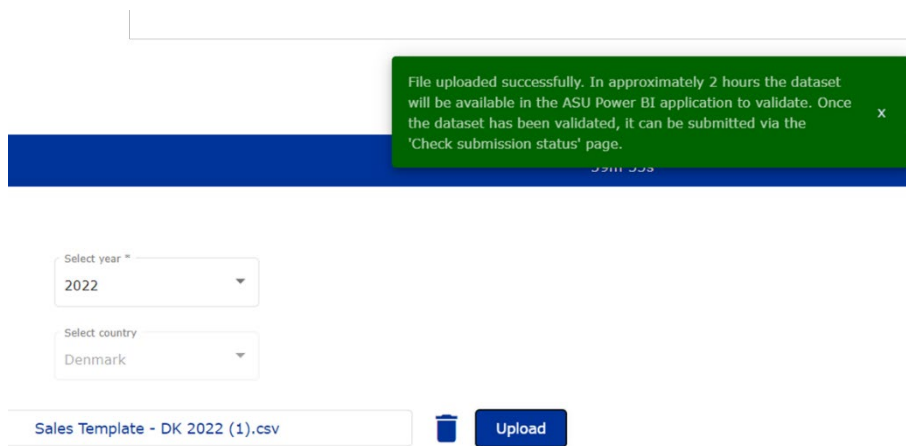
1. Click on the *ASU* navigation menu item.
2. Expand on one of the following submenu items, depending on the type of dataset they wish to upload:
 - a. *Sales data*
 - b. *Use data*
 - c. *Animal population data*
3. Click on the following options, based on the selected dataset type:
 - a. *Upload sales dataset (Figure 12)*
 - b. *Upload use dataset*
 - c. *Upload animal population dataset*
4. On the dedicated *Upload Data File* pages, select which dataset they wish to upload using the following dropdown menus (Figure 13):
 - a. Year
 - b. Country (only Admin users)
 - c. Animal Species (available only for the use dataset)
5. Click on the *select file* and select a file in the file explorer.
6. Click on the upload button.

Figure 12. Navigation to the *Upload sales dataset* page



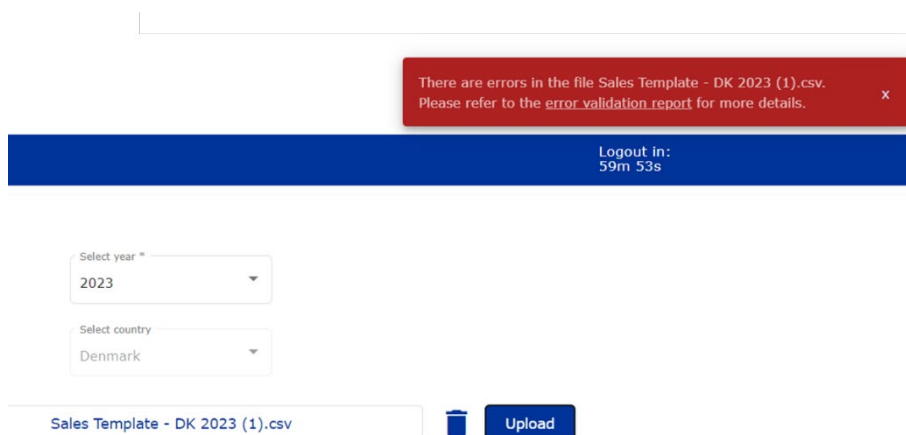
If the dataset is uploaded correctly without errors, the system informs the user accordingly with a green toaster message that also informs the user that the dataset will be available to validate in the ASU Power BI application within the following two hours (Figure 13).

Figure 13. Successful upload of a dataset toaster message



If the dataset contains errors and is not uploaded correctly, the system informs the user accordingly with a red toaster message that also contains a hyperlink to the corresponding error report (Figure 14).

Figure 14. Unsuccessful upload of a dataset toaster message



4.6. Error reports page

When a dataset is uploaded to the system but fails due to validation error(s), the system automatically generates a report to inform the user of which errors have been detected so that the user can correct them before attempting to re-upload the dataset to the ASU Platform.

To access the error validation reports the user should:

1. Click on the *ASU* navigation menu item.
2. Click on the *Error reports* menu item.
3. Select the corresponding year, country (only Admin user) and dataset type (sales, use or animal population) in the dropdown filters in the centre of the Error reports page (see the red box in Figure 15).
4. Click on the *Search* button.
5. Click on the *Error report* link in the search results table generated below the search filters (see the green box in Figure 15).

