



27 March 2017
EMA/131441/2010
Veterinary Medicines and Product Data Management

EVVET - Procedures to be followed in case of prolonged system failure

A. Actions on unavailability of services

Service	Impact	Planned?	Agency's Action	Procedure
EV WEB	Impossibility to create, send, receive or manage messages for non-gateway users	Yes	Send message 2 weeks in advance	Use alternative procedure (B.2.3) if in danger of not fulfilling legal obligations
		No	Send message if foreseen downtime > 8 hours	
Message processing (gateway + parsers)	Impossibility to send or receive messages for all users	Yes	Send message 2 weeks in advance	Use alternative procedure (B.1.3 or B.3.3) ¹ if in danger of not fulfilling legal obligations
		No	Send message if foreseen downtime > 8 hours	
Website	Impossibility to access to generic pharmacovigilance information in the veterinary domain	Yes	Send message 2 weeks in advance	
		No	Send message if foreseen downtime > 8 hours	

¹ Follow procedure B.1.3 or B.3.3 depending on which gateway fails (EudraVigilance/Partners).



B. Procedures:

B.1 Prolonged failure of EudraVigilance Gateway

B.1.1 Purpose

To describe the procedure to be followed by all EDI partners in case of prolonged non-availability of the EudraVigilance Gateway at the level of the EMA, in order to allow the Sender to comply with the mandatory expedited reporting obligations of suspected serious adverse reactions, as defined in Regulation (EC) No. 726/2004 and Directive 2001/82/EC as amended.

B.1.2 Scope

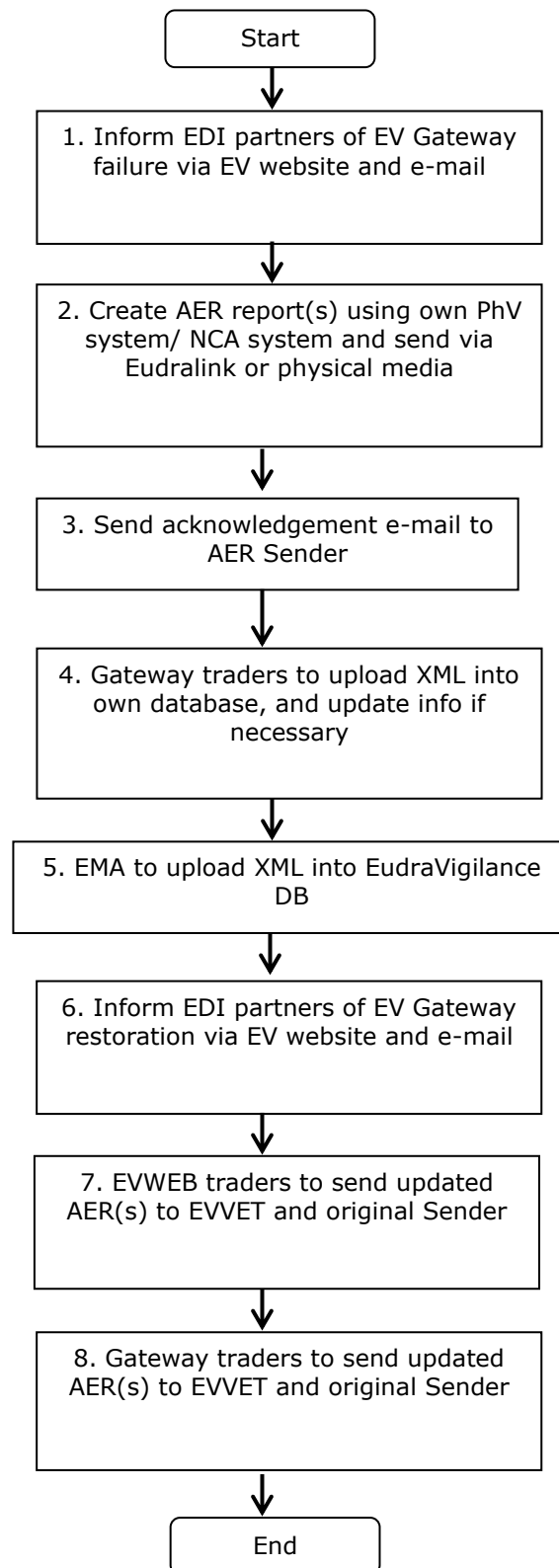
This procedure applies to all EDI partners and to the EMA (staff responsible for EudraVigilance in the Animal and Public Health section of the Veterinary Unit, to the Project Management Sector of the Communication and Networking Unit).

