EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2016
EMA/CVMP/65/2003- Version 2.2.2
Committee for Medicinal Products for Veterinary Use

Guideline on Data elements for the electronic submission of adverse reaction reports related top veterinary medicinal products authorised in the European Economic Area (EEA) including message and transmission specifications

Version 2.1.1. came into effect on:	1 September 2004
Revision agreed by Veterinary Joint Implementation Group	9 July 2005
Implementation in Eudravigilance Veterinary test system	28 November 2005
Implementation in Eudravigilance Veterinary production system	6 December 2005
Correction agreed by Veterinary Joint Implementation Group	16 April 2008
Implementation in Eudravigilance Veterinary production system	9 February 2009

Keywords	***Eudravigilance Veterinary, pharmacovigilance, adverse event, electronic reporting***

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1. Introduction

As set out in Council Regulation (EEC) No 2309/93 as amended and in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001, it is important to guarantee the continued safety of veterinary medicinal products (VMPs) in use. The roles and procedures for the expedited reporting of serious adverse reactions to veterinary medicines occurring within or outside the Community are also laid down in Community legislation and the relevant Community guidelines. To support these activities, it is necessary to ensure that pharmacovigilance systems in the Community are continually adapted to take account of scientific and technical progress. Furthermore the increasing use of electronic means of communication of information on adverse reactions to veterinary medicinal products marketed in the Community is intended to allow a single reporting point in the EEA for adverse reactions, at the same time ensuring that this information is shared with the competent authorities in all Member States.

In order to facilitate the exchange of information about pharmacovigilance within the Community, the European Commission, in consultation with the EMEA, Member States and the interested parties, as laid down in Article 77 of Directive 2001/82/EC, shall draw up guidance on the collection, verification and presentation of adverse reaction reports, including technical requirements for electronic exchange of veterinary pharmacovigilance information. This guidance shall take account of international harmonisation work carried out in the field of pharmacovigilance, and thus future agreements reached within international processes such as VICH regarding electronic transmission of pharmacovigilance information will influence the system described in this guideline. Furthermore, in order to facilitate the exchange of the pharmacovigilance information, the EMEA, in collaboration with the Member States and the European Commission shall set up a data-processing network, as laid down in Article 76 of Directive 2001/82/EC.

As a result, this note for guidance intends to assist competent authorities (CAs) in Member States including Iceland, Liechtenstein and Norway and all marketing authorisation holders (MAHs) in the Community in preparing for the electronic transmission of serious adverse reaction reports in veterinary pharmacovigilance.

The objective of this guideline is to standardise the data elements for transmission of adverse reaction reports relating to veterinary medicinal products authorised in the EEA. This includes adverse reactions for both pre- and post-authorisation periods, occurring within and outside the EEA.

For the purpose of this guideline, reports describing serious adverse drug reactions that need to be exchanged in pharmacovigilance between the various parties in accordance with the Community legislation are referred to as serious adverse reaction reports or safety reports. A serious adverse reaction report has to contain the information as defined in Volume 9 of The Rules Governing Medicinal Products in the European Union and the data elements specified in this guideline.

Any supporting information related to each case must be sufficiently described within the serious adverse reaction report with reference to the documents that are held by the sender, which may need to be provided on request. It is recognised that it is often difficult to obtain all details on a specific case. However, the complete information related to an individual case, that is available to the sender, has to be reported in accordance with the legal requirements as set out in the Community legislation. This also includes causality assessment. It is the responsibility of the sender to structure all information available in accordance with the data elements as defined in this guideline.

In addition, whenever more recent information on an adverse reaction is submitted, the complete (entire) information has to be provided and not only partial information e.g. changes or updates.

This does not only apply to the transmission of follow-up information but also if a serious adverse reaction report is highlighted for nullification. For those reports that are highlighted for nullification ('Report nullification', 'R.14', set to 'yes') the reasons for nullification must be indicated in detail.

The format for adverse reaction reports includes provisions for transmitting all the relevant data elements useful to assess individual adverse reactions. The data elements are sufficiently comprehensive to cover complex reports from most sources, different data sets, and transmission situations or requirements; therefore not every data element will be available for every transmission. In many, if not most instances, a substantial number of the data elements will not be known and therefore not included in the transmission. Where it was deemed important, provisions for unknown / not applicable were included (e.g. outcome, route of administration). However, since the transmission is intended to be electronic, it was thought to be unnecessary to include provisions to assign values of unknown for all data elements, the convention being that no entry equals unknown/not applicable.

Structured data are strongly recommended in electronic transmission and controlled vocabularies have been developed for this purpose. In certain instances, there are provisions for the transmission of some free text items. The transmission of other unstructured data, such as full clinical records or images is outside the scope of this guidance.

The minimum information for the transmission of a report should include at least an identifiable source, animal details: species, sex, age / human details: sex, age or adult/child, a suspect product (name and marketing authorisation number), and reaction details. According to Volume 9 this equals the minimum information required to constitute an adverse reaction report. In addition, to properly process the report, the following administrative information should be provided: the sender's safety report unique identifier (R.01), the date of receipt of the most recent information (R.07), the unique case identification number (R.05) and the sender identifier (H.05).

For the interpretation of other fields (denominated as 'Attribute' in column 3 of chapter 5) that are also indicated as 'mandatory' (that is contain 'Yes' in the last column in chapter 5), it is important to consider first the notation in brackets at entity level (bold print of the title in column 2, denomination as 'Entity' in column 3) that is also found in the 'mandatory' column, (1,1), (1,n), (0,1) and (0,n). This notation indicates whether a particular entity is required for a valid electronic adverse reaction report:

(1,1): The entity is required to be filled in with at least one and not more than one entry in the field marked with 'Yes'. The other fields of the entity should be completed if the information is available, but are not required for a valid electronic adverse reaction report.

(1,n): The entity is required to be filled with at least one entry in the subfield marked with 'Yes'. The other fields of the entity should be completed if the information is available, but are not required for a valid electronic adverse reaction report. The entity may be repeated as often as necessary.

(0,1): The entity is not required to be filled but may only be contained once in a valid electronic adverse reaction report. If selected, at least the field indicated with 'Yes' should be filled, the other fields to be completed if the information is available.

(0,n): The entity is not required to be filled but may be contained several (unlimited) times in a valid electronic adverse reaction report. If selected, at least the field indicated with 'Yes' should be filled, the other fields to be completed if the information is available.

The scope of this guideline does not encompass the definition of database structures, the design of paper report forms, quality control/quality assurance aspects, or technical security issues.

The XML schema Definition (XSD) based on the data elements as described in this guideline and the specifications for the acknowledgement message relating to electronic regulatory communications for Veterinary pharmacovigilance will be published in a separate document.

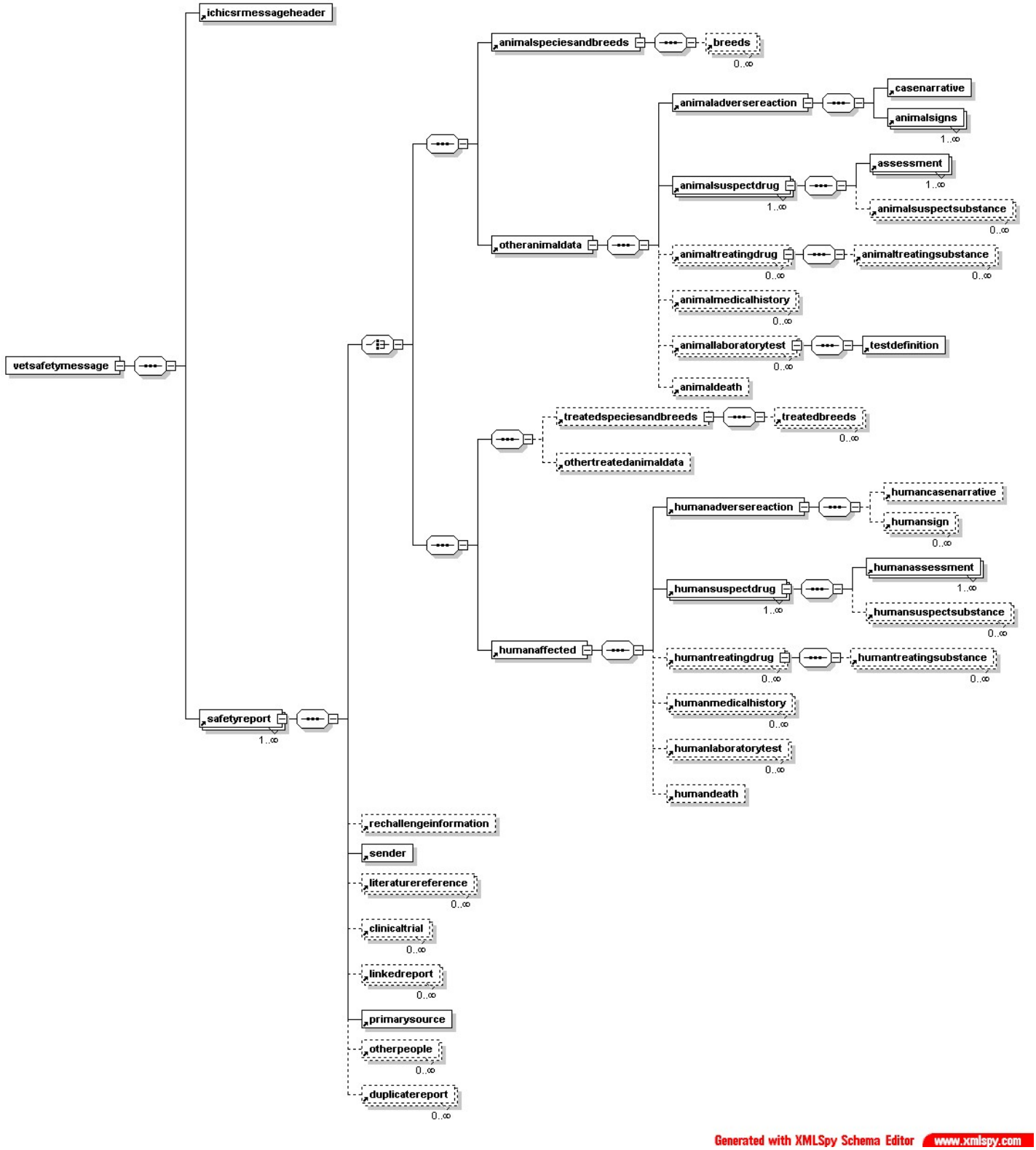
Administrative convention: Major changes to the message model will result in a new version, minor changes in a new release of the old version.

