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Veterinary Pharmacovigilance EVVET - Data Warehouse user manual

Version 3.0

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Content

1. Introduction

1.1. About this User Manual

This user manual is prepared to support the use of the business intelligence tool EVVET Data Warehouse (DWH). The document is composed of the following chapters:

- **Chapter 2**: presents a login overview of DWH application and how to access the catalog.
- **Chapter 3:** presents the AER received over a period of time and Organisation dashboard.
- **Chapter 4:** presents the adverse event overview dashboard.
- **Chapter 5:** presents the signal detection dashboard.
- **Chapter 6:** presents the signal evaluation dashboard.
- **Chapter 7:** presents the adverse event comparison between 2 periods dashboard.
- **Chapter 8:** presents the data stratification dashboard.
- **Chapter 9:** presents the signalling for reactions linked to a product or ingredient dashboard.
- **Chapter 10:** presents the line listing dashboard.
- **Chapter 11:** presents the list of products dashboard.
- **Chapter 12:** presents the Pharmacovigilance inspections dashboard.
- **Chapter 13:** presents the Sales dashboard.
- **Chapter 14:** presents how to group data for different products.
- **Chapter 15:** provides an oversight of the different dashboards implemented
- **Chapter 16:** elaborates on KPI's and ROR calculation.

Therefore, the scope of this user manual is to provide detailed explanation on each of the reports that has been implemented and its behaviour.

2. EVVET Data Warehouse (DWH)

2.1. DWH Login

EVVET3 DWH is accessible by clicking on https://bi.ema.europa.eu and using any modern browser.

Users are required to log in using their email address (which can differ for each organisation) instead of an EMA username and password. It is important to note not to use userId with suffix "*@id.ema.europa.eu*" as EMA has deprecated access like this.

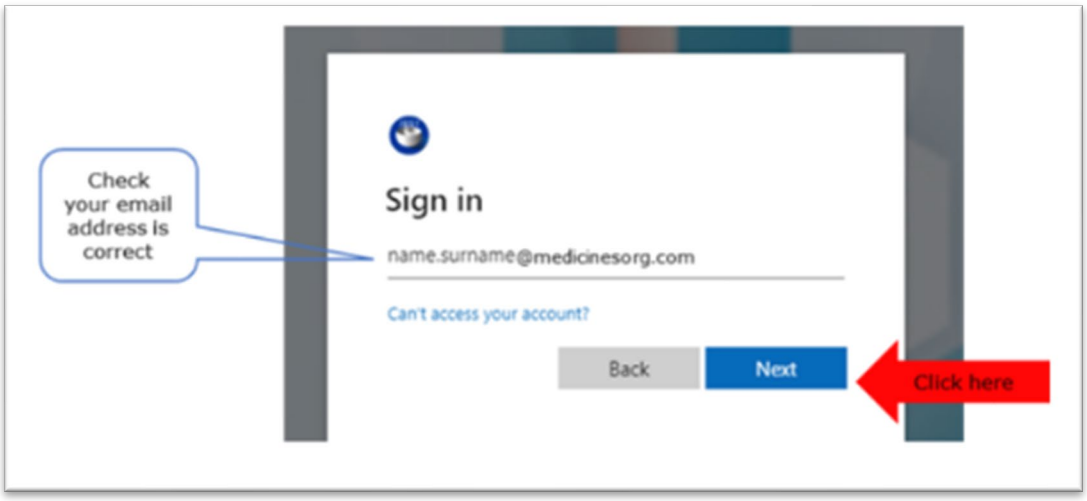


Image 1: Login to DWH application

When signing in it might take the user to another page related to the user's organisation where the user can enter their password, and if there is a single sign in authentication method configured it will result in a successful sign in. However, in some cases it may ask for a code depending on the authentication process in place. Again, this might differ for each organisation.

For more information regarding the authentication methods used please follow the link: Sign In · EMA Account Management where we can find detailed instructions.

Image 2: Authentication window associated with organisation domain

When a user logs in, the user is prompted to the Home page from EMA Business Intelligence tool, where Oracle BI standard features are displayed (i.e.: user's recent dashboards or analysis among other options):

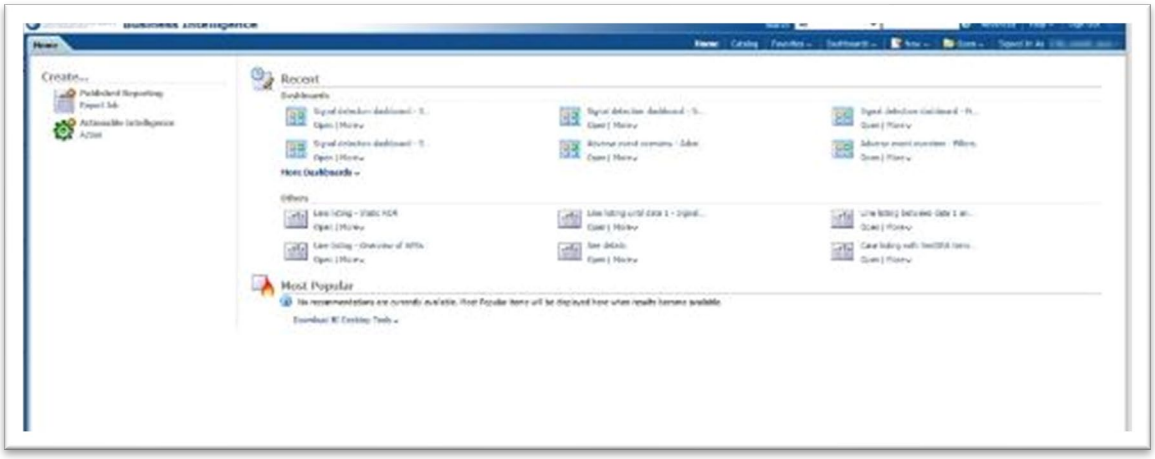


Image 3: BI Home page

2.2. Catalogue access

Over the main menu located on the top of the screen, the user can access the datawarehouse catalogue of reports:

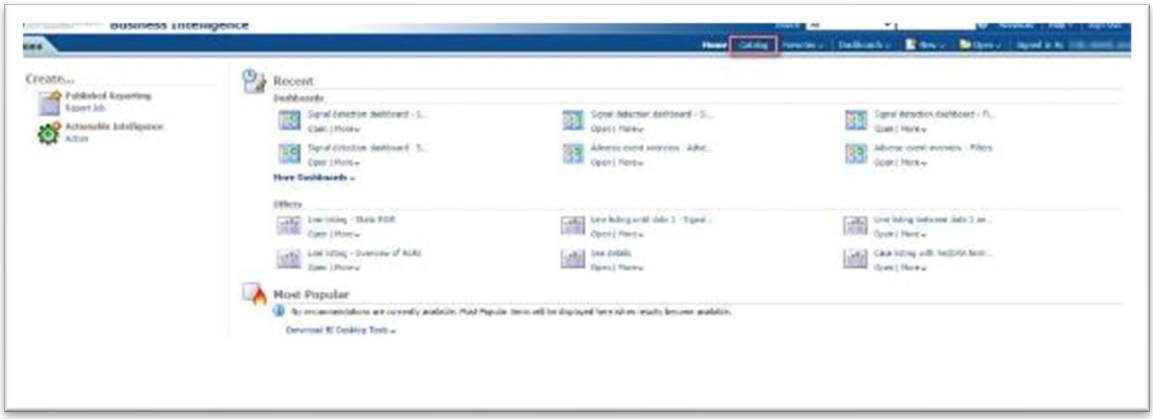


Image 4: Access catalogue

Depending on whether the user is a national competent authority (NCA) or marketing authorisation holder (MAH) they will see different folders in the catalogue section.

If the user is an **NCA** they should see on the left side of the screen and have access to the following folders:

- 'EVVET3 DWH'
- 'EVVET3 DWH NCA'
- 'EVVET3 DWH Answers Community'

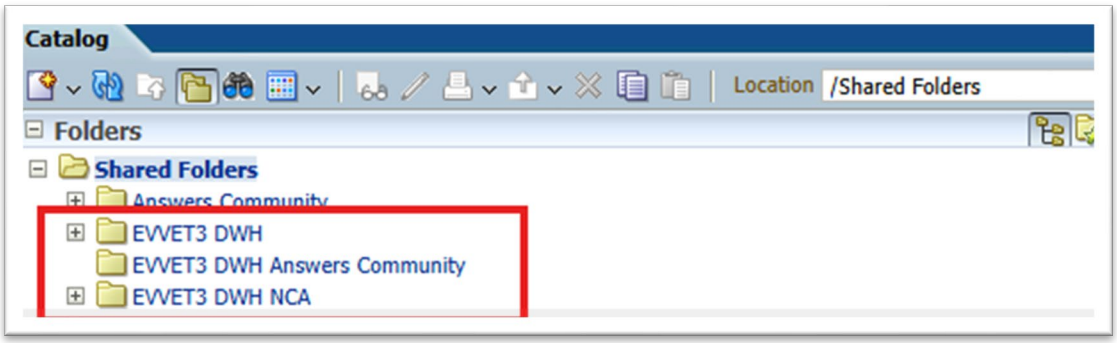


Image 5: NCA users catalogue access

If the user is an **MAH,** they should see on the left side of the screen and have access to the following folder:

- 'EVVET3 DWH'

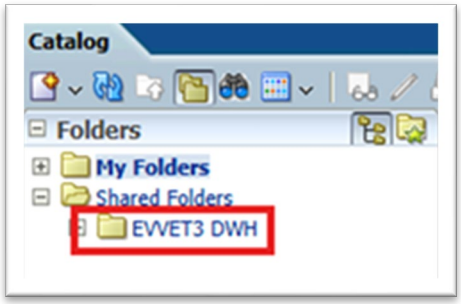


Image 6: MAH users catalogue access

In each of these folders it will contain a subfolder called 'Dashboards' followed by each of the reports pertaining to that folder.

The folder 'EVVET3 DWH' contains the following dashboards (NCAs, MAH, EMA Staff):

- Administrative reports
- Adverse event overview
- Adverse events comparison between 2 periods
- Basic queries- AER & product data overview
- Data stratification
- EMA internal reports
- Line listing

- List of products
- Signal detection
- Signal evaluation
- Signalling for reactions linked to a product or ingredient
- Trends analysis

The folder 'EVVET3 DWH NCA' contains the following dashboards (only for NCAs and EMA staff):

- Pharmacovigilance inspections
- Sales data

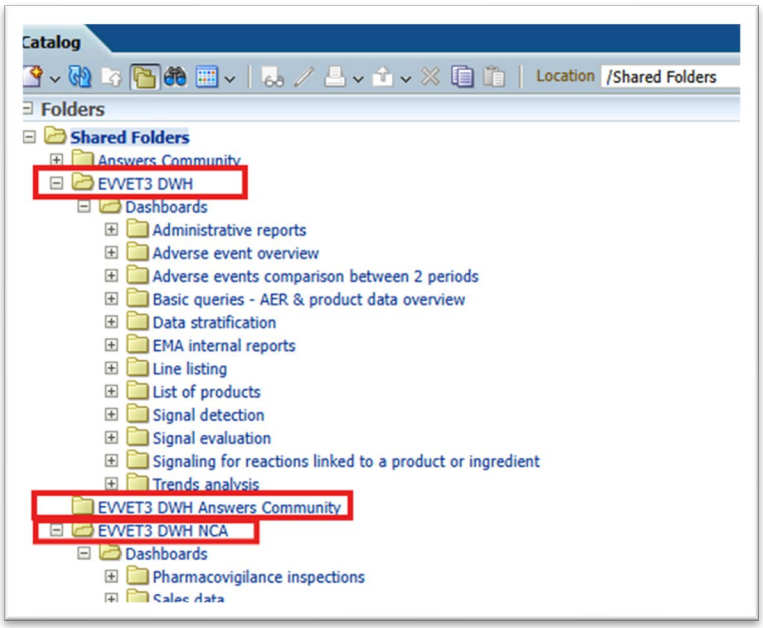


Image 7: Dashboard of reports

The next chapters of this user manual will guide the user through each of the above dashboards.

Note: each dashboard can be accessed in different ways, in addition to the above-mentioned, such as: searching on the top menu by the name of the dashboard or adding it to your favourites and consult the tab 'Favourites'.

3. ER received over a period of time and Organisation compliance

This dashboard displays several AERs metrics, so the user can get an overview of the data based on correctness, classification or message received date, as well as get the organisation compliance report related to the information set in the filters page.

The dashboard is divided into two tabs: the 'AER received over a period of time' and the 'Organisation compliance report'.

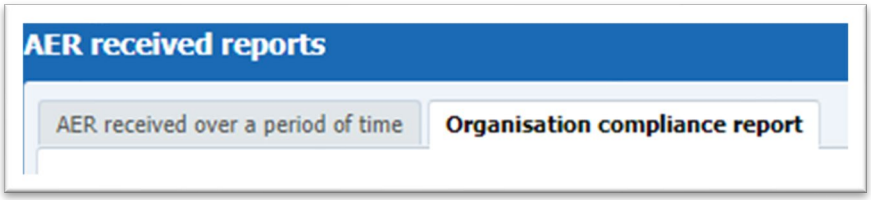


Image 8: AER received reports

Image 9: AER Received reports

3.1. Filters

Filters for this dashboard are distributed in the following sections:

1. **Timing Filters**

In this prompt, the user should select the received date range to apply to the dashboards.

2. **Geographic Filters**

In this prompt, the user can select:

- Region: EEA or non-EEA countries
- Occurrence country

3. **Organisation filters**

Non-mandatory prompts for selecting the organisation type (MAH or NCA) or a specific organisation.

4. **AER filters**

Non-mandatory prompt for selecting the submission type.

5. **Historical data**

No answer is required for this prompt. By default, a snapshot of the day will be set. In case the user needs to have the information as it was in a past date, then it's needed to inform this date in this prompt.

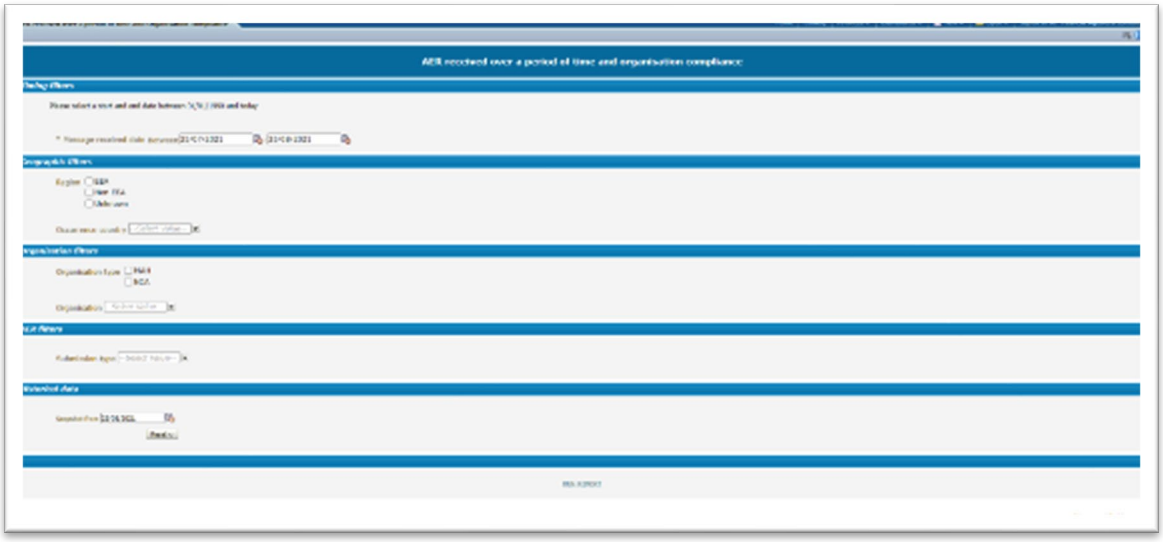


Image 9: Filter options

3.2. AER received over a period of time

In the first tab the user will navigate to the AER received over a period of time, with the following structure:

At the top of the dashboard, there are two drop-down menus for the user to select Correctness and Classification.

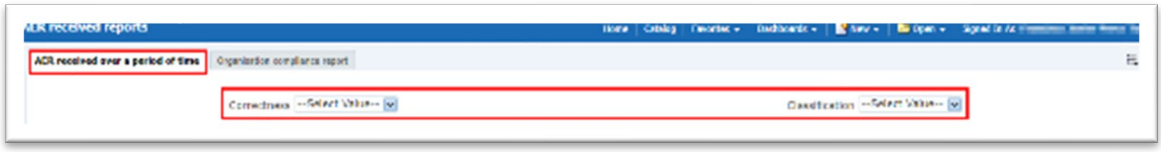


Image 10: Correctness and Classification drop-down menus

Below, two pie charts will be displayed:

- **Number of AERs by correctness:** displaying correct reports in green, report with errors in red and report with warning in yellow.
- **Number of AERs by classification:** displaying case report in green, error report in red, nullified report in white and replaced report in yellow.

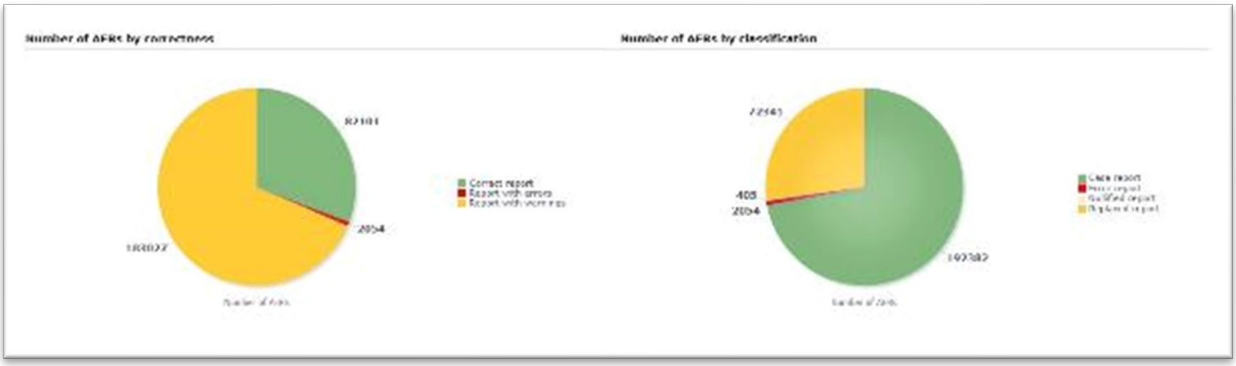


Image 11: Correctness and Classification charts

Below, two more charts will be displayed with the following information:

- Number of AERs by message received date: Showing the number of AERs per message received date on a monthly basis.
- Number of AERs by message received year (last 5 years): Showing number of AERs per message received date on a year basis, always for the last 5-year span.

Right below, two links: Switch to table, for the user to visualise the information in table format and return to filters to go back to the filters page and edit the query or start over. In addition, the user will see the filters applied to the charts by looking at the bottom, as follows:

Image 12: Filters set

3.3. Organisation compliance report

In the second tab the user will navigate to the Organisation compliance report, with the following structure:

At the top of the dashboard, there is a series of checkboxes for the user to select: Animal/Human, Seriousness and Information Type.

- Right below, two pie charts are being displayed:
- Message received date is set to the original received date.
- Message received date to the most recent information date.
- Both represent compliant in green, and non-compliant in red.

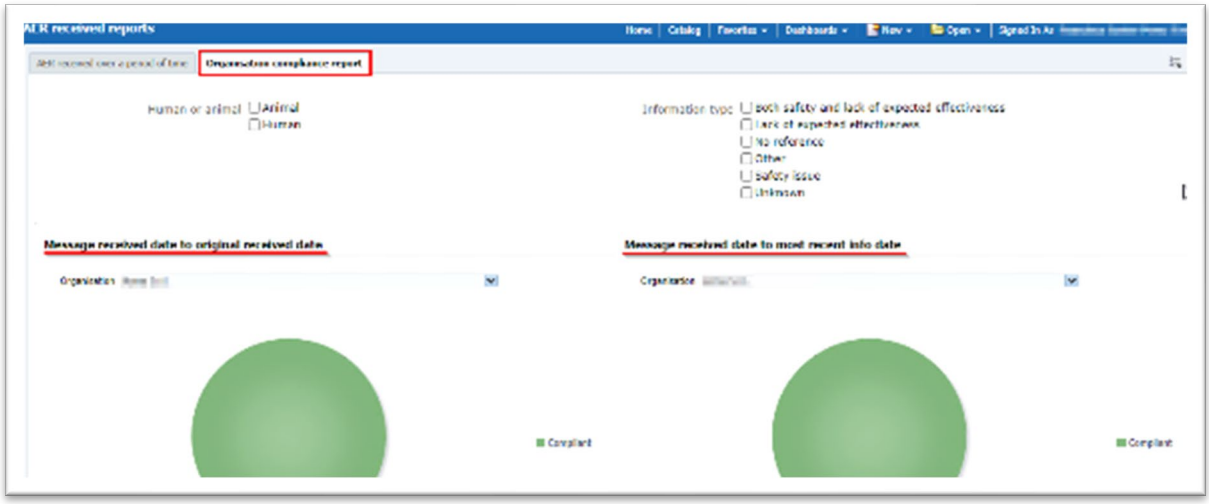


Image 13: Received date to original and most recent charts

Above the charts, the user will find a drop-down menu to jump between organisations. Right below, two links: 'Switch to table', for the user to visualise the information in table format, and 'Return to filters' to go back to filters page and edit the query or start over.

Additionally, the user will see the filters applying to the charts by looking at the bottom, as follows:

Image 14: Filters set

Lastly, by clicking on the sections of both pie charts the user will get the chance to navigate to the line listing reports:

Image 15: Line listing view

And the Reports and duplicates:

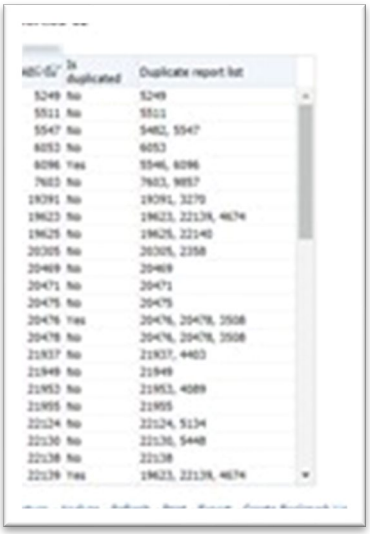


Image 16: Detailed view

4. Adverse event overview

This dashboard displays several quantitative metrics, so the user can get an overview of the data for a product, substance or group of products in terms of number of cases, animals affected, animals died or fatal cases for the selected period.

The dashboard also contains links that allow the user to navigate to the signal detection dashboard, Current Product and Associated Products detail tables, as well as get ROR-based calculations related to the parameters previously set in the filters page.

