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EudraVigilance access policy for medicines for veterinary use

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Consultation with the Committee for Veterinary Medicinal Products (CVMP)	April 2008
Consultation with the Heads of Medicines Agencies	April 2008
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Executive summary

This document outlines the policy for granting access to information on adverse events that are suspected to be related to the use of medicinal products for veterinary use authorised in the European Union (EU) and are reported into the central EU database system called Eudravigilance Veterinary (EVVet).

All relevant regulatory agencies within the EU receive full access to the complete dataset in EVVet for surveillance purposes in view of the protection of public and animal health.

The general public, including health care professionals, will be able to view summary data of adverse events contained within Eudravigilance Veterinary, suspected to be related to an active ingredient, a fixed combination of active ingredients or a veterinary medicinal product. The summary data that are extracted from the data fields and that are made accessible have been carefully assessed in line with the EU data privacy legislation ensuring that the requirements to protect personal data and the identifiability of data subjects are guaranteed.

Marketing authorisation holders will receive access to the same data as the general public and will be able to use specific tools for surveillance purposes.

Specific access to EVVet data for research purposes may also be granted when considered in line with the public health objectives of the European Medicines Agency.

1. Introduction (background)

The core responsibility of the European Medicines Agency (EMA) is the protection and promotion of public and animal health through the evaluation and supervision of medicines. Central to this responsibility is the evaluation and coordination of the safety of medicines including the collection, management and dissemination of information on adverse events to medicines (pharmacovigilance). The key European Union (EU) resource to support this activity with respect to veterinary medicinal products is Eudravigilance Veterinary (EVVet), the European database of adverse events. Marketing authorisation holders (MAH) and regulatory authorities are legally obliged to report all serious adverse events to the central database via well established procedures.

The access levels that are defined in this document relate to the provisions laid down in Article 57(1)(d) of Regulation 726/2004, where the Agency should grant 'appropriate levels' of Eudravigilance access to the stakeholders mentioned in Article 57(1)(d) (i.e. Healthcare Professionals, Marketing Authorisation Holders and the General Public) whereby personal data protection should be guaranteed. The same access levels also apply when access is requested to the data in EVVet in line with Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

This document has been prepared in collaboration with all relevant stakeholders, in particular national competent authorities, marketing authorisation holders, and healthcare professionals. The principles underlying this policy are those of transparency and freedom of information.

The practical implementation of these principles is dependent on the availability both of data of sufficient quality and of the tools to make them available in a manner that is useful and equitable to all stakeholders. In particular, the practical operational principles and requirements for the policy include;

- The need to allow national competent authorities full access to all data in EVVet for effective surveillance of veterinary medicinal products, to ensure protection of public and animal health.
- The need to release relevant information to the general public in a timely and clear manner with the ability to search the data for information on a particular active substance or veterinary medicinal product.
- The necessity for MAH to access all adverse event reports that involve any veterinary medicinal product under the responsibility of the MAH in order to facilitate surveillance by the MAH.
- The need to ensure that sufficient background information and warning is provided to the general public in order to prevent taking unwarranted conclusions that might influence the use of a veterinary medicine.
- The need to foresee specific access to data that may be requested for research or other purposes.
- The requirement to guarantee personal data protection.

2. Access to Eudravigilance Veterinary Data

2.1. Access for national competent authorities in the EEA, the European Commission and the European Medicines Agency

Access is granted to:

- The full information contained in Eudravigilance Veterinary related to adverse event reports for all types of veterinary medicinal products independent of the authorisation procedure,
- All original and any subsequent follow-up reports.

Mode of Access

Secure and permanent online access is granted to all registered users of European Economic Area (EEA) national competent authorities, the Commission and the Agency to the reporting tools and the analysing tools of Eudravigilance Veterinary in order to allow surveillance of the safety of veterinary medicinal products.

