Title: **Procedure for Management of 15-day Suspected Adverse Reaction (SAR) reports to a centrally authorised veterinary medicinal product**		Document no.: CVMP/SOP/693/99-Rev.2
Applies to: Marketing Authorisation Holders (MAHs), CVMP members and alternates, CVMP Pharmacovigilance Working Party members, Rapporteur, European Commission and EMEA		Effective Date: 09.12.2005
PUBLIC		Review Date: 20.06.06
		Supersedes: CVMP/SOP/693/99-Rev.1
Prepared by EMEA	Approved by CVMP	Authorised for issue by
Name: Jos Olaerts	Name: H. Hoogland	Name:
Signature:	Signature:	Signature:
Date: 05.12.2005	Date:	Date:

1. Purpose

To enable a transparent procedure for the management of SARs for centrally authorised veterinary medicinal products that require reporting within 15 days, once received by the MAH or the Member State Competent Authority. This SOP relates to reports transmitted electronically through EudraVigilance and transmitted on paper reporting forms.

2. Scope

This Standard Operating Procedure (SOP) addresses the management of SARs that require reporting within 15 days (expedited SARs): serious SARs in animals occuring within the EU[1], serious unexpected SARs in animals occurring outside the EU, any suspected transmission of an infectious agent via a medicinal product occuring outside the EU, and human SARs occurring within and outside the EU. It applies to Marketing Authorisation Holders, CVMP chairperson, members and alternates, and in particular Rapporteurs, CVMP Pharmacovigilance Working Party members, European Commission and EMEA.

3. Responsibilities

The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 7 of this SOP.

4. Forms needed for this SOP

- Common EU reporting form for MAHs (EMEA/CVMP/601/02-FINAL, also Table A of Volume 9 of The Rules Governing Medicinal Products in the European Union, Part II, section 1)
- Fax templates (annex I) for
  I) sending expedited SARs to the CVMP Rapporteur
  II) confirming need for action as seen by Rapporteur to EMEA

[1] As clarified in the revision of Volume 9, this is considered to include the reporting of suspected transmission of any infectious agent via a medicinal product.

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5. Related documents

- Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004[2]
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001, as amended by Directive 2004/28/EC of 31 March 2004
- Commission Regulation (EC) No 540/95, of 10 March 1995
- Volume 9 of the Rules governing medicinal products in the European Union, in particular the guidance also contained in:
  - CVMP Guideline EMEA/CVMP/183/96-Rev.2-Consultation (tbc) on Pharmacovigilance of veterinary medicinal products - Guidance on procedures for MAHs
  - CVMP Guideline EMEA/CVMP/345/98-Rev.1-FINAL Procedures for competent authorities for pharmacovigilance information of veterinary medicinal products
- Guidelines relating to EudraVigilance Veterinary:
  - EMEA/CVMP/065/03 Guideline on Data Elements for the Electronic Submission of Adverse Reaction Reports related to Veterinary Medicinal Products Authorised in the European Economic Area (EEA) including message and transmission specifications
  - EMEA/CVMP/280/04 Guideline on EudraVigilance Veterinary – XML Schema Definition (XSD) Version 2.1.1 and veterinary acknowledgement XSD Version 1.0.0

6. Definitions

CVMP: Committee for Medicinal Products for Veterinary Use
MAH: Marketing Authorisation Holder
PhV: Pharmacovigilance
PhVWP-V: CVMP Pharmacovigilance Working Party
SAR: Suspected Adverse Reaction, see Directive 2001/82/EC as amended for relevant defititions
expedited SAR: a Suspected Adverse Reaction, that requires reporting within 15 days of receipt. Legislation specifically mentions:

- serious SARs in animals occuring within the EU (including suspected transmission of any infectious agent via a medicinal product – see revised Volume 9),
- serious unexpected SARs in animals occurring outside the EU,
- suspected transmission of any infectious agent via a medicinal product occuring outside the EU, and
- human SARs occurring within and outside the EU

Follow-up reports of expedited SARs that were incomplete upon first notification are treated as new expedited SARs and they will undergo the complete cycle described in this SOP.