2. Electronic Standards for the Transfer of Regulatory Information (ESTRI)

With regard to all aspects of the electronic regulatory communications for Veterinary pharmacovigilance the standards and recommendations as adopted at the level of ICH apply accordingly, in particular:

- ICH M2 Recommendation 1.2: Gateway Recommendation for the Electronic Transfer of Regulatory Information (ESTRI Gateway)

3. Safety Message (adverse reaction reports) diagram



4. Definition of elements and attributes

Reference code	Title	Description	Schema Descriptor	Field Type	Mandatory
A	veterinary message	Root Entity	vetsafetymessage		(1,1)
H	veterinary message header	Entity	ichicsrmessageheader		(1,1)
H.01	Type	Attribute	messagetype	*Text(20)*	Yes
H.02	Version	Attribute	messageformatversion	*Text(3)*	Yes
H.03	Release	Attribute	messageformatrelease	*Text(3)*	Yes
H.04	Message number	Attribute	messagenumb	*Text(100)*	Yes
H.05	Sender identifier	Attribute	messagesenderidentifier	*Text(60)*	Yes
H.06	Receiver identifier	Attribute	messagereceiveridentifier	*Text(60)*	Yes
H.07	Message send date format	Attribute	messagedateformat	*Number(3)*	Yes
H.08	Message send date	Attribute	messagedate	*Text(14); YYCC-MMDDHHMISS*	Yes
R	Safety report	Entity	safetyreport		(1,n)
R.01	Report identification Number	Attribute	reportid	*Text(60)*	Yes
R.02	Type of report submission	Attribute	reporttype	*Report type list*	
R.03	Type of information in report	Attribute	Informationtype	*Information type list*	Yes
R.04	Case registration type	Attribute	casetype	*Case type list*	Yes
R.05	Unique case registration number	Attribute	Casenumber	*Case number Text(60)*	Yes
R.06	Original receive date format	Attribute	originalreceivedateformat	*Number(3)*	Yes
R.07	Date originally received by reporter	Attribute	originalreceivedate	*Date Time*	Yes

Reference code	Title	Description	Schema Descriptor	Field Type	Mandatory
R.08	Date of most recent information format	Attribute	mostrecentinfodateformat	*Number(3)*	Yes
R.09	Date of most recent information	Attribute	mostrecentinfodate	*Date Time*	Yes
R.10	Primary source country	Attribute	primarysourcecountry	*Country code*	
R.11	Occur country	Attribute	occurcountry	*Country code*	
R.12	Human VEDDRA version	Attribute	htermversion	*Human VEDDRAveddra number*	
R.13	VEDDRA version	Attribute	veddraversion	*VEDDRA number*	Yes
R.14	Nullification report	Attribute	nullificationreport	*Yes No*	
R.15	Nullification reason	Attribute	nullificationreason	*Text(200)*	
R.16	Suspect duplicate	Attribute	suspectduplicate	*Yes No*	
Section for animal adverse reactions to VMPs					
R.17	Animal species and breeds	Entity	animalspeciesandbreeds		(1,1)
R.17.01	Species code	Attribute	speciescode	*Species code list*	Yes [1] if no R.17.02
R.17.02	Species if not listed	Attribute	species	*Text(160)*	Yes [2] if no R.17.01
R.17.03	Animal breeds	Entity	breeds		(0,n)
R.17.03.01	Breed code	Attribute	breedcode	*Breed code list*	Yes [2] if no

[1] Either the code or the attribute is required to be reported, reporting of both will not be accepted at validation (this is to allow proper transfer of data from e.g. a US database with additional different breeds that could not be mapped)

Section for animal adverse reactions to VMPs					
					R170302
R.17.03.02	Breed if not listed	Attribute	breed	Text(160)	Yes [2] if no R170301
R.18	Other animal data	Entity	otheranimaldata		(1,1)
R.18.01	Exposed number	Attribute	exposednumber	*Animal Number*	Yes
R.18.02	Affected number	Attribute	affectednumber	*Animal Number*	Yes
R.18.03	Sex	Attribute	sex	*Sex of animal list*	Yes
R.18.04	Animal role	Attribute	animalrole	*Animal role list*	
R.18.05	Production type	Attribute	productionstatus	*Production types list*	
R.18.06	Female physiological status	Attribute	physiologicalstatus	*Physiological status list*	
R.18.07	Weight type	Attribute	weighttype	*Measure type*	
R.18.08	Minimum weight	Attribute	minweight	*Animal weight number*	
R.18.09	Weight	Attribute	weight	*Animal weight number*	
R.18.10	Maximum weight	Attribute	maxweight	*Animal weight number*	
R.18.11	Age type	Attribute	agetype	*Measure type*	
R.18.12	Minimum age	Attribute	minage	*Animal age number*	
R.18.13	Age	Attribute	age	*Animal age number*	
R.18.14	Maximum age	Attribute	maxage	*Animal age number*	
R.18.15	Age unit	Attribute	ageunit	*Time units*	
R.18.16	Animal adverse reaction	Entity	animaladversereaction		(1,1)
R.18.16.01	Reaction start date format	Attribute	reactionstartdateformat	*Number(3)*	Yes
R.18.16.02	Reaction start date	Attribute	reactionstartdate	*Variable date*	Yes

Section for animal adverse reactions to VMPs					
R.18.16.03	Time to onset of reaction	Attribute	reactiononsettime	*Time interval range*	
R.18.16.04	Duration	Attribute	duration	*Duration number*	
R.18.16.05	Duration unit	Attribute	duration unit	*Time unit*	
R.18.16.06	Reaction end date format	Attribute	reactionenddateformat	*Number(3)*	
R.18.16.07	Reaction end date	Attribute	reactionenddate	*Variable date*	
R.18.16.08	Reaction serious	Attribute	seriousnessdecision	*Yes No*	Yes
R.18.16.09	Results in death?	Attribute	seriousnessdeath	*Yes No*	
R.18.16.10	Life Threatening?	Attribute	seriousnesslifethreatening	*Yes No*	
R.18.16.11	Disabling/Incapacitating?	Attribute	seriousnessdisabling	*Yes No*	
R.18.16.12	Congenital anomaly?	Attribute	seriousnesscongenitalanomaly	*Yes No*	
R.18.16.13	Other medically important condition?	Attribute	seriousnessother	*Yes No*	
R.18.16.14	Outcome ongoing	Attribute	outcomeongoing	*Animal Number*	
R.18.16.15	Outcome Recovered	Attribute	outcomerecovered	*Animal Number*	
R.18.16.16	Outcome alive with sequelae	Attribute	outcomealivewithsequelae	*Animal Number*	
R.18.16.17	Outcome died	Attribute	outcomedied	*Animal Number*	
R.18.16.18	Outcome killed	Attribute	outcomekilled	*Animal Number*	
R.18.16.19	Outcome unknown	Attribute	outcomeunknown	*Animal Number*	
R.18.16.20	Case narrative	Entity	casenarrative		(1,1)
R.18.16.20.01	Narrative text including clinical	Attribute	narrativeincludeclinical	*Text(10000)*	Yes
R.18.16.21	Animal signs	Entity	animalsigns		(1,n)
R.18.16.21.01	Reaction veddra termcode	Attribute	veddratermcode	*VEDDRA LLT term code*	Yes
R.18.16.21.02	Reaction veddra term	Attribute	veddraterm	*VEDDRA LLT term*	

Section for animal adverse reactions to VMPs					
R.18.17	Animal suspect drug	Entity	animalsuspectdrug		(1,n)
R.18.17.01	Treatment start date format	Attribute	treatmentstartdateformat	*Number(3)*	
R.18.17.02	Treatment start date	Attribute	treatmentstartdate	*Variable date*	
R.18.17.03	Treatment duration	Attribute	treatmentduration	*Duration number*	
R.18.17.04	Treatment duration unit	Attribute	treatmentdurationunit	*Time units*	
R.18.17.05	Treatment end date format	Attribute	treatmentenddateformat	*Number(3)*	
R.18.17.06	Treatment end date	Attribute	treatmentenddate	*Variable date*	
R.18.17.07	Characterization	Attribute	charaterization	*Characterization list*	
R.18.17.08	Brand Name	Attribute	brandname	*Text(200)*	[2]
R.18.17.09	Dosage form	Attribute	dosageform	*Dosage form list*	
R.18.17.10	Authorization number	Attribute	authorizationnumber	*Text(35)*	
R.18.17.11	Authorization Holder/Company	Attribute	authorizationcompany	*Text(60)*	
R.18.17.12	Authorization country	Attribute	authorizationcountry	*Country code*	
R.18.17.13	Obtain country	Attribute	obtaincountry	*Country code*	
R.18.17.14	Lot number	Attribute	lotnumber	*Text(35)*	
R.18.17.15	Expiry date format	Attribute	expiringdateformat	*Number(3)*	
R.18.17.16	Expiry date	Attribute	expiringdate	*Month year date*	
R.18.17.17	Administration route	Attribute	administrationroute	*Administration route list*	
R.18.17.18	Dose per administration	Attribute	doseperadministration	*Dose numeric*	
R.18.17.19	Number of doses per dose interval	Attribute	numberdosesperinterval	*Dose numeric*	

[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.

Section for animal adverse reactions to VMPs					
R.18.17.20	Dose interval	Attribute	doseinterval	*Dose interval*	
R.18.17.21	Dose interval unit	Attribute	doseintervalunit	*Time unit*	
R.18.17.22	Dose unit	Attribute	doseunit	*Dosage unit*	
R.18.17.23	Dosage text	Attribute	dosagetext	*Text(100)*	
R.18.17.24	Action taken after reaction	Attribute	actiontakenafterreaction	*Action drug list*	
R.18.17.25	ATCvet code	Attribute	atcvetcode	*ATCvet code list*	
R.18.17.26	Who administered the VMP	Attribute	administrationvmp	*Categorization list*	Yes
R.18.17.27	Use according to label	Attribute	usingaccordinglabel	*Yes No*	
R.18.17.28	Off label use	Attribute	offlabeluse	*Off label use-list*	
R.18.17.29	Explanation	Attribute	explanation	*Text(500)*	
R.18.17.30	Assessment	Entity	assessment		(1,n)
R.18.17.30.01	Assessment source	Attribute	assessmentsource	*Assessment source list*	Yes
R.18.17.30.02	Assessment classification	Attribute	assessmentclassification	*Assessment list*	Yes
R.18.17.30.03	Assessment comment	Attribute	assessmentcomment	*Text (4000)*	
R.18.17.31	Animal suspect substance	Entity	animalsuspectsubstance		(0,n)
R.18.17.31.01	Role	Attribute	role	*Substance role*	
R.18.17.31.02b	Characterization	Attribute	characterization	*Characterization list*	
R.18.17.31.03	Substance name	Attribute	substancename	*Text(200)*	Yes
R.18.17.31.04	Strength	Attribute	strength	*Dose numeric*	
R.18.17.31.05	Strength Unit	Attribute	strengthunit	*Dosage unit*	
R.18.18	Animal treating drug	Entity	animaltreatingdrug		(0,n)
R.18.18.01	Start date format	Attribute	startdateformat	*Number(3)*	
R.18.18.02	Start date	Attribute	startdate	*Variable date*	
R.18.18.03	Duration	Attribute	duration	*Duration number*	