The dashboard is divided into two tabs, the 'Filters' tab and the 'Adverse Event Overview' tab, in which the user gets to see the result of the query.

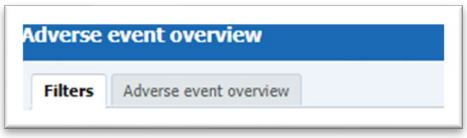


Image 17: Adverse event overview menus

4.1. Filters

1. **Choose from all attributes in the product information (required)**

In this prompt, the user can select at what level of the product hierarchy you want to run your query. These levels are:

- **Active substance level:** results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products belonging to the selected ATCVet Code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- **Product composition level (Composition, Strength, Formulation, Pharma Product)**: results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

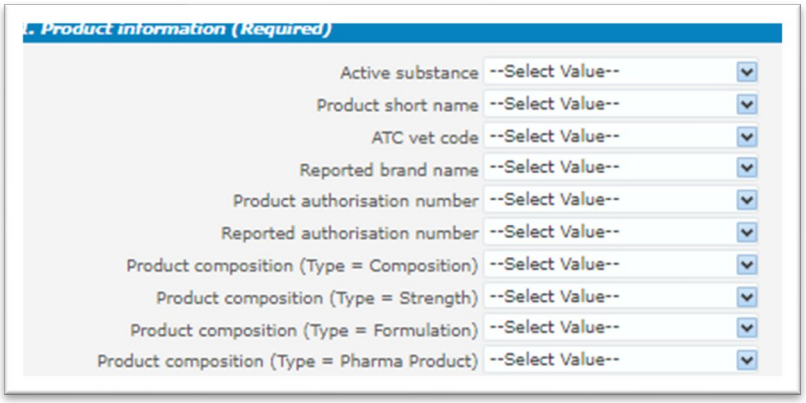


Image 18: Filter criteria

2. Message received date range (required)

In this prompt you select a range of dates.

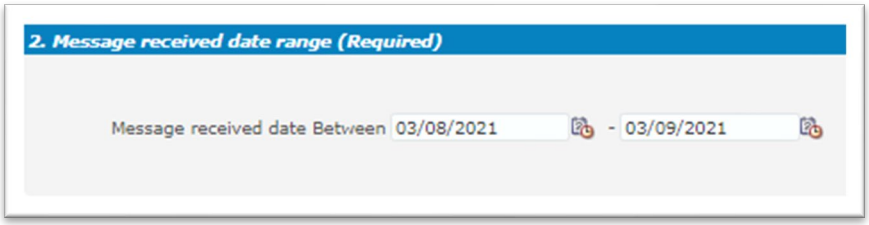


Image 19: Message received date filter

3. VedDRA hierarchy

In this prompt you select one or multiple VedDRA terms at different levels.

Image 20: VedDRA hierarchy filter

4. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both, by selecting both Animal and Human.

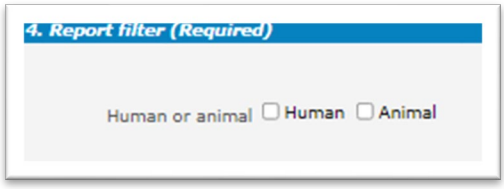


Image 21: Human or animal filter

5. All cases or new cases (required)

In this prompt, the user will have to select one of the two options ("All Cases" is selected by default). Selecting "New cases" will return data related only to **new reports** received in EVVET during the selected period and will exclude from the data set follow-ups to reports initially received in EVVET prior to the selected period.

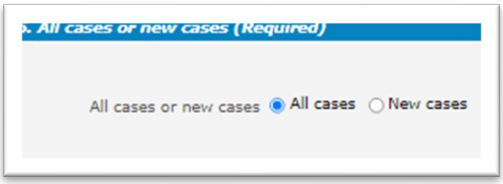


Image 22: All or new cases filter

6. Choose from the list of optional AER filters

No answer is required for this prompt. By applying any of these filters, the results dataset will be restricted to AERs that meet the selected conditions.

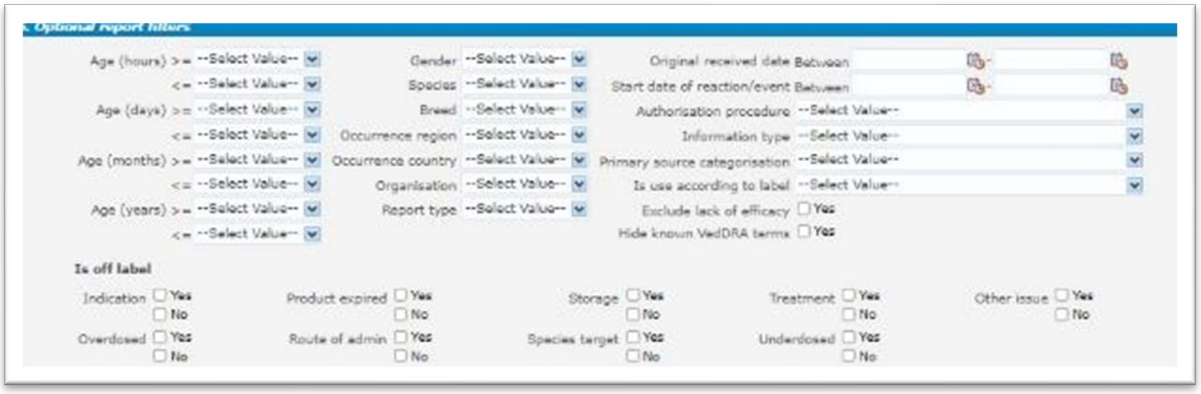


Image 23: Additional filters

- **Original Received Date**: date that the MAH or NCA first received the message.
- **Serious**: the system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy**: if you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

7. Threshold ROR (Required)

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

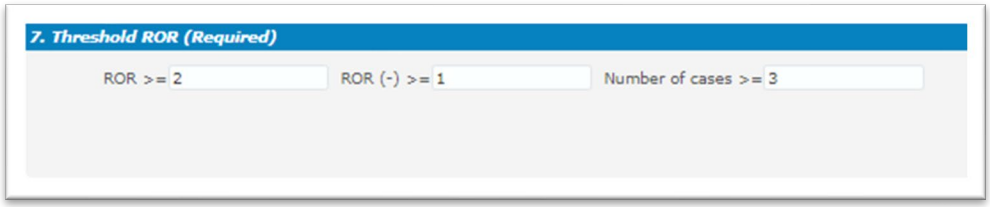


Image 24: ROR threshold

8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the date selected, excluding data received after the selected date.

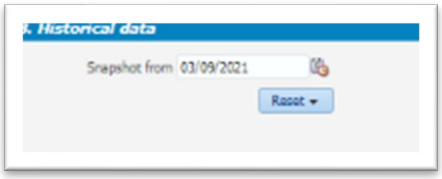


Image 25: historical data

4.2. Adverse event overview

The Adverse Event Overview tab shows the result of the query, grouped in a series of charts of different kinds, as well as a header including some key figures, together with a filter for selecting Species. A summary of the filters applied is also available at the very top, so the user is able to have this information in sight while doing the analysis.

Every chart has a title on top describing the content and sometimes a clarification about the information included (between brackets) and a little disclaimer at the bottom in case additional details are required.

Image 26: Adverse event overview results

The charts displayed in the Adverse Event Overview tab from top to bottom are as follows:

- **Number of cases by region (Specified period):** the pie chart shows the number of cases by EEA and Non-EEA for the period specified on the filters page.
- **Number of cases by region (All cases):** the pie chart shows the number of cases by EEA and Non-EEA, but not limited to the period specified on the filters page.

Image 27: Number of cases (period vs all time) charts

By clicking on any sector of the pie chart, the charts will break down on EEA/Non-EEA countries, with a link enabled to go back to previous state, just as follows:

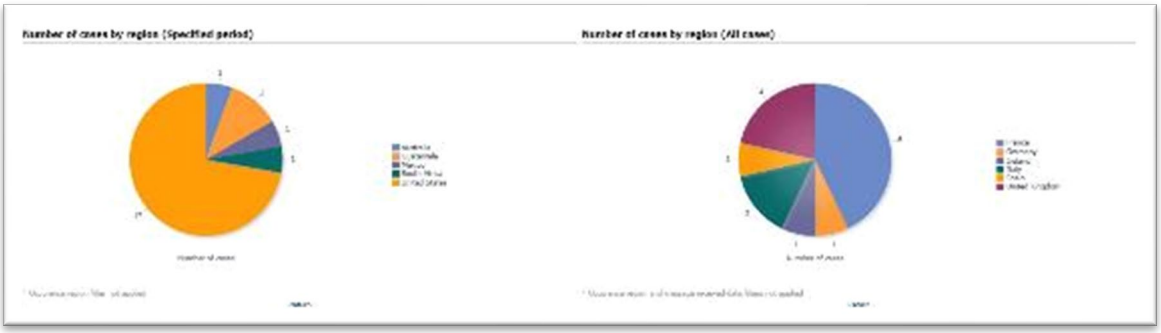


Image 28: detailed chart view at country level

- **Number of cases and fatal cases (LAST 10 YEARS):** the bar chart shows the number of cases and fatal cases for the last 10 years, not applying the message received dates included in the filters page.
- **Number of fatal cases over average (LAST 10 YEARS):** the line chart shows the number of fatal cases over average for the last 10 years, not applying the message received dates included in the filters page.

Image 29: number of fatal cases and average chart

By clicking on any bar, the chart will give the user access to a see details functionality. A new tab will open up with a detailed table containing several metrics for that specific year and product at VedDRA PT level, just as follows:

Image 30: VedDRA level detailed line listing

At the same time, by clicking in the blue line of the right chart, for a specific year, the user navigates into that year's 12 month-span, just as follows:

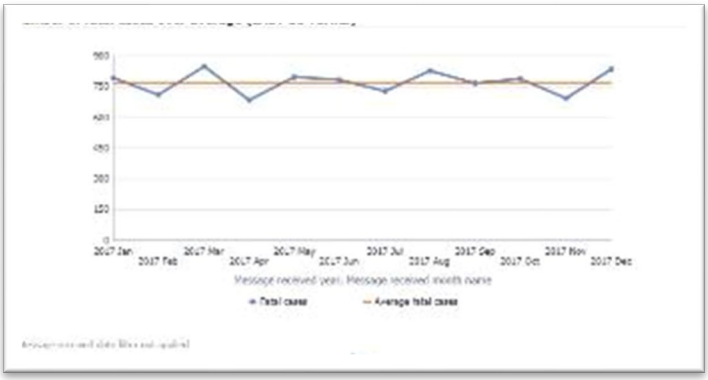


Image 31: 12 month-span chart

- **Number of cases by species and VedDRA SOC over product:** the heat map shows the cases classified by species and VedDRA SOC for the product selected in the filters page. This table uses a different tone of blue depending on the number of cases. The larger the quantity of cases for that species and reaction, the darker the blue.
- **Number of animals affected, and animals died (LAST 10 YEARS):** the bar chart shows the number animals affected and died over the last 10 years, not applying the message received dates included in the filters page.

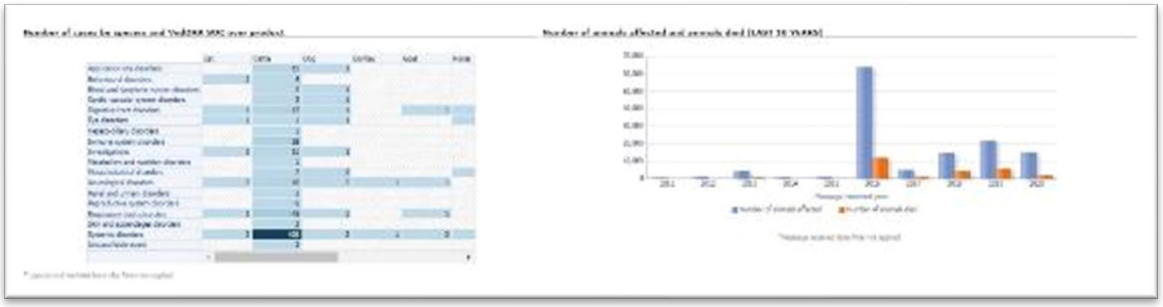


Image 32: Number of cases by species and VedDRA SOC over product and animal affected over died charts

Both charts have second level reports: in regards of the heatmap, the user will get access to the See Details table with detailed information, to the Signal Detection dashboard through the Animal/Human adverse events overview as well as to the Associated medicinal products & VedDRAs in the last of the options displayed in the drop-down menu.

All three second level reports will show the information in regards of that set of specific cases.

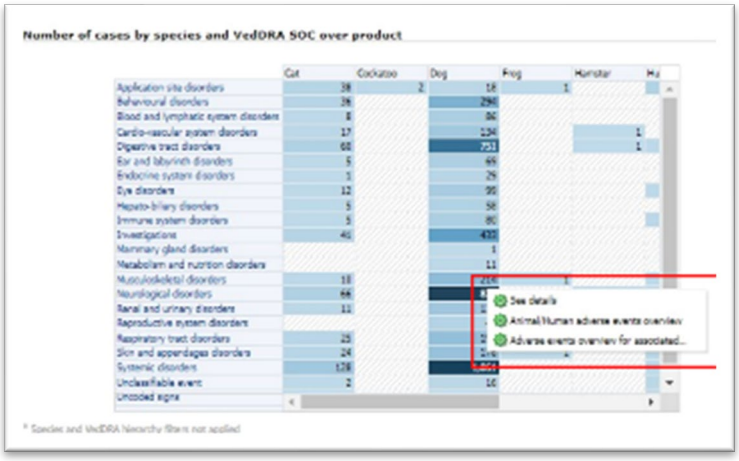


Image 33: Number of cases by species and VedDRA SOC over product

By clicking on any of the bars of the bar chart, the user gets to navigate to the ROR calculation using animals affected for the year selected:

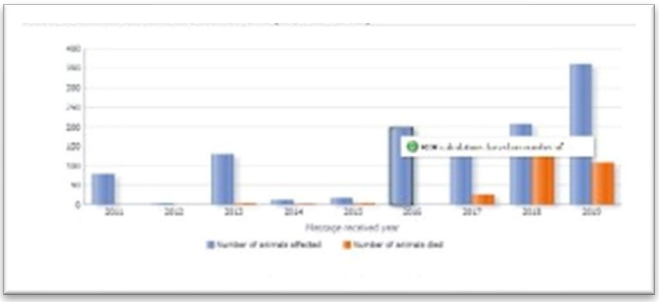


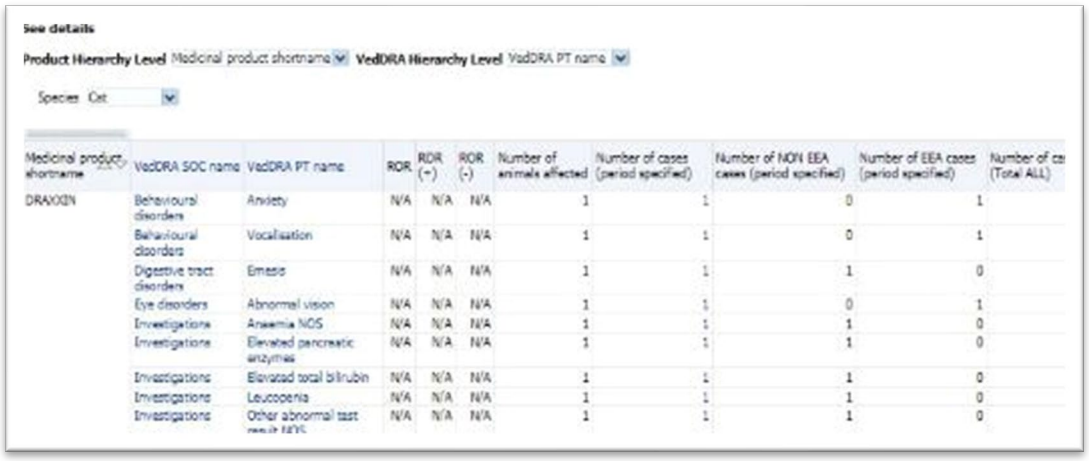
Image 34: Animal affected over died chart

Image 35: detailed view

At the bottom of this tab, we find a series of links with different functionalities:

4.2.1. See details

By clicking on see details the user navigates to a new window with the detailed information for the filters included in the query. At the top, the user will also find both Product Hierarchy and VedDRA hierarchy level drop-down menu as well as a Species filter to switch between potential species related to the product or products involved in the analysis.


See details

Product Hierarchy Level Medicinal product shortname VedDRA Hierarchy Level VedDRA PT name

Species Cat

Medicinal product shortname	VedDRA SOC name	VedDRA PT name	ROR	ROR (+)	ROR (-)	Number of animals affected	Number of cases (period specified)	Number of NON EEA cases (period specified)	Number of EEA cases (period specified)	Number of ca (Total ALL)
DRAXXIN	Behavioural disorders	Anxiety	N/A	N/A	N/A	1	1	0	1	
	Behavioural disorders	Vocalisation	N/A	N/A	N/A	1	1	0	1	
	Digestive tract disorders	Emesis	N/A	N/A	N/A	1	1	1	0	
	Eye disorders	Abnormal vision	N/A	N/A	N/A	1	1	0	1	
	Investigations	Anaemia NOS	N/A	N/A	N/A	1	1	1	0	
	Investigations	Elevated pancreatic enzymes	N/A	N/A	N/A	1	1	1	0	
	Investigations	Elevated total bilirubin	N/A	N/A	N/A	1	1	1	0	
	Investigations	Leucopenia	N/A	N/A	N/A	1	1	1	0	
	Investigations	Other abnormal test result NEC	N/A	N/A	N/A	1	1	1	0	

Image 36: Detailed view

The see details table include the following columns: *Medicinal product shortname, VedDRA SOC, VedDRA PT, ROR, ROR(+), ROR(-), Number of animals affected, Number of cases (period specified), Number of non-EEA cases (period specified), Number of EEA cases (period specified), Number of cases (Total ALL), Number of NON EEA cases, Number of EEA cases, Number of cases (Total ALL reactions), Number of fatal cases (period specified), Number of fatal cases, Reaction count, Case count by product (filter applied) , Case count (filter not applied), Reaction count total, Percentage of reactions and Percentage of cases.*

What's more, the See Details table includes second level reports which is enabled at the Number of cases (period specified) column, just as follows:

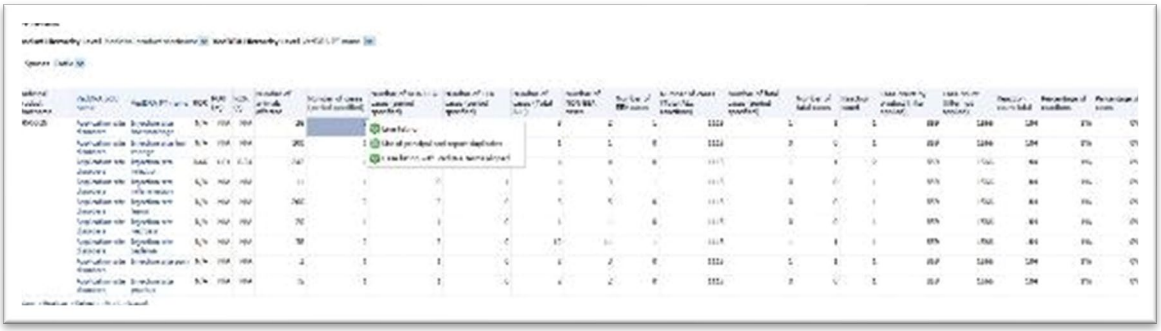


Image 37: Detailed view

By clicking over any number, the user will have access to the following functionalities:

- **Line listing**: A new tab will open with the most detailed table the user has access to, basically with full information about the cases of the line selected.

Image 38: Line listing view

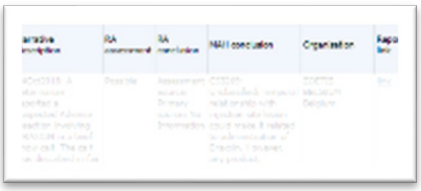
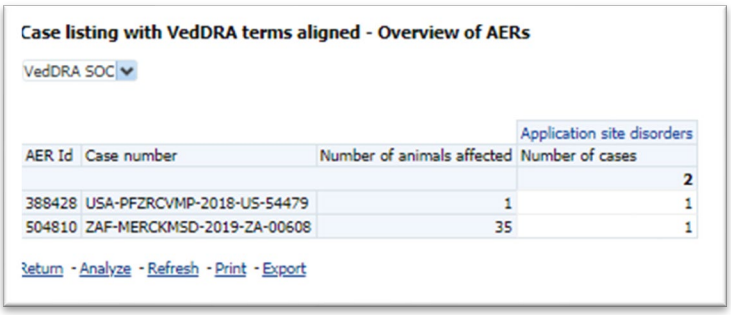


Image 39: Line listing view

- List of principal and report duplicates: A new tab will open with a detailed table including the duplicate reports, if any.
- Case listing with VedDRA terms aligned: The user can see the list of cases with VedDRA terms aligned and the number of animals affected involved.



Case listing with VedDRA terms aligned - Overview of AERs

VedDRA SOC

			Application site disorders
AER Id	Case number	Number of animals affected	Number of cases
			2
388428	USA-PFZRCVMP-2018-US-54479	1	1
504810	ZAF-MERCKMSD-2019-ZA-00608	35	1

Return - Analyze - Refresh - Print - Export

Image 40: Case listing with VedDRA terms aligned view

4.2.2. Links to signal detection reports

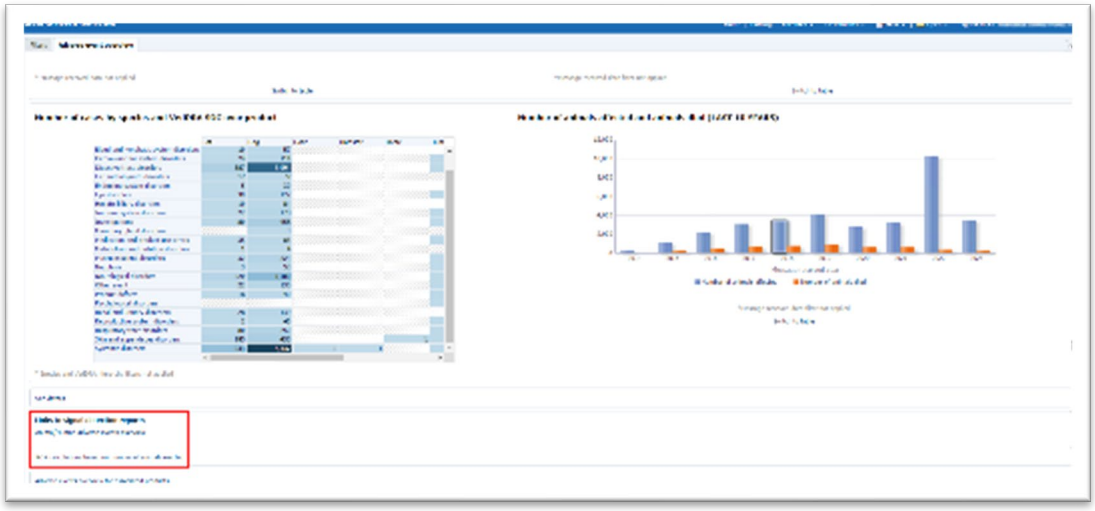


Image 41: Links

4.2.2.1. Animal/Human adverse events overview

This link allows the user to navigate to the Signal Detection and visualise this dashboard applying the same filters selected for the purpose of the current adverse event analysis.