Implementation of the policy

Full access to the Eudravigilance Veterinary data is already available since 2005 while access to the specific analysing tools became available in September 2009 for all national competent authorities in the EEA.

2.2. Access for health care professionals and the general public

Access is granted to:

All adverse event reports for all types of veterinary medicinal products authorised in the EEA independent of the authorisation procedure, which will be implemented gradually depending on the available product data in a central European product database (see further under Implementation of the policy). Access will be to the latest information available for a particular report. Access is not permitted to data from specific fields that have been designed to contain personal data for storage in the originator database, the release of which would contravene personal data protection legislation. Also data fields that may lead to easy identification of a particular case and hence the persons that may be involved will not be accessible. Data fields that are designed to contain text and which may contain personal data have also been excluded; e.g. the narrative. An overview of the available data fields in the central database of EudraVigilance Veterinary and the corresponding access levels can be found in Annex A.

Mode of Access

Data are made available by means of search functions on the Agency's website. The search functions include selecting data related to specific active substances, combination of active substances or specific veterinary medicinal products, related to certain species or breeds. The user will be able to view aggregated information on the number of reports, frequency of reactions terms (Veddra) related to e.g. the product and/or species of its choice. It will also be possible to generate a listing of the individual reports for e.g. a particular product and/or species chosen.

Prior to accessing the aggregated data, the potential reader should agree to have read a disclaimer notice that provides guidance and includes the following key elements and information;

Adverse event reports are only a subset of data being dealt with in the framework of pharmacovigilance to safeguard public and animal health. In certain cases, a thorough evaluation may require additional measures to assess the safety of medicines, e.g. the conduct of post-authorisation studies which may therefore not be reported via EVVet.

- The data in EVVet need to be analysed with caution to take into account biases and the absence of reliable exposure data, e.g. sales volumes. There are also confounding factors that need to be considered, such as the health status of the animals and off label use. Certain adverse events may be considered normal for a particular product and are occurring at accepted frequencies while the same event may be considered unusual for another product. It is often the case that insufficient data are available to be able to reach a scientific valid conclusion on the likely causality of the event.
- Individual adverse event reports from the EEA are initially assessed by national competent authorities. An overall assessment of the data is performed at regular intervals by either the national competent authorities or the European Medicines depending on the type of products. Such assessment follows established procedures and takes into account additional information that marketing authorisation holders are legally required to provide at specific intervals. The conclusions reached in the overall assessments may lead to regulatory or other actions such as changes in the product literature or the authorisation status of individual or groups of products.

Implementation of the policy

In line with the elements outlined above in the disclaimer, it is important to limit the risk for misinterpretation of the data that could lead to certain products or substances being perceived as having a relative higher or lower risk profile. The quality of the available data is depending predominantly on the data provided by the initial reporter. The aggregated data provided to the general public are summaries of the type and number of adverse reactions observed for a particular active substance or product and therefore depend on the linkage and the standardisation of the products and substances identified in the individual reports to the product database within Eudravigilance Veterinary. Reliable summary data require that the particular product or substance is available in the product database and that the corresponding product can be identified and linked in the individual reports which is often problematic as the reporting of the suspected products in a report has not been standardised yet.

Fully automated standardisation depends on the availability of a validated EU veterinary medicinal product and substance database.

In the first instance, automated and manual processes allow the Agency to link the relevant information in the adverse event reports to the available data for centrally authorised products in the product database of Eudravigilance Veterinary. Therefore, in the first instance access to EVVet data for health care professionals and the general public will be limited to adverse events that have been linked to centrally authorised products.

Access to data related to other EU Veterinary authorised products will become available gradually whenever the specific product data become available in the EVVet product database and consistent linking of the information contained in the reports to these products has been achieved.