R.18.18.04	Duration unit	Attribute	durationunit	*Time units*	
R.18.18.05	End date format	Attribute	enddateformat	*Number(3)*	
R.18.18.06	End date	Attribute	enddate	*Variable date*	
R.18.18.07	Brand Name	Attribute	brandname	*Text(200)*	
R.18.18.08	Dosage form	Attribute	dosageform	*Dosage form list*	
R.18.18.09	Authorization number	Attribute	authorizationnumber	*Text(35)*	
R.18.18.10	Authorization Holder/Company	Attribute	authorizationcompany	*Text(60)*	
R.18.18.11	Authorization country	Attribute	authorizationcountry	*Country code*	
R.18.18.12	Administration route	Attribute	administrationroute	*Administration route list*	
R.18.18.13	Additional information	Attribute	additionalinformation	*Text(100)*	
R.18.18.14	Animal treating substance	Entity	animaltreatingsubstance		(0,n)
R.18.18.14.01	Substance name	Attribute	name	*Text(200)*	Yes
R.18.18.14.02	Strength	Attribute	strength	*Dose numeric*	
R.18.18.14.03	Strength Unit	Attribute	strengthunit	*Dosage unit*	
R.18.19	Animal medical history	Entity	animalmedicalhistory		(0,n)
R.18.19.01	Episode name code	Attribute	Episodecode	VEDDRA term code	Yes
R.18.19.02	Episode name	Attribute	episodename	VEDDRA term	
R.18.19.03	Primary source episode name	Attribute	primarysourceepisodename	*Text(250)*	
R.18.19.04	Comments	Attribute	comments	*Text(2000)*	

R.18.20	Animal laboratory test	Entity	animallaboratorytest		(0,n)
R.18.20.01	Test description	Attribute	description	*Text(500)*	
R.18.20.02	Test result range	Attribute	testresultrange	*Test result range list*	
R.18.20.03	Test definition	Entity	testdefinition		
R.18.20.03.01	High level test type	Attribute	testtype	*Laboratory/Biochemical test Test type list*	Yes

R.18.20.03.02	Test name	Attribute	testname	*Laboratory/Biochemical test name list*	
R.18.21	Animal death	Entity	animaldeath		(0,1)
R.18.21.01	Was the necropsy done?	Attribute	necropsydone	*Yes No*	
R.18.21.02	Date of death format	Attribute	deathdateformat	*Number(3)*	
R.18.21.03	Date of death	Attribute	deathdate	*Variable date*	
R.18.21.04	Primary source death cause	Attribute	primarysourcedeathcause	*Text (500)*	Yes
R.18.21.05	Death cause for the sender	Attribute	deathcause	*Necropsy result list – to be developed*	
R.18.21.06	Further Information	Attribute	furtherinfo	*Text(500)*	

Section for human adverse reactions to VMPs					
R.19	Treated animal species and breeds	Attribute	treatedspeciesandbreeds		(0,1)
R.19.01	Species code	Attribute	speciescode	Species code list	Yes [2] if no R.19.02
R.19.02	Species if not listed	Attribute	species	Text(160)	Yes [2] if no R.19.01
R.19.03	Treated animal breeds	Attribute	treatedbreeds		(0,n)
R.19.03.01	Breed code	Attribute	breedcode	Breed code list	Yes [2] if no R190302
R.19.03.02	Breed if not listed	Attribute	breed	Text(160)	Yes [2] if no

[2] Either the code or the attribute is required to be reported, reporting of both will not be accepted at validation (this is to allow proper transfer of data from e.g. a US database with additional different breeds that could not be mapped)

Section for human adverse reactions to VMPs					
					R190301
R.20	Other treated animal data	Attribute	othertreatedanimaldata		(0,1)
R.20.01	Exposed number	Attribute	exposednumber	Animal Number	Yes
R.20.02	Sex	Attribute	sex	Sex of animal	
R.20.03	Animal role	Attribute	animalrole	Animal role list	
R.20.04	Comments	Attribute	comments	Text(250)	
R.21	Human affected	Entity	humanaffected		(1,1)
R.21.01	Patient identification	Attribute	patientid	Text(30)	
R.21.02	Number exposed	Attribute	hexposednumber	Human number	
R.21.03	Number affected	Attribute	haffectednumber	Human number	
R.21.04	Time between exposure and onset of adverse reaction	Attribute	reactiononsettime	Time interval range	
R.21.05	Onset age	Attribute	onsetage	Human age number	
R.21.06	Onset age unit	Attribute	onsetunit	Time unit	
R.21.07	Age group	Attribute	agegroup	Age group list	
R.21.08	Sex	Attribute	humansex	Sex of Human	Yes
R.21.09	Categorization of person affected	Attribute	categorization	Categorization list	
R.21.10	Human adverse reaction	Entity	humanadversereaction		(1,n)
R.21.10.01	Reaction start date format	Attribute	overallstartdateformat	Number(3)	
R.21.10.02	Reaction start date	Attribute	overallstartdate	Variable date	
R.21.10.03	Duration	Attribute	duration	Duration number	
R.21.10.04	Duration unit	Attribute	duration unit	Time unit	
R.21.10.05	Reaction end date format	Attribute	overallenddateformat	Number(3)	
R.21.10.06	Reaction end date	Attribute	overallenddate	Variable date	

Section for human adverse reactions to VMPs					
R.21.10.07	Outcome	Attribute	outcome	Outcome list	
R.21.10.08	Case narrative	Entity	humancasenarrative		(1,1)
R.21.10.08.01	Narrative text including clinical	Attribute	narrativeincludeclinical	*Text(10000)*	Yes
R.21.10.09	Human signs	Entity	humansign		(1,n)
R.21.10.09.01	Reaction Human VEDDRA term code	Attribute	reactiontermcode	*Human VEDDRA term*	Yes
R.21.10.09.02	Reaction Human VEDDRAVEDDRA term	Attribute	reactionhterm	*Human VEDDRA term code*	
R.21.11	Human suspect drug	Entity	humansuspectdrug		(1,n)
R.21.11.01	Exposure start date	Attribute	exposurestartdateformat	*Number(3)*	
R.21.11.02	Exposure start date	Attribute	exposurestartdate	*Variable date*	
R.21.11.03	Exposure duration	Attribute	exposureduration	*Duration number*	
R.21.11.04	Exposure duration unit	Attribute	exposuredurationunit	*Time units*	
R.21.11.05	Exposure end date	Attribute	exposureenddateformat	*Number(3)*	
R.21.11.06	Exposure end date	Attribute	exposureenddate	*Variable date*	
R.21.11.07	Characterization	Attribute	characterization	*Characterization list*	
R.21.11.08	Brand Name	Attribute	brandname	*Text(200)*	
R.21.11.09	Dosage form	Attribute	dosageform	Dosage form list	
R.21.11.10	Authorization number	Attribute	authorizationnumber	*Text(35)*	
R.21.11.11	Authorization Holder/Company	Attribute	authorizationcompany	*Text(60)*	
R.21.11.12	Authorization	Attribute	authorizationcountry	*Country code*	

	country				
R.21.11.13	Obtain country	Attribute	obtaincountry	*Country code*	
R.21.11.14	Lot number	Attribute	lotnumber	*Text(35)*	
R.21.11.15	Expiry date format	Attribute	expiringdateformat	*Number(3)*	
R.21.11.16	Expiry date	Attribute	expirydate	*Month year date*	
R.21.11.17	Administration route	Attribute	administrationroute	*Administration route list*	
R.21.11.18	Reason for exposure	Attribute	exposurereason	*Exposure reason list*	
R.21.11.19	Dose per administration	Attribute	doseperadministration	*Dose numeric*	
R.21.11.20	Number of doses per dose interval	Attribute	numberdosesperinterval	*Dose numeric*	
R.21.11.21	Dose interval	Attribute	doseinterval	*Dose interval*	
R.21.11.22	Dose interval unit	Attribute	doseintervalunit	*Time unit*	
R.21.11.23	Dose Unit	Attribute	doseunit	*Dosage unit*	
R.21.11.24	Exposure details	Attribute	exposuredetails	*Text(500)*	
R.21.11.25	Action taken after reaction	Attribute	actiontakenafterreaction	*Action drug list*	
R.21.11.26	ATCvet code	Attribute	atcvetcode	*ATCvet code list*	
R.21.11.27	Who administered the VMP	Attribute	administrationvmp	Categorization list	

R.21.11.28	Assessment	Entity	Humanassessment		(1,n)
R.21.11.28.01	Assessment source	Attribute	assessmentsource	*Assessment source list*	Yes
R.21.11.28.02	Assessment classification	Attribute	assessmentclassification	*Assessment list*	Yes
R.21.11.28.03	Assessment comment	Attribute	assessmentcomment	*Text(4,000)*	
R.21.11.29	Human suspect substance	Entity	humansuspectsubstance		(0,n)
R.21.11.29.01	Role	Attribute	role	*Substance role*	
R.21.11.29.02	Characterization	Attribute	characterization	*Characterization*	

				list	
R.21.11.29.03	Substance name	Attribute	name	*Text(200)*	Yes
R.21.11.29.04	Strength	Attribute	strength	*Dose numeric*	
R.21.11.29.05	Strength Unit	Attribute	strengthunit	*Dosage unit*	
R.21.12	Human treating drug	Entity	humantreatingdrug		(0,n)
R.21.12.01	Start date format	Attribute	startdateformat	*Number(3)*	
R.21.12.02	Start date	Attribute	startdate	*Variable date*	
R.21.12.03	Duration	Attribute	duration	*Duration number*	
R.21.12.04	Duration unit	Attribute	durationunit	*Time units*	
R.21.12.05	End date format	Attribute	enddateformat	*Number(3)*	
R.21.12.06	End date	Attribute	enddate	*Variable date*	
R.21.12.07	Brand Name	Attribute	brandname	*Text(200)*	
R.21.12.08	Authorization number	Attribute	authorizationnumber	*Text(35)*	
R.21.12.09	Authorization Holder/Company	Attribute	authorizationcompany	*Text(60)*	
R.21.12.10	Authorization country	Attribute	authorizationcountry	*Country code*	
R.21.12.11	Dosage form	Attribute	dosageform	*Dosage form list*	
R.21.12.12	Administration route	Attribute	administrationroute	*Administration route list*	
R.21.12.13	Dosage text	Attribute	dosagetext	*Text(100)*	
R.21.12.14	Human treating substance	Entity	humantreatingsubstance		(0,n)
R.21.12.14.01	Substance name	Attribute	name	*Text(200)*	Yes
R.21.12.14.02	Strength	Attribute	strength	*Dose numeric*	
R.21.12.14.03	Strength Unit	Attribute	strengthunit	*Dosage unit*	
R.21.13	Human medical history	Entity	humanmedicalhistory		(0,n)
R.21.13.01	Episode code	Attribute	Episodecode	*Human VEDDRA term code*	
R.21.13.02	Episode name	Attribute	Episodename	*Human VEDDRA terminology (160)*	