[2] Supersedes, with a date of coming into effect of 20 November 2005, Council Regulation (EEC) No 2309/93, of 22 July 1993,

7. Procedure

Step	Action	Document reference	Responsibility
0	**Expedited SAR reporting for cases having occurred** a) **within** the EU, go to 1.0 b) **outside** the EU, go to 2.0		
1.0	**Expedited SAR reporting within the EU**[3]		
1.1	Inform within 15 days of being notified of an expedited SAR a) the EMEA b) the EMEA and the MS where the reaction occured		a) Member State[4] b) MAH[5]
1.2	Check for new expedited SAR reports - in EudraVigilance Veterinary on a regular basis (at least weekly) - on veterinary unit fax for expedited SARs exceptionally not reported electronically		EMEA EudraVigilance team EMEA PhV project manager
1.3	Was the expedited SAR report sent electronically? - if **Yes**, go to **1.8** - if **No**, go to **1.4**		EMEA PhV project manager
1.4	Was expedited SAR received by fax under exceptional circumstances - if **Yes**, go to **1.6** - if **No**, go to **1.5**		EMEA PhV project manager
1.5	Request electronic submission from MAH, then go to **1.3**		EMEA PhV project manager
1.6	Send the expedited SAR report to the PhVWP-V members as representatives of the competent authorities of Member States, using their general fax number		EMEA PhV project manager
1.7	Ensure that the expedited SAR report is entered into EudraVigilance[6], then go to **1.9**		EMEA EudraVigilance team
1.8	Send the expedited SAR report to all Member States via EudraVigilance		EMEA EudraVigilance team
1.9	Collect and compile SARs reports for a specific product and send to Rapporteur on a monthly basis for review and decision on need for action.	e-mail template	EMEA PhV project manager
1.10	Need for action to be communicated and discussed by the Rapporteur during the CVMP meeting or in writing before the CVMP meeting in case of non attendance. Go to **3.0**		Rapporteur

[3] Follow-up reports of expedited SARs that were incomplete upon first notification are treated as new expedited SARs and they will undergo the complete cycle another time

[4] For reports received directly from a non-MAH primary reporter, and reports received from MAHs, after entry into force of Regulation (EC) 726/2004 in particular reports from healthcare professionals

[5] After entry into force of Regulation (EC) 726/2004 for all other reports except from healthcare professionals

[6] Responsible for entry in EudraVigilance Veterinary: EMEA for non-electronic reports under exceptional circumstances, relevant MS for all others

Step	Action	Document reference	Responsibility
2.0	**Expedited SAR reporting from cases having occurred outside the EU**[7] (date of receipt by EU MAH representative = start date for notification deadline of minimum reaction details)		
2.1	Send expedited SAR from third country to the EMEA and all MS		MAH
2.2	Check for new expedited SAR reports - in EudraVigilance Veterinary on a regular basis (at least weekly) - on veterinary unit fax for expedited SARs not reported electronically		EMEA EudraVigilance team & EMEA PhV project manager
2.3	Was the expedited SAR report sent electronically? - if **Yes**, go to **2.7** - if **No**, go to **2.4**		EMEA PhV project manager
2.4	Was expedited SAR received by fax under exceptional circumstances[8]? - if **Yes**, go to **2.6** - if **No**, go to **2.5**		EMEA PhV project manager
2.5	Request electronic submission from MAH, then go to **2.3**		EMEA PhV project manager
2.6	Ensure that the expedited SAR report is entered into EudraVigilance[9],		EMEA EudraVigilance team
2.7	Collect and compile SARs reports for a specific product and send to Rapporteur on a monthly basis for review and decision on need for action.	e-mail template	EMEA PhV project manager
2.8	Need for action to be communicated and discussed by the Rapporteur during the CVMP meeting or in writing before the CVMP meeting in case of non attendance.		Rapporteur
3.0	**Report to CVMP and CVMP decision**		
3.1	Provide in the first mailing for each CVMP meeting a line listing compilation of all expedited SAR received		EMEA PhV project manager
3.2	Send comments to Rapporteur, CVMP chairperson, members and alternates, and EMEA		CVMP chair, members and alternates
3.3	Is an action required? - if **Yes,** go to 3.4 - if **No,** go to 3.9		CVMP
3.4	Is urgent action required? - if **Yes,** go to 3.7 - if **No,** and go to 3.5		CVMP
3.5	Schedule issue for discussion and decision at the next		EMEA PhV project manager

[7] Follow-up reports of expedited SARs that were incomplete upon first notification are treated as new expedited SARs and they will undergo the complete cycle another time

[8] Such exemption will be further defined in Volume 9.