B.1.3 Procedure

Step	Action	Responsibility
1	On becoming aware of the non-availability of the EudraVigilance Gateway, immediately inform the EudraVigilance Community by publishing a message on the EVVET webpage, stating the non-availability of the EudraVigilance Gateway and the procedure to be followed by EV users. Send e-mail notification to specified EDI partner's contact persons (QPPV and technical contact person if available).	EMA
2	Generate AE(s) using own PhV system and submit XML and a readable version (RTF, PDF) of the AER to the relevant CA / MAH / EMA via Eudralink, or via post (CD, ...). Additionally, the MAH paper form could be used and these paper forms should be sent via Eudralink. For cases having occurred in countries that have national system, use established national systems to create and submit reports.	EDI partner (AER sender)
3	AER receiver: Firstly, send an e-mail acknowledging the receipt of the AER(s) to the Sender. Then, if you are a Gateway user (CA or MAH), go to step 4. If EMA, go to step 5. If you are a Webtrader (CA or MAH), go to step 7.	EDI partner (AER Receiver)
4	Upload the XML file(s) into receiver's own database. Update AER with any additional information and/ or Causality Assessment.	EDI partner (AER Receiver)

Step	Action	Responsibility
	Once EV Gateway is restored, go to step 8	
5	Load the AER(s) provided via physical media into the EudraVigilance system.	EMA - Project Management Sector
6	Once EV gateway is restored, immediately inform the EudraVigilance Community by publishing a message on the EVVET website stating that the EudraVigilance Gateway is operating normally and that electronic transmission of Safety messages can be resumed. Send e-mail notification to specified EDI partner's contact persons (QPPV and technical contact person if available).	EMA
7	Upload the received XML file(s) in EudraVigilance using the "Webtrader Local Import" function (see tutorial in EVVET website for detailed instructions), or enter the information received via the MAH paper form by using EVWEB. Update AER data if necessary, add assessment, and send to EVVET and to MAH.	EDI partner (AER Receiver)
8	Send updated AERs to EVVET and to original Sender.	EDI partner (AER Receiver)

B.1.4 Process Map(s)/ Flow Chart(s)



B.2. Failure of EVWEB

B.2.1 Purpose

To describe the procedure to be followed by all EDI partners in case of prolonged non-availability of EVWEB, to allow the Sender to comply with the mandatory expedited reporting obligations of suspected serious adverse reactions as defined in Regulation (EC) No. 726/2004 and Directive 2001/82/EC as amended.

B.2.2 Scope

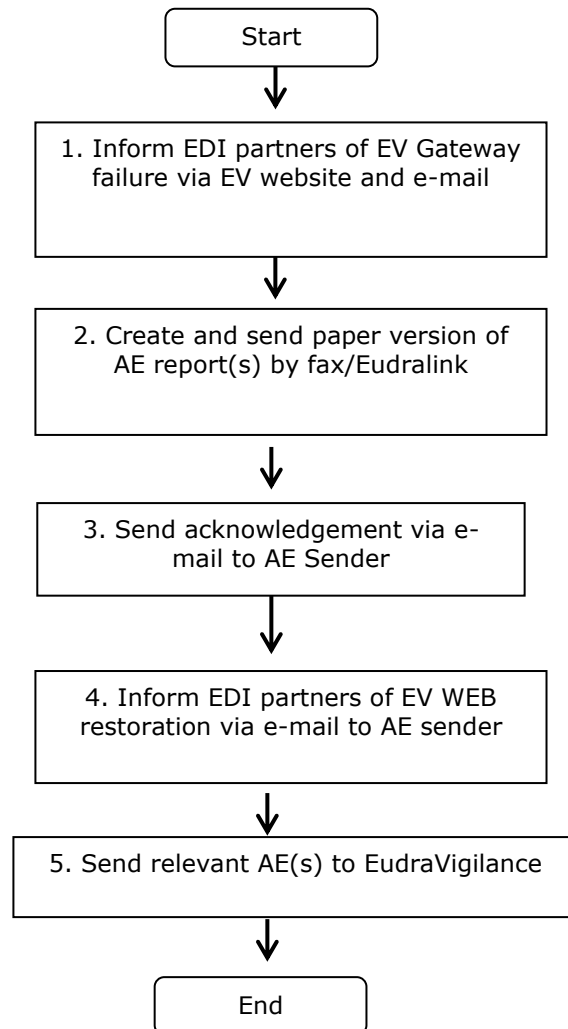
This procedure applies to all EDI partners and to the EMA (staff responsible for EudraVigilance in the Animal and Public Health section of the Veterinary Unit, to the Project Management Sector of the Communication and Networking Unit).

