EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PhV reporting – EV VET3 – Implementation

FVE webinar

Presented by Laura Descalzo on 30 March 2021

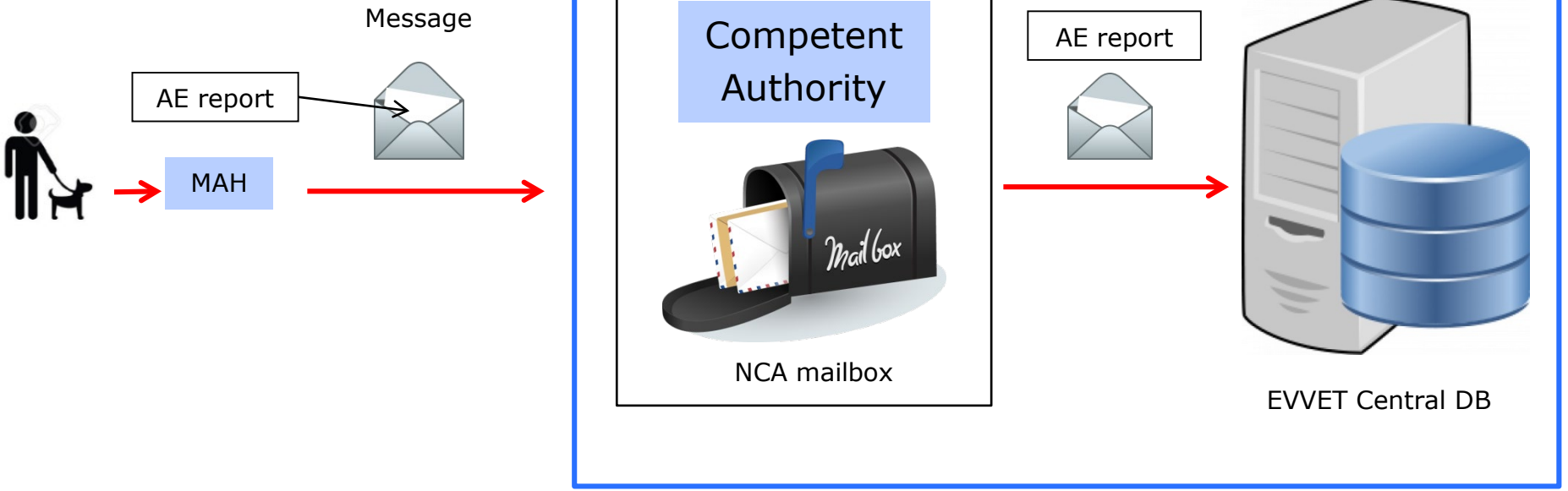
AGENDA

EUROPEAN MEDICINES AGENCY

1. Electronic reporting of Adverse Events: now and future (from Jan 2022)
2. EVVET components
3. Data collection
4. Data analysis / assessment
5. Publication of data
6. Questions/AOB

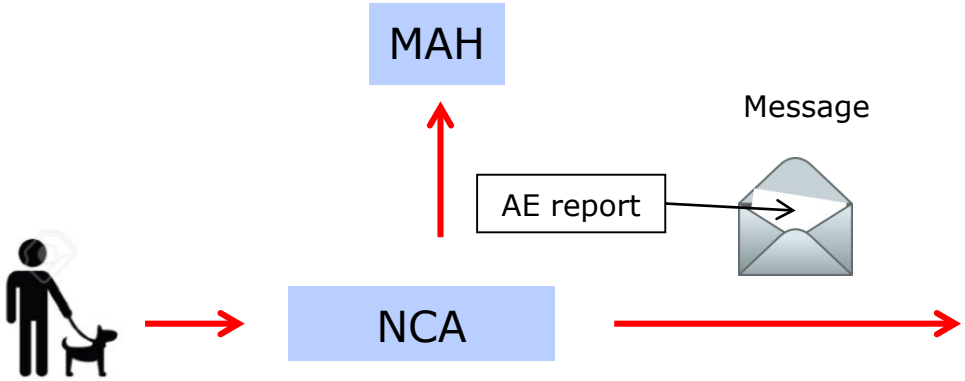
EUROPEAN MEDICINES AGENCY

MESSAGING FLOW - EEA reports (option 1)



EUROPEAN MEDICINES AGENCY

MESSAGING FLOW - EEA reports (option 2)