R.21.13.03	Primary source episode name	Attribute	primarysourceepisodename	*Text(250)*	Yes
R.21.13.04	Comments	Attribute	comments	*Text(250)*	

R.21.14	Human laboratory test	Entity	humanlaboratorytest		(0,n)
R.21.14.01	High level Test name	Attribute	Testnamecode	*Laboratory/Biochemical Test type list*	
R.21.14.02	Low level Test name	Attribute	Testname	*Laboratory/Biochemical test name list*	
R.21.14.03	Test description	Attribute	description	*Text(500)*	Yes
R.21.14.04	Test result range	Attribute	testresultrange	*Test result range list*	
R.21.15	Human death	Entity	humandeath		(0,1)
R.21.15.01	Was the autopsy done?	Attribute	authopsydone	*Yes No*	
R.21.15.02	Date of death format	Attribute	humandeathdateformat	*Number(3)*	
R.21.15.03	Date of death	Attribute	humandeathdate	*Variable date*	
R.21.15.04	Death cause for primary source	Attribute	primarysourcedeathcause	*Text(250)*	Yes
R.21.15.05	Death cause for the sender code	Attribute	deathcausecode	*Human VEDDRA code*	
R.21.15.06	Death cause for the sender	Attribute	deathcause	*Human VEDDRA term*	
R.21.15.07	Further information	Attribute	furtherinfo	*Text(500)*	

Sections below relate to both animal and human adverse reactions to VMPs					
R.22	Dechallenge-rechallenge information	Entity	rechallengeinformation		(0,1)
R.22.01	Previous exposures?	Attribute	previousexposure	*Yes No*	Yes
R.22.02	Previous adverse reactions?	Attribute	previousar	*Yes No*	

Sections below relate to both animal and human adverse reactions to VMPs					
R.22.03	Did reaction abate after stopping?	Attribute	abateafterstopping	*Yes No*	
R.22.04	Did reaction reappear after reintroduction?	Attribute	reappearafterreintroduction	*Yes No*	
R.23	**Sender**	Entity	sender		(1,1)
R.23.01	First name	Attribute	firstname	*Text(50)*	Information must be entered in at least one of the fields in this section
R.23.02	Middle name	Attribute	middlename	*Text(50)*	
R.23.03	Last name	Attribute	lastname	*Text(50)*	
R.23.04	Street address	Attribute	streetaddress	*Text(100)*	
R.23.05	City	Attribute	city	*Text(50)*	
R.23.06	State/County	Attribute	state	*Text(40)*	
R.23.07	Postcode	Attribute	postcode	*Text(35)*	
R.23.08	Country code	Attribute	country	*Country code*	
R.23.09	Telephone	Attribute	telephone	*Text(50)*	
R.23.10	Fax	Attribute	fax	*Text(50)*	
R.23.11	Email	Attribute	email	*Text(100)*	
R.23.12	Organization	Attribute	organization	*Text(60)*	
R.23.13	Department	Attribute	department	*Text(60)*	
R.23.14	Categorization	Attribute	Categorization	*Categorization list*	

R.24	**Literature Reference**	**Entity**	**literaturereference**		**(0,n)**
R.24.01	reference	Attribute	reference	*Text(200)*	
R.25	Clinical trial	Entity	clinicaltrial		(0,n)
R.25.01	Study name	Attribute	studyname	*Text(100)*	Yes
R.25.02	Sponsor study number	Attribute	sponsorstudynumber	*Text(35)*	Yes
R.25.03	Study type in which the reactions were observed	Attribute	observestudytype	*Study type list*	Yes
R.26	Linked report	Entity	linkedreport		(0,n)

R.24	Literature Reference	Entity	literaturereference		(0,n)
R.26.01	Case number	Attribute	casenumber	*Text(60)*	Yes
R.26.02	Link type	Attribute	linktype	*Link reference list*	
R.27	Primary source	Entity	primarysource		(1,1)
R.27.01	First name	Attribute	firstname	*Text(50)*	
R.27.02	Middle name	Attribute	middlename	*Text(50)*	
R.27.03	Last name	Attribute	lastname	*Text(50)*	Yes
R.27.04	Street address	Attribute	streetaddress	*Text(100)*	
R.27.05	City	Attribute	city	*text(50)*	
R.27.06	State/County	Attribute	state	*Text(40)*	
R.27.07	Postcode	Attribute	postcode	*Text(35)*	
R.27.08	Country code	Attribute	Country	*Country code*	
R.27.09	Telephone	Attribute	telephone	*Text(20)*	
R.27.10	Fax	Attribute	fax	*Text(50)*	
R.27.11	Email	Attribute	email	*Text(100)*	
R.27.12	Organization	Attribute	organization	*Text(60)*	
R.27.13	Department	Attribute	department	*Text(60)*	
R.27.14	Categorization	Attribute	Categorization	*Categorization list*	Yes
R.28	Other people	Entity	otherpeople		(0,n)
R. 28.01	First name	Attribute	firstname	*Text(50)*	
R. 28.02	Middle name	Attribute	middlename	*Text(50)*	
R.28.03	Last name	Attribute	lastname	*Text(50)*	Yes
R.28.04	Street address	Attribute	streetaddress	*Text(100)*	
R.28.05	City	Attribute	city	*text(50)*	
R.28.06	State/County	Attribute	state	*Text(40)*	
R.28.07	Postcode	Attribute	postcode	*Text(35)*	
R.28.08	Country code	Attribute	countrycode	*Country code*	
R.28.09	Telephone	Attribute	telephone	*Text(20)*	
R.28.10	Fax	Attribute	fax	*Text(50)*	
R.28.11	Email	Attribute	email	*Text(100)*	

R.24	Literature Reference	Entity	literaturereference		(0,n)
R.28.12	Organization	Attribute	organization	*Text(60)*	
R.28.13	Department	Attribute	department	*Text(60)*	
R.28.14	Categorization	Attribute	categorization	*Categorization list*	
R. 29	Suspect duplicate reports	Entity	duplicatereports		(0,n)
R.29.01	Duplicate source	Attribute	duplicatesource	*Text(60)*	Yes
R.29.02	Duplicate number	Attribute	duplicatenumber	*Text(60)*	Yes

5. Definition of field types (controlled vocabulary)

Type	Schema Type	Values
Action drug list	actiondrugType	1 Drug withdrawn 2 Drug reduced 3 Drug increased 4 Dose not changed 5 Unknown 6 Not applicable
Administration route list	adminrouteType	Route of administration (EMEA/127428/2007)
Age group list	humanagegroup	1 Neonate 2 Infant 3 Child 4 Adolescent 5 Adult 6 Elderly
All date formats	receivedateformat receiptdateformat reactionstartdateformat reactionenddateformat treatmentstartdateformat treatmentenddateformat overallstartdateformat overallenddateformat exposurestartdateformat	204 CCYYMMDDHHMMSS 203 CCYYMMDDHHMM 102 CCYYMMDD 610 CCYYMM 602 CCYY

Type	Schema Type	Values
	exposureenddateformat expiringdateformat startdateformat enddateformat deathdateformat humandeathdateformat	
Animal age number	animageType	Float numeric field XXX.X
Animal Number	animnumberType	Integer numeric field 10 figures at most
Animal role	animalrole	1 Production 2 Companion 3 Exotic
Animal weight number	animalweightType	Float numeric field XXXX.XXX
Assessment list	assessmentType	1 - A: probable 2 - B: possible 3 - O: unclassifiable / unassessable 4 - N: unlikely 5 - No assessment performed 6 - O1: inconclusive 7 - O2: unclassified
Assessment source		*1 Competent Authority* 2 MAH 3 Primary source
Breed code	xs:string	See list of species and breeds – EMEA/CVMP/553/03-FINAL
Breed list	xs:string	See list of species and breeds – EMEA/CVMP/553/03-FINAL
Case type	caseType	1 CA 2 MAH
Categorization list	peoplecategorization Type	1 Veterinarian 2 Pharmacist 3 Other health professional 4 Animal owner Animal tender Other

Type	Schema Type	Values
		Unknown
Characterization list	characterizationType	1 Suspect 2 Concomitant 3 Interacting
Country code	countrycodeType	ISO3166 2 characters country codes (EMEA/127430/2007)
Dosage form list	dosageformType	Dosage form list (EMEA/127431/2007)
Dosage unit	DosageunitType	Dosage unit list (EMEA/127432/2007)
Dose interval	doseintervalType	Integer numeric field XXXX
Dose numeric	Dosenumeric type	Float numeric field XXXX.X
Duration number	durationnumericType	Float numeric field XXX.X
Exposure reason list	Exposurereason Type	*1 Accidental (unintended) exposureIngestion* *2 Accidental (unintended) exposureTopical exposure* *3 Accidental (unintended) exposureInjection* *4 Accidental (unintended) exposureAirborne exposure/Inhalation* *5 Accidental (unintended) exposureImmersion* *6 Accidental (unintended) exposureContact with the treated animal* *7 Accidental (unintended) exposureOcular exposure* *8 Accidental (unintended) exposureOther accidental exposure* *9 Suicidal intent Ingestion* *10 Suicidal intent Injection* *11 Suicidal intent Inhalation* *12 Suicidal intent Other suicidal intent* *13 Other N/a*

Type	Schema Type	Values
		14 Unknown N/a
Female physiological status list	physiologicalstatusType	1 Pregnant-Lactating 2 Non-pregnant – Lactating 3 Pregnant – Non-lactating 4 Non-pregnant – Non-lactating 5 Mixed 6 Not applicable 7 Unknown
Human age number	humageType	Float numeric field XXX.X
Human number	humannumberType	Integer numeric field 10 figures at most
Human VEDDRA number	Vetdecimal_low_type_nil	Float numberic field XXX.X excluding the value zero, as use of Human VEDDRA is not mandatory
Human VEDDRA term	hterminologytermType	Reference to a Human VEDDRA LLT term Human VEDDRA
Human VEDDRA term code	hterminologytermTypeCode	Reference to a Human VEDDRA LLT term code Human VEDDRA
Human weight	humweightType	Float numeric field XXX.XX
Information type list	Informationtype	1 Safety issue 2 Lack of expected efficacy 3 Withdrawal period issue 4 Environmental issue 5 Infectious agent transmission issue
Laboratory/biochemical test names list	labtestnamelist	Laboratory/biochemical test names list
Laboratory/biochemical test type list	labtesttypelist	2 Haematology 3 Other Microscopy 4 Urinalysis 5 Faecal analysis 6 Tissue analysis