B.2.3 Procedure

Step	Action	Responsibility
1	On becoming aware of the non-availability of the EVWEB, immediately inform the EudraVigilance Community by publishing a message on the EV Veterinary webpage, stating the non-availability of EVWEB and the procedure to be followed by EV users that are at risk of failing to meet regulatory obligations. Send e-mail notification to specified EDI partner's contact persons (QPPV and technical contact person if available..	EVTM
2	In case of prolonged failure of EVWEB, the EDI partner may submit those AERs to the relevant CA / MAH / EMA by sending paper reports via fax. Additionally, the MAH paper form could be used and these paper forms should be sent via Eudralink. Send the reports via Fax or Eudralink to the relevant Receiver (CA, MAH or EMA), clearly notifying the AER Receiver that the failure of EVWEB is the reason for using Fax / Eudralink as the method of transmission. For cases having occurred in in countries that have national system, use established national systems to create and submit reports.	EDI partner (AE Report Sender)
3	The AER Receiver will send an e-mail acknowledging receipt of the AE Report to the AER Sender.	EDI partner (AE Report Receiver)
4	Once EVWEB is restored, immediately inform the EudraVigilance Community by publishing a message on the EudraVigilance Website stating that EVWEB is now operating normally, and informing Senders that the cases sent via fax / Eudralink need to be entered into EudraVigilance by the original Sender. Send e-mail notification	EMA

Step	Action	Responsibility
	to specified EDI partner's contact persons (QPPV and technical contact person if available..	
5	Send relevant AERs to EudraVigilance.	EDI partner (AE Report Sender)

B.2.4 Process Map(s)/ Flow Chart(s)



B.3. Prolonged failure of an EDI Partner's Gateway

B.3.1 Purpose

To describe the procedure to be followed by all EDI partners in case of failure of Safety or Acknowledgment Message transmission on the Sender's Gateway, when the Sender is in a position to generate Safety Messages and needs to comply with the mandatory expedited reporting obligations of suspected serious adverse reactions, as defined in Regulation (EC) No. 726/2004 and Directive 2001/82/EC as amended.

B.3.2 Scope

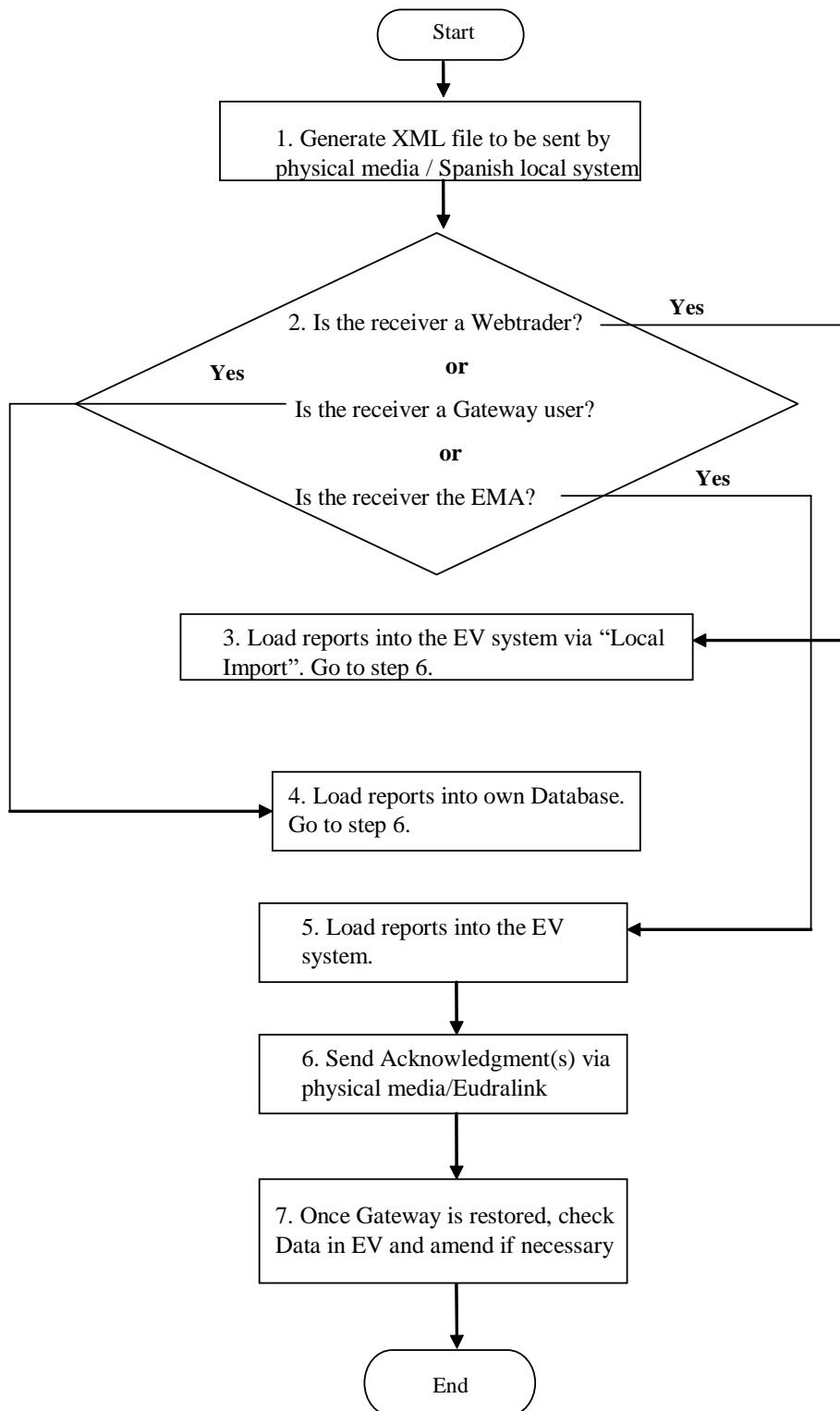
This procedure applies to all EDI partners and to the EMA (staff responsible for EudraVigilance in the Animal and Public Health section of the Veterinary Unit, to the Project Management Sector of the Communication and Networking Unit).