2.3. Access for marketing authorisation holders (MAHs):

Access is granted to:

All adverse event reports for all types of veterinary medicinal products authorised in the EEA independent of the authorisation procedure. Access will be to the latest information available for a particular report. Access is not permitted to data from specific fields that have been designed to contain personal data for storage in the originator database, the release of which would contravene personal data protection legislation. Also data fields that may lead to easy identification of a particular case and hence the persons that may be involved will not be accessible. Data fields that are designed to contain text and which may contain personal data have also been excluded; e.g. the narrative. An overview of the available data fields in the central database of EudraVigilance Veterinary and the corresponding access levels can be found in Annex A.

Mode of Access

Secure and permanent online access is granted for all registered users representing MAHs, to the reporting tools and the analysing tools of Eudravigilance Veterinary. The MAH will be able to benefit from the analysing tools and the statistical measures made available in view of the surveillance responsibilities for its veterinary medicinal products.

Implementation of the policy

MAHs have and will continue to have access to all reports included in messages that they have submitted directly to the central database of EVVet.

Under the current legislation, MAHs receive all adverse event reports related to the use of its products authorised in the EU and the MAHs will therefore continue to be able to perform surveillance on its own pharmacovigilance systems. The availability of specific data warehouse tools for MAHs to allow to review data from the current EudraVigilance Veterinary 2 system is under consideration however it is more likely that the full availability of such tools will only be achieved at the finalisation of the new EudraVigilance Veterinary System 3 (EVVet3) that is being developed.

As part of the EVVet3 development it is also being considered how to further limit the risk of personal data in data fields that are considered useful for the surveillance, e.g. in the narrative. The access policy and in particular access for MAH will therefore be reviewed at that stage with the objective to allow MAHs to use the same analysing tools on the same data as the regulatory authorities in order to improve the efficiency of the pharmacovigilance surveillance procedures in the EEA.

2.4. Access for research or other purposes

Access to Eudravigilance Veterinary data for the purpose of research, in particular, will be granted in line with the following principles:

a) The Agency supports in principle any efforts that aim to directly improve public health and work which aims to improve procedures for protecting public health.

b) The data access to be granted should be sufficient to carry out work aimed at either objective named above.

c) Data access should observe EU legislation on protection of personal data and confidentiality data.

d) The Agency may request advice from its scientific committees related to a particular request.

e) The request may be refused if the potential public health value is unconvincing or if it is judged that the request is in conflict with the public health and legal responsibilities of the Agency.

f) Those given access to Eudravigilance Veterinary data for research purposes should make appropriate efforts to publish their research.

g) The Agency has the right to view any publication resulting from EudraVigilance Veterinary data before submission (maximum period for initial Agency review will be six weeks), and any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.

h) A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.

i) A confidentially agreement must be signed by the party applying for data access for research purposes. Data may not be transferred to any third party.

j) The Agency will have a standard timescale for response to requests for data.

k) The data quality will be the best available to the Agency at the time of request. Issues of data quality may be raised with the Agency but no guaranteed timescale can be given for resolution of such issues.

3. References (scientific and / or legal)

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Official Journal L 136, 30/4/2004 p. 1 - 33).

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use as amended by Directive 2004/28/EC and Directive 2009/9/EC (Official Journal of the European Communities 28.11.2001 L 311 p.1-66, Official Journal of the European Communities 30.4.2004 L 136 p.58-84 and Official Journal of the European Communities L 44, 14/2/2009 p. 10 - 61)

Annex 1.

Basis: Data elements guideline (2.2.1)

Detailed access levels for General Public and Marketing Authorisation Holders to the data elements of EVVet