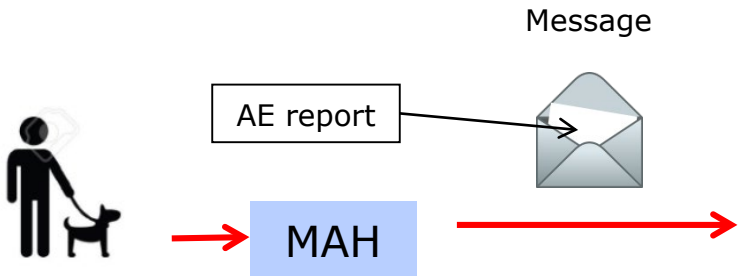


EudraVigilance Veterinary

EVVET Central DB

EUROPEAN MEDICINES AGENCY

MESSAGING FLOW- non-EEA reports

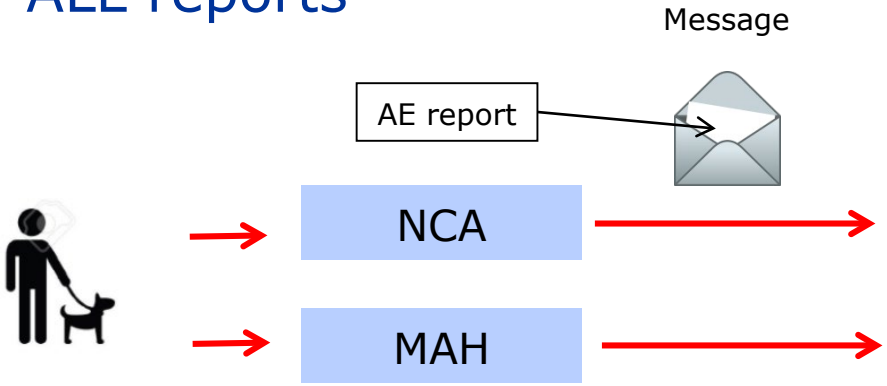


EudraVigilance Veterinary

EVVET Central DB

EUROPEAN MEDICINES AGENCY

MESSAGING FLOW
ALL reports

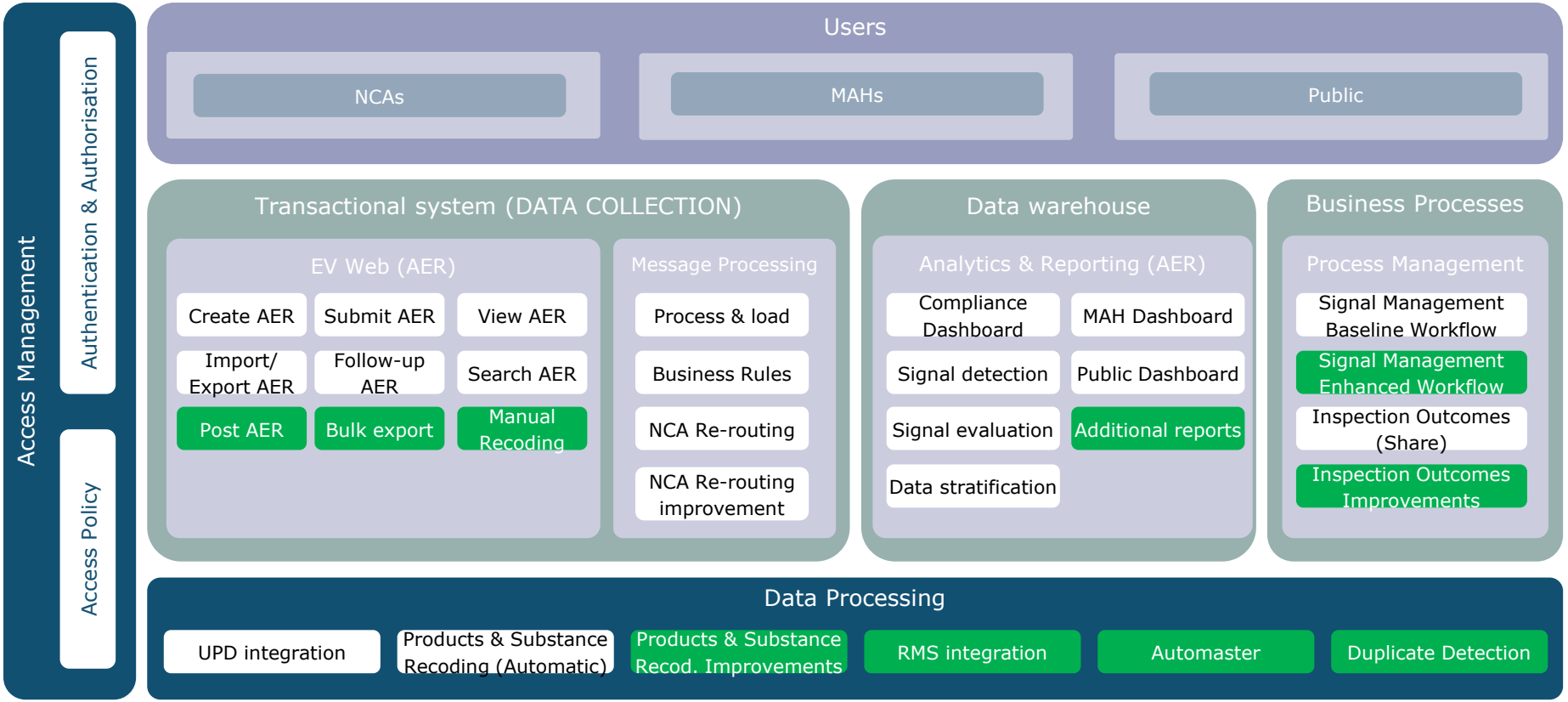


EudraVigilance Veterinary

EVVET Central DB

EVVET COMPONENTS

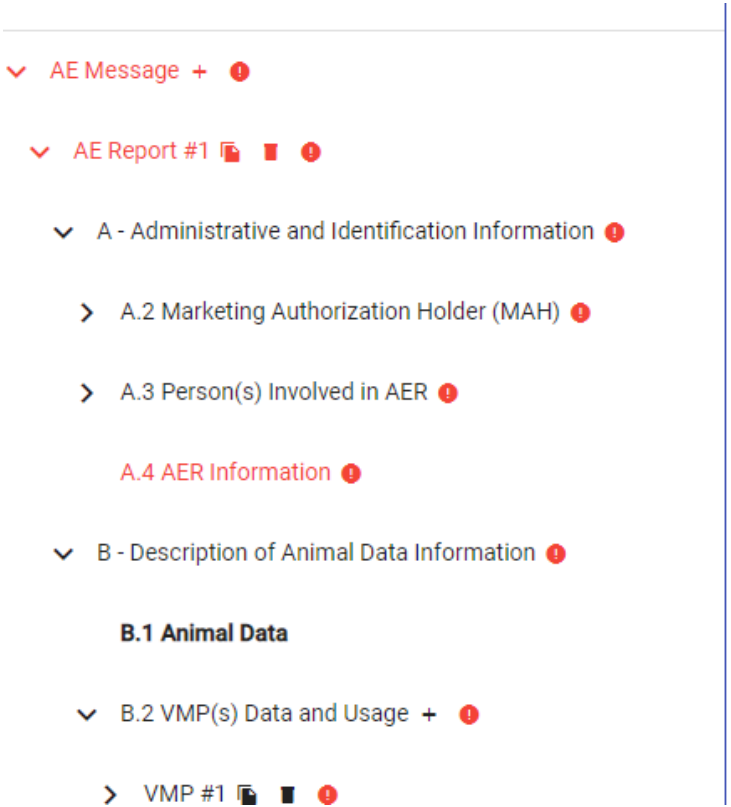
EUROPEAN MEDICINES AGENCY



- 28th of Jan 2022
- Post 28th of Jan 2022

DATA COLLECTION – EVVET (1)

EUROPEAN MEDICINES AGENCY



Animal/Human Data

Number of Animals Treated

1

Number of Animals Affected *

1

Attending Veterinarian's Assessment of Health Status

Species (Type of Species) *

Dog

Breed

Purebred

Akita

DATA COLLECTION – EVVET (2)

EUROPEAN MEDICINES AGENCY

B.1 Animal Data

B.2 VMP(s) Data and Usage +

VMP #1

B.2.1 Registered or Brand Name

B.2.2 Active Ingredient(s) +

B.2.3 Lot Number +

B.2.4 Who Administered the VMP

B.2.5 Use According to Label

B.3.9 Previous Exposure to the VMP

B.3.10 Previous AE to VMP

B.4 Dechallenge-Rechallenge Information

B.3 Adverse Event Data

B.5 Assessment of AE

B.6 Report Number(s) of Linked Report(s)

B.7 Supplemental Documents

DATA COLLECTION – EVVET (3)

EUROPEAN MEDICINES AGENCY

Narrative of AE *

This field is required

Adverse Clinical Manifestations

AER Term Name *	Number of Animals	Accuracy of the Number of Animals *
Application site abscess	1	Actual
Lethargy	1	Actual

+ Add

Choose a Date Format *: Day, Month and Year

Date of Onset of AE (AE Start Date) *: 2021/03/02

Length of Time between Exposure to VMP & Onset of AE: <12 hours

Duration of AE

Duration (Time): 3

DATA COLLECTION – EVVET (4)

EUROPEAN MEDICINES AGENCY

Label Usage

Use According to Label

Was the animal underdosed?

Explanation for Off-Label Use

Was the treatment regimen Off-label?

Was the target species Off-label?

Was the indication Off-label?

Was the route of administration Off-label?

Was the storage condition Off-label?

Was the animal overdosed?

DATA ANALYSIS – METHODOLOGY (1)

EUROPEAN MEDICINES AGENCY

DATA ANALYSIS – METHODOLOGY (2)

Overview of data:
Number of reports, data distribution, eg. Species, geographic origin

Identify which AEs should be investigated
Focus on VeDDRA terms not included in the SPC taking into account:

- Relative frequency of the VeDDRA terms
- Nature and severity of the VeDDRA terms

Identify issues that might need urgent attention
Screen the data for issues that may require urgent consideration e.g. human reports, or high numbers of animal deaths.