Figure 15. Error reports page

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	17/01/2024 15:46	Sales Data	ASU_NCA_User_DK	Error report
Denmark	2023	Sales Template - DK 2023 (1).csv	17/01/2024 15:44	Sales Data	ASU_NCA_User_DK	Error report

Once the user selects a particular Error report, they will see a table listing the errors found in the uploaded dataset. The table presents the following headers:

- ID: error ID.
- Row with error: number of the row in the template csv file that has the error.
- Error description
- Submitted value: value submitted by the user.
- Prefilled value: value originally prefilled by the system (if applicable).
- Column(s): column in the template csv file that has the error.

When there are blocker errors in the file, such as wrong format, empty file, different or missing headers, the system does not verify the remaining content. For all other type of errors,

no specific hierarchy exists, and all errors will appear in the error validation report. If there are more than twenty validation errors, the errors will not be displayed in the Error reports and the user will be requested to download the prefilled template again. Users have the option to print or to save in pdf format the generated error validation report by clicking on the *Print* button in the top righthand corner. Finally, users can return to the general Error report page by clicking on the *Back* button next to the *Print* button (see Figure 16).

A list of the validation errors the ASU system checks can be found in [Annex 4](#).

Figure 16. Error validation report example.

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)

4.7. Validation of datasets in Power BI

Once a user uploads a dataset to the ASU Platform, it can take up to two hours for it to appear in the ASU Power BI application. This is because data is synchronised and refreshed between the two systems every two hours. Users will not receive a notification informing them that their dataset is available for analysis in the ASU Power BI application, therefore they are advised to wait the maximum two hours before checking if their dataset is available.

Users can access the ASU Power BI application by using:

- a) The ASU Power BI reports item of the main ASU menu.
- b) The link available in the Useful links area of the different Data overview pages.
- c) The link available in the pop-up message that appears when NCA users submit a dataset for the first time (see Figure 19).

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 NCA users [\[5\]](#).

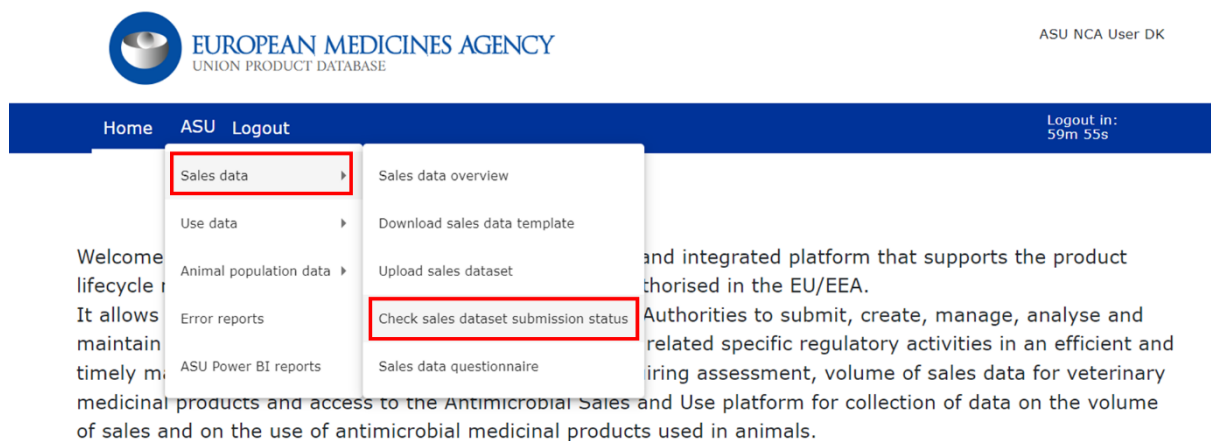
4.8. Submit data

Upon the successful upload of a dataset and its subsequent validation in Power BI, the users are expected to navigate to the *Check dataset submission status* page of each type of data and to submit their dataset. To navigate to the corresponding page, the NCA users should:

1. Click on the *ASU* navigation menu item.

2. Expand on of the following submenu items, depending on the type of data for which they wish to submit data:
 - a. *Sales data*
 - b. *Use data*
 - c. *Animal population data*
3. Click on the following options, based on the selected data type:
 - a. *Check sales dataset submission status (Figure 17)*
 - b. *Check use dataset submission status*
 - c. *Check animal population dataset submission status*

Figure 17. Navigation to the *Check sales dataset submission status* page



Once the NCA user reaches the *Check data submission status* page, they should do the following to submit their dataset:

