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4 EudraVigilance Access Policy for Medicines for Veterinary Use

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Executive summary

The European Medicines Agency (hereafter referred to as "the Agency") and the medicines regulatory authorities collectively comprise the European Union (EU) regulatory network. The network's responsibilities are the protection and promotion of public health through the evaluation and supervision of medicines and the continuous safety monitoring and benefit-risk assessment of medicines, including the collection, management and dissemination of information on suspected adverse reactions to medicines (pharmacovigilance). The key EU resource to support this activity is EudraVigilance Veterinary (EVVET), a centralised European database of suspected adverse reactions related to veterinary medicinal products authorised in the European Economic Area (EEA).

In December 2010, the EMA Management Board adopted an EVVET Access Policy, which came in force in July 2011. This policy outlined the data elements for and the principles of providing access to reports of suspected adverse reactions referred to as Adverse Event Reports (AERs) in EVVET as regards medicines regulatory authorities in the EEA, also referred to as NCAs, and marketing authorisation holders (MAHs), healthcare professionals, patients and consumers (hereafter referred to as "public") as well as academia.

The EudraVigilance Veterinary system that came into operation in 2005 adhered to the legal requirements related to pharmacovigilance for veterinary medicinal products outlined by Regulation (EC) No 726/2004 and Directive 2001/82/EC and furthermore Volume 9b of The Rules Governing Medicinal Products in the European Union.

In 2010, the international guideline VICH[1] GL42; data elements for submission of adverse event reports was adopted followed in 2013 by two further technical guidelines VICH GL35; Electronic standards for transfer of data and VICH GL30 Controlled list of terms. The current EVVET system will be updated accordingly to comply with the international standards. In addition, the updated EVVET system which is due to become available in January 2022 will support the legal requirements set out by the veterinary medicinal products regulation, Regulation (EU) 2019/6.

Consequently, the EVVET Access Policy adopted in December 2010 was updated in 2018, whilst maintaining adherence to EU data protection rules. The aim was to provide the access necessary for stakeholders with legal obligations in pharmacovigilance as well as to give the highest possible degree of transparency while minimising the necessity to engage in ad-hoc individual requests. In 2020, in order to increase transparency, a minor revision has been introduced to simplify MAH access to AERs mentioning their products sent by other stakeholders by granting access to the case narratives without the need to submit a formal request.

The methods by which stakeholders are provided with access to EVVET based on defined AER data elements and in accordance with EU data protection legislation have been further elaborated based on experience gained and taking into account the international guidelines.

In summary:

- No changes in the EudraVigilance Access Policy have been introduced for the following stakeholders:
  - Medicines regulatory authorities, the Agency and the European Commission, who maintain access to all AER data (Section 5.2.5.1. and Table 3);

[1] VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (http://www.vichsec.org/)

- Healthcare professionals and the public (Section 5.2.5.2. and Table 4).
- Academia (Section 5.2.5.4. and Table 6.);
- The main changes in the EudraVigilance Access Policy are:

  MAHs will be provided with additional Level 2 access to defined AER data element sets in support of their signal detection, validation and other pharmacovigilance obligations (Section 5.2.5.3. and Table 5);

Regulation (EU) 2019/6 includes additional specific requirements regarding access of the general public to information on incidence as well as outcomes of signal management. These requirements are outside the scope of this revision. A further revision of this document will be necessary at the time of full implementation of the revised legislation.

1. Introduction (background)

MAHs and regulatory authorities in the EU have the obligation, for all authorised veterinary medicines, to electronically exchange adverse event reports which are centralised in the EU in one single database system, EVVET. The system is operational since 2005 and there has been a yearly increase in reporting, mainly related to improved adherence to the regulatory requirements as well as increased awareness of the value of pharmacovigilance reporting by veterinarians in the field. At the same time, the Agency is experiencing a significant increase in information requests from the general public related to such post-authorisation safety data. The initial access policy that came into force in 2011 was fully aligned with the access policy related to the Eudravigilance system for medicinal products for human use. However, while a dedicated web tool was put in place for the general public to access summary information of the data held in EudraVigilance Human, unfortunately such possibility was not put in place for Eudravigilance Veterinary due to lack of resources, which may partly explain the high number of requests for access to information which otherwise would have been readily obtainable from such web tool. The ongoing update of EVVET now also includes the availability of a web tool for the general public to access post-authorisation data related to veterinary medicinal products authorised in the EU.