Consider the possible association with the product at report level for each of the signals investigated:

- Geographic origin
- Breed
- Age
- Other reactions reported
- Time to onset, detailed dose, and route of administration
- Off label use?
- Narrative

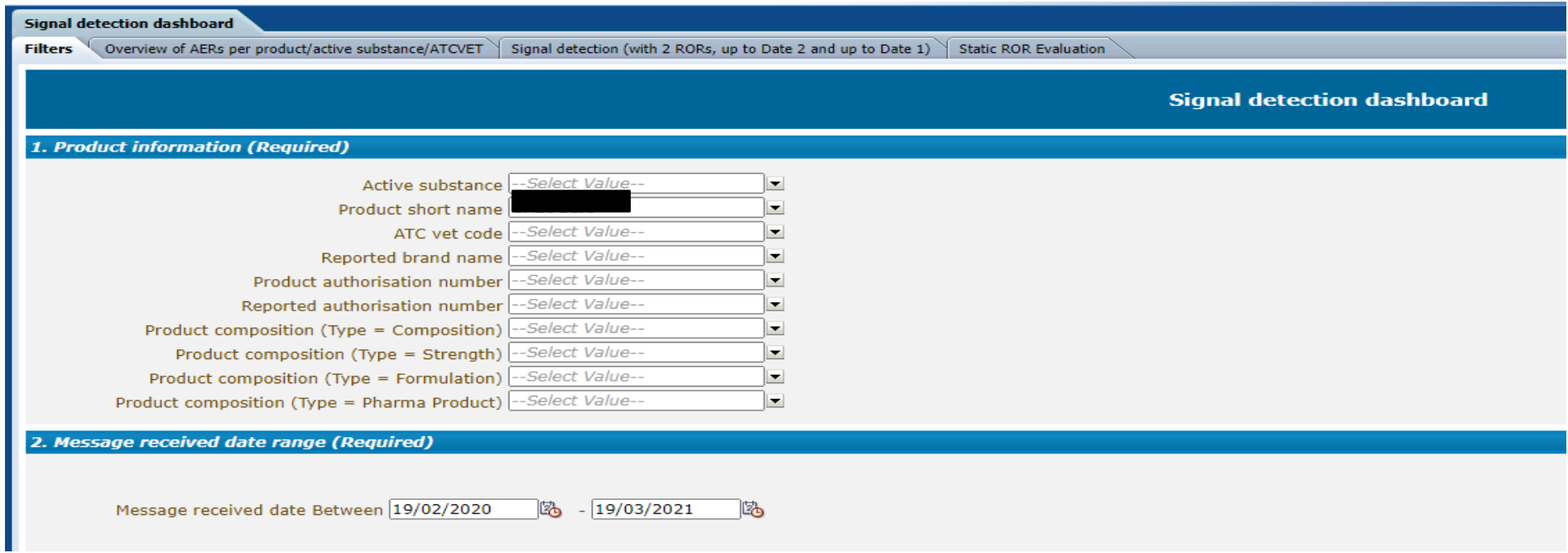
Many signals might be due to confounding factors. These are mainly of two types, confounding by disease (indication) and confounding by medication:

Confounded by disease
This is when it is considered that the AE might be regarded as symptoms of the disease the product has been administrated for, and not as a reaction to the product itself. However, it is important to consider that when the AE is typical for the indication it may also denote aggravation of the disease. Clinical judgment should be used.

Confounded by medication
This is when it is considered that the AE may be due to concomitant medication.

EUROPEAN MEDICINES AGENCY

Filters selection page (1)



EUROPEAN MEDICINES AGENCY

Filters selection page (2)

3. Report filter (Required, only apply for signal detection and static ROR)

Human or animal ☑ Animal ☑ Human

4. Optional report filters

Age (hours) >= --Select Value-- <= --Select Value--
Age (days) >= --Select Value-- <= --Select Value--
Age (months) >= --Select Value-- <= --Select Value--
Age (years) >= --Select Value-- <= --Select Value--

Gender --Select Value--
Species --Select Value--
Breed --Select Value--
Occurrence region --Select Value--
Occurrence country --Select Value--
Organisation --Select Value--
Report type --Select Value--
Serious --Select Value--

Original received date Between -
Start date of reaction/event Between -
Authorisation procedure --Select Value--
Information type --Select Value--
Primary source categorisation --Select Value--
Is use according to label --Select Value--
Exclude lack of efficacy ☐ Yes
Hide known VedDRA terms ☐ Yes

Is off label

Indication ☐ Yes ☐ No
Product expired ☐ Yes ☐ No
Storage ☐ Yes ☐ No
Treatment ☐ Yes ☐ No
Other issue ☐ Yes ☐ No

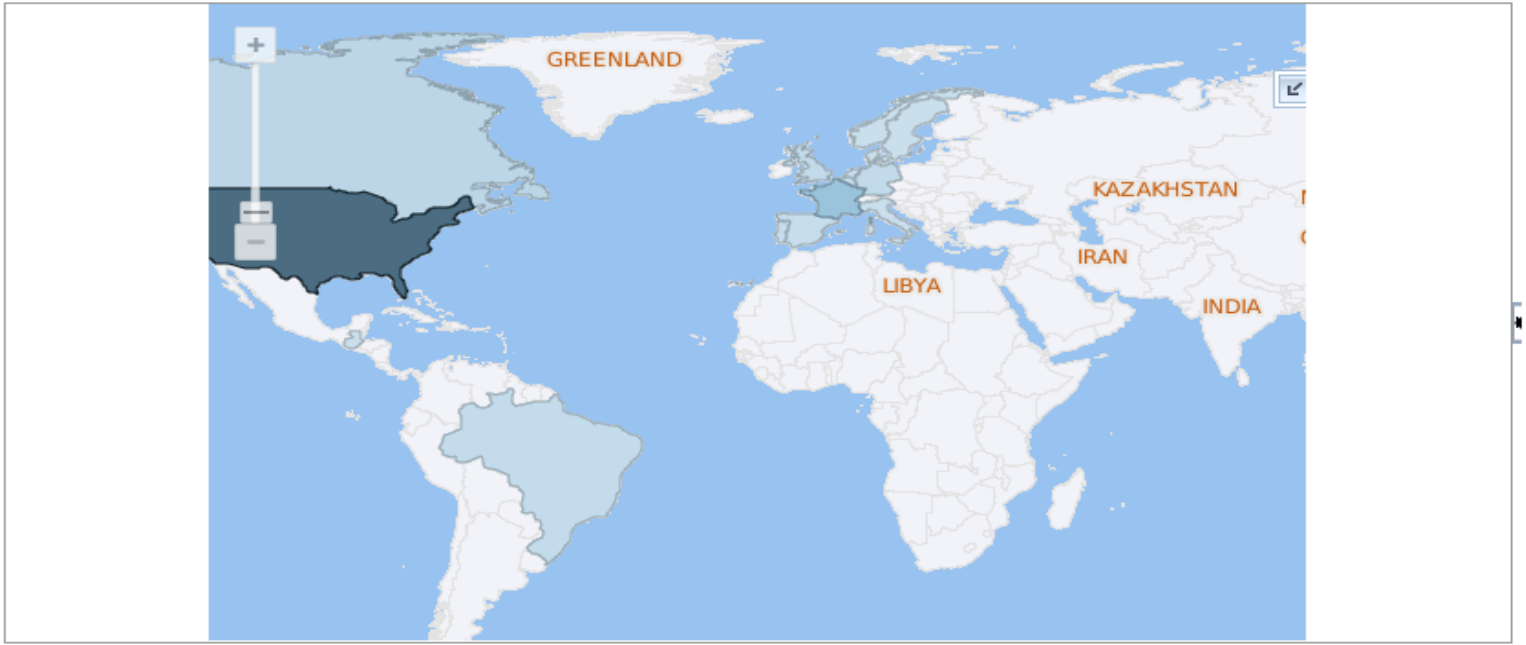
DATA ANALYSIS – EVVET DWH

EUROPEAN MEDICINES AGENCY

UCT/ACTIVE SUBSTANCE/ATCVET CODE

Species --Select Value--

Number of cases



Analyze - Refresh - Print - Export

DATA ANALYSIS – EVVET DWH

EUROPEAN MEDICINES AGENCY

Product Hierarchy Level Medicinal product shortname

		Human or animal	Animal				Human		Number of cases	Number reacted
		Seriousness	Yes		No		Unknown			
			Number of cases	Number reacted	Number of cases	Number reacted	Number of cases	Number reacted		
Medicinal product shortname	Occurrence region	Occurrence country								
[redacted]	EEA	Belgium			1	1			1	1
		Denmark			1	1			1	1
		France	25	25	33	43	1	1	59	69
		Germany	5	11	5	5	1	1	11	17
		Italy	2	2					2	2
		Netherlands	2	2	1	1			3	3
		Norway			1	1			1	1
		Portugal	4	4					4	4
		Spain	6	7					6	7
		Sweden			1	1			1	1
	Non EEA	Australia	2	2					2	2
		Brazil	9	9					9	9
		Canada	19	19					19	19