B.3.3 Procedure

Step	Action	Responsibility
1	<p>In case of a prolonged failure on an EDI partners gateway, and when the EDI partner is in danger of not fulfilling its obligations under articles 49 or 50 of Regulation 726/2004, the EDI partner shall submit those AERs to the relevant CA / MAH / EMA via physical media. These could be via Eudralink, or via post. The Sender will also specify the way they would like to receive the Acknowledgments: via physical media (by post), or via Eudralink to the provided e-mail address.</p> <p>Generate XML file(s) from database, save it and send it to the receiver in your chosen format.</p> <p>For cases having occurred in countries that have national system, use established national systems to create and submit reports.</p>	EDI partner (AER sender)
2	<p>AER receiver:</p> <p>If you are a Webtrader (CA or MAH), go to step 3.</p> <p>If you are a Gateway user (CA or MAH), go to step 4.</p> <p>If EMA, go to step 5.</p>	EDI partner (AER Receiver)
3	<p>Upload the received XML file(s) in EudraVigilance using the "Webtrader Local Import" function (see tutorial in EudraVigilance Website for detailed instructions).</p>	EDI partner (AER Receiver)
4	<p>Upload the XML file(s) into receiver's own database.</p>	EDI partner (AER Receiver)
5	<p>Load the AER(s) provided via physical media into the EudraVigilance system.</p>	EMA Project Management Sector

Step	Action	Responsibility
6	Send the Acknowledgment(s) to the Sender, via physical media by post, or via Eudralink to the specified e-mail address.	EDI partner (AER receiver) / EMA Project Management Sector
7	Once the Gateway has been restored, check AER data in EudraVigilance and update if necessary.	EDI partner (AER Sender)

B.3.4 Process Map(s)/ Flow Chart(s)



Process Map– Procedure to be followed by EDI partners in case of failure of Sender's Gateway

B4. Prolonged failure of an EDI Partner's database

B.4.1 Purpose

To describe the procedure to be followed by the relevant parties (MAHs, Competent Authorities & EMA) in case of mechanical, programme, electronic or communication failure that prevents a Sender from generating Safety or Acknowledgment Messages, in order to meet the mandatory electronic reporting obligations of suspected serious adverse reactions as defined in Regulation (EC) No. 726/2004 and Directive 2001/82/EC as amended.