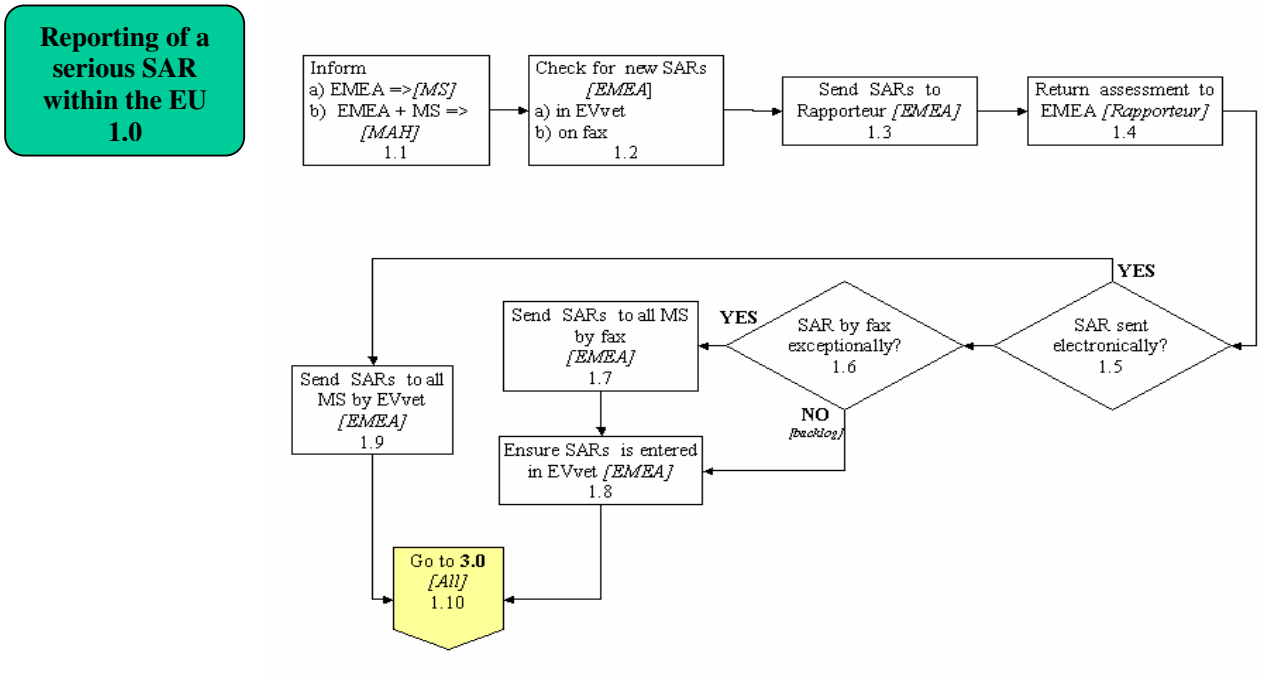
[9] Responsible for entry in EudraVigilance Veterinary: EMEA for non-electronic reports under exceptional circumstances, relevant MS for all others

Step	Action	Document reference	Responsibility
	meeting of the PhVWP-V		
3.6	Adopt PhVWP-V recommendations		PhVWP-V
3.7	Adopt CVMP decision		CVMP
3.8	Inform the MAH about CVMP decision, copy to EMEA product project manager		EMEA PhV project manager
3.9	End of process		

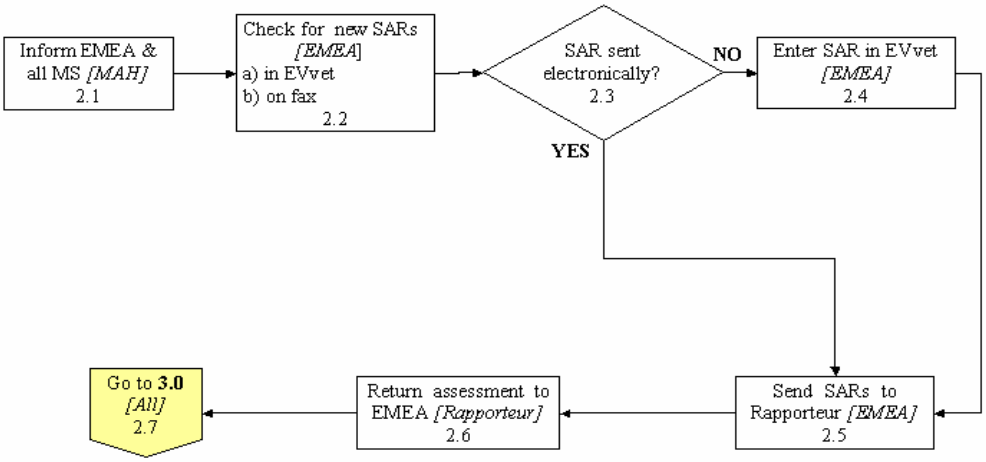
8. Records

When completed, approved and numbered, the retention of the hard copy of the serious SAR reports and Rapporteur/Co-Rapporteur's report will be the responsibility of the EMEA pharmacovigilance expert. Furthermore it is the responsibility of the EMEA pharmacovigilance expert to ensure that the CVMP decision is also filed in the Safety file of the products concerned and where necessary recorded in EudraVigilance Veterinary.