4.2.2.2. ROR calculations based on number of animals reacted

This link allows the user to navigate to the ROR calculation using animals affected applying the same filters selected for the purpose of the current adverse event analysis. This table shows a group of ROR metrics related to the animals affected for a preset product and dates.

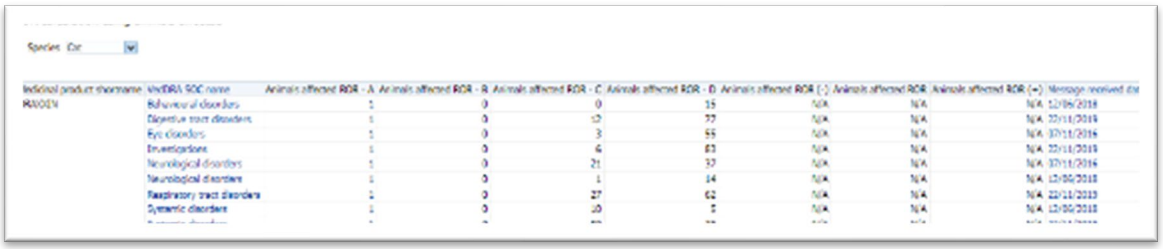


Image 42: ROR calculations based on number of animals reacted table

4.2.3. Link to data stratification report

4.2.3.1. Adverse events overview for associated products

This link allows the user to navigate to the data stratification report, displaying 2 different tables: The first one for the product selected in the filters page, detailing number of cases for the product, VedDRA SOC and the species set in the filter. The table also displays ROR(-), ROR(+) and ROR metrics for the product selected.

The second table shows the same information but, in this case, including the associated products (to the one selected in the filters page) and the metrics will be measuring the combination of both products instead of the product selected. The user will also find the reaction count and the number of animals affected columns.

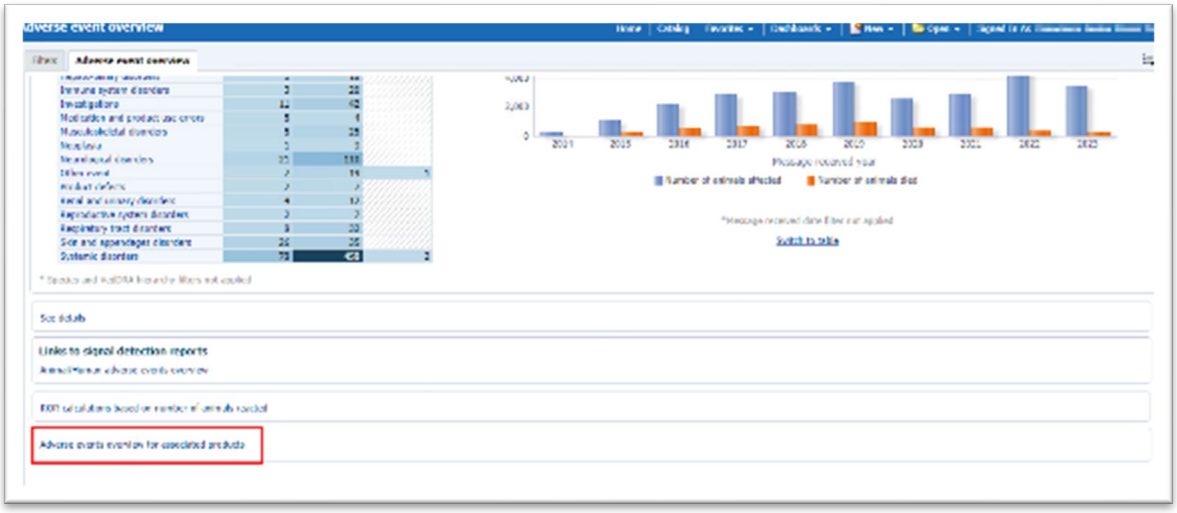


Image 43: Link to data stratification dashboard

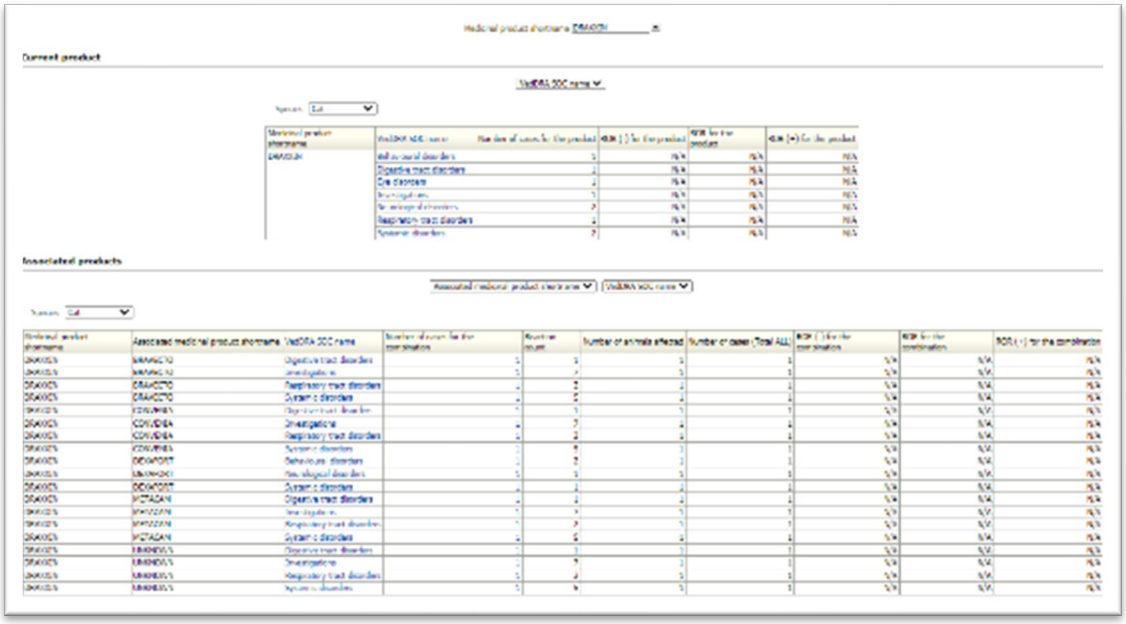


Image 44: Adverse events overview for associated products view

5. Signal detection dashboard

5.1. Signal detection pre-calculations

Through the pre-calculations functionality in Signal detection dashboard, it will be possible to get the results faster than using the common Signal detection dashboard, as these have been precalculated for the following predefined time frames (using a single product, active substance or product grouping):

- 1 year
- 6 months
- 3 months
- 1 month

5.1.1. Pre-calculations at product short name level in Signal detection dashboard

Image 45: Product shortname pre-calculations in Signal detection dashboard

'Signal detection Precalculated ROR by product' is the default option pre-selected in signal detection dashboard.

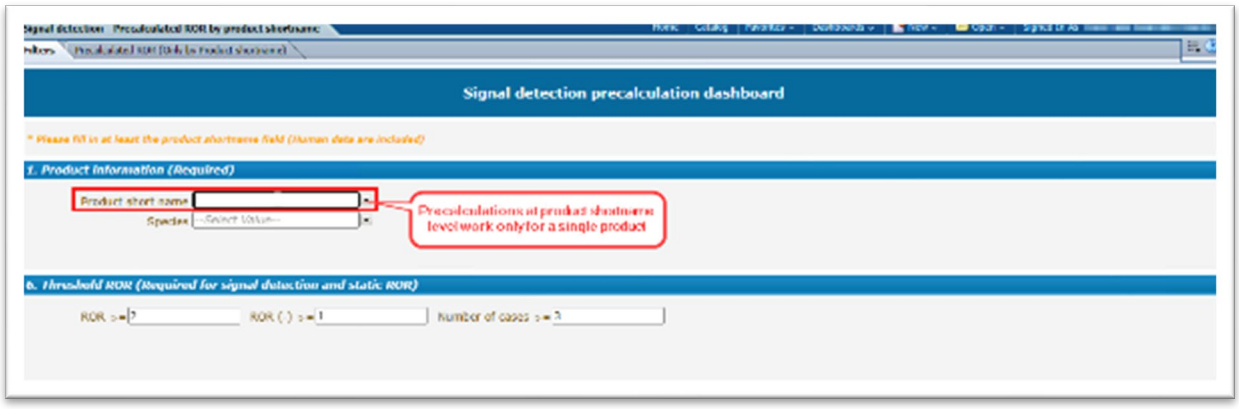


Image 46: Product short name filter in pre-calculations Signal detection

When using the pre-calculations functionality, we should select a single product as the pre-calculations cannot be done for more than one product.

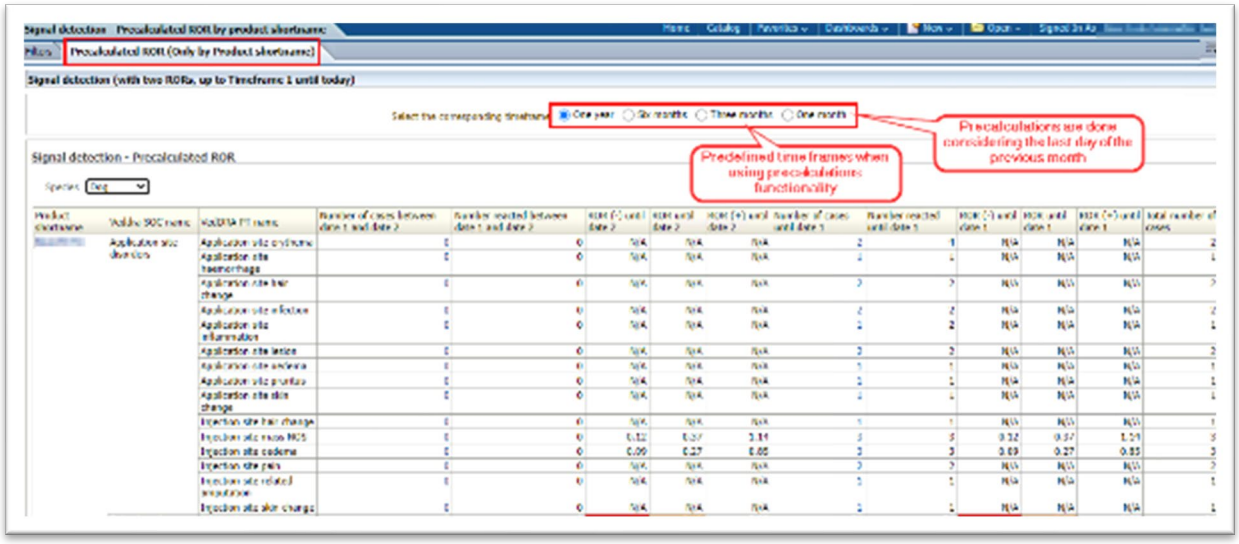


Image 47: Predefined time frames for pre-calculations

Note: Pre-calculations are done considering the last day of the previous month. Example: If we run the pre-calculations during April, all the time frames pre-calculations will retrieve the data until 31 March.

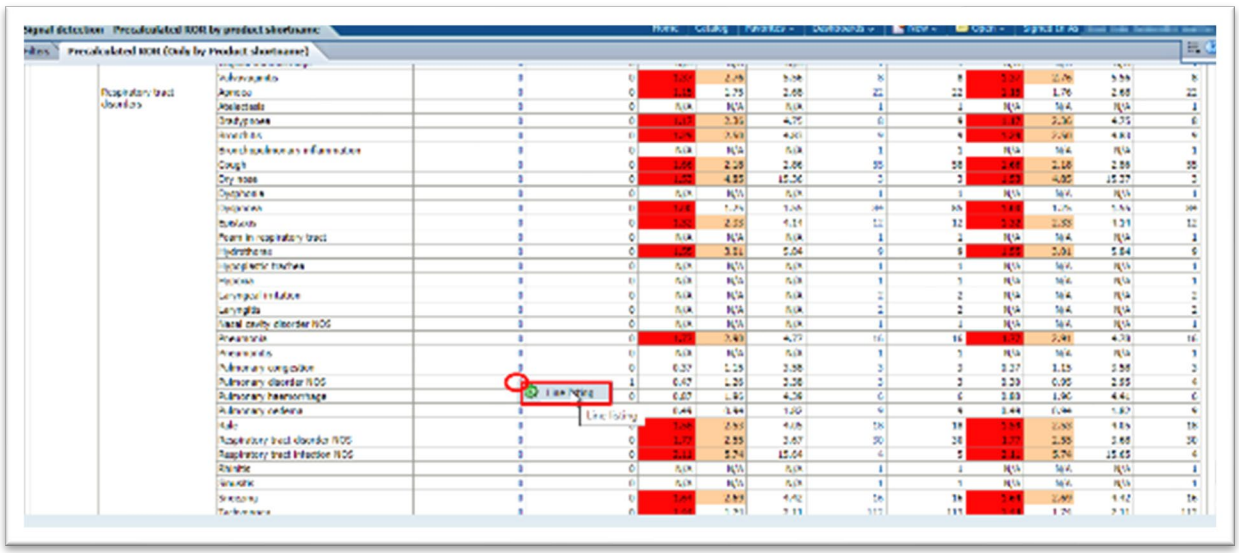


Image 48: Line listing functionality in pre-calculations

When clicking on the 'Number of cases between date 1 and date 2' values, it's possible to get the line listing for the selected value.

5.2. Signal detection dashboard

This dashboard displays several number of cases and animals affected as well as ROR metrics, so the user is able to get an overview of the data for a product, active substance or group of products for a selected period in order to check for potential signals.

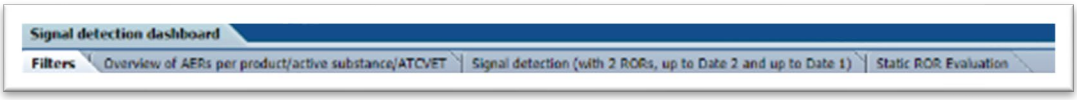


Image 49: Signal detection menu

The dashboard is broken down into four tabs: Overview of AERs per product /active substance/ATCVETVET, Signal detection (with 2 RORs, up to Date 2 and up to Date 1) and Static ROR Evaluation as well as the tab for filtering the query (Filters).

1. Filters choose from all attributes in the product information (required)

In this prompt you select at what level of the product hierarchy you want to run your query. The levels are:

- **Active substance level:** results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to th e selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, before standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- **Product composition level (Composition, Strength, Formulation, Pharma Product):** results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

Image 50: Filter options

2. Message received date range (required)

In this prompt you select a range of dates.

Image 512: Message received date range filter

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

Image 52: Report filter

4. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Image 53: Optional report filters

- **Original Received Date:** The date that the MAH or NCA first received the message.
- **Serious:** The system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy:** If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

5. Threshold ROR

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

Image 54: Threshold ROR

6. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per selected date, excluding data received after the selected date.

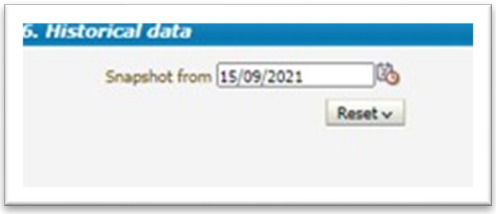


Image 55: Threshold ROR

5.2.1. Overview of AERs per product/active substance/ATCVETVET

The number of cases and number of animals affected can be seen in this first tab, distributed geographically in a map, including a drop-down menu on top to jump from one metric to the other. The darker the blue, the more cases associated with a specific country.

Image 56: Overview of AERs per product/active substance/ATC vet

Right below the map, the user will find a much more detailed table with the number of cases and number reacted for the product selected, split by occurrence region and country. In addition, Human or Animal and Seriousness flags will be also displayed, as well as the totals for number of cases and number reacted for each country included in the outcome.

Image 57: Number of cases and number reacted for the product selected detail

By the drop-down menu on top of the table, the user will be able to jump from Medicinal product shortname to Reported brand name, product composition, active substance or ATCvet code visualisation.

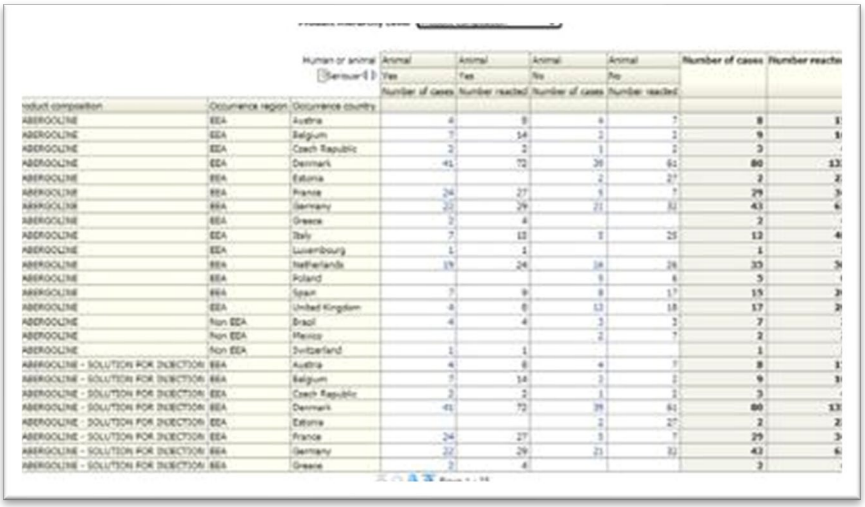


Image 58: Product composition detailed view

What's more, a drop-down menu for Species is included at the very top of this tab, so the user is able to apply this filter, impacting the data displayed both in the map and the table.

5.2.2. Signal detection (with 2 RORs, up to Date 2 and up to Date 1)

In this tab, the user is able to analyse a diverse set of metrics for the product and the period selected, broken down by VedDRA SOC and VedDRA PT levels. The number of cases and number reacted until date 1 and between date 1 and date 2 (period selected), together with ROR calculations are the core of this table.

Moreover, a product hierarchy and species drop-down menus have been included at the top, so the user is able to analyse information from different points of view and for any species for which AERs have been received for a particular product/substance.

- ROR until Date 2: cumulative ROR
- ROR until Date 1: ROR prior to the period selected.

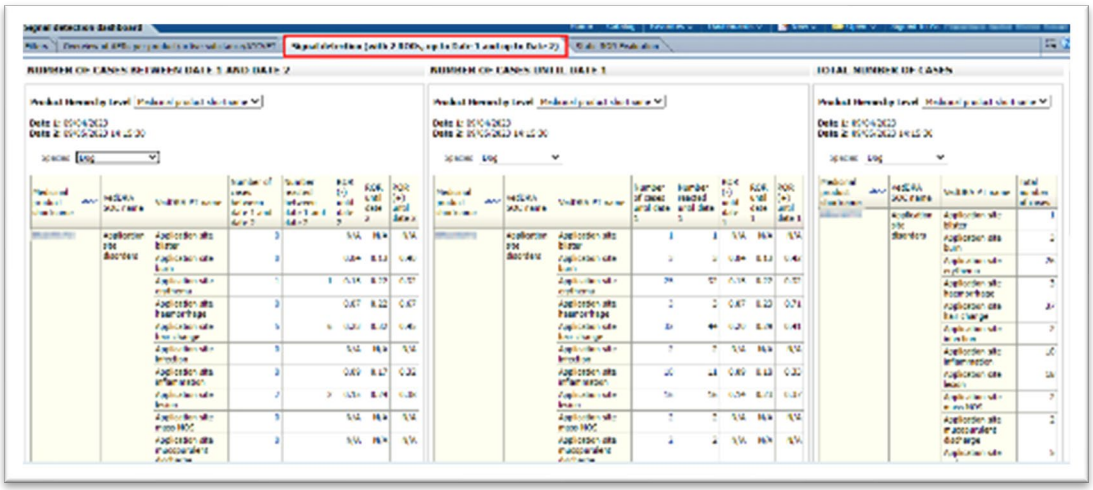


Image 59: Signal detection view

5.2.2.1. IRIS Line listing – List of signals

From the Signal detection dashboard, it is possible to get the List of signals line listing. To get this functionality, we need to access the third tab 'Signal detection (with 2 RORs, up to Date 1 and to Date 2)' and click on the Medicinal Product shortname. Once we click the product, 'List of signals' line listing option will be displayed to be selected.

NOTE: 'List of signals' line listing is also available in the precalculated Signal detection dashboard.