Reference code[1]	Title	Field Type	Access for General Public and Marketing Authorisation Holders
H.08	Message send date	*Text(14); YYCC-MMDDHHMISS*	Display as EV Gateway receipt date
R	**Safety report**		
R.01	Report identification Number	*Text(60)*	Yes
R.02	Type of report submission	*Report type list*	yes
R.03	Type of information in report	*Information type list*	yes
R.04	Case registration type	*Case type list*	yes
R.05	Unique case registration number	*Case number Text(60)*	No
R.06	Original receive date format	*Number(3)*	N/A
R.07	Date originally received by reporter	*Date Time*	yes
R.08	Date of most recent information format	*Number(3)*	N/A
R.09	Date of most recent information	*Date Time*	yes
R.10	Primary source country	*Country code*	Grouped by EU and Non-EU; For Non-Eu apply also grouping according to the United Nations Geoscheme, including macro-geographica regions (continents) and subcontinents)
R.11	Occur country	*Country code*	Grouped by EU and Non-EU; For Non-Eu apply also grouping according to the United Nationas Geoscheme, including macro-geographica regions (continents) and subcontinents)
R.12	Human VEDDRA version	*Human VEDDRAveddra number*	N/A
R.13	VEDDRA version	*VEDDRA number*	N/A
R.14	Nullification report	*Yes No*	yes
R.15	Nullification reason	*Text(200)*	no
R.16	Suspect duplicate	*Yes No*	yes
R.17	**Animal species and breeds**		
R.17.01	Species code	*Species code list*	yes
R.17.02	Species if not listed	*Text(160)*	yes
R.17.03	**Animal breeds**		
R.17.03.01	Breed code	*Breed code list*	yes

[1] The reference relates to Data elements for the electronic submission of adverse reaction reports related to veterinary medicinal products authorised in the European Economic Area (EEA) including message and transmission specifications. EMEA/CVMP/065/03-Version 2.2.1

R.17.03.02	Breed if not listed	**Text(160)**	yes
R.18	**Other animal data**		(1,1)
R.18.01	Exposed number	*Animal Number*	Yes
R.18.02	Affected number	*Animal Number*	Yes
R.18.03	Sex	*Sex of animal list*	Yes
R.18.04	Animal role	*Animal role list*	yes
R.18.05	Production type	*Production types list*	yes
R.18.06	Female physiological status	*Physiological status list*	yes
R.18.07	Weight type	*Measure type*	yes
R.18.08	Minimum weight	*Animal weight number*	yes
R.18.09	Weight	*Animal weight number*	yes
R.18.10	Maximum weight	*Animal weight number*	yes
R.18.11	Age type	*Measure type*	yes
R.18.12	Minimum age	*Animal age number*	yes
R.18.13	Age	*Animal age number*	yes
R.18.14	Maximum age	*Animal age number*	yes
R.18.15	Age unit	*Time units*	yes
R.18.16	**Animal adverse reaction**		
R.18.16.01	Reaction start date format	*Number(3)*	N/A
R.18.16.02	Reaction start date	*Variable date*	No
R.18.16.03	Time to onset of reaction	*Time interval range*	yes
R.18.16.04	Duration	*Duration number*	yes
R.18.16.05	Duration unit	*Time unit*	yes
R.18.16.06	Reaction end date format	*Number(3)*	N/A
R.18.16.07	Reaction end date	*Variable date*	No
R.18.16.08	Reaction serious	*Yes No*	Yes
R.18.16.09	Results in death?	*Yes No*	yes
R.18.16.10	Life Threatening?	*Yes No*	yes
R.18.16.11	Disabling/Incapacitating?	*Yes No*	yes
R.18.16.12	Congenital anomaly?	*Yes No*	yes
R.18.16.13	Other medically important condition?	*Yes No*	yes
R.18.16.14	Outcome ongoing	*Animal Number*	yes
R.18.16.15	Outcome Recovered	*Animal Number*	yes
R.18.16.16	Outcome alive with sequelae	*Animal Number*	yes
R.18.16.17	Outcome died	*Animal Number*	yes
R.18.16.18	Outcome killed	*Animal Number*	yes
R.18.16.19	Outcome unknown	*Animal Number*	yes
R.18.16.20	***Case narrative***		
R.18.16.20.01	Narrative text including clinical	*Text(10000)*	No
R.18.16.21	**Animal signs**		
R.18.16.21.01	Reaction veddra termcode	*VEDDRA LLT term code*	Available at PT level
R.18.16.21.02	Reaction veddra term	*VEDDRA LLT term*	Available at PT level
R.18.17	**Animal suspect drug**		
R.18.17.01	Treatment start date format	*Number(3)*	N/A
R.18.17.02	Treatment start date	*Variable date*	yes
R.18.17.03	Treatment duration	*Duration number*	yes
R.18.17.04	Treatment duration unit	*Time units*	yes
R.18.17.05	Treatment end date format	*Number(3)*	N/A