Type	Schema Type	Values
		7 Other body fluid analysis 8 Imaging 9 Other
Link reference list	linkreferenceType	1 Parent - Offspring 2 Same patient 3 Similar reports from same reporter (cluster) 4 Other 5 Unknown
Measure type	measureType	1 Exact 2 Approximate 3 Unknown
Necropsy result list		To be defined
Numerical value	Numericalvalue Type	Float numeric field XXXXXXX.XXX
Off-label use list		1 Unauthorised species/species sub group 2 Unauthorised indication 3 Unauthorised dosage – dose too high 4 Unauthorised dosage – dose too low 5 Unauthorised dosage – administration too frequent 6 Unauthorised dosage – administration not frequent enough 7 Unauthorised dosage – other 8 Unauthorised route of administration 9 Unauthorised storage conditions 10 Expired products 11 Other
Outcome list	outcomeType	1 recovered/resolved 2 recovering/resolving

Type	Schema Type	Values
		3 not recovered/not resolved 4 recovered/resolved with sequelae 5 fatal 6 unknown
Production types list	productionType	Text(50) Look up list to be defined but to include: For Mammals: Meat Milk Wool Other For Aves/Birds Layer Broiler Rearer Breeder
Report type	reportType	1 Spontaneous and expedited 2 Report from study 3 Other Not available to the sender PSUR
Sex of animal	sexofanimalType	1 Male 2 Female 3 Male-Neutered 4 Female-Neutered 5 Mixed 6 Unknown
Sex of Human	sexofhumanType	1 Male Female Unknown
Species code	xs:string	See list of species and breeds –

Type	Schema Type	Values
		EMEA/CVMP/553/03-FINAL
Species list	xs:string	See list of species and breeds – EMEA/CVMP/553/03-FINAL
Study type	studyType	1 Clinical trial 2 Field trial 3 Post-marketing surveillance study 4 Other studies
Substance role	substanceroleType	1 Active Substance 2 Excipient 3 Adjuvant
Test result	*Numerical value*	Decimal (12,4)
Test result range list		1 Within normal range 2 Higher than normal range 3 Lower than normal range 4 Other abnormal findings 5 Positive (test parameter present) 6 Negative (test parameter absent) 7 Other result
Text	xs:string	Any character
Time interval range	timeintervalrangeType	≤ 2 minutes 10 ≤ 30 minutes ≤ 1 hour 11 ≤ 6 hours 3 ≤ 12 hours 4 ≤ 24 hours 5 ≤ 48 hours 6 ≤ 7 days 7 ≤ 14 days 8 ≤ 30 days

Type	Schema Type	Values
		9 > 30 days
Time units	timeunitType	800 Decade 801 Year 802 Month 803 Week 804 Day 805 Hour 806 Minute 807 Second 810 Trimester
Variable date	variabledataType	A date supporting different possibility to express a date: YYYY YYYY-MM YYYY-MM-GG
VEDDRA number	Vetdecimal_low_type_	Float numberic field XXX.X excluding the value zero, as use of VEDDRA is mandatory
VEDDRA term	veddratermType	Reference to a VEDDRA LLT term
VEDDRA term code	veddratermTypeCode	Reference to a VEDDRA LLT term code
Yes No	yesnoType	1 Yes 2 No

6. Elements and attributes with description and user guidance

Reference code	Title	Description / User Guidance
A	Veterinary message	
H	Veterinary message header	The fields in this section are mandatory
H.01	Type	Type of Information being transmitted The information in this field distinguishes between the different types of reports that are transmitted via the

Reference code	Title	Description / User Guidance
		same gateway and the value would indicate that the report is a veterinary adverse reaction report.
H.02	Version	Version Number of Message Format (a new version number indicates major changes to the format); *automatically completed by the EudraVigilance system*
H.03	Release	Release number of the Message Format (a new release number indicates minor changes to the format; *automatically completed by the EudraVigilance system*
H.04	Message number	Message Number, i.e. identifier of the particular transaction; *EudraVigilance system could be configured for automatic completion*
H.05	Sender identifier	Message Sender Identifier; identifies the sender, (e.g. company name or competent authority name; attributed during registration for electronic reporting in the EU through EudraVigilance Veterinary). Completion of the field from a look-up list.
H.06	Receiver identifier	Message Receiver Identifier; identifies the receiver, (e.g., company name or competent authority name; attributed during registration for electronic reporting in the EU through EudraVigilance Veterinary). Completion of the field from a look-up list.
H.07	Message send date format	Indication of the format
H.08	Message send date	Date of transmission, format: YYCCMMDDHHMISS; *automatically completed by the EudraVigilance system (date of transmission as provided by the gateway)*
R	Safety report	
R.01	Sender Report identification Number	Safety Report Identifier; *number attributed to the report by the sender.* This identifier is assigned by the sender of an adverse reaction report and should remain constant (i.e. unchanged) in subsequent transmissions of the case by the same sender. Re-transmitters should replace this value with their own unique identifier. The value should be a concatenation of 'country code-company or competent authority name-report number'. 1. Country code is the country of the primary source of the report ('primarysourcecountry' XML field). It can be expressed as either 2-letter ISO 3166 or 3-letter ISO

Reference code	Title	Description / User Guidance
		3166 country code. 2. The company or competent authority name is an internationally unique abbreviation or code for the sender's organisation (attributed during registration for electronic reporting in the EU through EudraVigilance Veterinary). 3. The report number is the organisation's international case number. 4. Each component is separated from the other by a hyphen. Example: A report transmitted by a company to a competent authority concerning a case from France would populate this field with 'FR-companyname-12345' where 12345 is a company's unique case report number.
R.02	Type of report submission	Type of report, eg spontaneous, or report from study; choose from the controlled terminology - *Report type*
R.03	Type of information in report	Indicate what sort of information is being transmitted in the report, eg safety issue, lack of expected efficacy; *choose from the controlled terminology - Information type*
R.04	Case registration type	Indicate whether case was first registered by a competent authority or by the MAH; *choose from the controlled terminology - Case type*
R.05	Unique case registration number	The value should be a concatenation of "country code-company or competent authority name-report number". 1. Country code is the country of the primary source of the report ('primarysourcecountry' XML field). It can be expressed as either 2-letter ISO 3166 or 3-letter ISO 3166 country code. 2. The company or competent authority name is an internationally unique abbreviation or code for the sender's organisation (attributed during registration for electronic reporting in the EU through EudraVigilance Veterinary). 3. The report number is the organisation's international case number. 4. Each component is separated from the other by a hyphen. The contents of whichever item used should remain

Reference code	Title	Description / User Guidance
		unchanged for any transmissions subsequent to the original transmission. When a sender has not previously received a valid adverse reaction report electronically, the identifiers (content and format) in the 'reportid' XML field and in this field should be identical. Retransmitters should use their own sender's (case) safety report unique identifier ('reportid' XML field), but not change this XML field.
R.06	Original receive date format	Specify format of the 'originalreceivedate' XML field
R.07	Date originally received by reporter	Enter the date on which the report was first received from source
R.08	Date of most recent information format	Specify format of the 'mostrecentinfodate' XML field
R.09	Date of most recent information	Enter the date of receipt of the most recent information for this report; to be updated for follow-up information [important for classification algorithm in the format specified in the preceding field
R.10	Primary source country	Identification of the country of the primary reporter; pick 2 character code from a ISO 3166 conform list
R.11	Occur country	Identification of the country where the reaction occurred, if different from the 'primarysourcecountry' XML field; pick 2 character code from a ISO 3166 conform list
R.12	Human VEDDRA version	In manual user interface - Automatically filled
R.13	VEDDRA version	In manual user interface - Automatically filled
R.14	Nullification report	Choose NO / YES value from list.
R.15	Nullification reason	Indicate the reason for nullification of the report
R.16	Suspect duplicate	Choose NO / YES value from list. Further details can be entered in the section on duplicate reports

Section for animal adverse reactions to VMPs		
R.17	Animal species and breeds	Enter information on species of the treated animals
R.17.01	Species code	Choose appropriate code corresponding to the species name from the controlled terminology of the List of species

Section for animal adverse reactions to VMPs		
R.17.02	Species if not listed	Enter species if not found in the controlled list of species
R.17.03	Animal breeds	Enter information on breed, if applicable, of the treated animals
R.17.03.01	Breed code	Choose appropriate code corresponding to the breed name from the controlled terminology of the relevant Breed list
R.17.03.02	Breed if not listed	Enter breed is not found in the controlled list of breeds
R.18	Other animal data	Enter the remaining relevant data for treated and affected animals
R.18.01	Exposed number	Enter (estimated) number of animals exposed/treated
R.18.02	Affected number	Enter (estimated) number of animals affected in the adverse reaction report
R.18.03	Sex	Choose appropriate term from sex list: Female, Male, female-neutered, Male-neutered, mixed, Unknown
R.18.04	Animal role	Choose appropriate choice from the animal role list: production, companion or exotic
R.18.05	Production type	Choose appropriate term from the production type list
R.18.06	Female physiological status	Choose appropriate term from physiological status list: Pregnant-lacting, nonpregnant-lacting, pregnant-nonlacting, nonpregnant-nonlactating, mixed, not applicable, unknown
R.18.07	Weight type	Choose appropriate term from measure type list: Indicate whether exact, estimated or unknown weight
R.18.08	Minimum weight	Enter the numerical value of the minimum weight in kilograms, if more than one animal is treated
R.18.09	Weight	Enter the numerical value of the weight in kilograms of the animal treated. Average weight, if more than one animals is treated
R.18.10	Maximum weight	Enter the numerical value of the maximum weight in kilograms, if more than one animal is treated
R.18.11	Age type	Indicate whether exact, estimated or unknown age
R.18.12	Minimum age	Enter the numerical value of the minimum age, if more than one animal is treated
R.18.13	Age	Enter the numerical value of the age of the animal treated. Average age, if more than one animal is treated
R.18.14	Maximum age	Enter the numerical value of the maximum age, if more

