European Medicines Agency

EMEA/86607/2009
5 March 2009

EUDRAVIGILANCE VETERINARY

STATUS REPORT TO EMEA MANAGEMENT BOARD / VETJIG[1] / PHVWP-V[2] / CVMP[3] / HMA-V[4] / CMD-V[5]

This document is published on the EVVet Website:
http://eudravigilance.emea.europa.eu/veterinary

Issue/Summary

This document provides a succinct overview on the implementation status and development planning of the European Database for the collection of adverse events related to veterinary medicines; EudraVigilance Veterinary.

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[1] Veterinary Joint Implementation Group
[2] Veterinary Pharmacovigilance Working Party
[3] Committee for Veterinary medicinal Products
[4] Heads of Medicines Agencies - Veterinary
[5] The Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary

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1. INTRODUCTION

1.1. Legal and Regulatory framework

EudraVigilance Veterinary has been set-up in line with the legal provisions of Regulation 726/2004 (Art. 57) and Directive 2001/82/EC (Art. 73).

Guidelines specific to the electronic exchange of pharmacovigilance information (legally mandatory since November 2005) have been developed by the Veterinary Joint Implementation Group (VetJIG) and the Veterinary Pharmacovigilance Working Party (PhVWP-V) and have been included in the draft Volume 9B (currently at EC level for consultation). Relevant guidance had already been released on the dedicated Website: http://eudravigilance.emea.europa.eu/veterinary

The technical data-elements guideline for the original set-up of EudraVigilance Veterinary was released by the CVMP in July 2003 and subsequently revised by the VetJIG in July 2005. A further major revision to EVVet and its procedures will be required following the conclusion and formal adoption of the relevant VICH PhV guidelines (GL42, GL30, GL24).

The draft guideline on the access to the data in EVVet has been released in January 2009 for a consultation period of 3 months.

1.2. Partners and fora

While the original data elements guideline was released via the PhVWP-V and the CVMP, further releases and all technical discussions related to EudraVigilance Veterinary have been centralised in VetJIG. VetJIG meets 4 times per year with representatives from all Member States' authorities, IFAH Europe, European Group for Generic Veterinary Products and the Association of Veterinary Consultants

The regulatory authorities continue to exercise surveillance on the data available in the local databases as well as the data in EVVet to which all registered users of regulatory authorities have full access. Procedures are under development to strengthen the role of the PhVWP-V in the overall surveillance of the data in accordance with its mandate.

A further partner is the European Surveillance Strategy group (ESS) that was created in 2005 as a subgroup of HMA-V to make recommendations to HMA-V to improve the coordination and efficiency of pharmacovigilance across the EU.

2. IMPLEMENTATION OF ELECTRONIC REPORTING VIA EVVET AND STATUS OF REPORTING

2.1 EVVET Database overall

The database contains 23000 separate adverse event reports in animals and about 1100 separate adverse event reports from reactions observed in humans to a veterinary medicinal product. Of the total figures, 3550 reports were introduced by the Agency and contain data related to CAPS[6] (from adverse event reports and PSUR data reported before November 2005).

2.2 Implementation by EU Competent Authorities

There are 30 competent authorities registered with a total of 112 different users. Their reporting method can be found on the EVVet Website. http://eudravigilance.emea.europa.eu/veterinary
The Luxemburg, Maltese and Romanian authorities are requested to progress with the final registration to EVVet production system.

2.3 Implementation by EU Veterinary pharmaceutical industry

There are 50 organisations registered (MAHs and third parties) with a total of 70 different users. All major companies are now registered and operating electronic reporting via EVVet. Testing is being continued between Member States Gateway users and some of the major companies.

Submission of adverse event is now only accepted via electronic means; EVVet (Gateway or EVWEB), the Simplified Reporting form or other MS specific available electronic reporting system that is compliant with EVVet (see EVVet Website http://eudravigilance.emea.europa.eu/veterinary).

This has lead to an increased interest to the use the Simplified Reporting form from smaller local companies. Additional guidance is being prepared to be published on the EVVet Website in order to further facilitate and help the smaller companies that intend to use the Simplified Reporting Form.

With regard to submission of backlog data, IFAH Europe agreed to submit electronically all expedited adverse event reports for centrally authorised products received by industry as from 20 November 2005. VetJIG further noted the proposal for a cut-off date of 1 October 2008 for all other EU registered veterinary medicinal products. It was agreed for Member States, if considered necessary, to initiate a discussion at the level of HMA-V whether submission of electronic backlog data would be enforced for veterinary medicinal products other than CAPS[6] for adverse event reports received before the proposed date of 1 October 2008.