Signal detection with 2 RORs - Type of AEs reported for product or substance (1)

Product Hierarchy Level Medicinal product shortname

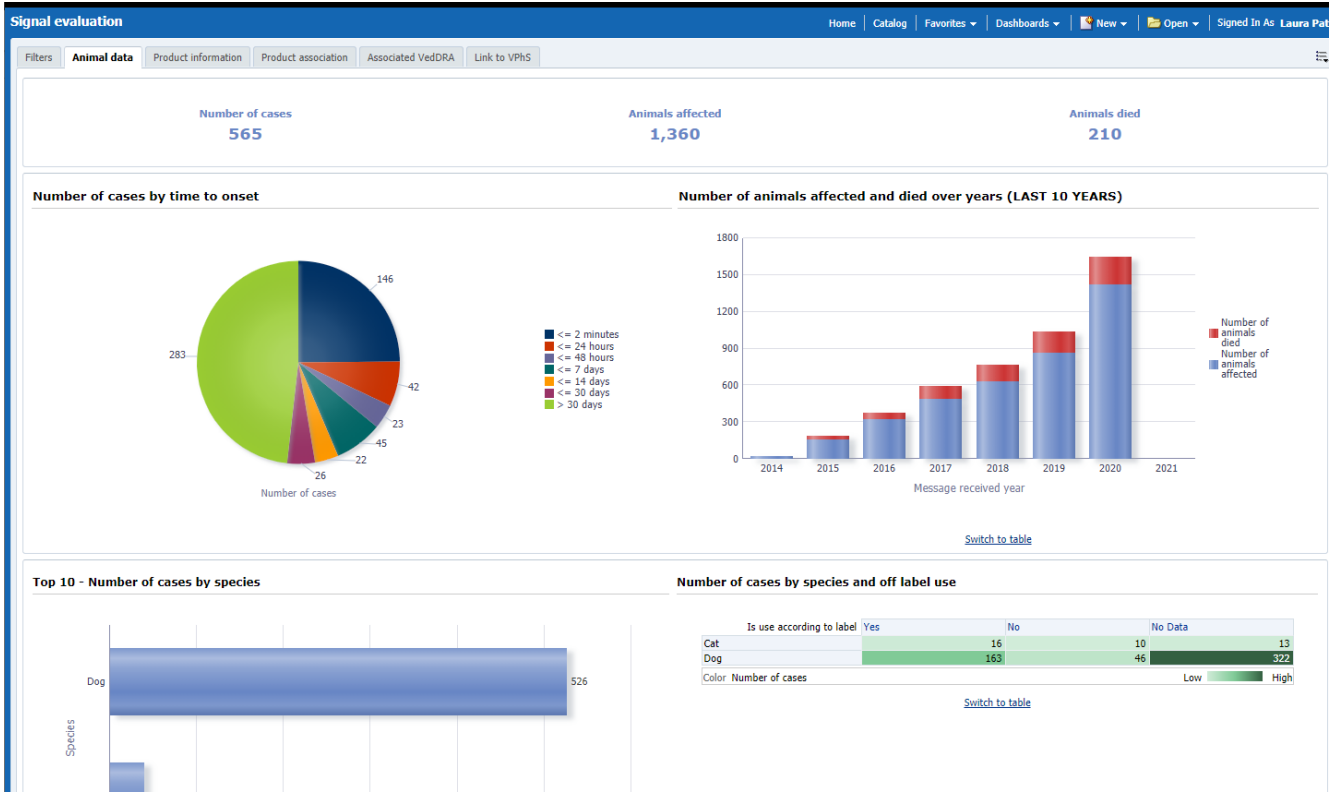
Date 1: 19/02/2020
Date 2: 19/03/2021

Species Cat

Medicinal product shortname	VedDRA SOC name	VedDRA PT name	Number of cases between date 1 and date 2	Number reacted between date 1 and date 2	ROR (-) until date 2	ROR until date 2	ROR (+) until date 2
[redacted]	Behavioural disorders	Aggression	2	2	1.52	1.80	2.14
		Anxiety	2	2	1.50	1.78	2.12
		Behavioural disorder NOS	5	5	1.14	1.35	1.59
		Grooming disorder	5	7	12.22	14.88	18.10
		Hallucination	0		N/A	N/A	N/A
		Hyperactivity	13	15	5.52	6.62	7.93
		Self mutilation	1	1	N/A	N/A	N/A
		Vocalisation	5	5	1.61	1.91	2.26
	Blood and lymphatic system disorders	Other blood disorder NOS	0		N/A	N/A	N/A
		Other coagulation abnormality	1	1	N/A	N/A	N/A
	Cardio-vascular system disorders	Bradycardia	0		N/A	N/A	N/A
		Cardiac arrest	0		N/A	N/A	N/A
		Cardiac insufficiency	0		N/A	N/A	N/A
		Circulatory shock	1	1	N/A	N/A	N/A
		Hypotension	0		3.27	3.92	4.70
		Murmur	0		N/A	N/A	N/A
		Pericardial effusion	1	1	N/A	N/A	N/A
		Tachycardia	3	3	2.07	2.45	2.90

EUROPEAN MEDICINES AGENCY

Signal evaluation: Species/breed, age, weight, time to onset, off label use analysis



DATA ANALYSIS –EVVET DWH (2)

EUROPEAN MEDICINES AGENCY

Number of cases by species and breeds

Species Dog

Age range	Number of cases	Number of animals affected	Number of animals died
0-0.49 years	11	11	4
0.5-0.99 years	14	14	2
1-6.99 years	279	279	21
13 and over years	33	33	6
7-12.99 years	151	152	40
Unknown	38	832	128

Species Dog

Weight range	Number of cases	Number of animals affected	Number of animals died
0-4.999 kg	100	895	141
10-24.999 kg	160	160	20
25-44.999 kg	133	133	25
45-69.999 kg	16	16	4
5-9.999 kg	116	116	11
70 and over kg	1	1	0

Species Dog Age range 0-0.49 years

Breed	Number of cases	Number of animals affected	Number of animals died
Alaskan Malamute	1	1	0
Chihuahua	1	1	0
Collie - Border	2	2	0
Crossbred Canine/dog	4	4	2
Shepherd Dog - German	1	1	1
Spaniel - Cocker American	1	1	0
Unknown	1	1	1