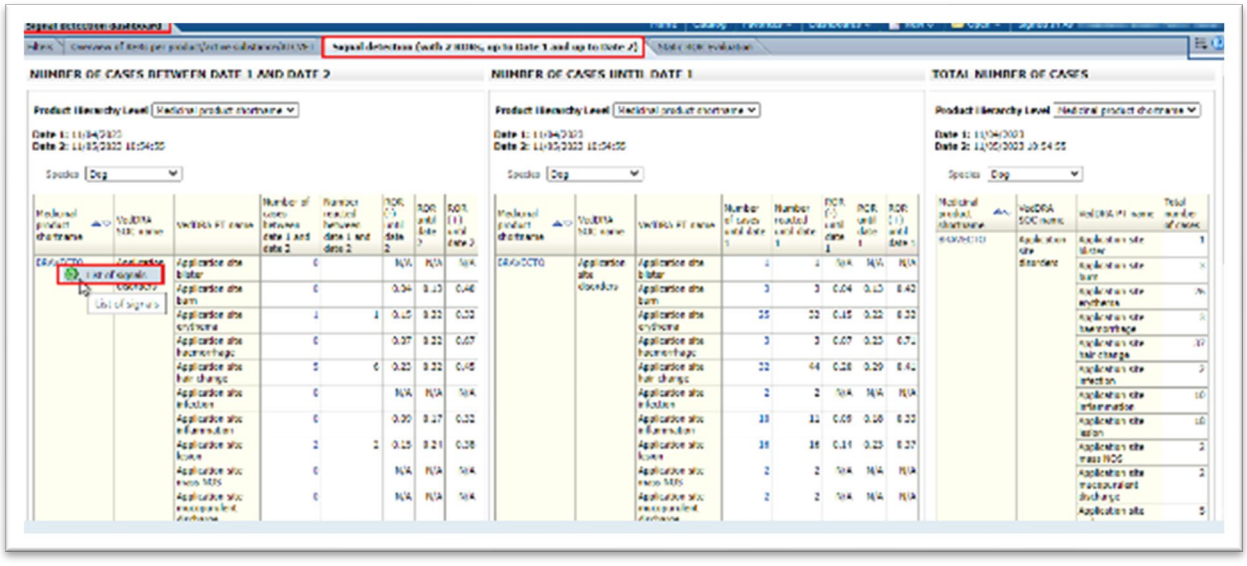


Image 60: List of signals option from Signal detection dashboard

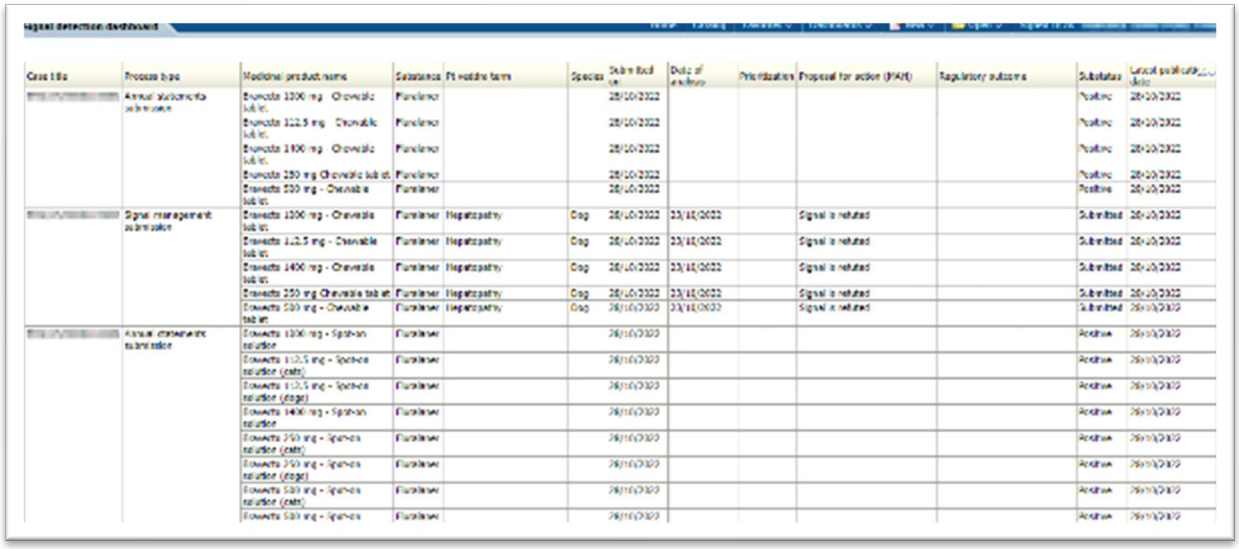


Image 61: List of signals line listing from Signal detection dashboard

5.2.3. Static ROR Evaluation

Static ROR is focused on the different inputs for the Reporting Odds Ratio calculation (ROR) as well as the ROR metric itself, including both lower and upper bounds, aka ROR(-) and ROR(+). All the metrics are displayed at VedDRA SOC level, but the user can change the VedDRA level via the VedDRA Output Level prompt.

At the top, same filters as in the Signal detection (with 2 RORs, up to Date 2 and up to Date 1) tab have been included, this is:

- Product Hierarchy Level, giving users the chance to visualise the data by medicinal product
- shortname, reported brand name, active substance, product composition or ATCvet code.
- Species filter so the user can analyse these metrics for every species impacted by the product.
- Reaction filters at the very top, so the user is able to filter at every level. Lastly, the number of animals affected metric is also displayed at VedDRA SOC level.

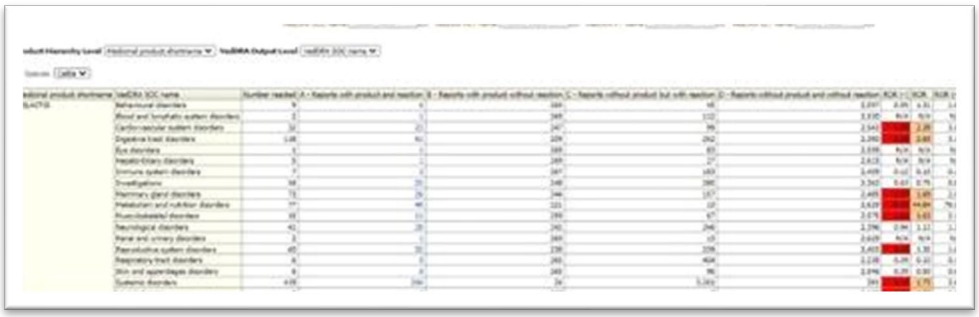


Image 62: Static ROR Evaluation

6. Signal evaluation

This dashboard enables the user to evaluate signals using different parameters (age, time to onset, off label use, geographical distribution, pharmaceutical form, other products involved, other VedDRA terms).

It is also focused on finding both associated products and VedDRAs, so the user is able to visualise the main products and reactions related to ones selected in the filters page.

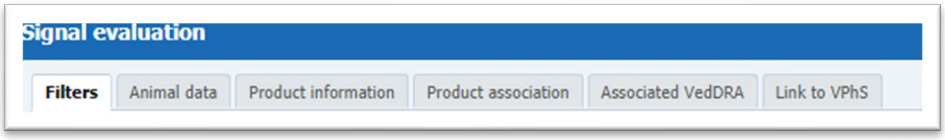


Image 63: Signal evaluation menus

The dashboard is broken down into four tabs: Animal Data, Product Information, Product Association and Associated VedDRA terms, as well as the tab for filtering the query (Filters) and one last tab with a link to VPhS.

At the top of every tab the user will find a header including the usual key figures, being for this dashboard: Number of cases, Animals affected, and Animals died, as follows.

Image 64: Signal evaluation key figures

6.1. Filters

1. **Choose from all attributes in the Product Information (required)**

In this prompt you select at what level of the product hierarchy you want to run your query. These levels are:

- **Active substance level:** Results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** Results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** Results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** Results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** Results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** Results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.

Product composition level (Composition, Strength, Formulation, Pharma Product): Results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

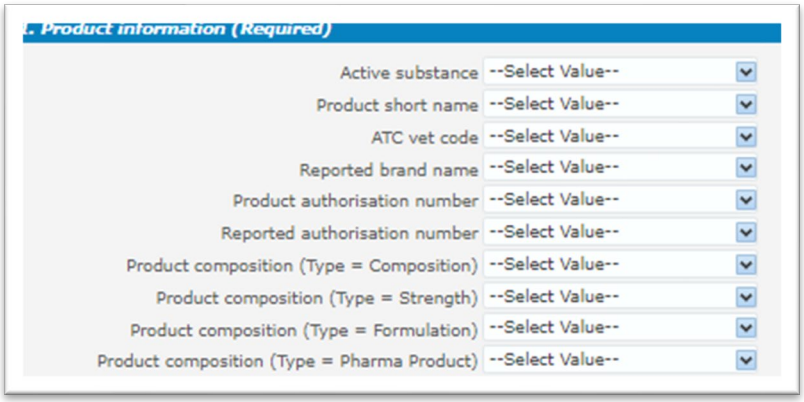


Image 65: Filter options

2. Message received date range (required)

In this prompt you select a range of dates.

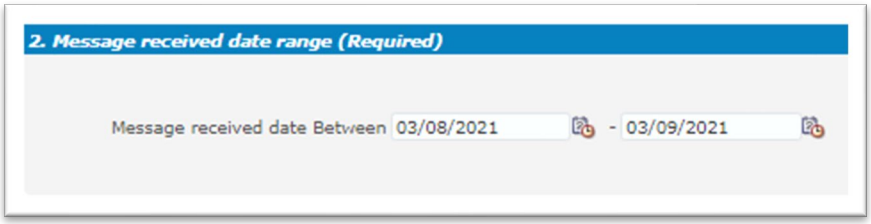


Image 66: Message received date range

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

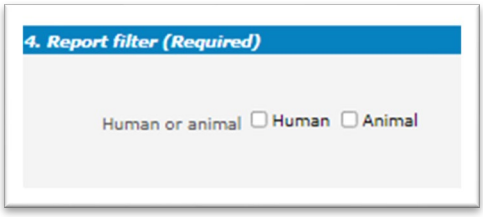


Image 67: Report filter

4. VedDRA hierarchy

In this prompt you select one or multiple VedDRA terms at different levels. By informing the left column of VedDRA terms, we can filter by one or multiple terms. When selecting only one term in each level, the query will return all cases where the VedDRA Terms selected have been reported simultaneously (AND). When using the drop-down menus both from the left and the right side, we will get all cases where at least one of the VedDRA terms informed has been reported (OR). In both sides, if more than one term is selected in the same level, the query will return all cases where at least one of the VedDRA terms selected has been reported (OR).

Image 68: VedDRA hierarchy

5. All cases or new cases (required)

In this prompt you have to must select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period, and period and the selected period will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.

Image 69: All cases or new cases

6. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

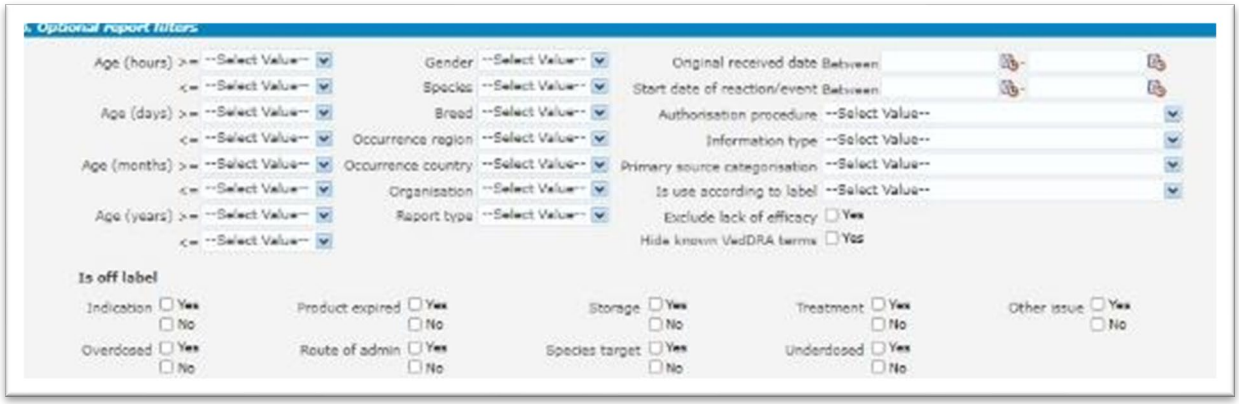


Image 70: Optional AE Report filters

- **Original Received Date**: The date that the MAH or NCA first received the message.
- **Serious**: The system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy:** If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

7. Threshold ROR (required)

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

Image 71:Threshold ROR

8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the date selected, excluding data received after the selected date.

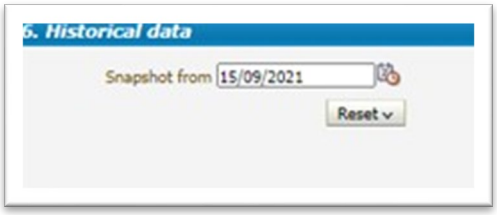


Image 72: Historical data

6.2. Animal data

The charts displayed in the Animal data tab from top to bottom are as follows:

- **Number of cases time to onset:** the pie chart shows the number of cases by time to onset for the product and period specified in thefilters page. Time to onset goes from <=2 minutes to >30 days.
- **Number of animals affected and died over years (LAST 10 YEARS):** the bar chart shows the number of animals affected and died over the last 10 years, so it is not limited by the period specified in the filters page. Product selected applies. Red bars show thenumber of animals died and blue bars the number of animals affected.

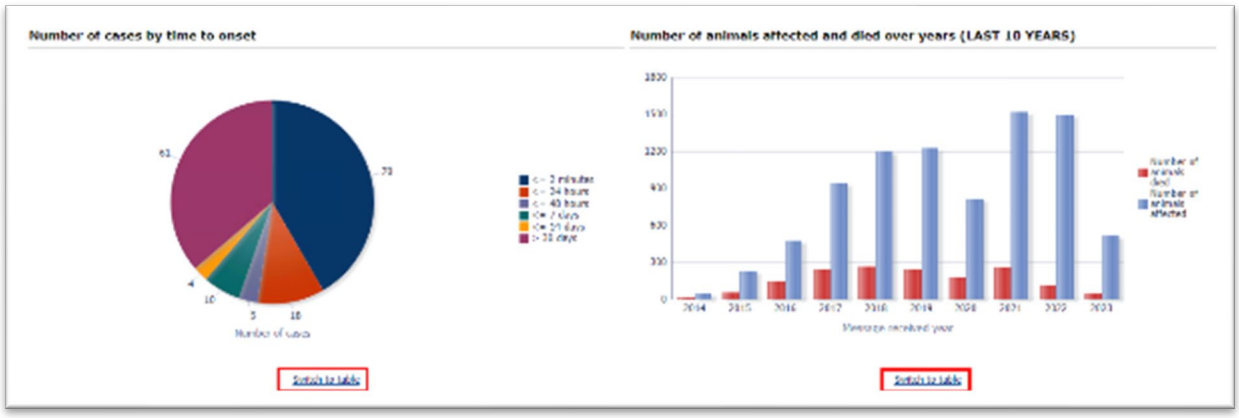
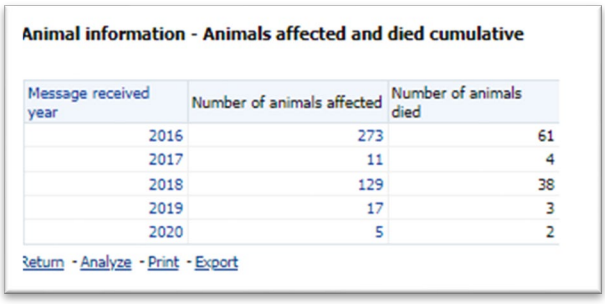


Image 73: Animal data charts

Below this second chart, the user will find a switch to table functionality so the information can be shown either as a chart or a classic table format.



Animal information - Animals affected and died cumulative

Message received year	Number of animals affected	Number of animals died
2016	273	61
2017	11	4
2018	129	38
2019	17	3
2020	5	2

Return - Analyze - Print - Export

Image 74: Animal data cumulative view

- **Number of cases by species:** the bar chart shows the number of cases by species for the product and period specified in the filterspage.
- **Number of cases by species and off-label use:** the heat map chart shows the number of cases by species together with the off-label use information,broken down into YES/NO/NO DATA.

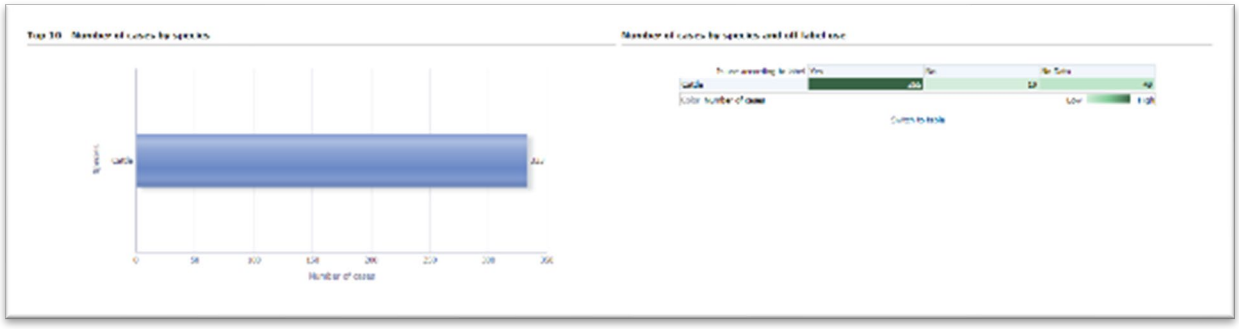
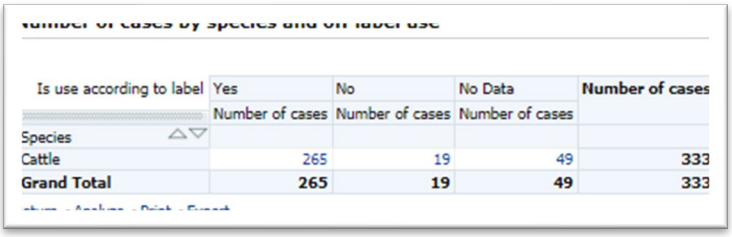


Image 75: Number of cases by species and off label use charts

Below this second chart, the user will find a switch to table functionality so the information can be shown both as a chart or a classic table format.



Is use according to label	Yes	No	No Data	Number of cases
	Number of cases	Number of cases	Number of cases	
Species				
Cattle	265	19	49	333
Grand Total	**265**	**19**	**49**	**333**

Image 76: Number of cases by species and off label use table

6.3. Product information

The charts displayed in the Product information tab from top to bottom are as follows:

- **Number of animals affected/died by country**: the map shows the number of animals affected/died by country for the product and period specifiedin the filters page. The darker the blue, the more cases associated with a specific country. A drop-down menu has also been included at the top in order to jump from animals affected to animals died. In addition, a link has been added at the bottom so the user can visualise in table format the Number of animals affected by pharmaceutical form or active substance.
- **Number of cases by country and species:** the bar chart shows the number of cases by country and species for the product and period specified in the filters page. Blue bars show the number of cases, orange bars show the number of animals affected and green bars show the number of animals died. Moreover, a Switch to table link at the bottom has been included so the user is able to display this same information in table format.

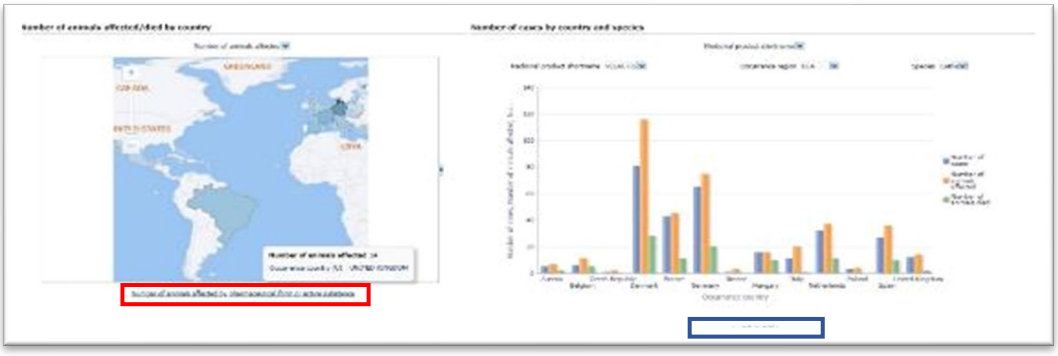
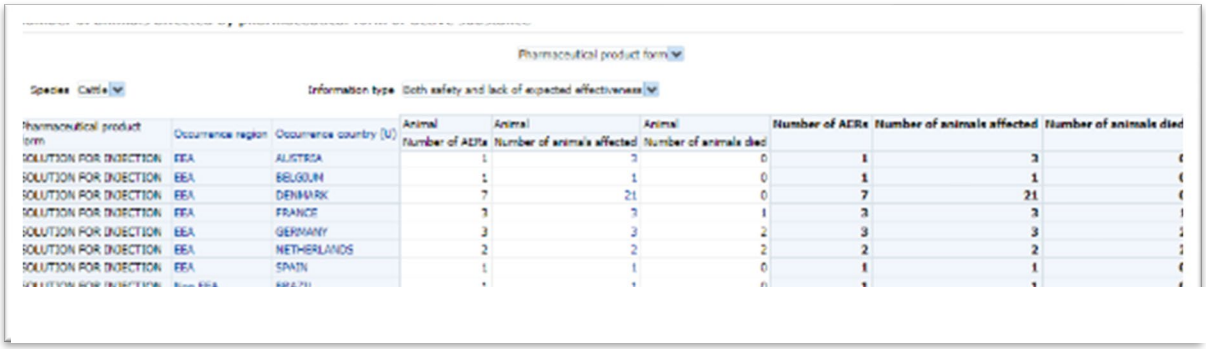


Image 77: Number of animals affected/died by country and by country and species chart

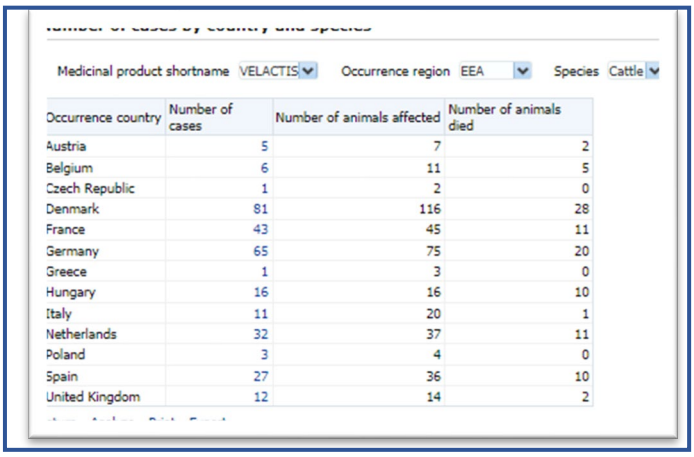


Pharmaceutical product form

Species: Cattle | Information type: Both safety and lack of expected effectiveness

Pharmaceutical product form	Occurrence region	Occurrence country (U)	Animal Number of AERs	Animal Number of animals affected	Animal Number of animals died	Number of AERs	Number of animals affected	Number of animals died
SOLUTION FOR INJECTION	EEA	AUSTRIA	1	3	0	1	3	0
SOLUTION FOR INJECTION	EEA	BELGIUM	1	1	0	1	1	0
SOLUTION FOR INJECTION	EEA	DENMARK	7	21	0	7	21	0
SOLUTION FOR INJECTION	EEA	FRANCE	3	3	1	3	3	1
SOLUTION FOR INJECTION	EEA	GERMANY	3	3	2	3	3	2
SOLUTION FOR INJECTION	EEA	NETHERLANDS	2	2	2	2	2	2
SOLUTION FOR INJECTION	EEA	SPAIN	1	1	0	1	1	0

Image 78: Number of animals affected by pharmaceutical form or active substance



Medicinal product shortname: VELACTIS | Occurrence region: EEA | Species: Cattle

Occurrence country	Number of cases	Number of animals affected	Number of animals died
Austria	5	7	2
Belgium	6	11	5
Czech Republic	1	2	0
Denmark	81	116	28
France	43	45	11
Germany	65	75	20
Greece	1	3	0
Hungary	16	16	10
Italy	11	20	1
Netherlands	32	37	11
Poland	3	4	0
Spain	27	36	10
United Kingdom	12	14	2

Image 79: Number of cases by country and species

- **Number of cases by information type:** the pie chart shows the number of cases by information type for the product and period specified in the filters page.

  A couple of interdependent drop-down menus have been included at the top, so the user is able to see the information as Medicinal product short name, Reported brand name, Product composition, Active substance or ATCvet code and broken-down consequently.

- **Number of cases over year (LAST 10 YEAR):** The bar chart shows the number of cases over the year for the last 10-year span, not applying the message received dates included in the filters page. Blue bars show the number of cases, and the orange line shows the cumulative number of cases.