R.18.17.06	Treatment end date	*Variable date*	yes
R.18.17.07	Characterization	*Characterization list*	yes
R.18.17.08	Brand Name	*Text(200)*	[2] no only the recoded term
R.18.17.09	Dosage form	*Dosage form list*	yes
R.18.17.10	Authorization number	*Text(35)*	no
R.18.17.11	Authorization Holder/Company	*Text(60)*	no
R.18.17.12	Authorization country	*Country code*	yes
R.18.17.13	Obtain country	*Country code*	yes
R.18.17.14	Lot number	*Text(35)*	yes
R.18.17.15	Expiry date format	*Number(3)*	N/A
R.18.17.16	Expiry date	*Month year date*	yes
R.18.17.17	Administration route	*Administration route list*	yes
R.18.17.18	Dose per administration	*Dose numeric*	yes
R.18.17.19	Number of doses per dose interval	*Dose numeric*	yes
R.18.17.20	Dose interval	*Dose interval*	yes
R.18.17.21	Dose interval unit	*Time unit*	yes
R.18.17.22	Dose unit	*Dosage unit*	yes
R.18.17.23	Dosage text	*Text(100)*	No
R.18.17.24	Action taken after reaction	*Action drug list*	yes
R.18.17.25	ATCvet code	*ATCvet code list*	yes
R.18.17.26	Who administered the VMP	*Categorization list*	Yes
R.18.17.27	Use according to label	*Yes No*	yes
R.18.17.28	Off label use	*Off label use-list*	yes
R.18.17.29	Explanation	*Text(500)*	No
R.18.17.30	**Assessment**		
R.19.17.30.01	Assessment source	*Assessment source list*	yes
R.18.17.30.02	Assessment classification	*Assessment list*	yes
R.18.17.30.03	Assessment comment	*Text (4000)*	No
R.18.17.31	**Animal suspect substance**		
R.18.17.31.01	Role	*Substance role*	yes
R.18.17.31.02b	Characterization	*Characterization list*	yes
R.18.17.31.03	Substance name	*Text(200)*	No only the recoded term
R.18.17.31.04	Strength	*Dose numeric*	yes
R.18.17.31.05	Strength Unit	*Dosage unit*	yes
R.18.18	**Animal treating drug**		
R.18.18.01	Start date format	*Number(3)*	N/A
R.18.18.02	Start date	*Variable date*	yes
R.18.18.03	Duration	*Duration number*	yes
R.18.18.04	Duration unit	*Time units*	yes
R.18.18.05	End date format	*Number(3)*	N/A
R.18.18.06	End date	*Variable date*	yes
R.18.18.07	Brand Name	*Text(200)*	No only the recoded term
R.18.18.08	Dosage form	*Dosage form list*	yes
R.18.18.09	Authorization number	*Text(35)*	no
R.18.18.10	Authorization Holder/Company	*Text(60)*	no
R.18.18.11	Authorization country	*Country code*	yes
R.18.18.12	Administration route	*Administration route*	yes

[2] Although "Brand name is not a mandatory field, in accordance to the business rules implemented in Eudravigilance, either a "Brand name" or a "Substance name" have to be entered in order to have a valid SAR.