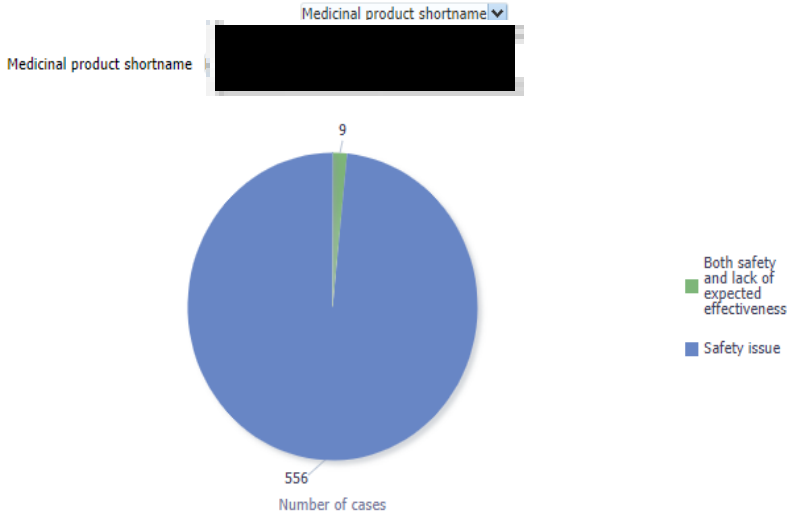
Species Dog Weight range 0-4.999 kg

Breed	Number of cases	Number of animals affected	Numbe
Akita	1	1	
Beagle	2	2	
Berger Picard or Sheepdog - Picardy	1	1	
Borzoi	1	1	
Boxer (German Boxer)	2	2	
Chihuahua	8	8	
Collie - Border	2	2	
Crossbred Canine/dog	19	19	
Dachshund - Miniature	1	1	
Dog (other)	7	7	
Maltese	5	5	
Papillon - Spaniel - Continental Toy (with erect ears or with dropped ears (Phaléne))	2	2	
Pekingese	1	1	
Pointing Dog - Hungarian Short-haired (Vizsla)	1	1	
Poodle - Toy	1	1	
Pug	1	1	
Retriever - Golden	1	1	
Retriever - Labrador	1	1	

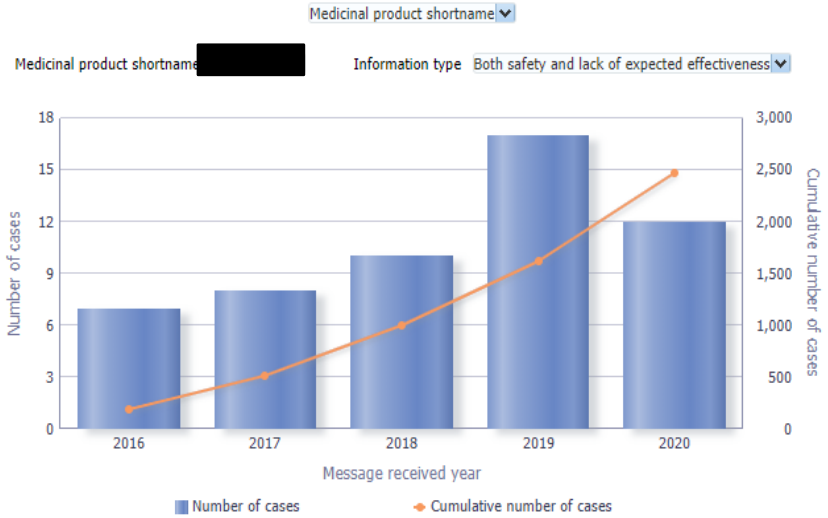
EUROPEAN MEDICINES AGENCY

Product information (Geographical, information type and pharma form breakdown)

Number of cases by information type



Number of cases over year (LAST 10 YEARS)



DATA ANALYSIS –EVVET DWH

EUROPEAN MEDICINES AGENCY

Product information (Geographical, information type and pharma form breakdown)

Number of animals affected by pharmaceutical form or active substance

Pharmaceutical product form

Species Cat

Information type Safety issue

			Animal			Number of AERs	Number of animals affected	Number of animals died
Pharmaceutical product form	Occurrence region	Occurrence country (U)	Number of AERs	Number of animals affected	Number of animals died			
CHEWABLE TABLET	Non EEA	UNITED STATES	3	3	0	**3**	**3**	**0**
SPOT-ON SOLUTION	EEA	FRANCE	2	2	0	**2**	**2**	**0**
		GERMANY	2	2	1	**2**	**2**	**1**
	Non EEA	AUSTRALIA	3	3	1	**3**	**3**	**1**
		BRAZIL	1	1	1	**1**	**1**	**1**
		CANADA	1	1	0	**1**	**1**	**0**
		NEW ZEALAND	1	1	1	**1**	**1**	**1**
		SOUTH AFRICA	2	2	1	**2**	**2**	**1**
		UNITED KINGDOM	1	1	0	**1**	**1**	**0**
		UNITED STATES	25	25	4	**25**	**25**	**4**
Grand Total			**39**	**39**	**9**	**39**	**39**	**9**

Return - Analyze - Print - Export

Publication of data – EMA WEBSITE

EUROPEAN MEDICINES AGENCY

[Pharmacovigilance page]

Publication of data – EMA WEBSITE

EUROPEAN MEDICINES AGENCY

Annual bulletins

The Agency publishes annual public bulletins to inform veterinarians and the public of the main **outcomes of post-marketing surveillance** activities for veterinary medicines in a calendar year. The bulletin summarises **recommendations** to amend safety warnings and highlights ongoing monitoring activities for centrally authorised products.

The 2019 veterinary pharmacovigilance bulletin provides an overview of the new warnings and recommendations agreed for Centrally authorised veterinary medicinal products during 2019. It is also highlighting the ongoing monitoring of potential specific events. The bulletin's aim is to inform veterinarians and the general public of current pharmacovigilance issues. It also contains an overview of other main pharmacovigilance events during 2019, which were discussed by the Pharmacovigilance working party.

- Veterinary pharmacovigilance bulletin 2019

The bulletin also includes a summary of the discussions and agreements by the Pharmacovigilance Working Party regarding pharmacovigilance issues concerning nationally authorised veterinary medicines.

For previous bulletins, see:

- Public bulletins: Veterinary pharmacovigilance

Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products

In addition to the annual pharmacovigilance bulletin, the pharmacovigilance regulatory recommendations include the changes agreed by CVMP during the year following the assessment of pharmacovigilance data for centrally authorised products.

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2021 (PDF/90.8 KB) (new)

First published: 22/02/2021
EMA/CVMP/PhVWP/105691/2021

Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020 (PDF/140.45 KB)

First published: 20/05/2020
Last updated: 15/12/2020
EMA/112926/2020

The document is updated monthly and is part of an ongoing effort of the Agency to accelerate and facilitate the communication to the stakeholders of regulatory actions related to the safe and efficacious use of centrally authorised products.

2. Adverse events in animals and humans involving centrally authorised products

There are now 211 CAPs that have marketing authorisations valid across the entire EU. An overview of the products and detailed information on each product, including the summary of product characteristics, is accessible on the EMA website (http://www.ema.europa.eu/ema/).

A total of 33,656 adverse event reports following exposure to CAPs were received in 2019. Of these, 32,797 adverse event reports related to animals and 859 related to humans.

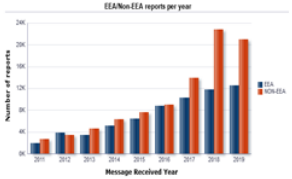


Figure 1. Total number of adverse events for centrally authorised products reported to EVVet from within and outside the EU/EEA between 2011 and 2019

A long-term, year-on-year increase in adverse event reporting (Figure 1) can be observed, which generally reflects the increasing number of CAPs authorised. In addition, in 2018 and 2019 we observe a significantly higher number of reports from non-EU/EEA countries, which is partly linked to the number of non-serious reports submitted to EVVet either on a voluntary basis by MAHs which have implemented the revised recommendation on basic surveillance that encourages reporting non-serious reports. Reports were received from a total number of 71 non-EU/EEA countries with the highest number of reports coming from the United States of America (11,811), Brazil (4,060), Canada (2,279), Australia (1,320), South Africa (345) and Japan (315).

The overall increase and volume of reports enhance the ability to investigate pharmacovigilance data and contribute to the robustness of the evaluation and helps obtain useful information on the use and safety of VMPs. The majority of the reports concern companion animals, with adverse event reports in dogs and cats accounting for 87% of the cases. Further descriptive statistics regarding the reports received in 2019 can be found in Annex 1.