Section for animal adverse reactions to VMPs		
		than one animal is treated
R.18.15	Age unit	Choose appropriate term from time units list including minutes, hours, days, weeks, months, years
R.18.16	Animal adverse reaction	
R.18.16.01	Reaction start date format	Specify format of the 'reactionstartdate' XML field
R.18.16.02	Reaction start date	Enter the (approximate) date of onset of the adverse reaction in the format specified in the preceding field. Where more than 1 animal reacted, enter the overall start date, i.e. date of first reaction in first animal.
R.18.16.03	Time to onset of reaction	Choose appropriate term from the *time interval list* for the length of time between last exposure to primarily suspect VMP and onset of adverse reaction. Primarily suspect VMPs are those for which the submitting MAH is responsible. If the submitting MAH is responsible for more than one of the products administered concomitantly, the most appropriate product should be chosen.
R.18.16.04	Duration	Enter the numerical value of the (approximate) length of time the adverse reaction lasted. Where more than 1 animal reacted, enter the overall duration from the first reaction in the first animal to the last reaction in the last animal.
R.18.16.05	Duration unit	Choose appropriate unit from the *time units list*
R.18.16.06	Reaction end date format	Specify format of the 'reactionenddate' XML field
R.18.16.07	Reaction end date	Enter the (approximate) end date of the adverse reaction; in the format specified in the preceding field. Where more than 1 animal reacted, enter the overall end date, i.e. date of last reaction in last animal.
R.18.16.08	Reaction serious	Yes/No field
R.18.16.09	Results in death?	Adverse reaction results in death
R.18.16.10	Life threatening	Adverse reaction is Life threatening
R.18.16.11	Disabling/Incapacitating?	Adverse reaction is Disabling/Incapacitating
R.18.16.12	Congenital anomaly?	Adverse reaction leads to Congenital anomaly/birth defect
R.18.16.13	Other medically important condition?	Adverse reaction leads to Other medically important condition

R.18.16.14	Outcome ongoing	Outcome to date: Ongoing, number of animals to be entered *[several of the Outcome fields may apply if larger numbers of animals are treated]*
R.18.16.15	Outcome recovered	Outcome to date: Recovered, number of animals to be entered
R.18.16.16	Outcome alive with sequelae	Outcome to date: Alive with sequelae, number of animals to be entered
R.18.16.17	Outcome died	Outcome to date: Died, number of animals to be entered
R.18.16.18	Outcome killed	Outcome to date: Killed/euthanised, number of animals to be entered
R.18.16.19	Outcome unknown	Outcome to date: Unknown (cases where the outcome of the adverse reaction is unknown), number of animals to be entered
R.18.16.20	Case narrative	
R.18.16.20.01	Narrative text including clinical	Full free text description of the adverse reaction and its evaluation including the reason for treatment.
R.18.16.21	Animal signs	
R.18.16.21.01	Reaction veddra term code (adverse clinical manifestation)	adverse clinical manifestation observed in the adverse reaction - corresponding LLT code to the appropriate terms from the *VEDDRA list of clinical terms database*
R.18.16.21.02	Reaction veddra term (adverse clinical manifestation)	adverse clinical manifestation observed in the adverse reaction –choose appropriate LLT terms from the *VEDDRA list of clinical terms database*

R.18.17	Animal suspect drug	*To be repeated for all drugs given immediately before onset of the adverse reaction.* *Until an appropriate medicinal products database is agreed, complete all fields in this section manually in strict accordance with the approved SPC.* *Once a medicinal products database is available, many fields in this section can be filled automatically upon selection of the appropriate product.*
R.18.17.01	Treatment start date format	Specify the format of the 'treatmentstartdate' XML field.
R.18.17.02	Treatment start date	Enter Date of first treatment of the animal(s) with the product in the format specified above.
R.18.17.03	Treatment duration	Enter numerical value for the duration of treatment
R.18.17.04	Treatment duration unit	Choose appropriate unit from the *time units list* for the

		unit in which duration of treatment is reported
R.18.17.05	Treatment end date format	Specify the format of the 'treatmentenddate' XML field
R.18.17.06	Treatment end date	Enter Date of last treatment of the animal(s) with the product in the format specified above.
R.18.17.07	Characterization	The product has to be qualified as suspect, concomitant or interacting; choose appropriate item from the *characterization list*. The characterization as judged by the sender should be entered. If it does not correspond to the judgment by the primary source, the discrepancy should be explained in the comments field of the assessment section.
R.18.17.08	Brand name	Brand name of the veterinary medicinal product (VMP) involved in the adverse reaction - enter the name
R.18.17.09	Dosage form	Dosage form of the VMP involved in the adverse reaction - Choose appropriate term from the *dosage form list*
R.18.17.10	Authorization number	Registration number of the VMP involved in the adverse reaction - text field, enter the value
R.18.17.11	Authorization Holder/Company	Company involved with the VMP involved in the adverse reaction - text field, enter the name of the Marketing Authorisation Holder (MAH)/distributor
R.18.17.12	Authorization country	Identification of the country where the VMP involved in the adverse reaction is authorised; pick country from a ISO 3166 conform list
R.18.17.13	Obtain country	Identification of the country where the VMP involved in the adverse reaction was obtained, if different from the 'authorizationcountry' XML element; pick country from a ISO 3166 conform list
R.18.17.14	Lot number	Enter the lot number of the VMP involved in the adverse reaction.
R.18.17.15	Expiry date format	Specify the format of the 'Expiry date' XML field.
R.18.17.16	Expiry date	Enter the expiry date of the lot using the format CCYY/MM
R.18.17.17	Administration route	Route of exposure/administration of the VMP involved in the adverse reaction - choose appropriate term from the *administration route list*
R.18.17.18	Dose per administration	Structured dosage information: Dose per administration, real dose administered, not by default the dosage as registered - enter numerical value of the dose; the units are specified in 'doseunit' XML field.
R.18.17.19	Number of doses per dose	Structured dosage information: Enter the number of

	interval	doses given per dose interval specified below (e.g. per day)
R.18.17.20	Dose interval	Structured dosage information: Interval of administration or frequency of administration of the VMP involved in the adverse reaction - enter numerical value of the dose interval, e.g. 1 for daily administration, 2 for administration every other day.
R.18.17.21	Dose interval unit	Structured dosage information: choose appropriate term from the *time units list, e.g. day.*
R.18.17.22	Dose unit	Structured dosage information: choose the appropriate term for all above doses from the *measure unit list*
R.18.17.23	Dosage text	If provision of structured dose information is not possible, explain the dosage regimen here - how many doses, how often, and for how long.
R.18.17.24	Action taken after reaction	Indicate whether treatment was continued, dose reduced or drug withdrawn after adverse reaction
R.18.17.25	ATCvet code	Choose appropriate term from the *ATCvet code list;* leave blank if no code has been attributed to the VMP.
R.18.17.26	Who administered the VMP	Indicate who actually administered the treatment (eg vet, owner); choose appropriate term from *Categorization list.*
R.18.17.27	Use according to label	Use according to label, Information on whether the VMP was used according to its label recommendations. [Yes/no]
R.18.17.28	Off label use	Structured information: enter reason for off label use; choose appropriate term from the *Off-label use list.*
R.18.17.29	Explanation	Free text information; explain reason for off-label use, why the VMP was not used according to its label. To be filled only if 'no' was selected in the 'useaccordinglabel' XML field and if structured information for the 'offlabeluse' XML field is not available.
R.18.17.30	Assessment	*This section is mandatory. It is repeatable to allow the indication of all available causality assessments.*
R.18.17.30.01	Assessment Source	1=Competent authority; 2=MAH; 3= Primary source.
R.18.17.30.02	Assessment classification	Structured assessment using the ABON code.
R.18.17.30.03	Assessment comment	Free text comments on assessment of association between VMP and adverse reaction. Examples:

		Primary source: include the reporter's comments on the diagnosis, causality assessment or other issues considered relevant. Sender: provide information concerning the sender's assessment of the case; describe disagreement with, and/or alternatives to the primary source diagnoses.
R.18.17.31	Animal suspect substance	
R.18.17.31.01	Role	Indicate whether active substance, excipient, or adjuvant; choose appropriate term from the *Substance role list.*
R.18.17.31.02	Characterization	Indicate whether suspect substance, concomitant or interacting; choose appropriate term from the *Characterization list.*
R.18.17.31.03	Substance name	Enter the substance name, using preferably INN, if not available the European Pharmacopoeia name and if that is not available an appropriate other name e.g. nationally approved names, national pharmacopoeia.
R.18.17.31.04	Strength	Strength, concentration of the active ingredient of the VMP involved in the adverse reaction - enter the numerical value.
R.18.17.31.05	Strength unit	Enter the units in which the strength is expressed; choose appropriate term from the *measure units list.*

R.18.18	Animal treating drug	*To be completed if the adverse reaction required treatment with (veterinary) medicinal products.* *Until an appropriate medicinal products database is agreed, complete all fields in this section ('animaltreatingdrug XML element) manually in strict accordance with the approved SPC.* *Once a medicinal products database is available, many fields in this section can be filled automatically upon selection of the appropriate product.* *Further comments can be made in the 'Narrative' field under 'Assessment'.*
R.18.18.01	Start date format	Specify the format of the 'Start date' XML field
R.18.18.02	Start date	Enter the Date of first treatment with the product in the format specified above.
R.18.18.03	Duration	Enter numerical value for the duration of treatment.
R.18.18.04	Duration unit	Units for the above duration of treatment: choose appropriate term from the *time units list.*
R.18.18.05	End date format	Specify the format of the 'End date' XML field
R.18.18.06	End date	Enter the Date of last treatment with the VMP in the

		format specified above.
R.18.18.07	Brand name	Brand name of the VMP used to treat the adverse reaction - enter the name.
R.18.18.08	Dosage form	Dosage form of the VMP used to treat the adverse reaction - Choose appropriate term from the *dosage form list.*
R.18.18.09	Authorization number	Registration number of the VMP used to treat the adverse reaction - text field, enter the value.
R.18.18.10	Authorization Holder/Company	Company involved with the VMP used to treat the adverse reaction - text field, enter the name of the MAH/distributor.
R.18.18.11	Authorization country	Identification of the country where the VMP used to treat the adverse reaction is authorised; pick country from a ISO 3166 conform list.
R.18.18.12	Administration route	Route of administration of the VMP used to treat the adverse reaction - choose appropriate term from the *route of administration list.*
R.18.18.13	Additional information	Enter any additional relevant information regarding VMP used to treat the adverse reaction.
R.18.18.14	Animal treating substance	
R.18.18.14.01	Substance name	Name, preferably INN of active substance, if INN not available the European Pharmacopoeia name and if that is not available an appropriate other name e.g. nationally approved names, national pharmacopoeia.
R.18.18.14.02	Strength	Strength, concentration of active ingredient(s) of the VMP used to treat the adverse reaction - enter the numerical value(s).
R.18.18.14.03	Strength unit	Enter the units in which the strength is expressed; choose appropriate term from the *measure units list.*

R.18.19	Animal medical history	Veterinary judgment should be exercised in completing this section. Information pertinent to understanding the case is desired such as diseases, conditions such as pregnancy, surgical procedures, etc. Each of the items in the table can be repeated as appropriate. If precise dates are not known and a text description aids in understanding the medical history, or if concise additional information is helpful in showing the relevance of the past medical history, this information can be included in the 'Comments'. *Further comments can be made in the 'Narrative' field in the section 'Assessment'.*
R.18.19.01	Episode name code	Choose code that corresponds to the appropriate term from the *indications list* or from *VEDDRA*, as appropriate.
R.18.19.02	Episode name	Choose appropriate term from the *indications list* or from