		list	
R.18.18.13	Additional information	*Text(100)*	No
R.18.18.14	**Animal treating substance**		
R.18.18.14.01	Substance name	*Text(200)*	No only the recoded term
R.18.18.14.02	Strength	*Dose numeric*	yes
R.18.18.14.03	Strength Unit	*Dosage unit*	yes
R.18.19	**Animal medical history**		
R.18.19.01	Episode name code	**VEDDRA term code**	yes
R.18.19.02	Episode name	**VEDDRA term**	yes
R.18.19.03	Primary source episode name	*Text(250)*	No
R.18.19.04	Comments	*Text(2000)*	**No**
R.18.20	**Animal laboratory test**		(0,n)
R.18.20.01	Test description	*Text(500)*	no
R.18.20.02	Test result range	*Test result range list*	yes
R.18.20.03	**Test definition**		
R.18.20.03.01	High level test type	*Laboratory/Biochemical test Test type list*	Yes
R.18.20.03.02	Test name	*Laboratory/Biochemical test name list*	yes
R.18.21	**Animal death**		
R.18.21.01	Was the necropsy done?	*Yes No*	yes
R.18.21.02	Date of death format	*Number(3)*	N/A
R.18.21.03	Date of death	*Variable date*	yes
R.18.21.04	Primary source death cause	*Text (500)*	no
R.18.21.05	Death cause for the sender	*Necropsy result list – to be developed*	N/A
R.18.21.06	Further Information	*Text(500)*	no
SECTION FOR HUMAN ADVERSE REACTIONS TO VMPS			
R.19	***Treated animal species and breeds***		
R.19.01	Species code	*Species code list*	yes
R.19.02	Species if not listed	*Text(160)*	no
R.19.03	**Treated animal breeds**		
R.19.03.01	Breed code	*Breed code list*	yes
R.19.03.02	Breed if not listed	*Text(160)*	*No*
R.20	**Other treated animal data**		
R.20.01	Exposed number	*Animal Number*	yes
R.20.02	Sex	*Sex of animal*	yes
R.20.03	Animal role	*Animal role list*	yes

R.20.04	Comments	*Text(250)*	No
R.21	**Human affected**		
R.21.01	Patient identification	*Text(30)*	No
R.21.02	Number exposed	*Human number*	yes
R.21.03	Number affected	*Human number*	yes
R.21.04	Time between exposure and onset of adverse reaction	*Time interval range*	yes
R.21.05	Onset age	*Human age number*	yes
R.21.06	Onset age unit	*Time unit*	yes
R.21.07	Age group	*Age group list*	yes
R.21.08	Sex	*Sex of Human*	Yes
R.21.09	**Categorization of person affected**	*Categorization list*	yes
R.21.10	**Human adverse reaction**		
R.21.10.01	Reaction start date format	*Number(3)*	N/A
R.21.10.02	Reaction start date	*Variable date*	No
R.21.10.03	Duration	*Duration number*	yes
R.21.10.04	Duration unit	*Time unit*	yes
R.21.10.05	Reaction end date format	*Number(3)*	N/A
R.21.10.06	Reaction end date	*Variable date*	No
R.21.10.07	Outcome	*Outcome list*	yes
R.21.10.08	**Case narrative**		
R.21.10.08.01	Narrative text including clinical	*Text(10000)*	No
R.21.10.09	**Human signs**		
R.21.10.09.01	Reaction Human VEDDRA term code	*Human VEDDRA term*	Available at PT level
R.21.10.09.02	Reaction Human VEDDRAVEDDRA term	*Human VEDDRA term code*	Available at PT level
R.21.11	**Human suspect drug**		
R.21.11.01	Exposure start date	*Number(3)*	No
R.21.11.02	Exposure start date	*Variable date*	No
R.21.11.03	Exposure duration	*Duration number*	yes
R.21.11.04	Exposure duration unit	*Time units*	yes
R.21.11.05	Exposure end date	*Number(3)*	No
R.21.11.06	Exposure end date	*Variable date*	No
R.21.11.07	Characterization	*Characterization list*	yes
R.21.11.08	Brand Name	*Text(200)*	No only when recoded
R.21.11.09	Dosage form	*Dosage form list*	yes
R.21.11.10	Authorization number	*Text(35)*	No
R.21.11.11	Authorization Holder/Company	*Text(60)*	No
R.21.11.12	Authorization country	*Country code*	No
R.21.11.13	Obtain country	*Country code*	No
R.21.11.14	Lot number	*Text(35)*	No
R.21.11.15	Expiry date format	*Number(3)*	yes
R.21.11.16	Expiry date	*Month year date*	yes
R.21.11.17	Administration route	*Administration route list*	yes
R.21.11.18	Reason for exposure	*Exposure reason list*	yes
R.21.11.19	Dose per administration	*Dose numeric*	yes
R.21.11.20	Number of doses per dose interval	*Dose numeric*	yes
R.21.11.21	Dose interval	*Dose interval*	yes