1. Select year, country (only admin user) and (optionally) a submission status.
2. Search for the dataset of interest in the *Search results* table that will appear under the search filters.
3. Click on the *Submit* button next to the dataset they wish to submit that will have the status *Uploaded* (see Figure 18).
4. The system will then display a pop-up message for the user to confirm that the respective dataset has been validated in the ASU Power BI application and that it meets the data quality requirements (see Figure 19). The user can choose to click:
 - a. The *Power BI* button if they wish to be directed to the Power BI Validation reports to validate their data.
 - b. The *Submit* button if they wish to proceed to submit their dataset. This button will only be enabled once the user clicks on the checkbox next to the confirmation message.
 - c. The *Close* button if they wish to cancel the submission process.

Figure 18. Check sales dataset submission status page.

Country	Year	File	Status	Submission date	Submitter	Actions
Denmark	2022	Sales Template - DK 2022 (1).csv	Uploaded	Jan 17, 2024, 3:48:49 PM	ASU_NCA_User_DK	<button>Submit</button> <button>Cancel</button>

Figure 19. Data quality requirements checkbox

I confirm that I validated the data in the ASU Power BI application and that the data meet the data quality requirements.

PowerBI Submit Close

If the user uploads and submits 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 is automatically cancelled by the system and its status is changed to *Cancelled*.

NCA users can also choose to 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. In the future, should it be necessary 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.

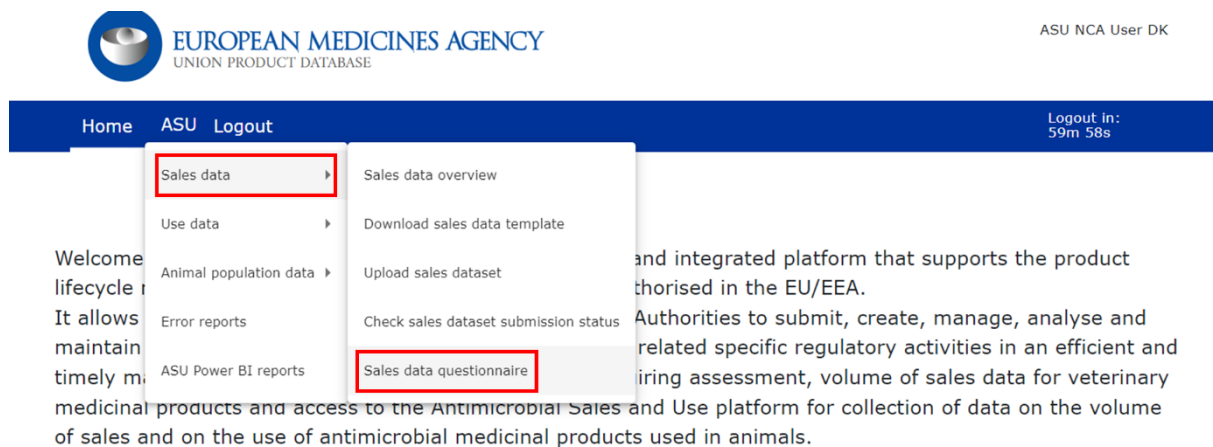
4.9. Provide answers to questionnaires

In addition to submitting sales, use and animal population data, NCA users also must respond to data questionnaires for each type of data. Data questionnaires are prepared by Admin users before a data call is opened based on the requirements laid out in the legislation. In the ASU Platform the submission of questionnaires is independent of the submission of datasets, therefore NCA users can submit their

responses to the different data questionnaires at any time during the data call. To respond to the different data questionnaires, NCA users should:

1. Click on the *ASU* navigation menu item.
2. Expand on of the following submenu items, depending on the type of data for which a user wishes to submit their questionnaire response:
 - a. *Sales data*
 - b. *Use data*
 - c. *Animal population data*
3. Click on the following options, based on the selected data type:
 - a. *Sales data questionnaire (Figure 20)*
 - b. *Use data questionnaire*
 - c. *Animal population data questionnaire*

Figure 20. Navigation to *Sales data questionnaire* page



Once on the corresponding *Data Questionnaire* page, to submit a response for the questionnaire the NCA user should:

1. Select the year and country (only Admin user) for which they would like to retrieve a questionnaire (Figure 21).
2. Click on the *Search* button.
3. The system will load the respective questionnaire which may contain the following types of questions (Figure 22):
 - a. Open text questions: which can be answered by writing in a free text field.
 - b. Checkbox questions: which can be answered by clicking on checkboxes. Multiple checkboxes can be selected for per question.
 - c. Radio button questions: which can be answered by clicking on radio buttons. Only one radio button can be selected per question.