		VEDDRA, as appropriate.
R.18.19.03	Primary source episode name	Enter the description of the previous episode as reported by the primary source
R.18.19.04	Comments	Any additional useful information; e.g. relevant past drug history other than de-/rechallenge
R.18.20	Animal laboratory test	*Describe tests and results performed to diagnose, confirm or investigate the adverse reaction, including tests done to investigate (exclude) a non-drug cause, (e.g., serologic tests for infectious hepatitis in suspected drug-induced hepatitis). Both positive and negative results should be reported. While structured information is preferable, provisions have been made to transmit the information as free text.*
R.18.20.01	Test description	Use to enter additional relevant information, eg indicate the date of the test, or to describe tests and tests results, which are not covered in the *Laboratory/Biochemical test list.*
R.18.20.02	Test result range	Enter the appropriate value from the controlled terminology (*test result range list*). The sender's assessment should be entered.
R.18.20.03	Test definition	*Choose first the appropriate test type from the Laboratory/Biochemical test type list and then the specific test from the test name list*
R.18.20.03.01	High level test type	Define the type of laboratory/biochemical test
R.18.20.03.02	Test name	Specify the test linked to the high level test type
R.18.21	Animal death	
R.18.21.01	Was the necropsy done?	Indicate yes or no. Leaving the field empty signifies 'unknown'.
R.18.21.02	Date of death format	Specify the format of the 'Date of death' XML field
R.18.21.03	Date of death	Enter the date of death; variable, in the format specified above.
R.18.21.04	Primary source death cause	Free text description of cause of death as reported by the primary source.
R.18.21.05	Death cause for the sender	Structured information on cause of death as judged by the sender; choose appropriate term from the *necropsy result list.*
R.18.21.06	Further Information	Any further relevant information in free text.

Section for human adverse reactions to VMPs		
R.19	Treated animal species and breeds	Information on treated animals relevant in relation to a human adverse reaction to a Veterinary medicinal product (VMP) is required in this and the following two sections.
R.19.01	Species code	Choose code corresponding to the appropriate name from the controlled terminology of the List of species.
R.19.02	Species if not listed	Enter species if not found in the controlled list of species
R.19.03	Treated animal breeds	
R.19.03.01	Breed code	Choose code corresponding to the appropriate name from the controlled terminology of the Breed list. This is a repeatable field, so more than one breed may be selected if appropriate. In order to indicate the breeds involved in crossbred animals, first select 'crossbred' from the breed list, then select the relevant breeds involved.
R.19.03.02	Breed if not listed	Enter species if not found in the controlled breed list. This is a repeatable field, so more than one breed may be selected if appropriate. In order to indicate the breeds involved in crossbred animals, first select 'crossbred' from the breed list, then select the relevant breeds involved.
R.20	Other treated animal data	
R.20.01	Exposed number	Enter (estimated) number of animals exposed (treated).
R.20.02	Sex	Choose appropriate term from sex list: Female, Male, female-neutered, Male-neutered, mixed, Unknown.
R.20.03	Animal role	Choose appropriate term from the animal role list: production, companion or exotic.
R.20.04	Comments	Enter any additional information relating to the animals and/or their treatment that is relevant to the assessment of the human adverse reaction.
R.21	Human affected	In this section information on the human being affected by the VMP should be entered.
R.21.01	Patient identification	Enter patient identification as appropriate to national law.
R.21.02	Number exposed	Enter the number of humans exposed to the VMP.
R.21.03	Number affected	Enter the number of humans reacting to the VMP.

Section for human adverse reactions to VMPs		
R.21.04	Time between exposure and onset of adverse reaction	Length of time between exposure to primarily suspect VMP(s) and onset of adverse reaction.
R.21.05	Onset age	Enter the numerical value of the age of the patient(s); if the exact age is not known, leave empty and complete the XML field 'agegroup'.
R.21.06	Onset age unit	Choose appropriate term from time units list.
R.21.07	Age group	If no exact information on the age is available, choose the appropriate age group from the Age group list.
R.21.08	Sex	Choose appropriate term from the Sex of Human list.
R.21.09	Categorization of person affected	Indicate the profession/person category of the person affected, choose from the Categorization list.
R.21.10	Human adverse reaction	
R.21.10.01	Reaction start date format	Specify the format of the 'Reaction start date' XML field
R.21.10.02	Reaction start date	Enter the (approximate) date of onset of the human adverse reaction in the format specified above.
R.21.10.03	Duration	Enter the numerical value of the duration of the human adverse reaction.
R.21.10.04	Duration unit	Choose the appropriate unit from the time unit list.
R.21.10.05	Reaction end date format	Specify the format of the 'Reaction end date' XML field
R.21.10.06	Reaction end date	Enter (approximate) end date of the human adverse reaction in the format specified above.
R.21.10.07	Outcome	Choose the appropriate term from the Outcome list.
R.21.10.08	Case narrative	
R.21.10.08.01	Narrative text including clinical	Full free text description of the adverse reaction and its evaluation.
R.21.10.09	Human signs	
R.21.10.09.01	Reaction Human VEDDRA term code (adverse clinical manifestation)	Adverse clinical manifestation observed in the reaction; code that corresponds to the appropriate term from the Human VEDDRA, MedDRA while awaiting the new terminology under development by CVMP.
R.21.10.09.02	Reaction Human VEDDRA term (adverse clinical manifestation)	Adverse clinical manifestation observed in the reaction; choose the appropriate term from the Human VEDDRA, MedDRA while awaiting the new terminology under development by CVMP
R.21.11	Human suspect drug	The fields in this section are similar to the fields in

Section for human adverse reactions to VMPs		
		section Animal suspect drug. Until an appropriate medicinal products database is agreed, complete all fields in this section manually in strict accordance with the approved SPC. Once a medicinal products database is available, many fields in this section can be filled automatically upon selection of the appropriate product.
R.21.11.01	Exposure start date format	Specify the format of the 'Exposure start date' XML field
R.21.11.02	Exposure start date	Enter Date of first exposure of the human, who reacted, to the VMP in the format specified above.
R.21.11.03	Exposure duration	Enter numerical value for the duration of exposure.
R.21.11.04	Exposure duration unit	Choose appropriate term from the time units list for the unit in which duration of exposure is reported.
R.21.11.05	Exposure end date format	Specify the format of the 'Exposure end date' XML field
R.21.11.06	Exposure end date	Enter Date of last exposure of the human, who reacted to the VMP in the format specified above.
R.21.11.07	Characterization	The suspect product has to be qualified as suspect, concomitant or interacting; choose appropriate term from the characterization list.
R.21.11.08	Brand Name	Brand name of the veterinary medicinal product (VMP) involved in the adverse reaction - enter the name.
R.21.11.09	Dosage form	Dosage form of the VMP involved in the adverse reaction - Choose appropriate term from the dosage form list
R.21.11.10	Authorization number	Registration number of the VMP involved in the adverse reaction - text field, enter the value.
R.21.11.11	Authorization Holder/Company	Company involved with the VMP involved in the adverse reaction - text field, enter the name of the MAH/distributor.
R.21.11.12	Authorization country	Identification of the country where the VMP involved in the adverse reaction is authorised; pick 2 character code from a ISO 3166 conform list.
R.21.11.13	Obtain country	Identification of the country where the VMP involved in the adverse reaction was obtained if different from the 'authorisation country' XML filed; pick 2 character code from a ISO 3166 conform list.
R.21.11.14	Lot number	Enter the lot number of the VMP involved in the adverse reaction.

Section for human adverse reactions to VMPs		
R.21.11.15	Expiry date format	Specify the format of the 'Expiry date' XML field as described below.
R.21.11.16	Expiry date	Enter the expiry date of the lot using the format CCYY/MM
R.21.11.17	Administration route	Enter normal route of administration for the VMP involved in the adverse reaction when treating animals - choose appropriate term from the route of administration list.
R.21.11.18	Reason for exposure	Enter the reason for the human exposure (e.g. accidental injection) - choose appropriate term from the Exposure reason list.
R.21.11.19	Dose per administration	Structured dosage information: Dose per administration, real dose administered, not by default the dosage as registered - enter numerical value of the dose; the units are specified in the 'dose unit' XML field below.
R.21.11.20	Number of doses per dose interval	Structured dosage information: Enter the number of doses given per dose interval specified below (e.g. per day).
R.21.11.21	Dose interval	Structured dosage information: Interval of administration or frequency of administration of the VMP involved in the adverse reaction - enter numerical value of the dose interval, e.g. 1 for daily administration, 2 for administration every other day.
R.21.11.22	Dose interval unit	Structured dosage information: choose appropriate term from the time units list, e.g. day.
R.21.11.23	Dose Unit	Structured dosage information: choose the appropriate choice for all above doses from the measure unit list.
R.21.11.24	Exposure details	If provision of structured dose information is not possible, explain the dosage regimen here - how many doses, how often, and for how long.
R.21.11.25	Action taken after reaction	Indicate whether treatment was continued, dose reduced or drug withdrawn after adverse reaction; for human reactions in many cases '6 - not appropriate' will be the most likely choice from the Action drug list.
R.21.11.26	ATCvet code	Choose appropriate term from the ATCvet code list; leave blank if no code has been attributed to the VMP.
R.21.11.27	Who administered the VMP	Indicate who actually administered the treatment (e.g. vet, owner); choose appropriate term from the Categorization list.

Section for human adverse reactions to VMPs		
R.21.11.28	Assessment	This section is mandatory. It is repeatable to allow the indication of all available causality assessments.
R.21.11.28.01	Assessment Source	1=Competent authority; 2=MAH; 3= Primary source.
R.21.11.28.03	Assessment comment	Free text comments on assessment of association between VMP and adverse reaction. Examples: Primary source: include the reporter's comments on the diagnosis, causality assessment or other issues considered relevant. Sender: provide information concerning the sender's assessment of the case; describe disagreement with, and/or alternatives to the primary source diagnoses.
R.21.11.29	Human suspect substance	Similar to the section 'Animal suspect substance'.
R.21.11.29.01	Role	Indicate whether active substance, excipient, or adjuvant; choose appropriate term from the Substance role list.
R.21.11.29.02	Characterization	Indicate whether suspect substance, concomitant or interacting; choose appropriate term from the Characterization list.
R.21.11.29.03	Substance name	Enter the substance name, using preferably INN, if not available the European Pharmacopoeia name and if that is not available an appropriate other name e.g. nationally approved names, national pharmacopoeia.
R.21.11.29.04	Strength	Strength, concentration of the active ingredient of the VMP involved in the adverse reaction - enter the numerical value.
R.21.11.29.05	Strength Unit	Enter the units in which the strength is expressed; choose appropriate term from the measure units list.
R.21.12	Human treating drug	To be completed if the adverse reaction required treatment with a medicinal products. As the future medicinal product database for use with EudraVigilance Veterinary, it cannot be used to populate the fields in this section. Further comments can be made in the 'Narrative' field under 'Assessment'.
R.21.12.01	Start date format	Specify the format of the 'Start date' XML field.
R.21.12.02	Start date	Enter the Date of first treatment with the drug used to treat the human adverse reaction in the format specified above.