  On top of that, two interdependent drop-down menus have been included so the user is able to see the information such as Medicinal product short name, Reported brand name, Product composition, Active substance or ATCvet code as well as display it by information type.

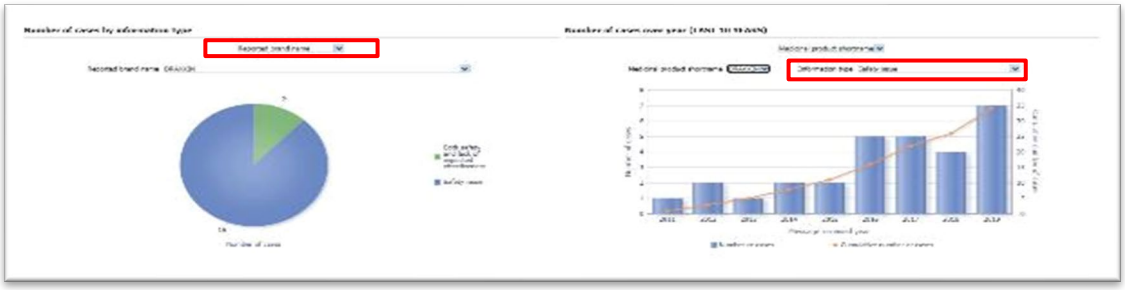


Image 80: Number of cases over year (LAST 10 YEARS) chart

6.4. Product association

The charts displayed in the Product association tab from top to bottom are as follows:

- **Number of cases by product used in association with others:** The tree map shows the number of cases by product used in association with others displayed as hierarchical data, so the user is able to see the concomitant products used together with the product selected in the filters page. The darker the blue, the higher the number of cases for the combination of products. Also, every rectangle has an area proportional to the number of cases.
- **Number of cases by species:** Horizontal bar chart. Interconnected to the tree map, in this chart, the user can see the number of cases by species for the concomitant products to the main product selected in the filters page. These products have to be selected in the drop-down menu enabled at the top for that purpose.

Number of cases by species: Heat map. Also interconnected to the tree map, in this heatmap the user can see the number of cases by species for the concomitant products related to the main product selected in the filters page, including also the reactions at VedDRA level.

Image 81: Number of cases by species

6.4.1. Cases with no other products reported

Additionally, two links have been enabled at the right side for the user to access to the detailed tablesfor cases without other products reported.

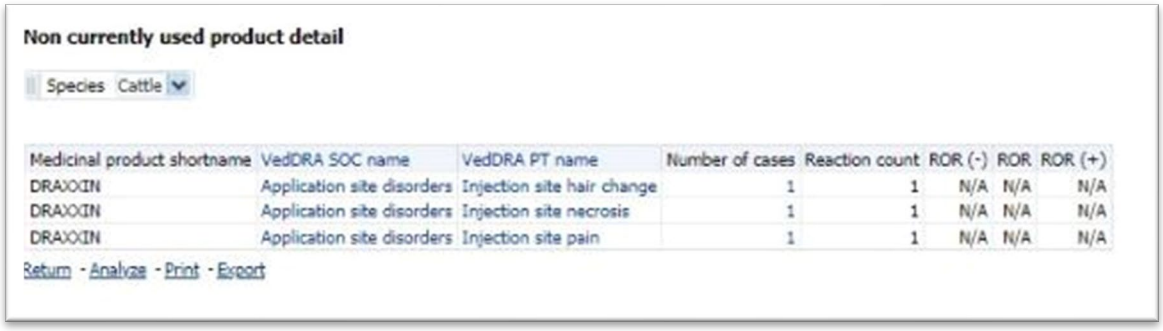


Image 82: Cases with no other products reported

6.4.2. Cases with other product reported

And with other products reported.

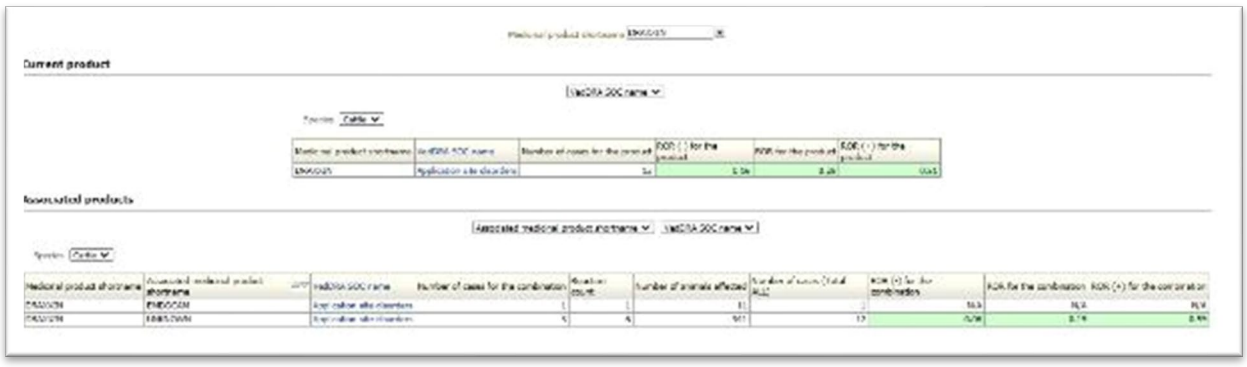


Image 83: Cases with other product reported

6.5. Associated VedDRA

The last tab of the Signal Evaluation dashboard is related to the reactions associated with the one selected in the filters page. A table like the one below will show up, displaying the VedDRA SOCs linked to the VedDRA term(s) previously set.

In addition to that, a VedDRA SOC drop-down menu has been included at the top in case the user selects more than one term. Right below, a couple of drop-down menus allow the user to jump from Medicinal short name to ATCVet code or active substance-based analysis, as well as associated VedDRA terms displayed at a different level.

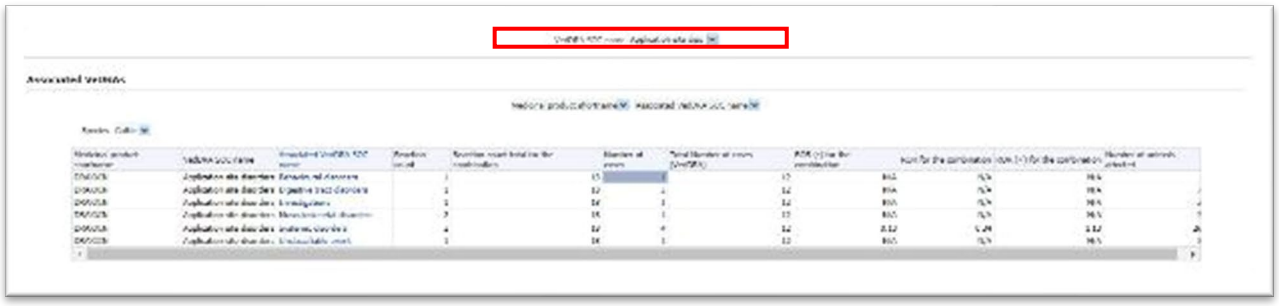


Image 84: Associated VedDRA

As usual, the Number of cases column includes access to the second-level reports (See 3.2.1. See Details).

6.6. Link to VPhS

Pending to be updated with a link to IRIS. Adverse events comparison between 2 periods. This dashboard allows users to compare data for two time periods based on three key dates:

- Message received date
- Original received date
- Date of onset

And three performance indicators:

- Number of cases
- ROR
- ROR(-)

Consequently, for the periods selected and date selected, the user will get the number of cases and ROR metrics for both the period 1 and the period 2 in the same chart so it can be quickly compared. The dashboard is broken in two tabs: one for the filters and the other for the actual charts:

Image 85: Adverse events comparison between 2 periods menu

6.7. Filters

1. **Choose from all attributes in the Product Information (required)**

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- **Active substance level:** results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number: r**esults will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- **Product composition level (Composition, Strength, Formulation, Pharma Product):** results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

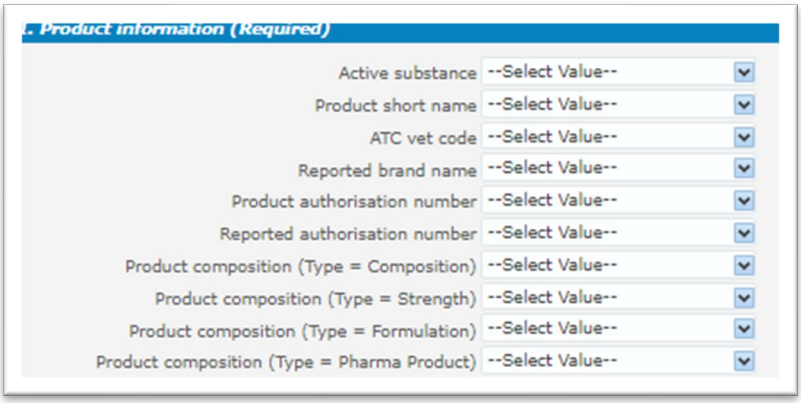


Image 86: Filter options

2. Time periods (required)

In this prompt the user sets the different time periods likely to be compared for the 3 indicators included in the dashboard: Message received date, Original received date and Date of onset.

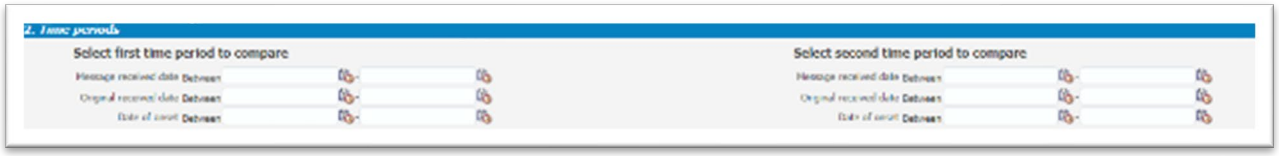


Image 87: Time periods

3. Report filter (required)

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

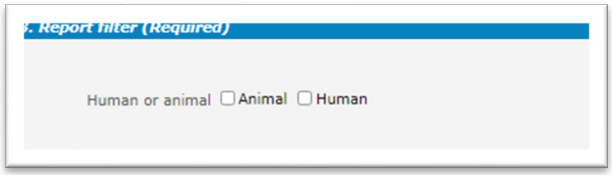


Image 88: Report filter

4. All cases or new cases (required)

In this prompt you have to select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period and will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.

Image 89: all cases or new cases

5. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

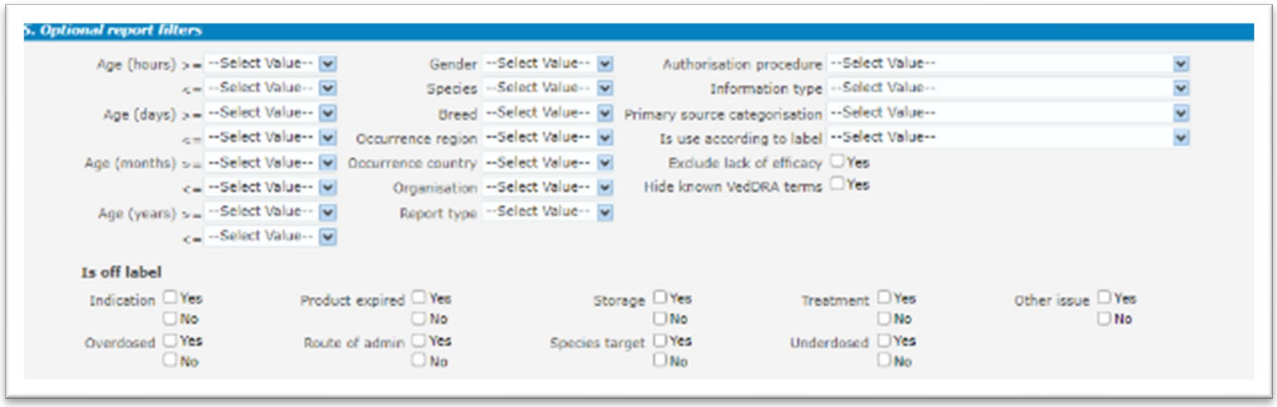


Image 90: Optional AE Report filters

- **Original Received Date**: date that the MAH or NCA first received the message.
- **Serious**: the system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy:** If you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

6. Threshold ROR (required)

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

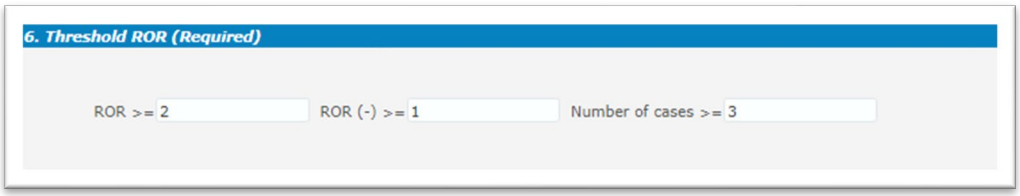


Image 91: Threshold ROR

7. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per the selected date, excluding data received after the selected date.

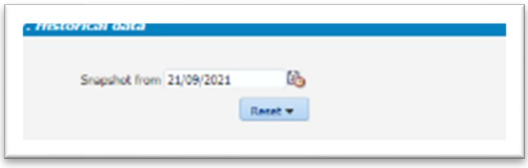


Image 92: Historical data

7. Adverse events comparison between 2 periods

After setting the time periods and the rest of required fields within the filters page, the user clicks on the "Adverse events comparison between 2 periods" tab to visualise the dashboard.

The first functionality the user is going to see is the radio buttons, at the very top. Using those, the user will be able to jump from one indicator to the others for the selected time period, which will be always stated right below.

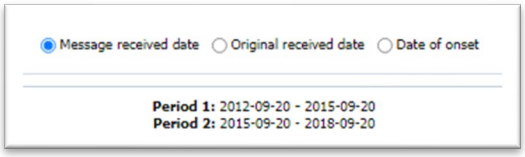


Image 93: Adverse events comparison between 2 periods date criteria

Apart from that, the user will visualise the 3 main elements included in the dashboard: the horizontal bar charts representing the following KPIs: Number of cases, ROR and ROR (-).

On top of every one of them, several drop-down menus have been included in order to:

- Visualise the charts by product, reported brand name, product composition, active substance or ATCvet code
- Jump from one VedDRA level to the others.
- Select all the species involved with this product and time periods.
- Jump between the products selected in the filters page.

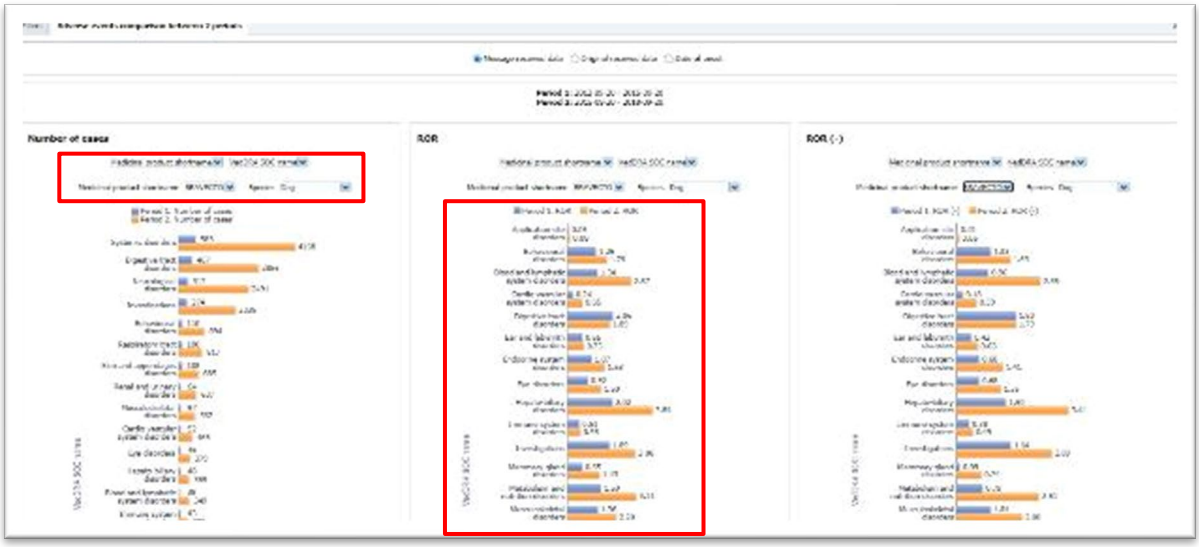


Image 94: Adverse events comparison between 2 periods dashboard

Additionally, two heatmaps in the bottom display the number of cases for the product and period selected, one for the Period 1 and another for the Period 2, optional filter for species not applicable.

Image 95: Period by period view

The heatmap can be visualised by product, reported brand name, product composition, active substance or ATCvet using the drop-down menus on top. After selecting the type of visualisation, the drop-down menus set right below will display a list accordingly.

7.1.1. Message received date – See details

At the very bottom of the dashboard, a link has been enabled for the user to navigate to the See details tables, and depending on the radio button selected this will display on date or the others.

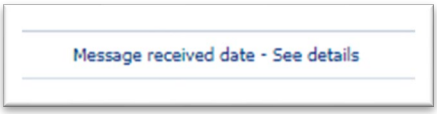


Image 96: Message received date – See details

By clicking this link, the user will open the table in a different tab, with the following information.

7.1.2. Original received date – See details

Same for the Original received date.

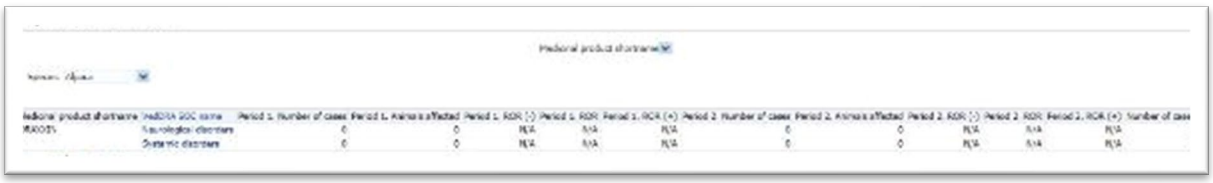


Image 97: Original received date – See details

7.1.3. Date of onset – See details

Same for the Date of onset.

8. Data stratification

This dashboard allows users to find products involved in a particular reaction or group of reactions by displaying the number of cases for that pre-set conditions (**Adverse events by VedDRA terms**). Additionally, using the second tab (Product stratification) the user can check the ROR for the product or group of products at all VedDRA levels, including or excluding a second product from the equation, as well as the Number of animals affected divided by species at VedDRA SOC level.

On all other dashboards, the ROR is calculated by comparing the number of cases for the selected product/substance to "all other products" in the EVVET database.

This dashboard aims to allow the user to exclude outliers or simply narrow the ROR for comparison purposes. The data stratification dashboard is divided in 3 tabs:

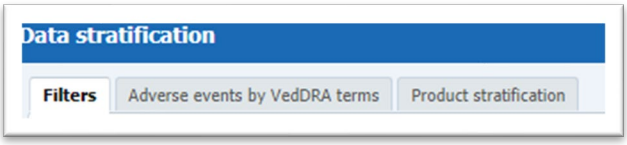


Image 98: Data stratification menu

8.1. Filters

1. Product information (required for product stratification)

The first prompt is product-oriented, and the user must fill it in to get an overview of the Product stratification tab. For that purpose and depending on the analysis, the user will check "Compared to"or "Compared to all except".

The user should select the product/substance subject to their evaluation on the left side. For instance, selecting "Compared to" and an ATCvet code on the filter on the right side will restrict the denominator of the ROR to products belonging to the selected ATCvet code.

Selecting "Compared to all except", and a product or substance on the left side will exclude the selected product/substance from the denominator of the ROR.

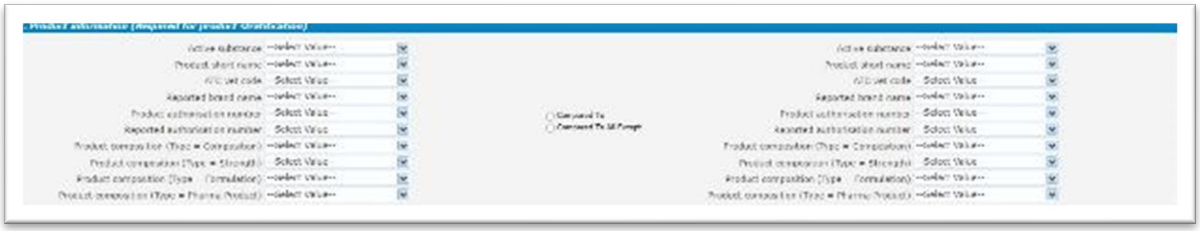


Image 99: Product information filters

2. VedDRA terms (required for adverse events by VedDRA terms)

The second prompt is related to AE reactions and the user must fill it in to get an overview of the Adverse events by VedDRA terms tab. For that purpose and depending on the analysis, the user will check "AND" or "AND NOT".

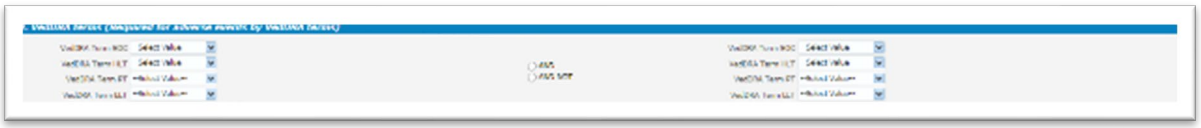


Image 100: VedDRA terms filter

3. Animal information (required)

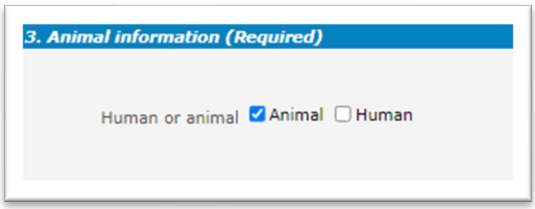


Image 101: Animal information filter

4. All cases or new cases (required)

In this prompt you have to select one of the two options, being "All Cases" selected by default. Selecting "New cases" will return data related only to new reports received in EVVET during the selected period and will exclude from the data set follow ups to reports initially received in EVVET prior to the selected period.