- d. Matrix questions: which can be answered by selecting the elements of a matrix, only one option can be selected per row.

At least all mandatory questions should be answered. Mandatory questions are marked with a red asterisk.

- 4. Click on the *Submit response* button at the end of the page.

Before submitting a response to a data collection questionnaire, NCA users also have the option to save a draft version of the questionnaire response by clicking on the *Save draft* button at the bottom of the page. The next time they access the same questionnaire, the draft questionnaire will be displayed and NCA users will be able to see their saved responses and will be able to continue providing answers. Users will also have the possibility to print or save their questionnaire response in PDF format by using the *Print* button.

Figure 21. Sales data questionnaire page

The screenshot shows the top navigation bar of the European Medicines Agency (EMA) website. On the left, there is the EMA logo and the text "EUROPEAN MEDICINES AGENCY UNION PRODUCT DATABASE". On the right, it says "ASU NCA User DK". Below the navigation bar, there are links for "Home", "ASU", and "Logout". In the top right corner of the page, it says "Logout in: 59m 58s". The main content area is titled "Select sales data questionnaire". It contains two dropdown menus: "Select year" with "2022" selected, and "Select country" with "Denmark" selected. Below these menus is a blue "Search" button.

Figure 22. 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

3.2 If you have responded no to the previous question, please justify:*

References

1. Official Journal of the European Union, Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. 2019: <https://eur-lex.europa.eu/eli/reg/2019/6/oj>.
2. Official Journal of the European Union, Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals 2021: http://data.europa.eu/eli/reg_del/2021/578/oj.
3. Official Journal of the European Union, Commission Implementing Regulation (EU) 2022/209 of 16 February 2022 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. 2022: http://data.europa.eu/eli/reg_impl/2022/209/oj.
4. EMA, Antimicrobial Sales and Use (ASU) technical implementation protocol (EMA/27838/2024). 2024: <https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinary-medicine/antimicrobial-sales-and-use-platform#ema-inpage-item-38759>
5. EMA, Antimicrobial Sales and Use (ASU) Power BI Application User guide for National Competent Authorities (EMA/27837/2024). 2024: <https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinary-medicine/antimicrobial-sales-and-use-platform#ema-inpage-item-38759>

Annex 1. Overview of ASU user roles

Table 10 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	✓	✓
	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		✓	✓
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		✓	✓

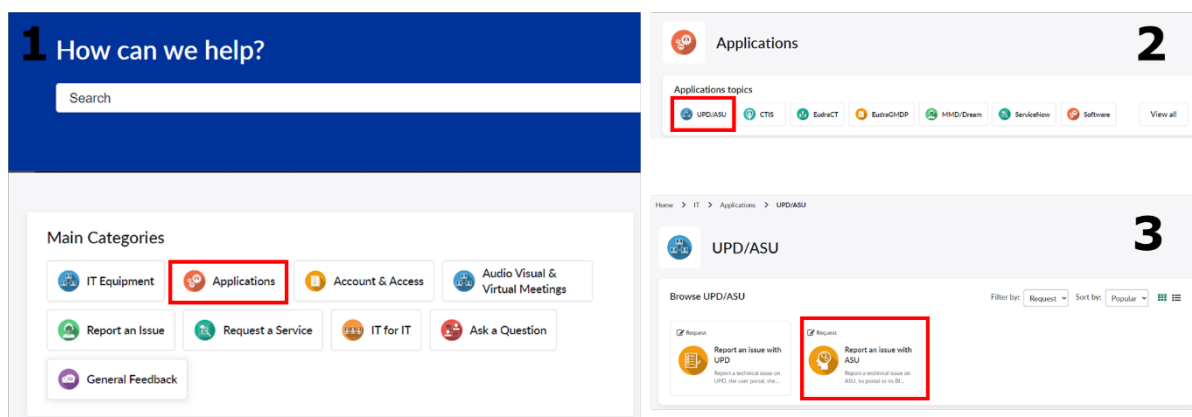
Menu	Functionalities	NCA user	Admin user
	Approve a Use dataset for publication	X	✓
	Publish a Use dataset	X	✓
	Cancel an uploaded, submitted or approved for publication Use dataset	✓	✓
	Cancel a published Use dataset	X	✓
	Save a Use questionnaire as draft	✓	✓
	Submit a Use questionnaire	✓	✓
Animal Population 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	X	✓
	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	X	✓
	Publish an APD dataset	X	✓
	Cancel an uploaded, submitted or approved for publication APD dataset	✓	✓
	Cancel a published APD dataset	X	✓
	Save an APD questionnaire as draft	✓	✓
	Submit an APD questionnaire	✓	✓
Error reports	View <i>Error reports</i> page	✓	✓
	Expand country dropdown	X	✓
	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	X	✓
	Package synchronisation	X	✓
	Upload TRACES data	X	✓
	Data call management	X	✓
	New questionnaire template	X	✓
	View questionnaire templates	X	✓
	DDDvet and DCDvet values	X	✓