During 2019, the CVMP and its PhVWP-V evaluated 159 PSURs. Further, the continuous monitoring of centrally authorised VMPs through signal detection identified approximately 740 potential safety signals or lack of expected efficacy events for consideration/investigation. All signals detected were further analysed and, for some products, have led to the recommendation to add additional warnings to the product information (PI). However, for most signals the analysis concluded that the observed signs were either not likely to be associated with the use of the product, were expected following use of the product and/or were adequately addressed in the product information. For a small number of signals analysed a potential causal relationship with the product administered could not yet be excluded and these issues remain under investigation in 2020 (see tables under section 3).

Seventy-six pharmacovigilance requests for information were received, in addition to 43 requests for access to document (i.e. requests to release EVVet line listings & PSURs), the majority of the requests concerned potential safety issues related to anti-parasitic products in dogs and cats.

3. Findings and recommendations for centrally authorised veterinary medicinal products

During 2019, the continued monitoring of signals and evaluation of PSURs resulted in the following findings and recommendations.

3.1. Companion animals

Product name (active substance)	**Regulatory actions and recommendations for the MAH in 2019**	**Suspected adverse events that continue to be monitored in 2020**[6]
Activyl (indoxacarb)		Blindness in relation to the oral ingestion in cats, neurological signs in dogs (blindness and deafness), gastrointestinal reactions, allergic reactions, lethargy and anorexia in dogs and cats
Activyl Tick Plus (indoxacarb/ permethrin)		Hypersensitivity, convulsions, seizures, myoclonus, permethrin intoxication in cats (medication error), especially in the EU/EEA
Advocate (imidacloprid/ moxidectin)		Convulsions, ataxia and muscle tremor
Apoquel (oclaticinib)		Seizures and convulsions
Bravecto tablets (fluralaner)	Update section 4.6 of the SPC by adding the following adverse reactions: Lethargy, muscle tremor, ataxia and convulsion have been reported very rarely in spontaneous reports. Most reported adverse reactions were self-limiting and of short duration.	Neurological disorders, hepatopathy, death, congenital eye disorders, potential birth defects in dogs, ataxia in cats, haemorrhagic diarrhoea as cases with death outcome have been reported after haemorrhagic diarrhoea in dogs
Bravecto spot-on (fluralaner)		Behavioural disorders, dyspnoea and hepatopathy in cats, convulsions/seizures in cats and convulsions/seizures, tremors and ataxia in dogs
Bravecto Plus (fluralaner)	Update section 4.6 of the SPC by adding the following adverse reactions: Tremors and anorexia have been reported very rarely after the use of this product based on post marketing safety experience (pharmacovigilance).	Behavioural disorders, dyspnoea and hepatopathy in cats, convulsions/seizures in cats
Broadline (fipronil, S-methoprene, epinomectin, praziquantel)	Update section 4.6 of the SPC by adding the following adverse reactions: Transitory blindness or impaired vision have been observed in very rare cases based on post marketing safety experience.	Neurological signs, death, blindness, LEE and human cases
Canigen L4/Nobivac (for active immunisation of dogs against *Leptospira*)		Monitor the impact of age, weight, breed/genetic predisposition on anaphylactic reactions, sudden death and immune-mediated reactions (Immune mediated haemolytic anaemia and immune

[6] This section includes adverse events that are under investigation and for which the potential causal association has not yet been established.

Publication of data – PhV reg. recommendations

EUROPEAN MEDICINES AGENCY

Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2021 (Updated monthly)

Please note that the recommendations shown in this document may not reflect the exact final wording that will appear in the actual package leaflet that still needs to be implemented by the marketing authorisation holders.

Previous regulatory recommendations and ongoing procedures are outlined in Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020 (EMA/112926/2020)

Product (active substance(s))	CVMP meeting date	Recommendation - SPC change
Felisecto Plus (Selamectin/Sarolaner)	**15-17 February 2021**	**Section 4.6 of SPC for Felisecto Plus** (additions to text in **bold**, deletions in ~~strikethrough~~): Use of the veterinary medicinal product may result in mild and transient pruritus at the application site. Mild to moderate alopecia at the application site, erythema and drooling have been uncommonly observed. **Neurological signs (convulsions, ataxia) and gastrointestinal signs (emesis, diarrhoea) have been reported very rarely based on post-marketing safety experience. In most cases these signs are transient.**