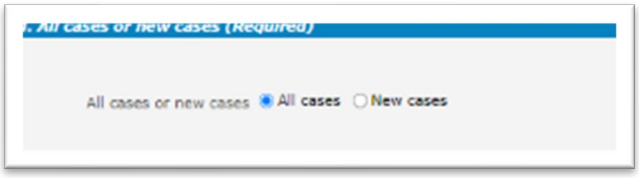


Image 102: All cases or new cases filter

5. Choose from list of optional AE Report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

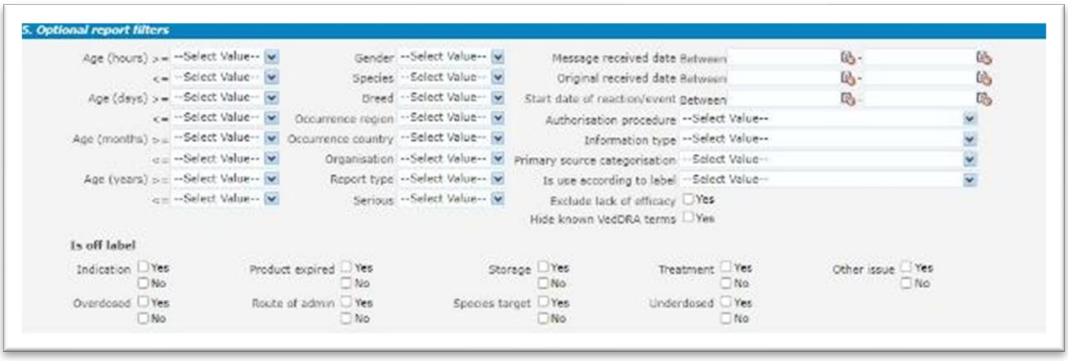


Image 103: Optional AE Report filters

- **Original Received Date:** date that the MAH or NCA first received the message.
- **Serious:** system will return only the serious or the non-serious reports.
- **Information type vs Exclude lack of efficacy:** if you want to exclude the lack of efficacy cases and you exclude "Lack of efficacy" within the Information type drop-down menu (by including all other information types), you will get the reports where LOE has been reported together with other issues/information types. However, if you tick the box "Yes" in "Exclude lack of efficacy", the system will exclude those reports where the VedDRA term "Lack of efficacy" has been reported.

6. Product MAH filter

By using 'Product MAH filter', it is possible to filter by one specific MAH, so the output of the query will only be data related to the informed MAH (its products)

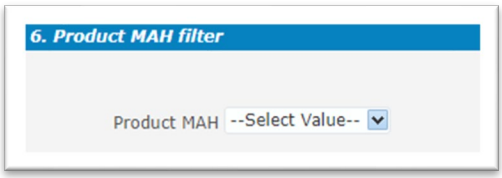


Image 104: Product MAH filter

7. Threshold ROR (Required)

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

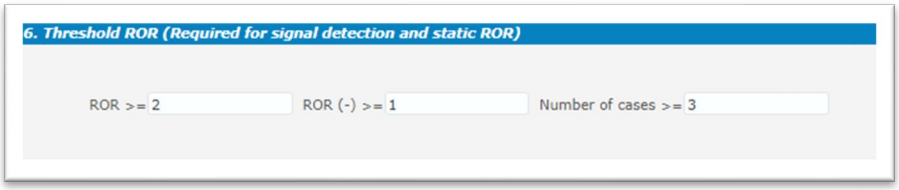


Image 105: Threshold ROR

8. Historical data

No answer is required for this prompt. By default, a snapshot of the day will be set. If a different date is selected, the results will reflect the data in EVVET as per selected date, excluding data received after the selected date.

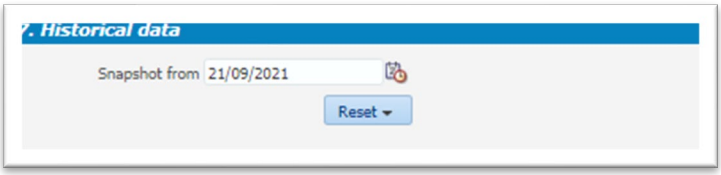


Image 106: Historical data

8.2. Adverse events by VedDRA terms

Filling prompt number 2 is required to visualise this tab. At the top of every tab the user will find a header including the usual key figures, being for thisdashboard: Number of cases, Product count and Animals affected, as follows:

Image 107: Adverse events by VedDRA terms key figures

Right below the header, two charts will display the Top 15 (15 products or less will be listed) of the products associated with the reactions set at the filters page. First chart shows products associated with the first product and second chart shows:

- Products associated with the combination of VedDRAs if the user selects "AND".
- Products associated with the first VedDRA selected and excluding the second from the equation if the user selects "AND NOT".

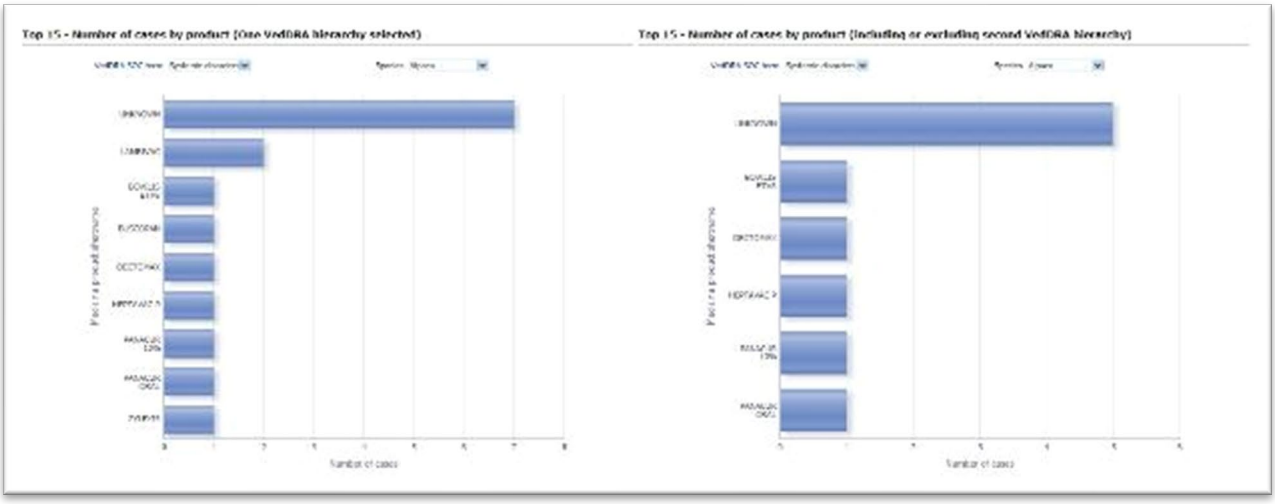


Image 108:Adverse events by VedDRA terms top 15

Product filters do not apply in this report.

Above the charts, two drop-down menus have been included, one for selecting the different VedDRA terms at SOC level (in case the user selects more than one) and the other for changing from one species to the others.

8.3. Product stratification

Filling prompt number 1 is required to visualise this tab.

Right below the header (see 7.2 Adverse events by VedDRA terms) 2 charts will display with the Top 15 (15 products or less will be listed) of reactions at VedDRA SOC level by ROR.

The first chart shows the ROR for the reactions (at SOC level) related with the first product selected and the second chart will show:

- ROR for the reactions (at SOC level) related to the product selected in the left prompt compared to other products **but** the product selected in the right prompt if "compared to all except" was selected.

  Or

- ROR for the reactions (at SOC level) related to the product selected in the left prompt compared all other products belonging to the selected ATCvet code if "Compared to" was selected.

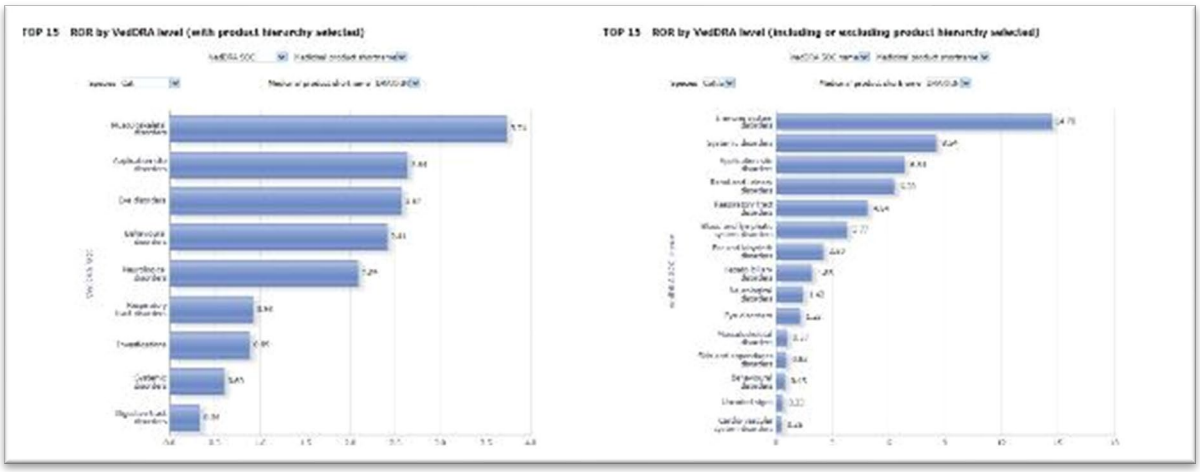


Image 109:Product stratification top 15

Above the charts, four drop-down menus have been included:

- For jumping between VedDRA levels.
- For jumping between Species.
- A product hierarchy level so the user will be able to display the chart by medicinal product short name, reported brand name, product composition, active substance or ATCvet code..
- A drop-down menu interconnected with the previous, displaying the selected product or active substance depending on the level selected on the product hierarchy above.

Another chart is included in this tab, a heatmap, showing the Number of animals affected by VedDRA, SOC terms and ATCvet code. The different blues indicate if that Species- SOC combination belongs to the first, second, third or fourth quartile.

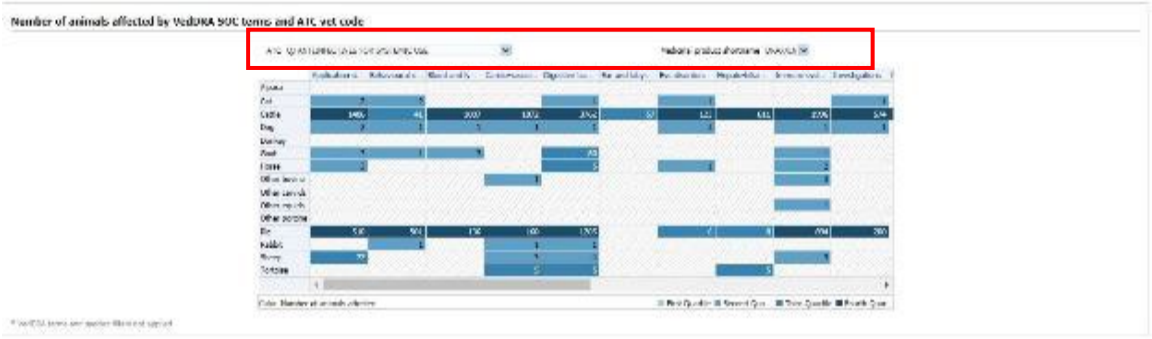


Image 110: Number of animals affected by VedDRA SOC and ATCvet code

On top of this the user will see a couple of drop-down menus, one for navigating between products (in case more than one is selected) and the other enabled to pick between the ATCvet codess involved.

8.3.1. See details

The "see details" table is only relevant and becomes enabled when the user has selected an ATCvet code for the "Compared to" option on the filters page. (See 3.2.1. See Details).

9. Signalling for reactions linked to a product or ingredient

9.1. Filters

1. **Output level (required)**

The user must select one of the output levels.

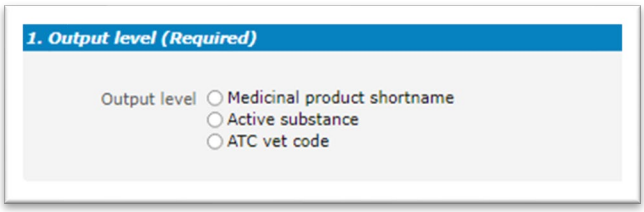


Image 111: Output level

2. **Message received date range (required)**

In this prompt you select a range of dates.

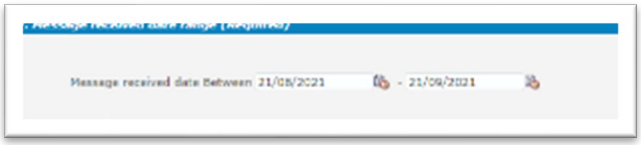


Image 112: Message received date range

3. **Report filter (required)**

Select whether your result should contain only **animal** or **human** AERs by ticking the relevant option, or both by selecting both Animal and Human.

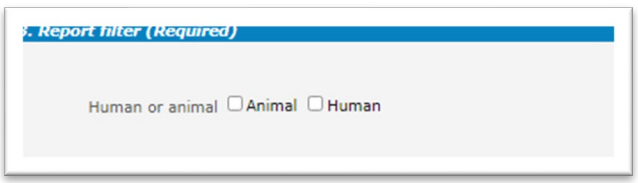


Image 113: Report filter (human or animal)

4. Product information

The user is required to select either the product MAH or the product authorisation country to enable the signalling for reactions tab.

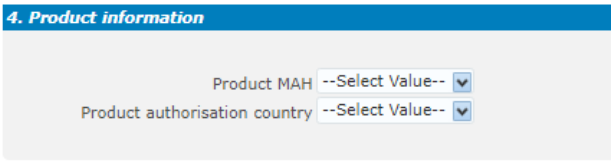


Image 114: Product information

5. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

Image 115: Optional report filters

6. Threshold ROR

This prompt is mandatory but filled by default with ROR>=2, ROR(-)>=1 and Number of cases>=3. The user is able to customize these values for the purpose of the analysis.

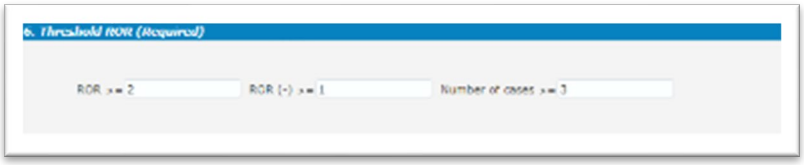


Image 116: Threshold ROR

9.2. Signalling for reactions linked to a product or ingredient

In this dashboard the user can see the Top 15 products/active substances/ATCvet codes by number ofcases between date 1 and date 2. ROR and ROR(-) are also included in the visualisation.

Image 117: Top 15 products/active substances/ATCvet codes by number of cases between date 1 and date

At the top the user will be able to jump between the species and reactions (at PT level) for the period and product information selected in the filters page.

9.2.1. See details

Link included at the bottom (See 4.2.1. See Details).

10. Line listing

The line listing dashboard is actually a two tabs line listing, the first tab being focused on the medicinal hierarchy, second tab on the occurrence country/occurrence region.

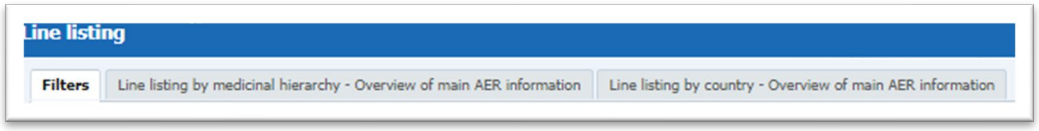


Image 118: Line listing menu

10.1. Filters

1. **Choose from all attributes in the Product Information (required)**

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- **Active substance level:** results will be related to AERs for products that contain the selected active substance(s).
- **Product Short name:** Results will be related to AERs for selected product(s) grouped by the product short name.

- **ATCVet code leve**l: results will be related to AERs for products that belong to the selected ATCVet code.
- **Reported Brand Name:** results will be related to AERs for a selected Product Brand Name as reported in the AER verbatim, prior to standardisation.
- **Product Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported Authorisation Number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- **Product composition level (Composition, Strength, Formulation, Pharma Product):** Results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

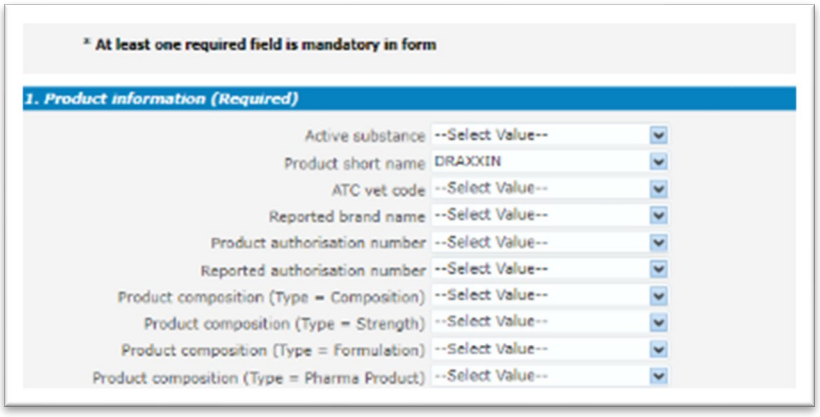


Image 119: Product information filters

2. Report filter (required)

Select whether your result should contain only animal or human AERs by ticking the relevant option, or both by selecting both Animal and Human.

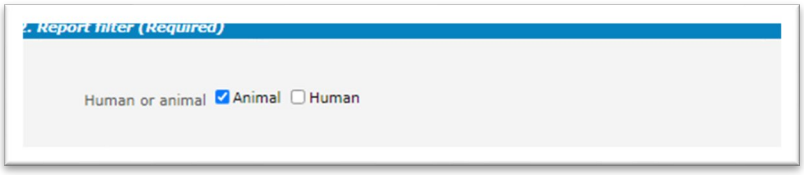


Image 120: Report filter (animal or human)

3. Product MAH filter

The user is required to select either the product MAH or the product authorisation country.

Image 121: Product MAH filter

4. Country filter (required)

The user is required to select either the occurrence region or the country.

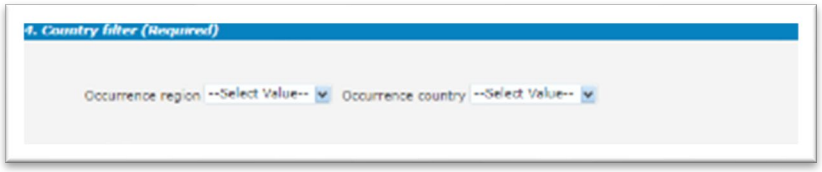


Image 122: Country filter

5. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

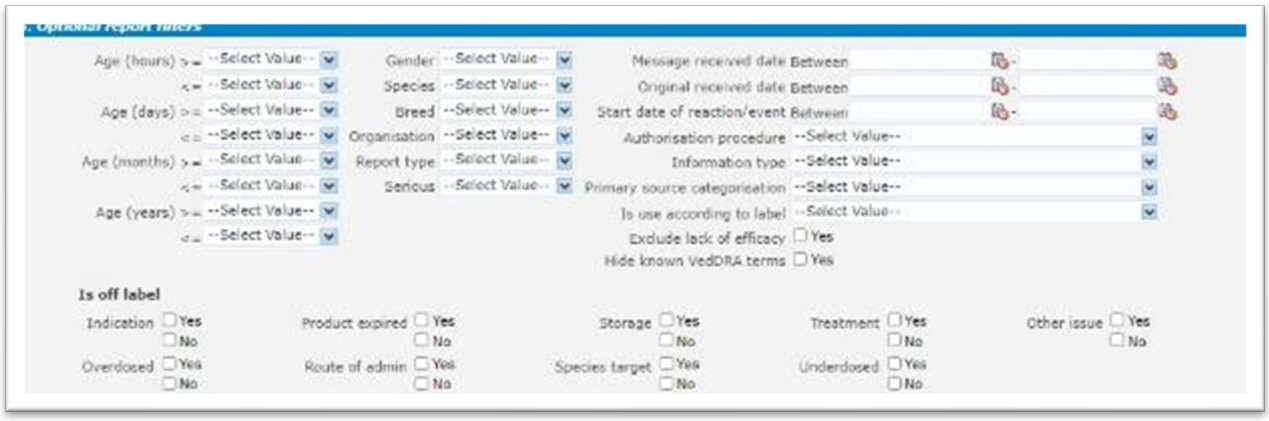


Image 123: Optional report filters

10.2. Line listing by medicinal hierarchy – overview of main AER information

After filling in the mandatory fields, the user clicks on the first tab and navigates to the line listing dashboard, with the usual second level's line listing report structure.

The line listing is the most detailed table the user has access to, basically with the full information about a case.

In the dashboard, though, a couple of drop-down menus have been included at the top. In regards of this first tab, the user will be able to select a product hierarchy (Medicinal product short name, reported brand name, product composition, active substance, ATCVet code) and then another interconnected drop-down menu to jump from one product, substance, etc. to the others.

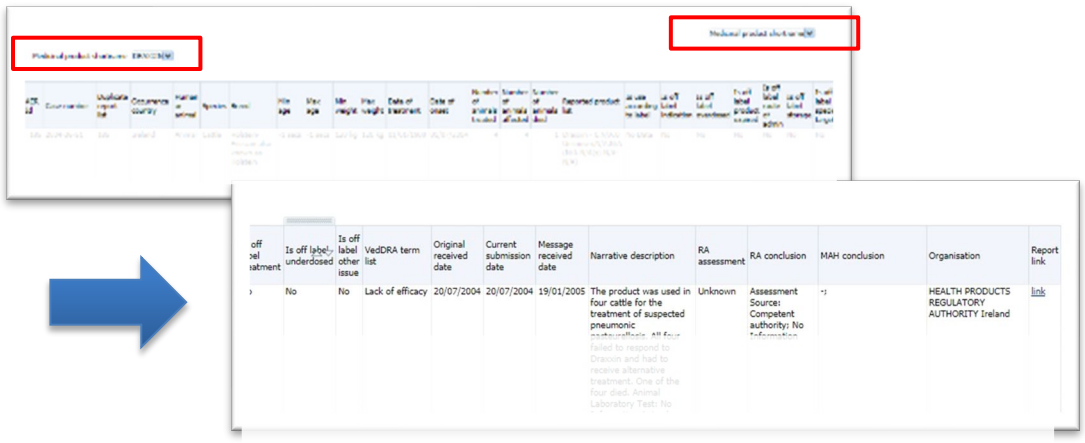


Image 124: Line listing by medicinal hierarchy – Overview of main AER information

10.3. Line listing by country – Overview of main AER information

In regards of the second tab, the user will be able to select between occurrence region or country, and then another interconnected drop-down menu to jump from one region or country to the others.