Annex 2. How to submit a technical query on ASU via EMA ServiceNow

If the NCA user encounters a technical issue or would like to provide feedback on the functionalities of the ASU Platform, they should do so by opening a ticket on the EMA ServiceNow page (<https://support.ema.europa.eu/esc>). Users can do this by clicking on one of two different options available in the *Main Categories* section of the ServiceNow homepage:

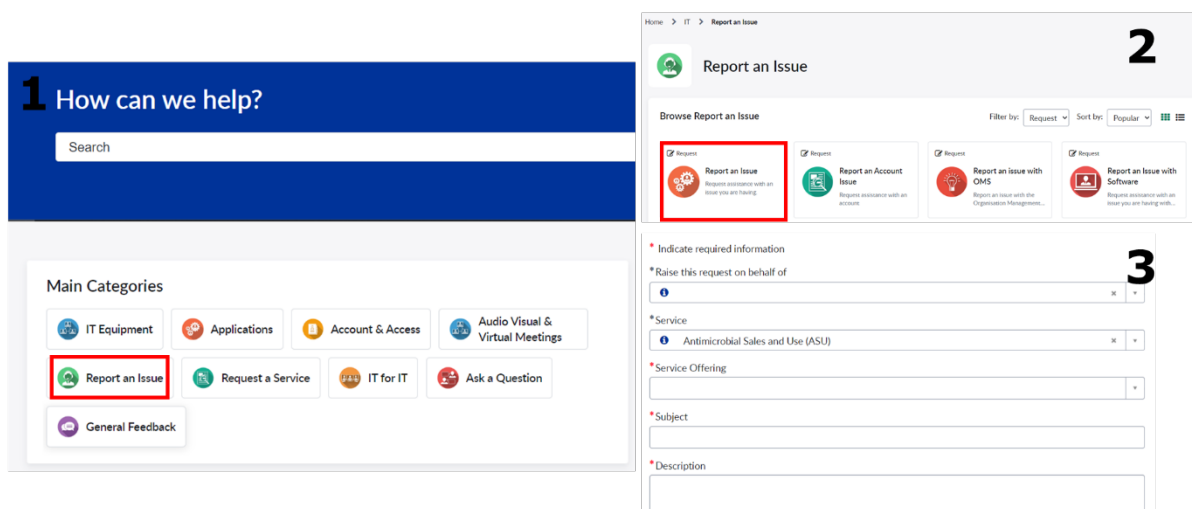
- (a) **Applications** (Figure 23 step 1):
- i) Within the *Applications* page, search for and click on the IT application *UPD/ASU* (Figure 23 step 2).
 - ii) Select to *Report an issue with ASU* (Figure 23 step 3).
 - iii) Complete the Service Now ticket with the subject of the issue, include a description and in the *Service Offering* dropdown menu indicate which is the affected component of the ASU Platform: the *ASU Portal* or the *ASU BI reports*.

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



- (b) **Report an issue** (Figure 24 step 1):
- i) Within the *Report an issue* page, click on *Report an issue* (Figure 24 step 2).
 - ii) Complete the Service Now ticket with the *Service of the issue* (please select *Antimicrobial Sales and Use (ASU)*), in the *Service Offering* dropdown menu indicate which is the affected component of the ASU Platform: the *ASU Portal* or the *ASU BI reports*, the subject of the issue and a description of the issue (Figure 24 step 3).