R.21.11.22	Dose interval unit	*Time unit*	yes
R.21.11.23	Dose Unit	*Dosage unit*	yes
R.21.11.24	Exposure details	*Text(500)*	No
R.21.11.25	Action taken after reaction	*Action drug list*	yes
R.21.11.26	ATCvet code	*ATCvet code list*	yes
R.21.11.27	Who administered the VMP	**Categorization list**	yes
R.21.11.28	**Assessment** (1,n)		
R.21.11.28.01	Assessment source	*Assessment source list*	Yes
R.21.11.28.02	Assessment classification	*Assessment list*	Yes
R.21.11.28.03	Assessment comment	*Text(4,000)*	No
R.21.11.29	**Human suspect substance** (0,n)		
R.21.11.29.01	Role	*Substance role*	yes
R.21.11.29.02	Characterization	*Characterization list*	yes
R.21.11.29.03	Substance name	*Text(200)*	No only the recoded term
R.21.11.29.04	Strength	*Dose numeric*	yes
R.21.11.29.05	Strength Unit	*Dosage unit*	yes
R.21.12	**Human treating drug** (0,n)		
R.21.12.01	Start date format	*Number(3)*	N/A
R.21.12.02	Start date	*Variable date*	No
R.21.12.03	Duration	*Duration number*	Yes
R.21.12.04	Duration unit	*Time units*	Yes
R.21.12.05	End date format	*Number(3)*	N/A
R.21.12.06	End date	*Variable date*	No
R.21.12.07	Brand Name	*Text(200)*	No only the recoded term
R.21.12.08	Authorization number	*Text(35)*	No
R.21.12.09	Authorization Holder/Company	*Text(60)*	No
R.21.12.10	Authorization country	*Country code*	No
R.21.12.11	Dosage form	*Dosage form list*	yes
R.21.12.12	Administration route	*Administration route list*	Yes
R.21.12.13	Dosage text	*Text(100)*	No
R.21.12.14	**Human treating substance** (0,n)		
R.21.12.14.01	Substance name	*Text(200)*	No only the recoded term
R.21.12.14.02	Strength	*Dose numeric*	Yes
R.21.12.14.03	Strength Unit	*Dosage unit*	Yes
R.21.13	**Human medical history** (0,n)		
R.21.13.01	Episode code	*Human VEDDRA term code*	Available at PT level
R.21.13.02	Episode name	*Human VEDDRA terminology (160)*	Available at PT level
R.21.13.03	Primary source episode name	*Text(250)*	No
R.21.13.04	Comments	*Text(250)*	No
R.21.14	**Human laboratory test** (0,n)		
R.21.14.01	High level Test name	*Laboratory/Biochemical Test type list*	No
R.21.14.02	Low level Test name	*Laboratory/Biochemical test name list*	No
R.21.14.03	Test description	*Text(500)*	No