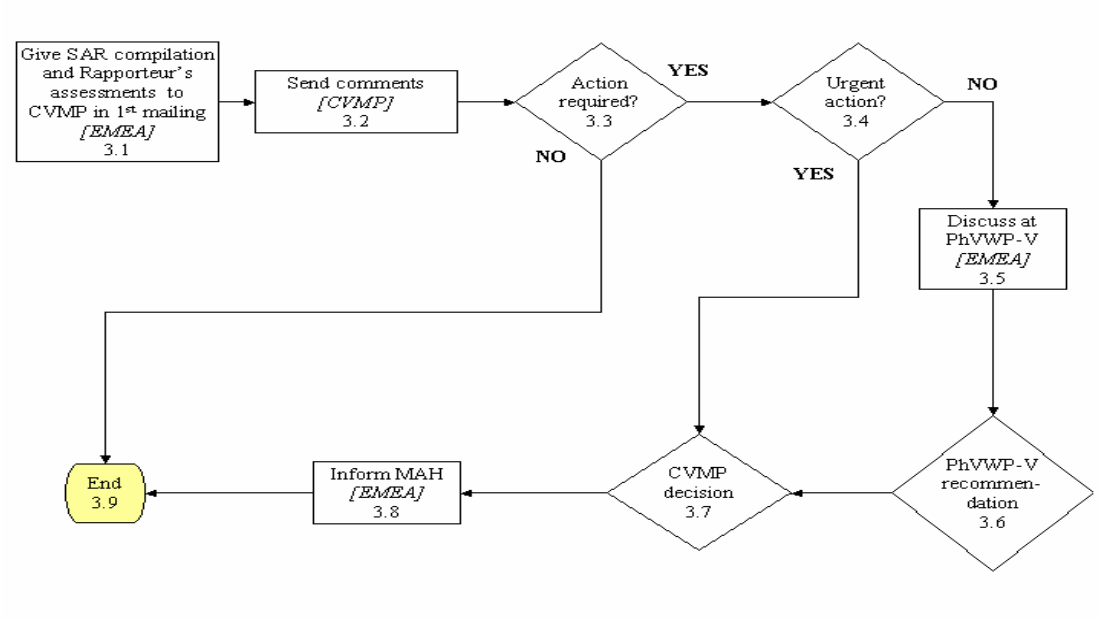
9. Process Map(s)/ Flow Chart(s)



15 day reporting of a SAR from outside the EU 2.0



CVMP report and decision 3.0



ANNEX I

Fax templates for sending/assessing SARs

European Medicines Agency
Veterinary Medicines and Inspections

TELEFAX MESSAGE

DATE:	18 May 2005	**OUR REF:**	EMEA/CVMP/693/1999
TO:		**PHONE:**	*Rapporteur's details*
	10. Rapporteur's details		
	Rapporteur's details	**FAX:**	*Rapporteur's details*
FROM:	EMEA PhV contact person Scientific Administrator	**PHONE:** **FAX:**	(44-20) 74 18 xx xx (44-20) 74 18 84 47

RE: SAR reportable within 15 days – request for review by Rapporteur
<Product name> <Authorisation number>
Unique report ID : xxx
Country where SAR occurred: xxx
Receipt date by EMEA: xxx

CC:

Number of Pages (including cover sheet): x *(2 + SAR page numbers)*

Original of this fax has been signed by the sender and is available upon request from the signatory.

MESSAGE

Dear Ms/Mr/Dr/Prof <Rapporteur>,

Please find attached the above suspected adverse reaction (SAR) report.

In accordance with the EMEA SOP CVMP/SOP/693/99-Rev.1 please return the second page of this fax to us, indicating whether any action is required in relation to this SAR. If you find that action is required, a recommendation on the appropriate action should be included in your reply, which should reach us by **date** (7 days later).

Compilations of recent SARs reported to the EMEA for centrally authorised products are circulated for each CVMP meeting, which you may wish to consult when carrying out your review. Please do not hesitate to contact us if you require further information on previous SARs.

Kind regards,

EMEA PhV contact person

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European Medicines Agency
Veterinary Medicines and Inspections

TELEFAX MESSAGE

DATE:	18 May 2005	**OUR REF:**	EMEA/CVMP/693/1999
TO:	EMEA PhV contact person Scientific Administrator	**PHONE:** **FAX:**	(44-20) 74 18 xx xx (44-20) 74 18 84 47
FROM:		**PHONE:**	
	11. Rapporteur's details		**12. Rapporteur's details**
		FAX:	*Rapporteur's details*
	13. Rapporteur's details		

RE: SAR reportable within 15 days – review from Rapporteur
<Product name> <Authorisation number>
Unique report ID : xxx
Country where SAR occurred: xxx
Receipt date by EMEA: xxx

CC:

Number of Pages (including cover sheet): 1

Original of this fax has been signed by the sender and is available upon request from the signatory.

MESSAGE

No action necessary ☐

Action necessary ☐

Recommended action *(for endorsement at the next CVMP meeting)*:

Date: _____ Signature: _____
Rapporteur's name in print

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