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



Annex 3. ASU Visual User Guide summaries

Figure 25. Summary of NCA user tasks

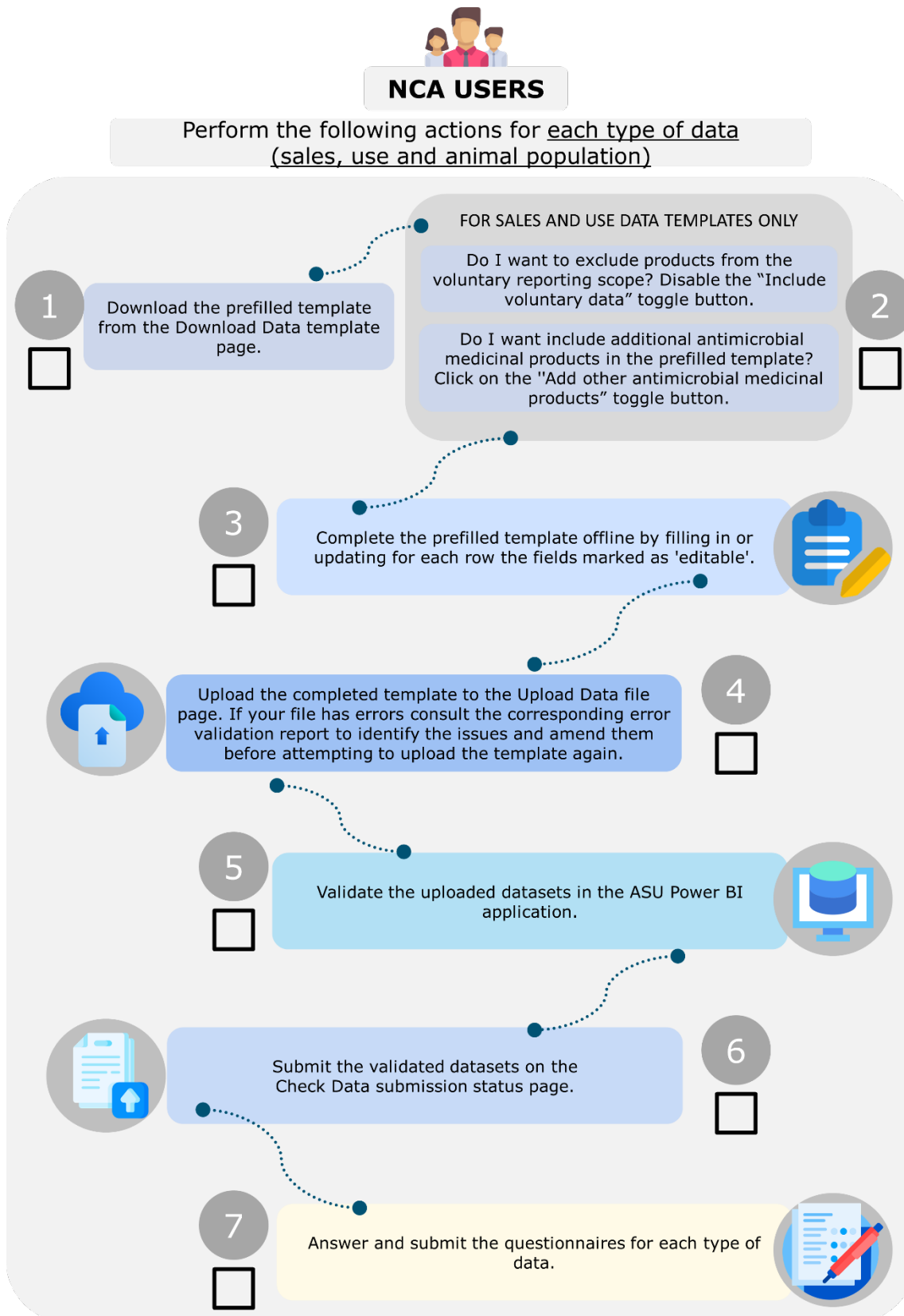




Figure 26. Summary of actions NCA users must perform on ASU sales template

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.