R.21.14.04	Test result range	*Test result range list*	No
R.21.15	**Human death** (0,1)		
R.21.15.01	Was the autopsy done?	*Yes No*	No
R.21.15.02	Date of death format	*Number(3)*	No
R.21.15.03	Date of death	*Variable date*	No
R.21.15.04	Death cause for primary source	*Text(250)*	No
R.21.15.05	Death cause for the sender code	*Human VEDDRA code*	yes
R.21.15.06	Death cause for the sender	*Human VEDDRA term*	yes
R.21.15.07	Further information	*Text(500)*	No
SECTIONS BELOW RELATE TO BOTH ANIMAL AND HUMAN ADVERSE REACTIONS TO VMPS			
R.22	**Dechallenge-rechallenge information** (0,1)		
R.22.01	Previous exposures?	*Yes No*	Yes
R.22.02	Previous adverse reactions?	*Yes No*	Yes
R.22.03	Did reaction abate after stopping?	*Yes No*	Yes
R.22.04	Did reaction reappear after reintroduction?	*Yes No*	Yes
R.23	**Sender** (1,1)		
R.23.01	First name	*Text(50)*	No
R.23.02	Middle name	*Text(50)*	No
R.23.03	Last name	*Text(50)*	No
R.23.04	Street address	*Text(100)*	No
R.23.05	City	*Text(50)*	No
R.23.06	State/County	*Text(40)*	No
R.23.07	Postcode	*Text(35)*	No
R.23.08	Country code	*Country code*	No
R.23.09	Telephone	*Text(50)*	No
R.23.10	Fax	*Text(50)*	No
R.23.11	Email	*Text(100)*	No
R.23.12	Organization	*Text(60)*	No
R.23.13	Department	*Text(60)*	No
R.23.14	Categorization	*Categorization list*	Yes
R.24	**Literature Reference** (0,n)		
R.24.01	reference	*Text(200)*	No
R.25	**Clinical trial** (0,n)		
R.25.01	Study name	*Text(100)*	No
R.25.02	Sponsor study number	*Text(35)*	No
R.25.03	Study type in which the reactions were observed	*Study type list*	Yes
R.26	**Linked report** (0,n)		
R.26.01	Case number	*Text(60)*	No
R.26.02	Link type	*Link reference list*	Yes
R.27	**Primary source** (1,1)		
R.27.01	First name	*Text(50)*	No
R.27.02	Middle name	*Text(50)*	No
R.27.03	Last name	*Text(50)*	No
R.27.04	Street address	*Text(100)*	No
R.27.05	City	*text(50)*	No

R.27.06	State/County	*Text(40)*	No
R.27.07	Postcode	*Text(35)*	No
R.27.08	Country code	*Country code*	No
R.27.09	Telephone	*Text(20)*	No
R.27.10	Fax	*Text(50)*	No
R.27.11	Email	*Text(100)*	No
R.27.12	Organization	*Text(60)*	No
R.27.13	Department	*Text(60)*	No
R.27.14	Categorization	*Categorization list*	Yes
R.28	**Other people** (0,n)		
R. 28.01	First name	*Text(50)*	No
R. 28.02	Middle name	*Text(50)*	No
R.28.03	Last name	*Text(50)*	No
R.28.04	Street address	*Text(100)*	No
R.28.05	City	*text(50)*	No
R.28.06	State/County	*Text(40)*	No
R.28.07	Postcode	*Text(35)*	No
R.28.08	Country code	*Country code*	No
R.28.09	Telephone	*Text(20)*	No
R.28.10	Fax	*Text(50)*	No
R.28.11	Email	*Text(100)*	No
R.28.12	Organization	*Text(60)*	No
R.28.13	Department	*Text(60)*	No
R.28.14	Categorization	*Categorization list*	Yes
R.29	Suspect duplicate reports (0,n)		
R.29.01	Duplicate source	*Text(60)*	No
R.29.02	Duplicate number	*Text(60)*	No