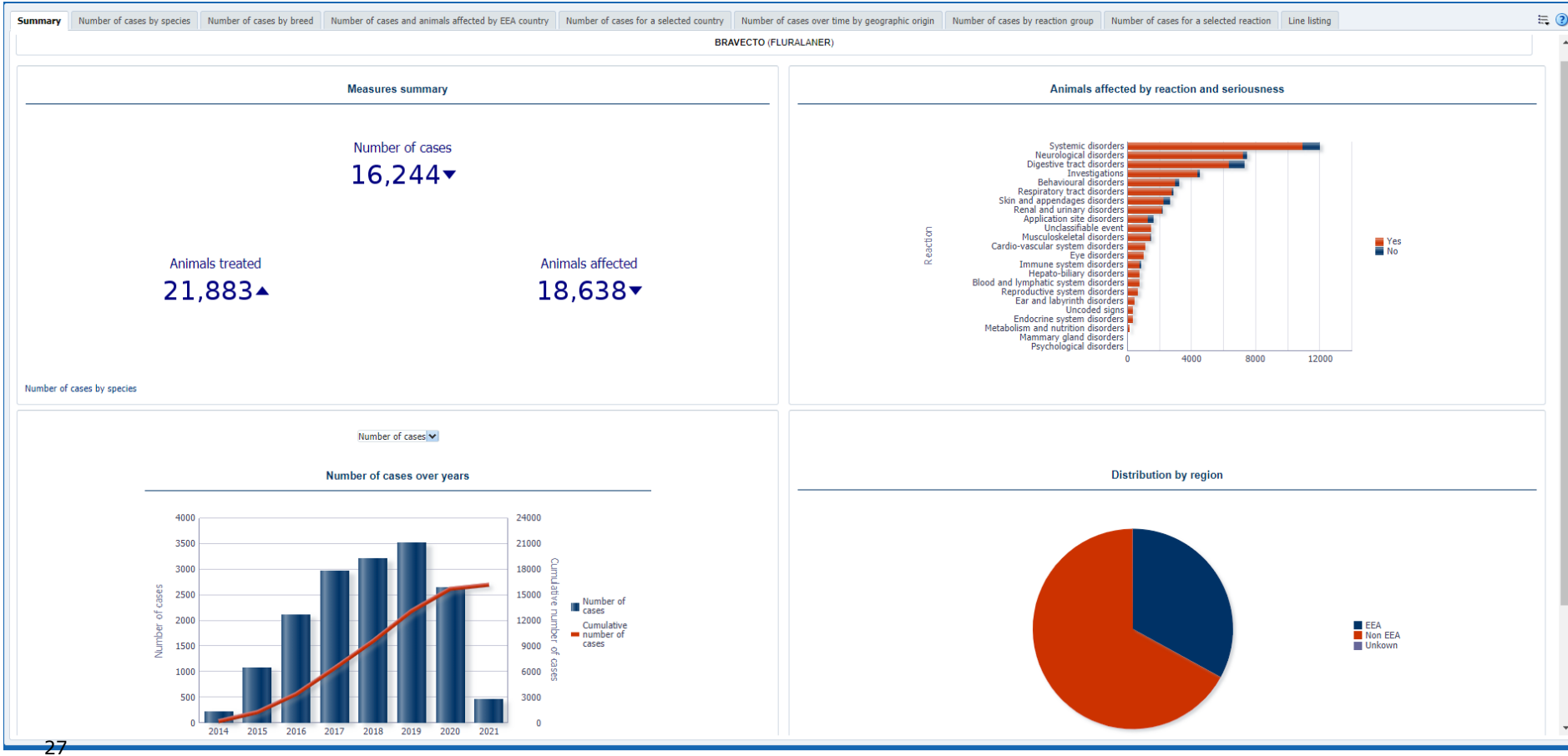
Publication of data – ADR website

EUROPEAN MEDICINES AGENCY

http://www.adrreports.eu

Publication of data – ADR website

EUROPEAN MEDICINES AGENCY



Publication of data – ADR website

EUROPEAN MEDICINES AGENCY

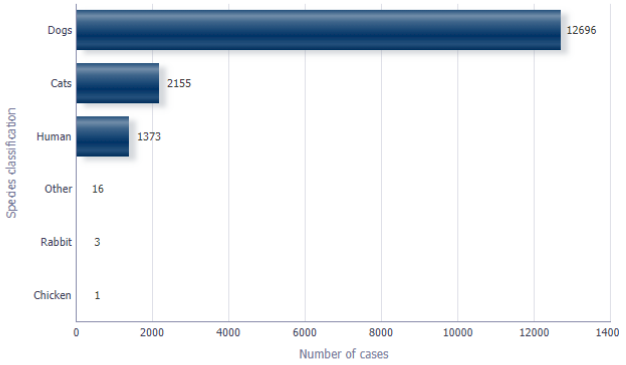
Summary | **Number of cases by species** | Number of cases by breed | Number of cases and animals affected by EEA country | Number of cases for a selected country | Number of cases over time by geographic origin | Number of cases by reaction group | Number of cases for a selected reaction | Line listing

The number of individual cases identified in EudraVigilance for **BRAVECTO** is **16244** (up to 21/03/2021)

Number of cases and animals affected by species

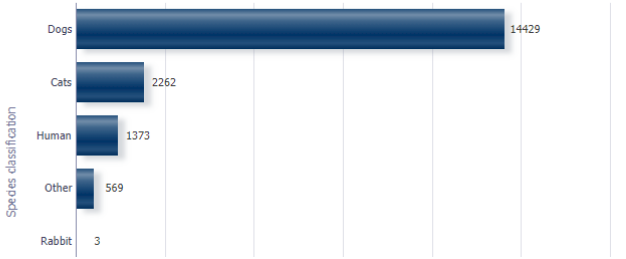
Number of cases

Animal/Human	Species classification	Number of cases	% Cases
Animal	Dogs	12696	78.16%
Animal	Cats	2155	13.27%
Animal	Other	16	0.10%
Animal	Rabbit	3	0.02%
Animal	Chicken	1	0.01%
Human	Human	1373	8.45%



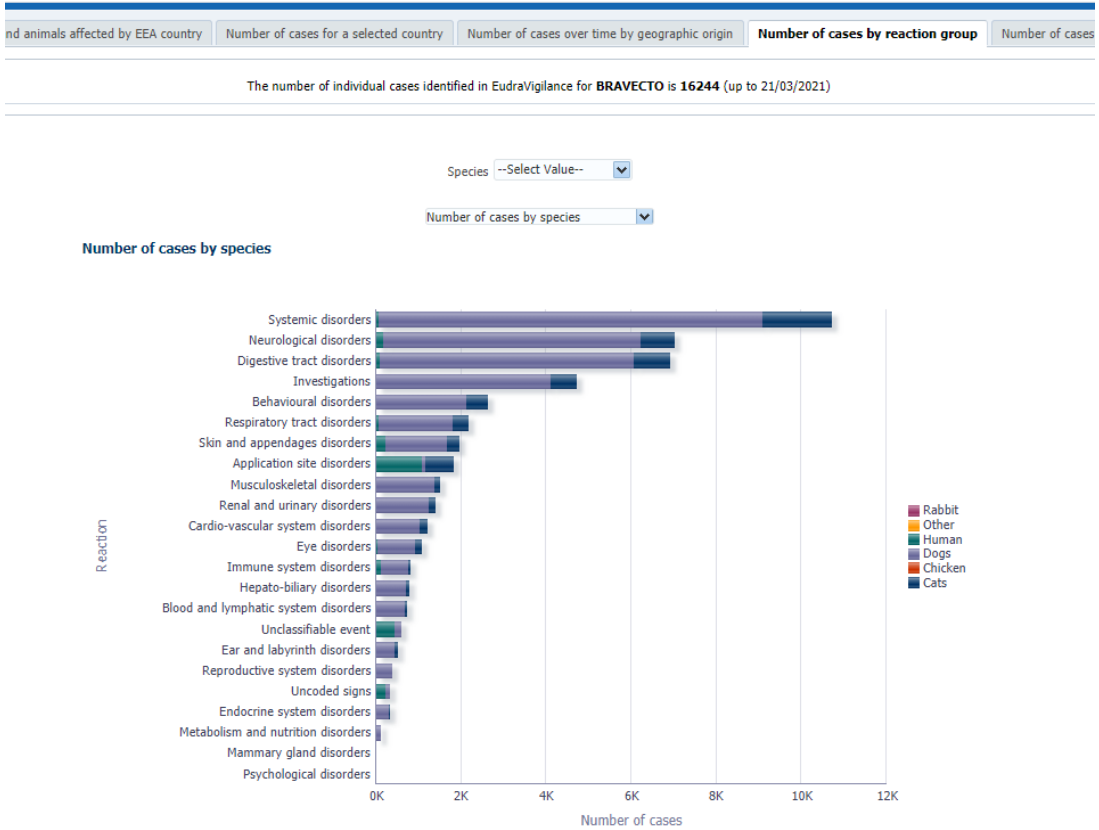
Animals affected

Animal/Human	Species classification	Animals affected	% Animals affected
Animal	Dogs	14429	77.42%
Animal	Cats	2262	12.14%
Animal	Other	569	3.05%
Animal	Rabbit	3	0.02%
Animal	Chicken	2	0.01%
Human	Human	1373	7.37%