Several Member States have organised particular training sessions for local industry; Warsaw (3-5/12/2006), Lisbon (12/10/2007), Brussels (16/04/2008), Fougères (22-23/09/2008), Dublin (09/10/2008), Berlin (28-29/10/2008). EMEA continues to participate in these training programmes on request.

In order to further facilitate reporting, an agreement has been reached during the VetJIG meeting on 16 July 2008 on the procedures to be followed depending on type of product, seriousness of the case, report originating in the EU or in a third country. These "reporting schemas" that will become part of Volume 9B[2], have already been published separately on the EVVet Website.

[6] CAPS: Centrally Authorised Products

3. EVVET AND ITS SYSTEMS – DEVELOPMENT STATUS

3.1 EudraVigilance Veterinary

Testing with MAHs has further revealed inconsistencies between the data elements guideline describing the system and the actual EVVet in operation. An agreement has been reached within VetJIG on an updated Data elements guideline version 2.2.1. however it was decided to postpone its release to early 2009 in order to allow MAHs to finalise testing with the current system by the 1 October 2008 deadline set by the EMEA for companies with CAPS. The agreed implementation date of EVVet 2.2.1. in the test system is 12 January 2009 followed by implementation in the production system on 9 February 2009.

Further major changes in the data elements guideline have also already been agreed within VetJIG but the actual implementation of version 2.3. is planned for January 2010 to July 2010 (see attached timeline).

The full revision of EVVet to also take into account new international standards is preliminary being planned for April 2011 onwards (see attached timeline).

The release notes of in between releases of EVVet (to e.g. ensure bug fixing) can be found on the EVVet Website (http://eudravigilance.emea.europa.eu/veterinary/documentation.html)

3.2 Recoding application.

The recoding application will allow proper linkage of the adverse reaction reports to the dictionary of the veterinary medicinal products (EVVetMPD) and will allow for the monitoring of data entry quality issues.

The application has been released end of December 2008 and is being tested further by the Veterinary Unit. Crucial data will now become available to estimate the necessary workload for manual recoding on product data in the reports that can not automatically be linked to the product data in the product dictionary via the automatic recoding facility. Procedures are under development to organise for the manual recoding.

A further improvement to the recoding application is scheduled by end June 09 (see attached timeline) and will facilitate easy transfer of new product data into the product dictionary.

3.3 Duplicate detection.

The development of the duplicate detection engine is ongoing in line with the development plan and will be released for testing soon. A second phase for additional improvements is foreseen between May and July 2010 (see attached timeline).

Discussions are ongoing within VetJIG to bring the draft VOL9b text in relation to duplicate detection management, in line with the principles of the duplicate detection engine which instead of producing a “master file” out of 2 identified duplicate reports (with nullification of both reports), will link and leave the original identified duplicate reports while ensuring adjustment of the metrics in the DataWarehouse (e.g. no double counts for same Veddra terms).

3.4 Automatic acknowledgment

On the request of the competent authorities, there will be an automatic acknowledgment generated when EVWEB users receive reports, which at present is only done automatically when reports are being sent to the central database. The development of this facility has been planned to start in March 2009 until end of June 2009 (see attached timeline).

3.5 EudraVigilance Veterinary Medicinal Product Dictionary (EVVetMPD)

The procedure for the update of the product dictionary that is linked to adverse event reports in the EVVet central database originally foresaw 6-monthly updates (agreed at HMA-V level). This planning has shown to be too ambitious with the available resources at the EMEA and at present only the second major product update is being finalised. The second update, finalised end 2008, involved data entry of about 900 products on top of the 600 products already in the current EVMPD.

Some MS have requested for a direct transfer of product data from the data transfers being performed for the Eudrapharm project. This has also become a priority in the telematics master plan however still needs to be organised and put in operation by EMEA C&N.

3.6 Simplified reporting form for MAHs (SEF)

The simplified reporting form is an additional HTML Web based form that allows MAHs with a relative low reporting frequency to report standardised information without the need to get familiar with the more complicated EVWEB application.

There is an increased interest from companies to choose this reporting form, also for companies responsible for CAPS.

There is however further need on transparency towards EU industry on the situation in each MS since some MS have own electronic reporting systems. Feedback is being provided on a questionnaire by all Member States in order to clarify the situation. The table has been further discussed at the VetJIG meeting on 15 October 2008 and will be finalised for adoption at the next VetJIG meeting in January 2009.