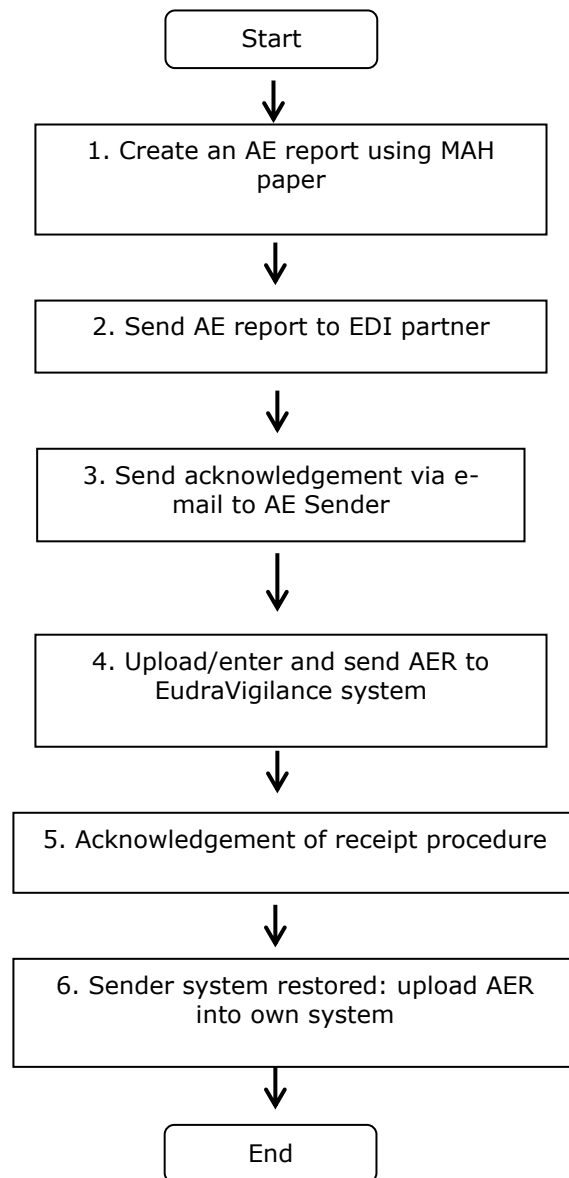
B.4.2 Scope

This procedure applies to all EDI partners and to the EMA (staff responsible for EudraVigilance in the Animal and Public Health section of the Veterinary Unit, to the Project Management Sector of the Communication and Networking Unit).

B.4.3 Procedure

Step	Action	Responsibility
1	<p>In case of a prolonged failure on an EDI partners database, and when the EDI partner is in danger of not fulfilling its obligations under articles 49 or 50 of Regulation 726/2004, the EDI partner shall submit the relevant AE Report(s) to the appropriate CA / MAH via paper form sent via Eudralink.</p> <p>For cases having occurred in countries that have national system, use established national systems to create and submit reports.</p>	EDI partner (AE Report sender)
2	Send the reports via MAH paper forms to the relevant Receiver (CA, MAH or EMA), clearly notifying the AER Receiver on the e-mail body of the failure of the Sender's database as reason for using the MAH paper forms as the method of transmission.	EDI partner (AE Report sender)
3	The AER receiver will send an e-mail acknowledging receipt of the AE Report to the AER Sender.	EDI partner (AE Report Receiver)
4	Enter information received via MAH paper form into EudraVigilance (EVWEB users) or own database (gateway users) using EVWEB or own system. Transfer any additional information inserted in the narrative into relevant fields, and add assessment. Send AE Report to EudraVigilance.	EDI partner (AE report Receiver)
5	The Acknowledgment of Receipt procedure is performed by the EudraVigilance system automatically.	EudraVigilance (EMA)
6	Once their system is restored, the original AE Report sender will be able to upload the AER information from EudraVigilance into their system.	EDI partner (AE Report sender)

B.4.4 Process Map(s)/ Flow Chart(s)



C. Information related to all procedures

C.1 Responsibilities

The responsibility for the execution of each step of this procedure is identified under point **8. Procedure**.

C.2 Documents needed for this procedure

EudraVigilance Veterinary system (<http://eudravigilance.ema.europa.eu/veterinary/>)

C.3 Related documents

- Note for Guidance on the electronic data interchange (EDI) of Suspected Adverse Reaction Reports (AEs) in Pharmacovigilance in the European Economic area (EEA) (EMA/131441/2010).
- Volume 9B of the Rules Governing Medicinal Products in the European Union (<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm>)

C.4 Definitions

Acknowledgement Message: Is an Electronic Data Interchange Message which contains information on the result of the Acknowledgement of Receipt procedure to acknowledge the receipt of one Safety Message and the Safety Report(s) contained in the Safety Message.