In 2010, new pharmacovigilance legislation was finalised related to medicinal products for human use and, consequently, the access policy for Eudravigilance human was updated in December 2015 to take into account the new requirements.

In addition, and following the adoption in 2010 and 2013 of further international guidelines related to adverse event reporting under VICH guidelines GL30, GL35 and GL42, there is a need to update the current EVVET system to become compliant with these guidelines, in particular with the internationally defined message format for an adverse event message. This implementation is taken place as part of the "EVVET3 project", and requires the update of the access policy to align the field access specifications for each stakeholder to the data fields as identified by the VICH international standards, and as being implemented for the updated EVVET system.

2. Scope

This Access Policy defines the overall principles for providing access to AER data held in EudraVigilance Veterinary in line with the EU legal framework and taking into account that the interest in and the use of the data may vary between stakeholders. Requirements to protect personal data based on Regulation (EC) No 45/2001 and reflected in the policy accordingly.

According to Regulation (EC) No 726/2004, the EudraVigilance database shall contain information on suspected adverse reactions in animals arising from use of the veterinary medicinal product within the terms of the marketing authorisation as well as suspected adverse reactions in animals and human beings from uses outside the terms of the marketing authorisation.

The Regulation defines the level of EVVET access as follows:

1. EVVET shall be fully accessible to the competent authorities of the Member States and to the Agency and the European Commission.
2. It shall also be accessible to MAHs to the extent necessary for them to comply with their pharmacovigilance obligations.
3. The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the EVVET database, while guaranteeing personal data protection.

The description of individual cases and AERs are further outlined in Annex A.

3. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy.
- Characteristics of the policy.
- Date of coming into effect of the policy.

4. Objectives

This Access Policy has been developed with the goal to facilitate the continuous monitoring of the safety of medicinal products for veterinary use, and the evaluation of the benefits and risks of medicines authorised in the EU, with the overall aim to promote and protect animal and public health.

Furthermore, the Access Policy aims to meet the EU principles of transparency and openness and to ensure compliance with EU personal data protection legislation. By providing proactive access to adverse reaction data collected in EVVET, the following objectives should be met:

- Providing openness to healthcare professionals and the public, who are directly affected by the EU Regulatory Network's decisions relating to the authorisation and supervision of medicinal products for veterinary use, including the monitoring and assessment of the safety of veterinary medicines;
- Facilitating the monitoring of the safety of veterinary medicines following their authorisation and marketing;
- Supporting signal detection and validation activities related to all authorised veterinary medicines in the EU;
- Allowing the use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research;
- Strengthening of the collaboration with medicines regulatory authorities in third countries as regards the safety monitoring of medicines.

5. Characteristics of the policy

5.1. EudraVigilance Veterinary and Medicinal Products for Veterinary Use

EVVET has multiple functions, which relate to the secure electronic transmission of AERs, the collection, administration and quality management of these reports in a centralised database, which serves the early detection of potential safety signals and the evaluation thereof. To support these functions, EudraVigilance Veterinary is composed of the following main system components:

Data processing and management system components

- **EudraVigilance Gateway**, a data-processing network for the secure electronic exchange of adverse reaction data.
- **EudraVigilance Veterinary (EVVET)** dedicated to the collection of AERs related to all medicinal products for veterinary use authorised in the EEA in line with Regulation (EC) No 726/2004 and Directive 2001/82/EC.

Note: EVET can be accessed through EVWEB by registered users, which provides a web interface with a set of functionalities to aid the creation, electronic reporting of and access to AERs. EVWEB includes the AER Export Manager, which permits the download of AERs in an internationally agreed format.

- **EudraVigilance Veterinary Medicinal Product Dictionary (EVVETMPD),** dedicated as reference source for the coding of substances and medicinal products reported in AERs.

Data analysis and signal detection component

- **EudraVigilance Data Warehouse and Analysis System (EVVET DWH),** dedicated to support the EU pharmacovigilance safety monitoring activities with the main focus on signal detection and evaluation of AERs.

Adrreports.eu portal

- The **portal** will allow to search and view data on suspected adverse reactions for authorised veterinary medicinal products in the EEA and provides guidance to aid the understanding of the reports.