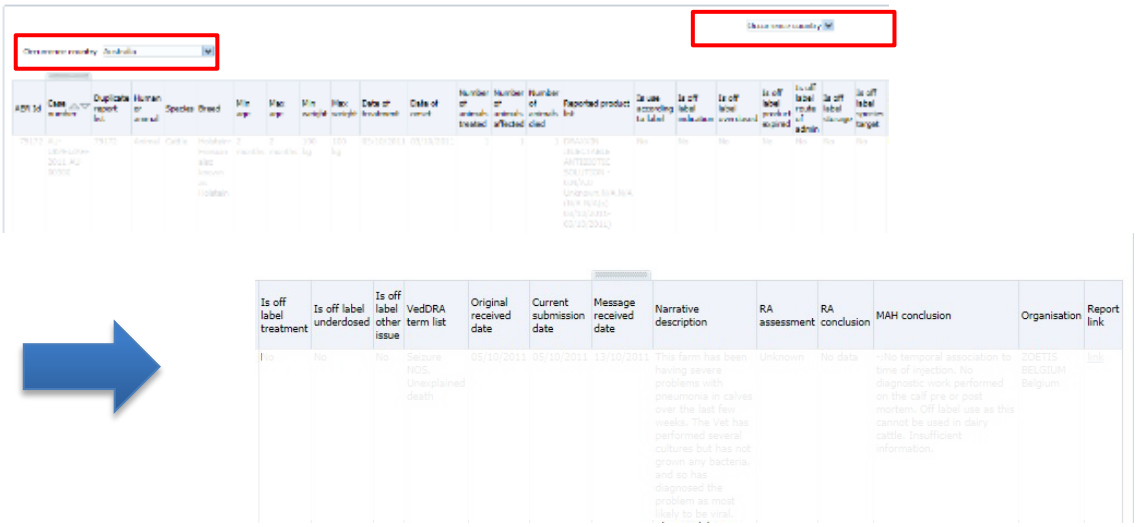


Image 125: Line listing by country – Overview of main AER information

11. List of products

11.1. Filters

1. Choose from all attributes in the product information (required)

In this prompt the user selects at what level of the product hierarchy you want to run your query. These levels are:

- **Active substance level:** results will be related to AERs for products that contain the selected active substance(s).
- **Product short name:** results will be related to AERs for selected product(s) grouped by the product short name.
- **ATCVet code level:** results will be related to AERs for products that belong to the selected ATC Vet Code.
- **Reported Brand Name:** results will be related to AERs for a selected product brand name as reported in the AER verbatim, prior to standardisation.
- **Product authorisation number:** results will be related to AERs for selected product(s) grouped by the product authorisation number stated in the product dictionary.
- **Reported authorisation number:** results will be related to AERs for selected product(s) grouped by the product authorisation number as reported in the AER.
- **Product composition level (Composition, Strength, Formulation, Pharma Product):** results will be related to AERs for products that are composed solely of the selected active substance(s), active substance(s) + strength(s), Active substance(s) + Pharmaceutical form(s), Active substance(s) Strength + Pharmaceutical form. This enables users to group products based on their composition, regardless of the trade names of the products.

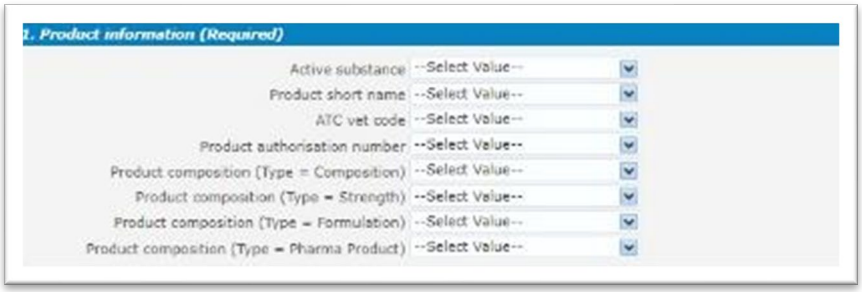


Image 126: Product Information filters

2. Optional report filters

No answer is required for this prompt. By applying any of these filters the results dataset will be restricted to AERs that meet the selected conditions.

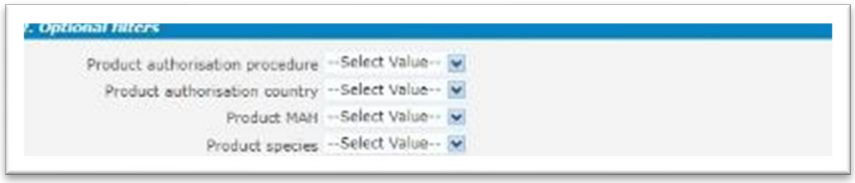


Image 127: Optional report filters

11.2. List of products

This dashboard displays several charts representing Number of cases metrics for the product or products selected in the filters page. At the top the user will find a header including the usual key figures, for this dashboard: Number of cases, Number of AERs and Fatal cases, as follows:

Image 128: List of products key figures

The first set of charts shows two pie charts with the number of cases by active substance and by medicinal product short name:

Image 129: Number of cases by active substance and by medicinal product short name

Second set of charts includes three pie charts with number of cases by ATCvet code, pharmaceutical form and authorisation procedure:

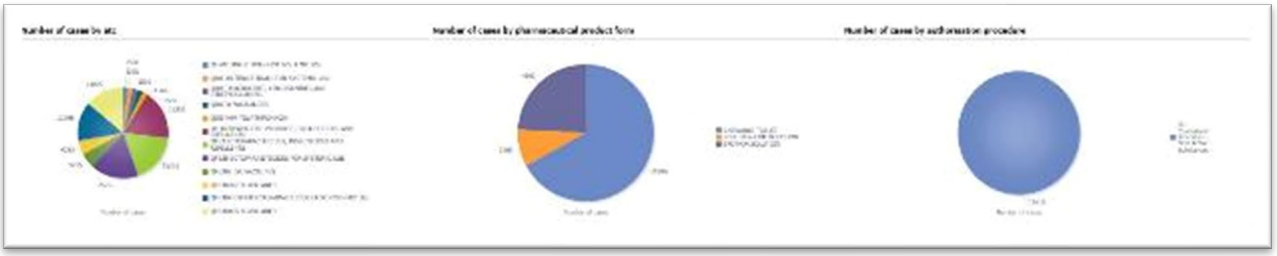


Image 130: Number of cases by ATCvet, pharmaceutical form and authorisation procedure

Third set includes a map representing the number of cases by authorisation country, a tree map for the number of cases by medicinal product authorisation number and finally a bar chart with the Top 15 number of cases by medicinal product:

Image 131: number of cases by authorisation country, number of cases by product and authorisation number and Top 15 number of cases by medicinal product

Lastly, two extra pie charts show the number of cases by MAH and by Species for the product or products selected in the filters page:

Image 132: Number of cases by MAH and by Species

11.2.1. See details

See 4.2.1. See Details.

11.3. List of products and substances without AERs associated

The second tab in 'list of products' dashboards will retrieve those products and substances that do not have any report associated. It means they were not reported in any AER.

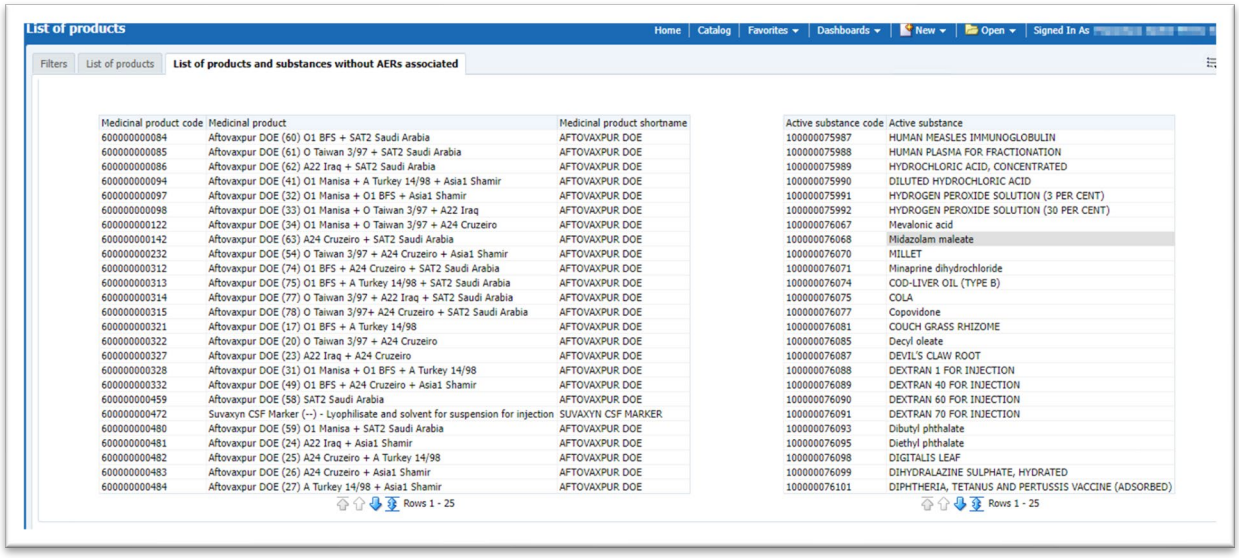


Image 133: List of products and substances without AERs associated

12. Pharmacovigilance inspections dashboard

The inspections dashboard is used to view the outcomes of the Pharmacovigilance (PhV) inspections that have been registered in IRIS. It displays, depending on the user's input, either a PSMF list that contains at least one CAP (centrally authorised product) with the corresponding dates related to the latest inspection of the PSMF, or a list of PSMFs that do not contain CAPs.

This dashboard can only be accessed by NCAs.

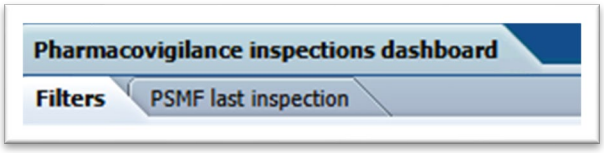


Image 134: Inspections dashboard tabs

12.1. Filters

Filters in this dashboard are distributed in the following manner:

1. **PSMF**

The user can select specific details regarding PSMF like reference, location and product MAH.

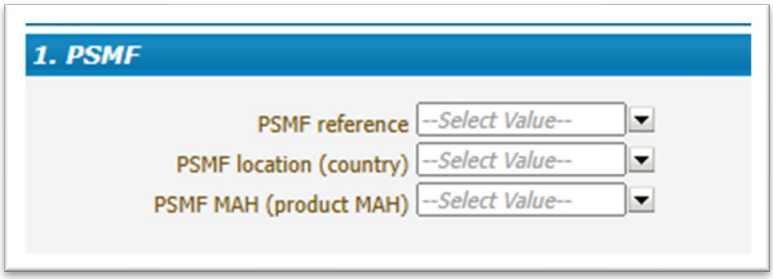


Image 135: PSMF Filter

- PSMF reference
- PSMF location (country)
- PSMF MAH (product MAH)

2. **Inspections**

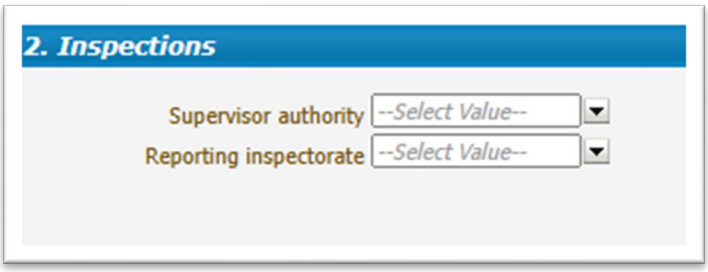


Image 136: Inspections Filter

- Supervisor authority
- Reporting inspectorate

12.2. PSMF last inspection

It displays a table containing a list of PSMF's covering at least one CAP. There is a filter available at the top of the dashboard for this.

It also displays PSMF location and reference and the MAHs related to each of those PSMFs. The latest pharmacovigilance inspection starts, and end date is also available in the table with QPPV for each PSMF.

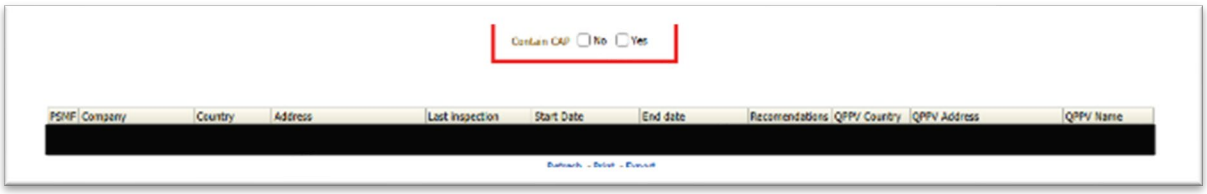


Image 137: PSMF last inspection table contents

Inside the 'PSMF' column the user is able to click and generate two different line listings, one per products listing and the other per inspection listing for the selected PSMF.

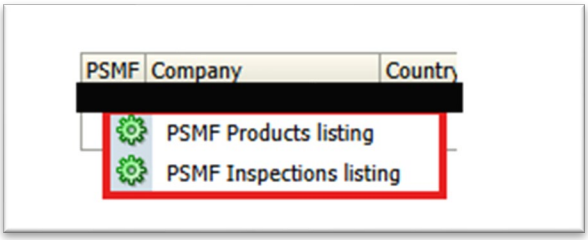


Image 138: PSMF line listing options (PSMF column)

Inside the 'Last inspection' column the user is able to click and generate a line listing showing the products for that inspection for that PSMF.

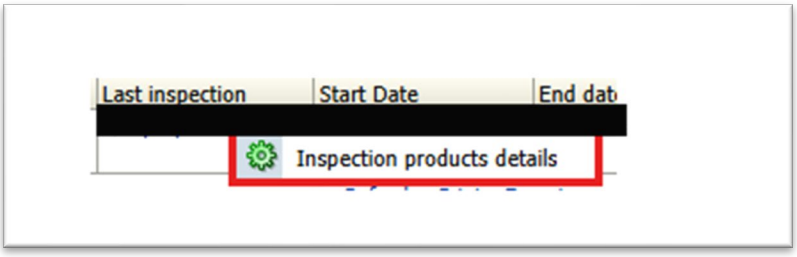


Image 139: PSMF line listing option (last inspection column)

12.2.1. PSMF products listing

It re-directs to a line listing table showing all the products covered by the current PSMF. The table consists of product short name, product name, product code, procedure type name, scientific product and MAH for the selected PSMF product.

12.2.2. PSMF inspections listing

It re-directs to a line listing table showing the inspections covered by the current PSMF. Table consists of inspection, start date, end date, country, company, address, supervisor authority, reporting inspectorate, recommendations, finding and grading.

12.2.3. Inspection products details

It re-directs to a line listing table showing products in the current PSMF at the time and location of this inspection. The table consists of inspection, start date, end date, product short name, product name, product code, procedure type name, MAH, QPPV country, QPPV address, QPPV name.

13. Sales Dashboard

This dashboard presents the sales data and incidence for all products for a selected period. This dashboard can **only** be accessed by NCAs.

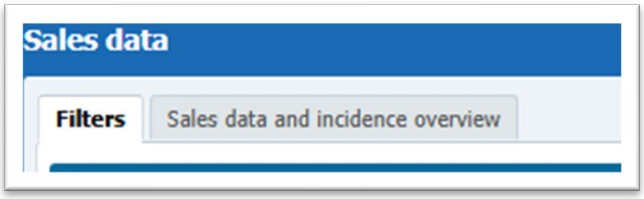


Image 140: Sales dashboard tabs

13.1. Filters

Filters in this dashboard are distributed in the following manner:

1. **Product information (required)**

User can select each medicinal product for which sales data is informed. It is not necessary to complete this information if you have filled out the MAH.

- Product short name
- Product group name
- Medicinal product

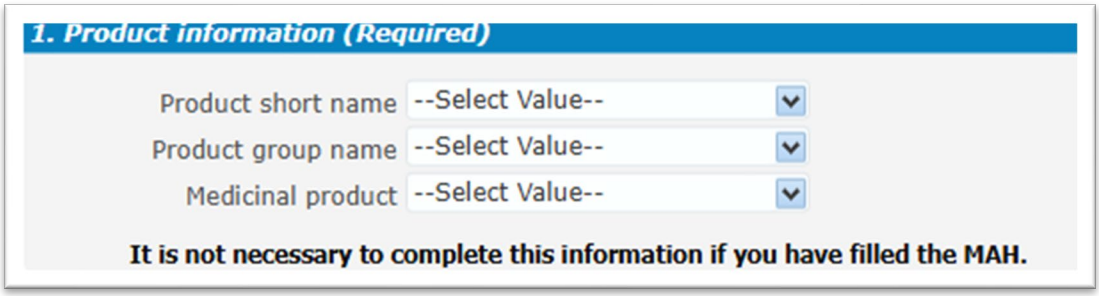


Image 141: Product information (required) filter

2. Sales data period (required)

Multiselect option must retrieve the complete years from sales data:

- Users can select one-year, multiple years or 'select all' option.
- When the filter is selected, the data that retrieved should be regarding the sales in that period (not related to AERs) --> Sales of 'X' product during the informed/selected period (year(s)).

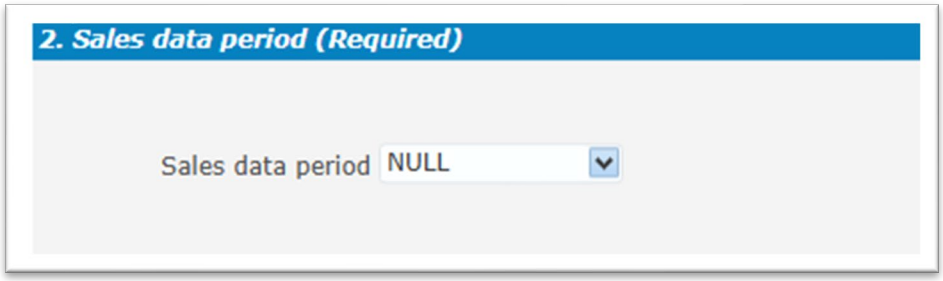


Image 142: Sales data period (required) filter

3. Product MAH filter

By using 'Product MAH filter', it is possible to filter by one specific MAH, so the output of the query will only be data related to the informed MAH (its products). Please note that you will at present only get results for MAHs with products for which there are adverse event reports.

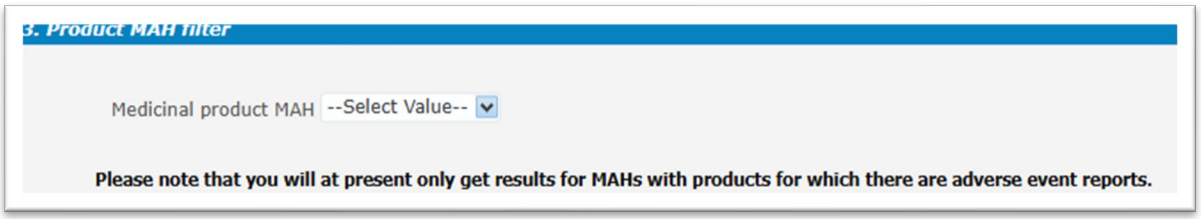


Image 143: Product MAH filter

4. VedDRA terms

In this prompt the user can select one or multiple VedDRA terms at different levels.

- VedDRA Term SOC
- VedDRA Term HLT
- VedDRA Term PT
- VedDRA Term LLT

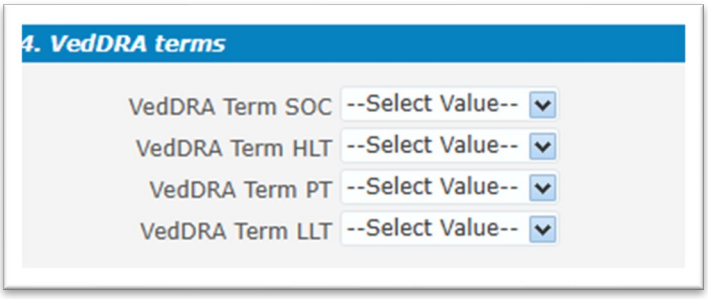


Image 144: VedDRA terms filter

5. Species

This filter retrieves all possible values if it was not informed in the filters page (if this information was given in the filters page, this field must only give the informed value in the filters page). The value(s) is retrieved based on the 'Species' related to each product in UPD (NOT affected species regarding AERs).

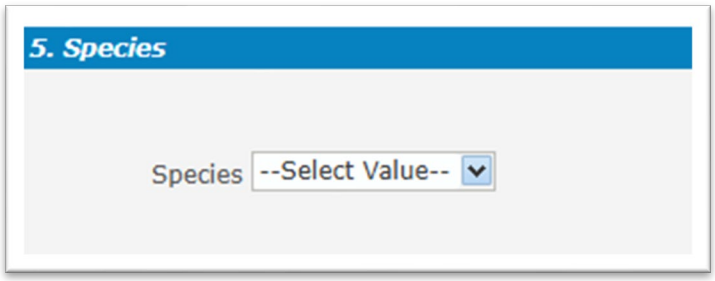


Image 145 : Species filter

6. Region/country

It must retrieve information regarding the sales data and not related to the AERs. The possible values are the following ones:

- EEA
- Non-EEA
- Unknown

Depending on the region selected it will filter out the specific country the user can select for a more specific analysis.

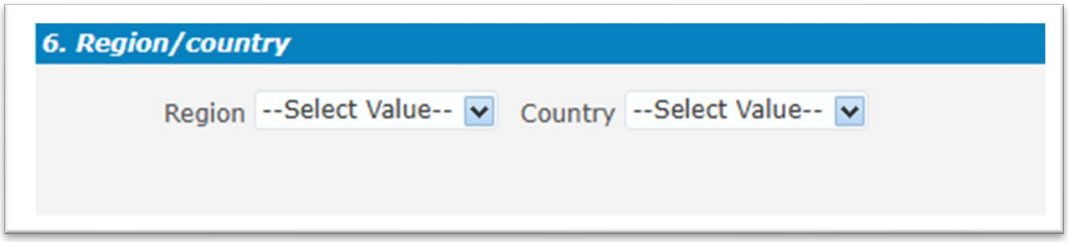


Image 146 : Region/country filter

13.2. Sales data and incidence overview

This dashboard displays the sales data information at medicinal product level, calculating:

- Volume of sales
- ENTA (estimated number of animals treated)
- Incidence calculation

The user is also able to re-select filters here again that apply to all the reports in this tab like sales data period, species, region/country.

The left side of the dashboard displays graphs related to sales and the right side of the dashboard displays graphs related to incidence.

Sales data and incidence overview

Composed of two maps and their respective tables below:

- Left map shows the volume of sales per country (hover over to see details). Below it displays a table with the same information, moreover, including the ENTA.
- ENTA (estimated number of animals treated) = No of units sold x %species x Dose Factor
- The right map shows the %incidence per country (hover over to see details). Below it displays a table with the %incidence for each of the PT VedDRA terms names (available filter).
- % incidence = (total number of animals displaying during a defined period/estimate of the number of animals treated during the same period) x 100

Image 147: Sales data and incidence overview (skeleton)

Both tables also include a dimension called Product Hierarchy Level to choose by which the user would like to display the data inside the left column of the table.

Image 148 : Product hierarchy level tables displaying volume of sales & %incidence

13.2.1. Line listing sales data

Available in the left-hand table when the user clicks on the specific medicinal product from the product hierarchy level chosen inside the column, they are able to generate in a separate report a line listing regarding sales.

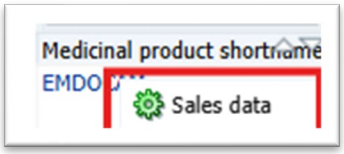


Image 149: Line listing for sales data

- When the user selects 'Medicinal product short name', it should get all the medicinal products sold under each product short name in the selected period.
- When the user selects 'Product group name', it should get all the medicinal products under the same Product grouping ID that have been sold in the informed period.