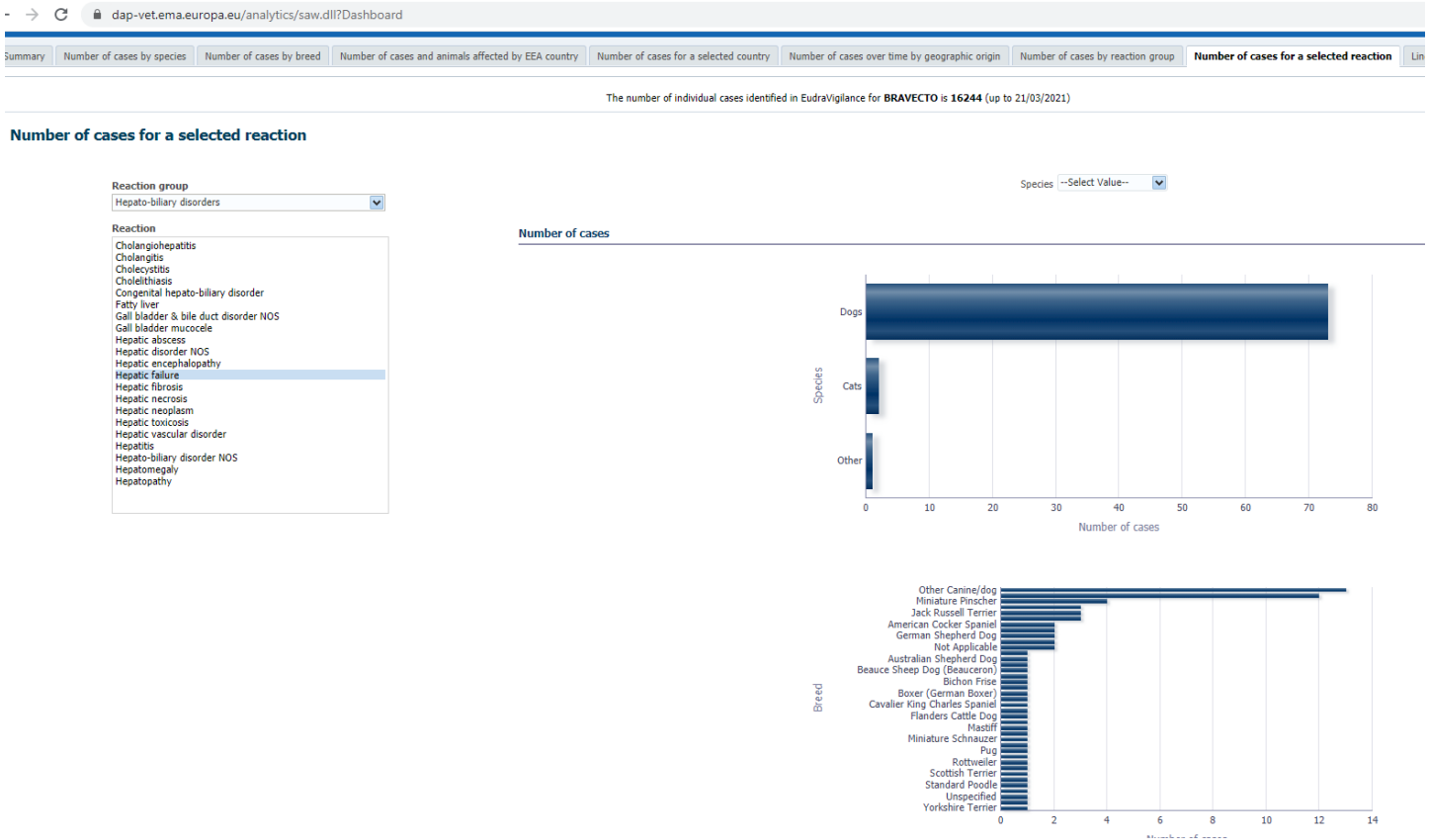


Publication of data – ADR website

EUROPEAN MEDICINES AGENCY



Publication of data – ADR website



Publication of data – ADR website

EUROPEAN MEDICINES AGENCY

The number of individual cases identified in EudraVigilance for **BRAVECTO** is **16244** (up to 21/03/2021)

Line listing selections

Species classification	Dogs
Breed	--Select Value--
Country	--Select Value--
Reaction group	Hepato-biliary disor
Reported reaction	--Select Value--
Gender	--Select Value--
* Gateway date	2021

Display line listing

For the interpretation of the results, please refer to the key considerations at www.adrreports.eu

MERCKMSD-2020-AR-00148	March 2021	owner									Mountain Dog	
AUS-MERCKMSD-2021-AU-00106	24 February 2021	Animal owner	Yes	Australia	Female-Neutered	Distension of abdomen,Enlarged liver,Drinking a lot,Lethargy (see also Central nervous system depression in 'Neurological'),Breathing difficulty,Increased appetite,Liver disorder NOS,Elevated blood urea nitrogen (BUN),Elevated aspartate aminotransferase (AST),Elevated alanine aminotransferase (ALT),Elevated total bilirubin,Elevated serum alkaline phosphatase (SAP),Emesis (multiple),Dental disease,Elevated cholesterol (total),Food refusal,Elevated globulins	1	1	Acepromazine,Alfaxan,BRAVECTO 250MG 1X2TAB 880,BRAVECTO SPOT ON DOG 250MG 1X1DS 880,Isoflurane,Metacam,Methadone	Canine/dog	Bichon Frise	AER
BRA-MERCKMSD-2020-BR-00219	10 March 2021	Animal owner	Yes	Brazil	Male	Hypersalivation,Convulsion,Inappetence,Apathy,Other abnormal test result NOS,Liver disorder NOS,Abdominal discomfort,Emesis (multiple)	1	1	BRAVECTO 112,5MG 1X1TAB 150	Canine/dog	Other Canine/dog	AER
BRA-MERCKMSD-2020-BR-03443	05 January 2021	Veterinarian	Yes	Brazil	Male	Leucocytosis NOS,Red blood cell disorder,Gastritis,Hepatic toxicosis,Adipsia,Decreased appetite,Hyperthermia,Apathy,Haematochezia,Decreased blood urea nitrogen (BUN) or creatinine	1	1	BRAVECTO 1000MG 1X1TAB 150,BRAVECTO TRANSDERMAL DOG 1000 1X1DS 500	Canine/dog	Border Collie	AER
CHL-MERCKMSD-2021-CL-00013	04 February 2021	Veterinarian	Yes	Chile	Female-Neutered	Emesis,Endometritis,Pruritus,Anorexia,Fever,Apathy,Generalised rash,Skin irritation,Liver disorder NOS,Hyperglycaemia,Hepato-biliary disorder NOS,Uterine disorder NOS,Hypochloraemia	1	1	BRAVECTO 112,5MG 1X1TAB 500	Canine/dog	Yorkshire Terrier	AER
CHL-MERCKMSD-2021-CL-00047	15 March 2021	Veterinarian	Yes	Chile	Female	Inappropriate urination,Crying,Diarrhoea,Enteritis,Hepatomegaly,Nephropathy,Frequent urination,Lethargy (see also Central nervous system depression in 'Neurological'),Incoordination,Liver disorder NOS,Neurological disorder NOS	1	1	BRAVECTO 250MG 1X1TAB 500,Rabies Vaccine.	Canine/dog	Boston Terrier	AER
GB-FRVIRBAC-VB-20210211-00543	12 March 2021	Veterinarian	Yes	United Kingdom	Male-Neutered	Vomiting,Inappetence,Lethargy (see also Central nervous system depression in 'Neurological'),Weight loss,Liver disorder NOS,Elevated serum alkaline phosphatase (SAP),Abnormal ultrasound finding	1	1	BRAVECTO 500MG 1X1TAB 541,Milpro 12.5 mg/125 mg Film-coated Tablets for Dogs	Canine/dog	English Springer Spaniel	AER
GBR-MERCKMSD-2020-UK-05342	22 January 2021	Veterinarian	Yes	United Kingdom	Female-Neutered	Miscellaneous eating disorder NOS,Diarrhoea,Gall bladder & bile duct disorder NOS,Hepatic insufficiency,Malaise,Hepatic disorder NOS,Pancreatitis,Elevated alanine aminotransferase (ALT),Elevated bile acids,Emesis (multiple),Elevated lipase,Chewing - pruritus (see also 'Oral cavity disorders'),Off food	1	1	BRAVECTO 112.5MG 1X1TAB 541	Canine/dog	Yorkshire Terrier	AER

Refresh - Print - Export

DATA PUBLICATION – ADR WEBSITE (1)

EUROPEAN MEDICINES AGENCY

AER **Individual case adverse event report form** EudraVigilance

General information	
EudraVigilance local report number	ARG-MERCKMSD-2020-AR-00148
Sender type	Pharmaceutical Company
Sender's organisation	Intervet International B.V.
Type of report	Spontaneous
Primary source country	Argentina
Is serious?	Yes
Animals treated	1
Animals affected	1

DATA PUBLICATION – ADR WEBSITE (2)

EUROPEAN MEDICINES AGENCY

Animal data			
Species	**Breed**	**Weight**	**Age**
Canine/dog	Bernese Mountain Dog	46	19 Month(s)

Reaction / Event		
VedDRA LLT	**Duration**	**Outcome**
Anorexia Hepatic failure Product problem Vomiting Weight loss		recovering/resolving

Drug information	
Product	**Dosage form**

Questions?