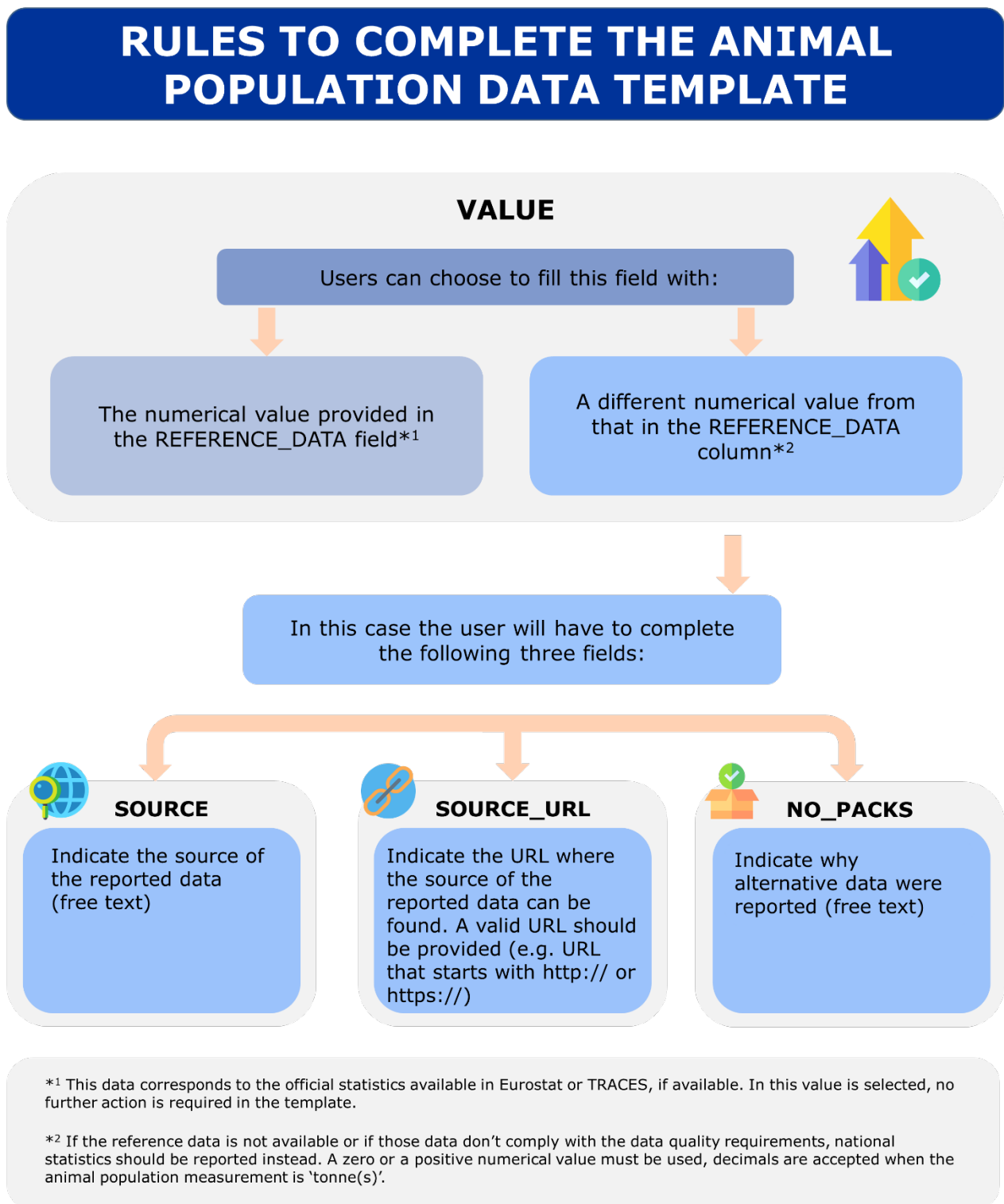
NO_PACKS 

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 4. ASU Platform validation errors

Table 9 lists all the validation errors that the ASU Platform detects when a dataset is uploaded and the error message that is displayed for each one.

Table 9. ASU validation errors

Affected Template(s)	Error name	Error	Affected field(s)
All	TEMPLATE_NOT_FOUND	The uploaded dataset has not been previously downloaded from the ASU Platform.	All
All	EMPTY_FILE	The file provided is empty.	All
All	INVALID_CSV_FORMAT	The file format must be csv.	All
All	COUNTRY_MISMATCH	COUNTRY does not match the one selected for file upload.	COUNTRY
All	COUNTRY_EMPTY	COUNTRY cannot be empty.	COUNTRY
All	YEAR_FORMAT	YEAR format is not as expected (YYYY).	YEAR
All	YEAR_MISMATCH	YEAR does not match the one selected for file upload.	YEAR
All	YEAR_EMPTY	YEAR cannot be empty.	YEAR
Animal Population	ANIMAL_POPULATION_HEADER_MISMATCH	The column headers of the uploaded dataset do not match those of the downloaded animal population template.	All
Animal Population	ANIMAL_POPULATION_USE_SPECIES_CATEGORY	ANIMAL_SPECIES cannot be manually modified.	ANIMAL_SPECIES
Animal Population	ANIMAL_POPULATION_INV_JUSTIFICATION	If a value different from that displayed in the REFERENCE_DATA field is reported, please indicate why in the JUSTIFICATION field.	JUSTIFICATION
Animal Population	CATEGORY_EMPTY	POP_CATEGORY cannot be empty.	POP_CATEGORY
Animal Population	ANIMAL_POPULATION_DUPL_CATEGORY_ID	Population categories cannot be duplicated in the template.	POP_CATEGORY
Animal Population	POP_MEASUREMENT_EMPTY	POP_MEASUREMENT cannot be empty.	POP_MEASUREMENT
Animal Population	ANIMAL_POPULATION_EXPECTED_COUNT	Rows cannot be deleted from the template.	Entire row
Animal Population	ANIMAL_POPULATION_INV_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.	SOURCE
Animal Population	ANIMAL_POPULATION_INV_SOURCE_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.	SOURCE, SOURCE_URL, JUSTIFICATION
Animal Population	ANIMAL_POPULATION_INV_URL	Please provide a valid URL that starts with http:// or https://.	SOURCE_URL