Sales Data and Incidence per year

Composed of a bar chart displaying volume of sales (bar) and % incidence (line) per year and selected Product Hierarchy Level dimension. (hover over bar to see details).

13.2.2. Incidence calculation see details

At the bottom of the dashboard there is a text available to click: 'Incidence calculation see details':

Image 150 : Incidence calculation see details link

It is composed of two tables with three columns:

- Top Table: Medicinal product chosen from Product Hierarchy Level Dimension, VedDRA SOC, %incidence
- Bottom Table: Medicinal product chosen from Product Hierarchy Level Dimension, VedDRA term chosen from VedDRA Hierarchy Level, %incidence

Based on the Product Hierarchy Level the results in the tables must show the corresponding VedDRAs that have been submitted. Global filters for both tables include Species, Year and Occurrence Country.

14. How to group data for different products

14.1. Introduction to product grouping

For contextual purposes, this grouping is related to 3 main scenarios:

- Grouping products with different names but referring to the same Medicinal Product.
- Grouping data based on the composition by selecting Scientific Product or Active Substance
- Ad-hoc aggregations for random analysis purposes

The guide will focus mainly on the first scenario and 2 specific medicinal products, analysing in detail how to group them as well as how this grouping impacts in the metrics recalculation. As mentioned, the analysis will consider:

- Active substance **ENROFLOXACIN**
- Products **PRODUCTX** and **PRODUCTX OTIC**
- MAH **BAYER B.V. HEALTHCARE ANIMAL HEALTH** and **BAYER S.P.A**

14.2. Demo

- Active substance **ENROFLOXACIN**
- Products **PRODUCTX** and **PRODUCTX OTIC**
- MAH **BAYER B.V. HEALTHCARE ANIMAL HEALTH** and **BAYER S.P.A**.

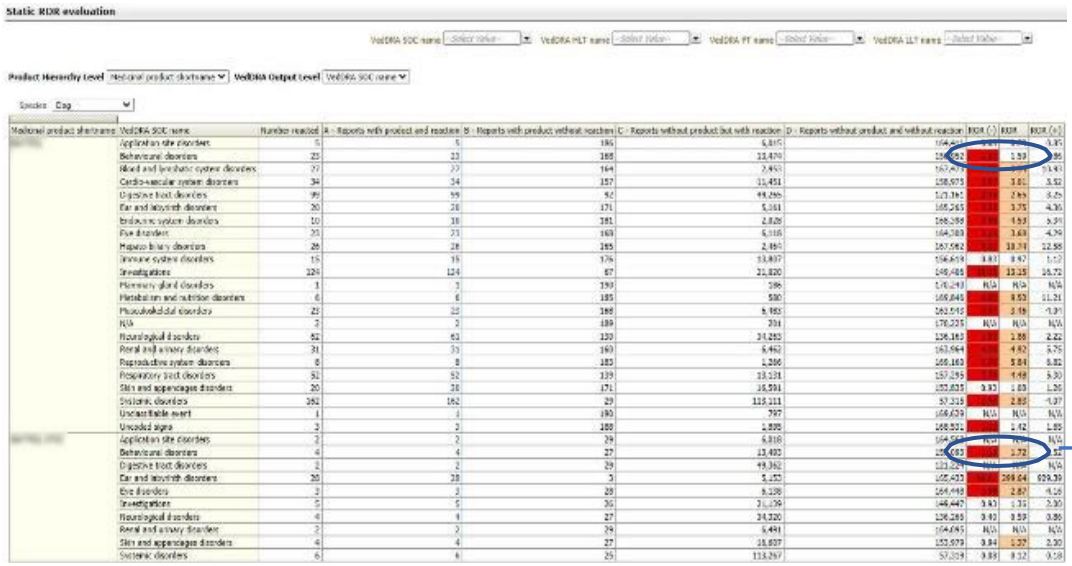
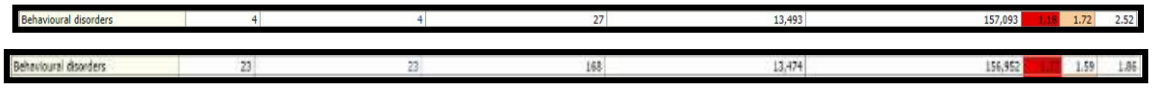


Image 151: Static ROR Dashboard for 2 medicinal products

We can see highlighted the ROR(-), ROR and ROR(+) for the VedDRA SOC behavioural disorders:



We filter by VedDRA SOC up in the dashboard, so we only see the 2 products under analysis, PRODUCTX and PRODUCTX OTIC and their respective metrics:

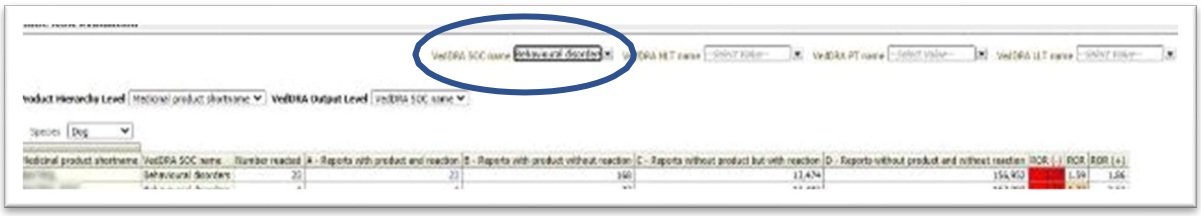


Image 152:Static ROR with VedDRA SOC filter applied

After removing the product (by clicking on the column header and then on "exclude column") the system deletes the Medicinal Product column and recalculates the RORs :

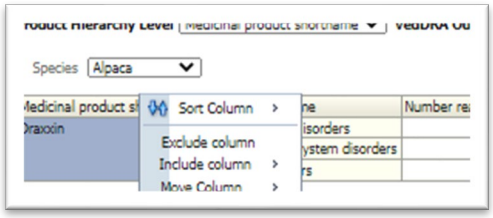


Image 153: Menu option where user can exclude column from table

Image 154: Recalculation from ROR after removing column split with of medicinal products

$$\text{ROR} = \frac{27/195}{13.470/156.925} = 1.61$$

15. Dashboard walkthrough

The purpose of this dashboard walkthrough is to make an itinerary through the different dashboards implemented, focusing the analysis on its diverse functionalities depending on the potential business scenarios.

The itinerary will cover the user's decision-making process, depending on a series of factors which will determine using one dashboard or group of dashboards to conduct a specific analysis.

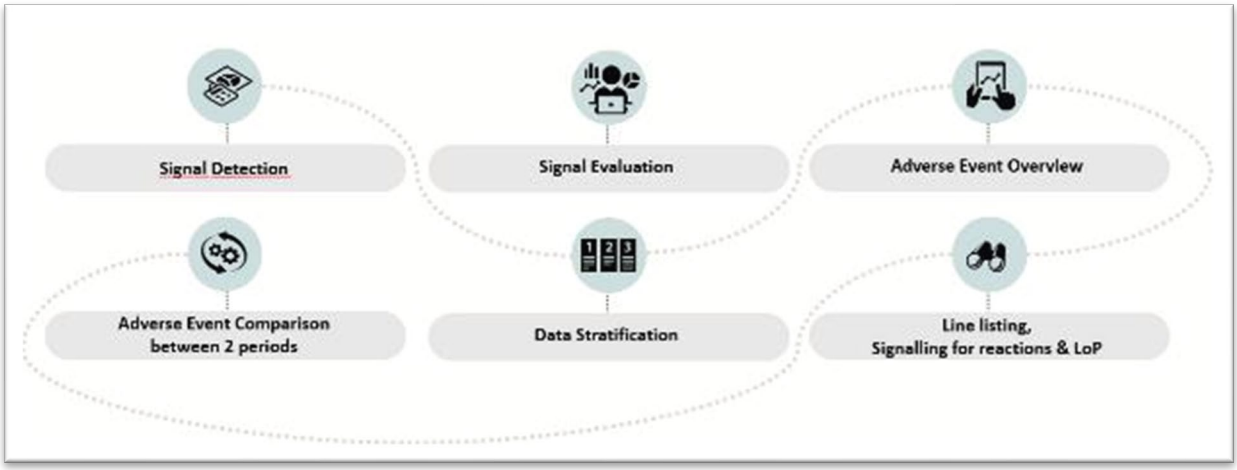


Image 155: Dashboard walkthrough

As a general rule, here's a schema of which dashboard is the most appropriate depending on the purpose of the query and what kind of information the user is trying to obtain:

- **Adverse Event Overview:** To get a simple overview of the data for a product, substance, groupof products
- **Signal Detection:** To view data for product, active substance, group of products in order to check for potential signals
- **Signal Evaluation:** To evaluate signals (age, time to onset, off label use, geographical distribution, pharmaceutical form, other products involved, other VedDRA terms)
- **Data Stratification:** To exclude outliers or simply narrow a query for comparison purposes
- **Adverse Event Between 2 Periods of Time:** To compare data for 2 time periods
- **Line Listing:** To list the cases for a product, substance, group of products, MAH, country
- **Signalling for Reactions:** To monitor data for MAH/NCA products or substances (weekly,monthly)
- **List of Products:** To monitor number of cases (by active substance, product, pharmaceutical form, ATCVET, authorisation country, number, MAH, species)

In terms of searching for concrete metrics or products, some useful tips for the user would be:

- **Number of Cases:** When the question is about the number of cases for a product, the user should use the Adverse Event Overview dashboard.
- **Statistical measure of signals:** In order to know about the type of reaction with relative frequency at a specific level, the user should go either through the Adverse Event or the Signal Detection Dashboards.

- **Products involved:** In regards of the products involved in a specific group of cases, the user should either go to the Data Stratification Dashboard or jump to it from the Adverse Event Overview query by using the link at the bottom.
- **Number of fatalities**: To see the number of animals treated with a product and died or euthanized as a consequence of this, the user should go to the Signal Evaluation and selecting a concrete period and VedDRA terms (death, death by euthanasia).
- **Period analysis:** If the user wants to see the number of cases within a period or from a specific date onwards, Adverse Event Overview is the way to go.

In this sense, we will divide those potential business scenarios in 3 different paths, depending on the profile of the user and/or the purpose of the analysis, just as follows:

1. Standard data exploring query for both NCA and MAH users.
2. MAH users monitoring their own products or ingredients on a weekly/monthly basis.
3. NCA users conducting an active substance class -based analysis.

15.1. Standard path

In the case of what we have named "standard path", we will go through a set of practical questions for a concrete product and reaction, in this case a signal has been found for **Product A** for the VedDRA term recumbency, so the following concerns emerge in a standard analysis process:

15.1.1. How many cases for Product A have occurred?

- The user goes to dashboard Adverse Event Overview and selects Product A in the firstprompt in the filter Product Shortname
- Enter the Message Received Date range as required. i.e. 1 year
- Select VedDRA Hierarchy, VedDRA PT name = Recumbency and tick the box for "Animal" and then run the query

15.1.2. Which signs have been reported on the cases of Product A at PT level? Which PT VedDRA terms have the highest number of reports?

- In the same dashboard (Adverse Event Overview) the user can see a table with all VedDRA terms reported in the cases for the product at SOC level
- Go to "See details" and a table will appear with the cases at PT level, or…
- Click the link to Signal Detection and go to the tab "Signal detection with 2 RORs"

15.1.3. Where have the majority of the cases occurred? How many animals have been affected?

- In the Adverse Event Overview, the user clicks on Animal/Human adverse events overview which is a link to the Signal Detection dashboard
- It will automatically navigate to the Overview of human/animal AERs per product/active substance/ATCvet code tab

15.1.4. Are other products involved?

- Go to the "Signal evaluation" dashboard and select Product A in the first prompt in the filter "Product short name".
- Enter the "Message received date range" as required i.e. last 5 years
- Select "VedDRA Hierarchy, VedDRA PT name = Recumbency". Tick the box for "animal" in the 4th prompt and then run the query. Go to the "Product association"tab

15.1.5. How many animals treated with Product A, have died? How many of those have been euthanised?

- "Adverse event overview" query gives you the number of animals died (Select Product A, click the animal box and make sure to select the dates that include the whole period when Product A has been on the market)
- To see the number of animals euthanised, select the VedDRA term LLT "Death by euthanasia".

15.1.6. How many cases have been reported between 01/03/2016 and 31/05/2016 and how many cases in total?

- "Adverse event overview"" select Product A, and select the dates.
- In the column "Number of cases (Period specified)", you have the n. of cases for specified period. To see the total n. of cases, either remove the date filters, or go to "see details". In the column "N. of cases (Total ALL)" you have the n. of total cases inthe database per VedDRA term
- In the column "N. of cases (Case count (filter not applied)" you have the n. of total cases for the product.

15.1.7. Which other products are associated with recumbency? Which product has the highest number of cases of recumbency after Product A?

- Go to the "Data stratification" dashboard and select "VedDRA terms, VedDRA PT name = Recumbency"
- Then click on "and", then select "VedDRA term PT = Death"
- Tick the box for "Animal" then run the query by clicking on "Adverse events by VedDRA terms. The first graph will give you the answer

15.1.8. Which other signs have been reported together with recumbency? Which pair has the highest count?

- Go to the dashboard "Signal Evalution" and select Product A in the first prompt in the filter "Product short name"
- Enter the "Message received date range" as required e.g. last 5 years
- Tick the box for "animal" in the 3rd prompt.
- Select "VedDRA Hierarchy, VedDRA PT name = Recumbency" and go to "Associated VedDRA"

15.2. MAHs path

In the case of MAH users, we will follow 2 different potential scenarios.

15.2.1. Continuous monitoring scenario (with two alternatives):

1. **List of Products:**

- Use "Product MAH" filter to get an overview of data for all products owned by MAH, with or without "Product authorisation procedure" and/or "Product authorisation country"
- Select specific product(s), active substance(s) or ATCVet codes to focus the analysis on a specific area

2. **Signalling for reactions linked to a product or ingredient:**

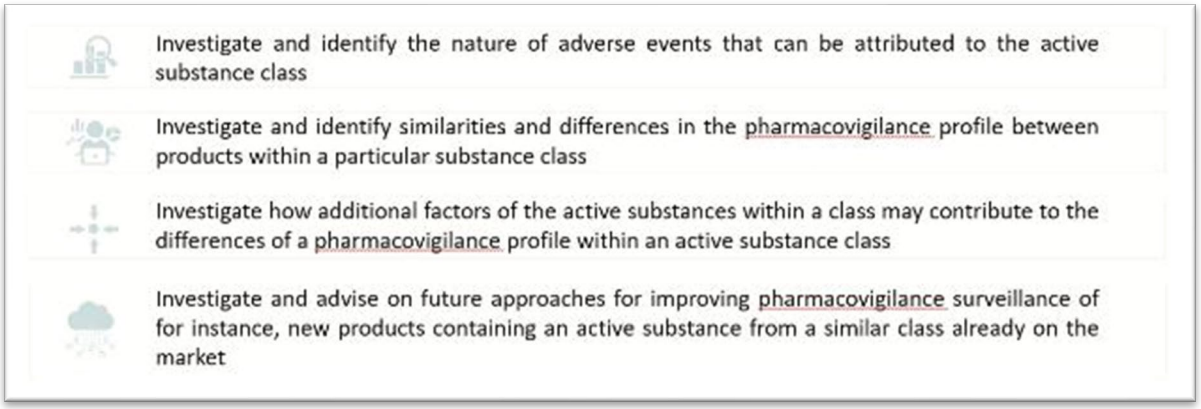
- Run signalling for reactions linked to a product or ingredient to find potential new signals.
- Frequency: Weekly, monthly…

15.2.2. Product-based analysis scenario (with four alternatives):

1. Adverse Event Overview: To obtain baseline data: Number of AERs per product and species, Number of animals affected, Number of fatalities
2. Signal Detection: To view the type of Adverse Events reported for a selected product or group of products (at SOC and PT) and to compare the frequency to the number of reports involving other products and other clinical signs = ROR / ROR(-)
3. Signal Evaluation: To analyse the profile of affected animals (i.e. breed, age) for adverse reactions of interest (potential signs) and identify potential risk factors, effects of co-medication, geographical distribution or pharmaceutical form
4. Data Stratification: To compare a product to products of the same class, or to identify and exclude certain products from the comparison (products with a disproportionate number of reports for a specific AE)

15.3. NCAs path

To conduct an active substance class-based analysis for a class of products (e.g. antiparasitics), some guidelines should be taken into account, such as:



In the case of NCA users, this active substance class-based analysis is therefore based on the following generic 2 steps methodology and the dashboards associated to do so:

Define baseline: Identify the products and their active substances, target species, pharma forms, any combination products:

- Collect sales data
- Run queries to get overview of the number of reports in the database (per active substance / pharma form /species)

This defining baseline procedure would be achieved using the Adverse Event Overview dashboard.

AEs profile in target species (including human reactions): What is the clinical profile of adverse reactions in each target species: is there a "class effect", a disproportion of reporting of a given sign for a particular product/active substance/pharma form, or for the entire group:

- Profile of affected animals (e.g. breed, age) for all adverse reactions
- Effect of co-medication
- Incidence calculation
- ROR with/without stratification (antiparasitics)

This profiling step would be achieved on the other hand by using Signal Detection, Signal Evaluationand Data Stratification dashboards.

Summing up:

- **Define baseline:** Number of AEs for all the products per species, Number of AEs per product and species, Number of affected animals/Number of fatalities.
- **Clinical profile and comparison with the current SPCs:** To capture the clinical profile of adverse reactions focusing on medically important events, obtain the number of reports per VedDRA term at SOC and PT level. To identify similarities and differences in this profile based on the species, pharmaceutical form, therapeutic class:
    - Global (all substances/products)
    - Tablets versus spot-on
    - Per active substance
    - Per product
- **Relate the number of adverse event reports for a particular product or group of products:**
    - To the sales volumes of this product/group of products = INCIDENCE
    - To the number of reports involving other products and other clinical signs= ROR.
- **ROR analysis:** For selected PTs, in each species, calculate a ROR for each product in comparison to:
    - All the products included in the subgroup analysis.
    - Only the products with the same route of administration withing the subgroup analysis.
    - Exclude potential overrepresented products based on the VedDRA term of interest.

16. Annex

16.1. KPIs explanation

- **Number of cases**: Number of cases with the same Case number within the adverse event report.
- **Number of animals affected:** Animals affected within the adverse event report which will also include indirectly exposed animals, e.g. treated during pregnancy or lactation, co - mingled, infectious spread, etc.
- **The total number of animals affected includes**: Recovered/Normal, Recovered with Sequela, Died, Euthanized, Unknown.
- **Number of animals reacted:** Animals experimenting reactions to VMPs within the adverse event report.
- **Number of animals died:** Animals died as a consequence of an adverse reaction to VMPs within the adverse event report.
- **The total number of animals died includes:** Died, Euthanized.

16.2. ROR

16.2.1. ROR calculation

The Reporting Odds Ratio (ROR) calculates the odds of a certain event occurring with your medicinal product, compared to the odds of the same event occurring with all other medicinal products in the database.

A signal is considered when the lower limit of the 95% confidence interval of the ROR is greater than one. The 95% confidence interval gives an indication of the precision of the estimate of the ROR.

For instance, if the ROR is 3, the odds of reports of this event with the medicinal product are x3 times higher than the odds of reports of this event among all other reports in the database.

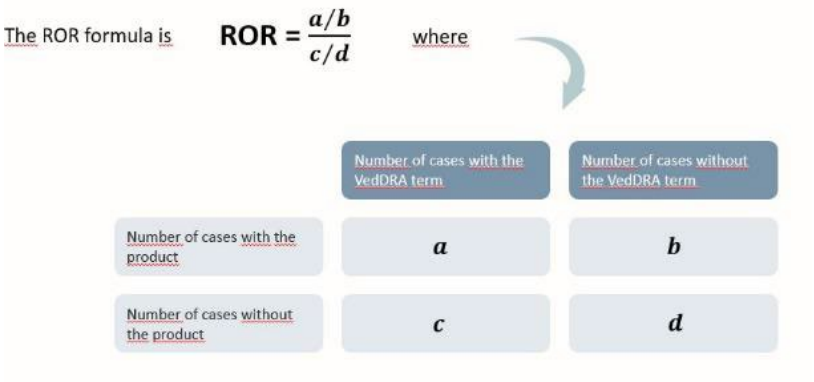


Image 156: ROR Calculation formula

16.2.2. ROR calculation for data stratification

ROR calculation for data stratification follows the same logic as the regular ROR calculation does. Same 4 variables apply, this is:

- Number of cases with the VedDRA term and without the VedDRA term
- Number of cases with the Product and without the Product

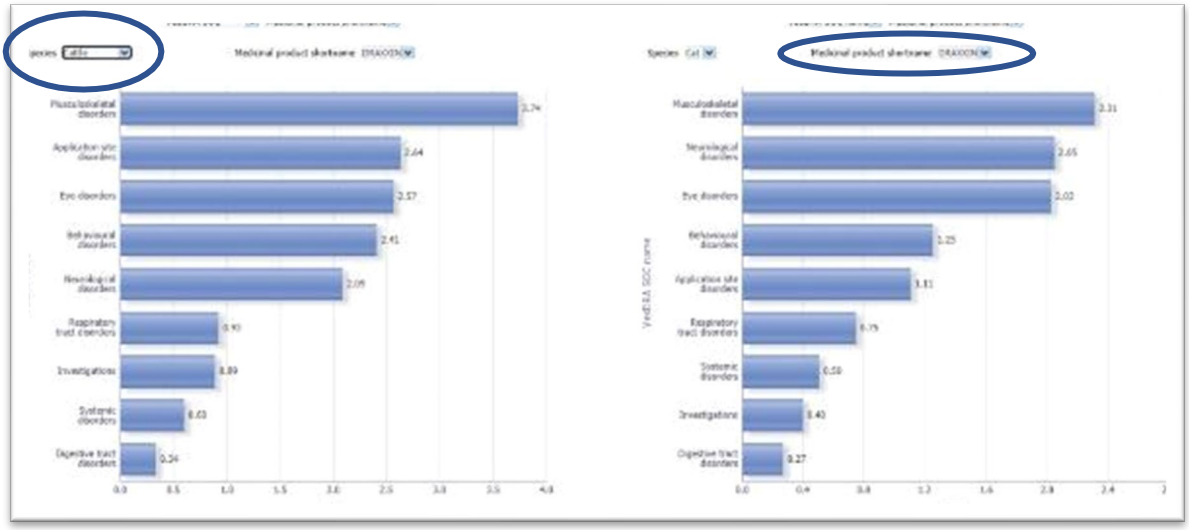


Image 157: ROR calculation for data stratification

It is important to state that changes in the scope (Products or Species involved in the calculation) will impact in the ROR metrics since these modifications have a direct impact in the variables of the formula explained in the ROR Calculation (See 14.2.1 ROR Calculation) and potentially changing the outcome.