Section for human adverse reactions to VMPs		
R.21.12.03	Duration	Enter numerical value for the duration of treatment.
R.21.12.04	Duration unit	Units for the above duration of treatment: choose appropriate term from the time units list.
R.21.12.05	End date format	Specify the format of the 'End date' XML field.
R.21.12.06	End date	Enter the Date of last treatment with the drug in the format specified above.
R.21.12.07	Brand Name	Brand name of the drug used to treat the human adverse reaction - enter the name.
R.21.12.08	Authorization number	Registration number of the drug used to treat the human adverse reaction - text field, enter the value.
R.21.12.09	Authorization Holder/Company	Company involved with the drug used to treat the human adverse reaction - text field, enter the name of the MAH/distributor.
R.21.12.10	Authorization country	Identification of the country where the drug used to treat the human adverse reaction is authorised; pick 2 character code from a ISO 3166 conform list.
R.21.12.11	Dosage form	Dosage form of the drug used to treat the human adverse reaction - Choose appropriate term from the dosage form list.
R.21.12.12	Administration route	Route of administration of the drug used to treat the human adverse reaction - choose appropriate term from the route of administration list.
R.21.12.13	Dosage text	Describe the dosage regimen for the drug used to treat the human adverse reaction.
R.21.12.14	Human treating substance	
R.21.12.14.01	Substance name	Name, preferably INN of active substance, if INN not available the European Pharmacopoeia name and if that is not available an appropriate other name e.g. nationally approved names, national pharmacopoeia.
R.21.12.14.02	Strength	Strength, concentration of the active ingredient of the drug used to treat the human adverse reaction - enter the numerical value.
R.21.12.14.03	Strength Unit	Enter the units in which the strength is expressed; choose appropriate term from the measure units list.

R.21.13	Human medical history	*Medical judgment should be exercised in completing this section. Information pertinent to understanding the case is desired such as diseases, conditions such as*

		pregnancy, surgical procedures, etc. Each of the items in the table can be repeated as appropriate. If precise dates are not known and a text description aids in understanding the medical history, or if concise additional information is helpful in showing the relevance of the past medical history, this information can be included in the 'Comments'. *Further comments can be made in the 'Narrative' field under 'Assessment'.*
R.21.13.01	Episode code	Choose appropriate code that corresponds to the term from *the Human VEDDRA.*
R.21.13.02	Episode name	Choose appropriate term from *the Human VEDDRA.*
R.21.13.03	Primary source episode name	Free text - Enter the description of the previous episode as reported by the primary source.
R.21.13.04	Comments	Free text - Any additional useful information; e.g. relevant past drug history other than de-/rechallenge.
R.21.14	Human laboratory test	*Describe test and results performed to diagnose, confirm or investigate the adverse reaction, including tests done to investigate (exclude) a non-drug cause (e.g., serologic tests for infectious hepatitis in suspected drug-induced hepatitis). Both positive and negative results should be reported. While structured information is preferable, provisions have been made to transmit the information as free text.*
R.21.14.01	High level test name	Choose appropriate code that corresponds to the test name from *the Laboratory/biochemical test type list*
R.21.14.02	Low level test name	Choose appropriate test name from *the* Laboratory/biochemical test names list
R.21.14.03	Test description	Use to enter additional relevant information, e.g. indicate the date of the test, or to describe tests and tests results, which are not covered in standard list.
R.21.14.04	Test result range	Choose the appropriate value from the controlled terminology (*test result range list*). The sender's assessment should be entered.
R.21.15	Human death	Similar to XML element 'Animal Death'
R.21.15.01	Was the autopsy done?	Indicate yes or no. Leaving the field empty signifies 'unknown'.
R.21.15.02	Date of death format	Specify the format of the 'Date of death' XML field
R.21.15.03	Date of death	Enter the date of death in the format specified above.
R.21.15.04	Death cause for primary	Free text description of cause of death as reported by

	source	the primary source.
R.21.15.05	Death cause for the sender code	Structured information on cause of death; choose code that corresponds to the appropriate term from *the Human VEDDRA.*
R.21.15.06	Death cause for the sender	Structured information on cause of death; choose appropriate term from *the Human VEDDRA.*
R.21.15.07	Further information	Any further relevant information in free text.

Sections below relate to both animal and human adverse reactions to Veterinary Medicinal Products		
R.22	Dechallenge-rechallenge information	
R.22.01	Previous exposures?	Previous exposure to the primarily suspect VMP(s) Only exposures outside the dates mentioned in the XML elements 'Animal adverse reaction' and 'Human adverse reaction'. If yes is selected, put the dates of previous exposure in the 'Narrative' XML element.
R.22.02	Previous adverse reactions?	Previous adverse reaction to the primarily suspect VMP(s). Only reactions outside the dates mentioned in the XML elements 'Animal adverse reaction' and 'Human adverse reaction'.. If yes is selected, put the clinical signs in the 'Narrative' XML element.
R.22.03	Did reaction abate after stopping?	Indicate whether adverse reaction abated after stopping the primarily suspect VMP(s)? 'Not applicable' is used when there is no repeated dose or long-lasting signs.
R.22.04	Did reaction reappear after reintroduction?	Indicate whether adverse reaction reappeared after re-introduction of the primarily suspect VMP(s). 'Not applicable' is used when the primarily suspect VMP(s) is not stopped or not re-introduced.
R.24	Sender	*In this section enter the contact details of the sender, i.e. name of person in the company or agency who is responsible for the authorization of report dissemination. This would usually be the same person who signs the covering memo for paper submissions.*
R.24.01	First name	
R.24.02	Middle name	
R.24.03	Last name	
R.24.04	Street address	
R.24.05	City	

Sections below relate to both animal and human adverse reactions to Veterinary Medicinal Products		
R.24.06	State/County	
R.24.07	Postcode	
R.24.08	Country code	
R.24.09	Telephone	
R.24.10	Fax	
R.24.11	Email	
R.24.12	Organization	
R.24.13	Department	
R.24.14	Categorization	Indicate the professional qualification of the sender; choose appropriate term from the *Categorisation list.*
R.25	Literature Reference	*Use this section to indicate if the adverse reaction was reported in the scientific literature. References are provided in the Vancouver Convention (known as "Vancouver style") as developed by the International Committee of Medical Journal Editors. The standard format as well as those for special situations can be found in the following reference, which is in the Vancouver style. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. N Engl J Med 1997; 336:309-15.*
R.25.01	reference	
R.26	Clinical trial	*Indicate in this section if the adverse reaction was observed during a clinical trial or other study types.*
R.26.01	Study name	
R.26.02	Sponsor study number	
R.26.03	Study type in which the reactions were observed	Choose the appropriate term from the *study type list*.
R.27	Linked report	*This section should be used to identify reports or cases that warrant being evaluated together. This includes, but is not limited to, a parent-offspring pair where both had reactions, several reports involving the same patient, several similar reports from same reporter (cluster).*
R.27.01	Case number	Enter the relevant case number.

R.27.02	Link type	Choose appropriate term from the *Link reference list.*
R.28	Primary source	*The primary source(s) of the information is a person who reports the facts (also called 'reporter'). This should be distinguished from senders (secondary sources) who are transmitting the information, (e.g., industry to competent authority). Usually the reporter would be the attending veterinarian or the animal owner. In the case of a published study or published individual case, the reporter would be the investigator or first author, and details on publication and trial type should also be provided. In the case of a published study or published individual case, the reporter would be the investigator or first author, and details on publication and trial type should also be provided.*
R.28.01	First name	
R.28.02	Middle name	
R.28.03	Last name	
R.28.04	Street address	
R.28.05	City	
R.28.06	State/County	
R.28.07	Postcode	
R.28.08	Country	
R.28.09	Telephone	
R.28.10	Fax	
R.28.11	Email	
R.28.12	Organization	
R.28.13	Department	
R.28.14	Categorization	Indicate the professional qualification/category of the primary source; choose the appropriate term from the *Categorisation list.*
R.29	Other people	*In this section information on other people involved can be given. For example: If the primary source is the veterinarian, the details of the animal owner can be given here and vice versa.*
R.29.01	First name	
R.29.02	Middle name	
R.29.03	Last name	

R.29.04	Street address	
R.29.05	City	
R.29.06	State/County	Indicate state or county, as applicable.
R.29.07	Postcode	
R.29.08	Country	
R.29.09	Telephone	
R.29.10	Fax	
R.29.11	Email	
R.29.12	Organization	
R.29.13	Department	
R.29.14	Categorization	Indicate the professional qualification/category of the other people; choose the appropriate term from the *Categorisation list.*
R.30	Suspect duplicate reports	*Use this section to identify possible duplicate reports, which may require merging to one report, when yes was entered in the 'suspectduplicate' XML element (child element of the 'safetyreport XML element). This entity may also be used to notify cases where the unique identifier needed to be changed: the previous number is notified as a duplicate report.*
R.30.01	Duplicate source	Enter the name of the organisation notifying the duplicate (e.g. name of the competent authority, name of the MAH)
R.30.02	Duplicate number	Enter the unique identifier of the reports identified as possible duplicates

7. Versioning history

Version	Implementation date	Comment
2.2.1	9 February 2009	The corrections implemented in version 2.2.1 are:R.18.16.09 seriousnessdeath, R.18.16.10 seriousnesslifethreatening, R.18.16.11 seriousnessdisabling, R.18.16.12 seriousnesscongenitalanomaly, R.18.16.13 seriousnessother – Editorial changes ("s" removed from Schema Descriptor in accordance with implemented XSD) R.18.16.20.01 narrativeincludeclinical – field size increased to 10000 characters R.21.10.09 Humansign made mandatory R.21.11.07 Characterization made non-mandatory R.17.02, R.17.03.02, R.19.02, R.19.03.02 "Species list" & "Breed list" replaced by "Text(160) Standard terms lists: Assessment list – re-coded in accordance with list implemented in EVVET Labtesttypelist - – re-coded in accordance with list implemented in EVVET
2.2.2	29 February 2016	Taking into account the implementation of the VICH GL30, 35 and GL42 guidelines in certain VICH regions it was considered necessary to specify that the R.05 Unique case registration number field can be expressed as either using a 2-letter ISO3166 or 3-letter ISO3166 country code, This decision was taken conjointly by the Consultative Group on Veterinary pharmacovigilance Systems (CGVPhS) on 20 January 2016.