The EMEA has communicated to interested companies, the conditions for the use of SEF in particular on the upper limit of 30 cases over a 12 month period since in contrast to direct reporting to EVVet, SEF reports require additional data input by the recipient into EVVet.

3.7 EudraVigilance Veterinary Data Warehouse

Iteration 4 was released in December 2008 and is further being updated following internal and external testing. The update of the corresponding development specifications is ongoing.

It will be the combination of the recoding facility, the update of the product dictionary (EVMPD), the release of the queries from the 4th iteration and later the duplicate detection engine that will allow for the full use of EVVet for surveillance purposes. A dedicated sub-PhVWP-V group is planning this stage including training on the Data Warehouse. Training dates for regulatory authority representatives are being planned for 19-20/03/2009, 23-24/03/2009, 21-22/04/2009, 28-29/04/2009, 12-13/05/2009 and 16-17/06/2009.

Work has started on multimedia tutorials for the Data Warehouse.

3.8 EVVet Website

The feel and look of the Website has been updated in November 2008. The tutorials section has also been completed with newly developed multimedia tutorials[7] on the use of EVVet. These tutorials are considered a significant improvement to guide and assist MAHs.

[7] http://eudravigilance.emea.europa.eu/veterinary/index_tutorials.html

4. GUIDELINES AND INTERNATIONAL STANDARDISATION

4.1 Volume 9B Part III

Part III and relevant annexes have been prepared within the volume 9B drafting group, the PhVWP-V and VetJIG. Following adoption of CVMP, Volume 9B has been forwarded to the Commission.

Because of the need to already provide adequate guidance at this stage to the EU MAH stakeholders it was decided to publish the "reporting schemas" ahead of the finalisation and release of Volume 9B (see http://eudravigilance.emea.europa.eu/veterinary/whatsnew.html).

4.2 Draft Access Policy

The draft access policies for EVVet data as well as EVHuman data have been endorsed by the HMA (11-12 July 2008) and MB (10 June 2008). The EMEA is preparing a consultation plan. A three month period of consultation will start in January 2009.

4.3 VICH / ISO / EUTCT

Considerable work is ongoing in relation to the standard lists being used in EudraVigilance Veterinary.

EMEA, being topic leader for the VICH GL30 Standard terms guideline, has lead the discussions that took place during the first meeting of the GL30 Task force on the development of standard lists in Berlin. A working procedure has been agreed to allow finalisation of the lists by February 2009. Consultation with VetJIG members and PhVWP-V has taken place.

The Veddra list is being updated following the agreed yearly procedure. The exercise of merging Veddra Human with the Veddra Animal list has been completed in a dedicated meeting of the Veddra subgroup on 19 November 2008. Implementation of the combined Veddra lists is foreseen for November and December 2009 (see attached timeline).

Support is provided to the EUTCT[8] group in the development of several relevant lists, including the species and breeds list and other lists currently part of the data elements guideline. A proposal to implement the species, Veddra and MRL status / tissue lists in the relevant QRD SPC guidance will be presented to the CVMP in February 2009 for consideration.

Regular teleconferences are being held by a ISO/HL7 working group to develop the next version of the ICSR message standards. EMEA veterinary participation to this topic has been limited but is also being required to increase in order to ensure that the EU reporting and message standards are being taken into account for the development of these international standards.

[8] EU Telematics Controlled Terms Working Group.

5. OTHER

5.1 Electronic reporting form for Veterinarians

The pilot testing phase has been concluded, having received comments from the Spanish, Danish, Belgian and Polish authorities. Further feedback has been requested through VetJIG from all Member States to indicate their position on the use of such form before further planning on the finalisation and release of the veterinary form. The development of the electronic form for veterinarians is not a legal requirement and has received lower priority.

5.2 Upcoming Meeting dates

VetJIG meeting: 23 April 2009
15 July 2009
21 October 2009

ANNEX

EudraVigilance Veterinary high level - Development plan

2009											
Jan	**Febr**	**March**	**April**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
Duplicate detection (1st version)		Functional improvements: Webtrader flagging, Auto ack; "Single Click recoding"								VEDDRA implementation	

2010											
Jan	**Febr**	**March**	**April**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
Implementation Data Elements Guideline 2.3 (part I)				*Duplicate detection (2nd version)*			Implementation Data Elements Guideline 2.3 (part II)				

2011											
Jan	**Febr**	**March**	**April**	**May**	**June**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
Access policy implementation (Part I)				Access policy implementation (Part II)							
			EVVet 3.x development								