Acknowledgement of Receipt: The procedure by which the syntax and semantics of a Safety Message are checked upon receipt.

Competent Authority: An authority within the EEA including the EMA and the European Commission responsible for the granting of marketing authorisations for medicinal products and the supervision of marketing of such products in accordance with the relevant laws and regulations established under Community law.

EDI: Electronic Data Interchange is the electronic transfer, from computer to computer, of commercial and administrative data using an agreed standard to structure an EDI message. EDI is based on the use of structured and coded messages, the main characteristic of which is their ability to be processed by computers and transmitted automatically and without ambiguity. This makes EDI specific in comparison with other data exchange such as electronic mail.

EDI Message: An EDI Message consists of a set of segments, structured using an agreed standard, prepared in a computer readable format and capable of being automatically and unambiguously processed.

EDI Partner: An organisation exchanging EDI Messages in the area of pharmacovigilance with another organisation. For the purpose of this document, EDI partners in pharmacovigilance are:

- Competent Authorities in the EEA
- Marketing Authorisation Holders in the EEA

Eudralink: Is the secure electronic system designed to enable files to be sent securely over the Internet. Access to Eudralink is available to the EMA, Member State Agencies, Industrial Pharmaceutical Companies, Members of Working Parties/Committees and Experts.

EudraVigilance (EV): The European data processing network and management system, which has been developed according to internationally agreed standards and allows the European Medicines

Agency (EMA) to manage the electronic data exchange of Safety Reports (AEs) and to support the pharmacovigilance activities at Community level.

EudraVigilance Gateway: The data-processing network as defined in the Community Legislation. It provides a single point of contact between MAHs and Competent Authorities in the EEA. By doing so, the EudraVigilance Gateway is considered a hub and all connections to the EDI Partners are known as spokes. Safety, Acknowledgement and Medicinal Product Report Messages are routed through the hub to the desired spoke.

EudraVigilance team member (EVTM): Refers to a person working in the EudraVigilance team in the Animal and Public Health section of the Veterinary Unit.

Marketing Authorisation Holders: All Marketing Authorisation Holders (MAHs) holding a valid marketing authorisation for a medicinal product in the EEA including any part thereof, independent of the authorisation procedure of this medicinal product.

Receiver: The intended recipient of the EDI Message.

Sender: The person/entity creating an Electronic Data Interchange (EDI) Message for transmission.

Suspected Adverse Reaction (AE) Report: A document providing the most complete information related to an individual case at a certain point of time. An AE report may be also referred to as Safety Report.

C.5 Records

AEs referred to in Point 8 "Procedure" are stored in the EudraVigilance system.

C.6 Table of contact email addresses for pharmacovigilance purposes

Country	Email address contact
Austria	basg-v-phv@ages.at
Belgium	adversedrugreactions_vet@fagg-afmps.be
Bulgaria	Contact the National Agency
Croatia	hrvoje.pavasovic@vef.hr
Cyprus	Contact the National Agency
Czech Rep.	adr@uskvbl.cz
Denmark	dk-vet-biv@dkma.dk
Estonia	Veterinaarravimid@ravimiamet.ee
Finland	vethava@fimea.fi
France	secphv@anses.fr
Germany BVL	uaw@bvl.bund.de
Germany PEI	vigilanz-vet@pei.de
Greece	vetpharmacovigilance@eof.gr
Hungary	E-Inspectorate@nebih.gov.hu

Country	Email address contact
Iceland	Contact the National Agency
Ireland	vetsafety@hpra.ie
Italy	r.quondam@sanita.it
Latvia	liene.burkane@pvd.gov.lv
Liechtenstein	Contact the National Agency
Lithuania	budrumas@lvvpi.it
Malta	Contact the National Agency
The Netherlands	vetpharvig@cbg-meb.nl
Norway	vetsar-no@noma.no
Poland	adrwet@urpl.gov.pl
Portugal	farmacovigilancia.vet@dgav.pt
Romania	farmacovigilenta@ansvsa.ro
Slovakia	feldmarova@uskvbl.sk
Slovenia	V-farmakovigilanca@jazmp.si
Spain	fv_vet@aemps.es
Sweden	central.biv@mpa.se
United Kingdom	Adverse.events@vmd.defra.gsi.gov.uk