Affected Template(s)	Error name	Error	Affected field(s)
Animal Population	ANIMAL POPULATION_URL_NO_VALUE	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.	SOURCE_URL
Animal Population	ANIMAL POPULATION_INV_NO_VALUE	VALUE cannot be empty. Please complete this information.	VALUE
Animal Population	ANIMAL POPULATION_INV_VALUE	VALUE can only be zero '0' or positive values (decimals are only accepted when POP_MEASUREMENT = 'tonnes').	VALUE
Sales	HEADER_MISMATCH	The column headers of the uploaded dataset do not match those of the downloaded sales template.	All column headers
Sales	ARTICLE_116_EMPTY	ARTICLE_116 cannot be empty.	Article 116
Sales	ARTICLE_116_WRONG_VALUE	The only allowed value for VMP presentations that appear prefilled in the sales template is 'N'. For those VMP presentations added by the user 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.	Article 116
Sales	COMPANION_ANIMALS_EMPTY	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'.	COMPANION ANIMALS
Sales	COMPANION_ANIMALS_NO_CHANGED	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.	COMPANION ANIMALS
Sales	COMPANION_ANIMALS_WRONG_VALUE	Please enter 'Y' if the VMP is authorised for companion animals only, otherwise enter 'N'.	COMPANION ANIMALS
Sales	NO_PACKS_EMPTY	NO_PACKS cannot be empty. Please complete this information.	NO_PACKS
Sales	NO_PACKS_NEGATIVE	NO_PACKS can only be zero or positive values (decimals are accepted).	NO_PACKS
Sales	MANDATORY_SALES_MISSING	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.	Entire row
Sales	MISSING_SALES_PRODUCT	Package identifier(s) or Permanent identifier(s) not previously present in the downloaded sales template cannot be added manually.	Entire row (Permanent/Package ID)
Sales and Use	FORM_EMPTY	FORM cannot be empty.	FORM
Sales and Use	INTRAM_FORM_SUFFIX	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	FORM

Affected Template(s)	Error name	Error	Affected field(s)
		lactating or drying-off animals. If the VMP is intended for use in both, please update to 'INTRAMAM-LC'.	
Sales and Use	ORAL_POWD_ALT	The only alternative values allowed for 'ORAL POWD' are 'ORAL SOLU' or 'PREMIX'.	FORM
Sales and Use	DUPLICATE_PRODUCT_ID	Package identifiers cannot be duplicated. The same PERMANENT_ID cannot have duplicated PACKAGE_IDs.	Entire row
Sales and Use	REFERENCE_NUMBER_WRONG_FORMAT	REF_NUMBER can only include letters, digits, dashes, underscores and it cannot be longer than 255 characters.	REF_NUMBER
Use	HEADER_MISMATCH_USE	The column headers of the uploaded dataset do not match those of the downloaded use template.	All column headers
Use	LONG_ACTING	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).	LA
Use	LONG_ACTING_INJ	The identification of products with long-acting/ prolonged-release dosage forms is only applicable to parenteral products (form = INJ).	LA
Use	NO_PACKS_EMPTY_USE	NO_PACKS cannot be empty. Please complete this information.	NO_PACKS
Use	NO_PACKS_NEGATIVE_USE	NO_PACKS can only be zero or positive values (decimals are accepted).	NO_PACKS
Use	MANDATORY_USE_MISSING	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.	Entire row
Use	MISSING_USE_PRODUCT	Package identifier(s) or Permanent identifier(s) not previously present in the downloaded use template cannot be added manually.	Entire row (Permanent/Package ID)
Use	SPECIES_EMPTY	SPECIES cannot be empty.	SPECIES
Use	SPECIES_MISMATCH	Animal species does not match the one selected for file upload.	SPECIES