Adequate quality of AERs as reported to EVVET is paramount in implementing this Access Policy. The Agency is operating procedures that ensure the quality and integrity of the information reported in EVVET. This is performed in collaboration either with the MAH or with the Member State that submitted an AER to EVVET. This refers in particular to the responsibilities of these stakeholders with EVVET reporting obligations to:

- Adequately document individual cases and follow-up information in accordance with the regulatory pharmacovigilance requirements;
- Operate local duplicate detection and management procedures;
- Adhere with the reporting timelines of suspected adverse reactions;
- Comply with personal data protection requirements as set out in Regulation (EU) No 679/2016 or the General Data Protection Regulation (GDPR);

and the responsibility of the Agency for the:

- Coding of veterinary medicinal product information reported in AERs;

- Operation of procedures to ensure the quality and integrity of AERs reported in EVVET including the detection and management of duplicated individual cases;
- Compliance with personal data protection requirements as set out in Regulation (EC) No 45/2001 on the protection of personal data and any new Regulation which will replace Regulation (EC) No 45/2001.

5.2. Access to EudraVigilance Veterinary Data

5.2.1. Stakeholder Groups

The stakeholders being granted access to EVVET data can be grouped as follows:

- Medicines regulatory authorities in EEA Member States, the European Commission and the Agency
- Marketing Authorisation Holders (MAH)
- Academia
- Medicines regulatory authorities in third countries.
- Healthcare Professionals and the Public

5.2.2. General Principles

Reports of suspected adverse events (AERs) are collected in EVVET as derived from legal obligations placed on medicines regulatory authorities and MAHs in EEA Member States.

Access to AER data in EVVET is provided independent of the primary source (i.e. the person who provides the facts about the AER), the sender of the report (e.g. a medicines regulatory authority or a MAH) or the country where the suspected adverse reaction occurred or was reported.

The data elements for AERs are defined in the "VICH GUIDELINES GL42 & GL35"

Access is defined based on the stakeholder's interests and needs as well as the requirement to comply with EU personal data protection legislation (Regulation (EU) 679/2016 on the GDPR and Regulation (EC) No 45/2001)). The protection of personal data is a fundamental right of EU citizens. Therefore, the access is further defined in different levels taking into account that due to the nature of the information not all data elements can be disclosed to avoid a potential re-identification of data subjects.

Annex A lists all AER data elements (excl. batch wrapper and message header) and outlines those that can be accessed by each stakeholder group based on the levels defined in Table 1.

Table 1. Description of access levels

Access Level	Description
Level 1	Public subset of AER data elements with main focus on Healthcare professionals and the general public
Level 2	Extended subset of AER data elements including case narratives with main focus on • MAHs to validate signals. • Academia to directly advance public health and work, which is

Access Level	Description
	intended to improve procedures for protecting public health. • Regulatory authorities in 3rd countries, thus fostering protection of public health outside the EEA
Level 3	All AER data elements without restrictions with main focus on • NCAs in EEA, the EC and the Agency, taking into account their roles and responsibilities to protect public health. • MAHs to fulfil their pharmacovigilance obligations based on the AERs that a MAH has sent to EudraVigilance.

It needs to be recognised that not all data elements of AERs are always completed. This means that although access is provided to certain data elements, information may not always be available given the type of the report or the primary source of the information. Moreover, the new VICH AER format foresees the use of additional data elements previously not available. This implies that with the implementation of the VICH AER standard, information for these data elements may not be available for legacy data i.e. AERs reported previously to EVVET in the Data elements guideline (DEG) format.

A detailed description of access to AER data held in EVVET for each stakeholder group is provided in chapter 5.2.5.

For the purpose of access to AER data in EVVET by healthcare professionals and the public, MAHs, academia and medicines regulatory authorities in third countries, the information held in the Union Product Database (UPD) serves as a reference for data coding and data retrieval purposes.

5.2.3. Personal Data Protection

The Agency, medicines regulatory authorities in EEA Member States, and MAHs are responsible for:

- Ensuring confidentiality of AER data and Protecting personal data by implementing appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss in accordance with the applicable law on personal data protection.

Personal data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identified number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity (Article 2(a) of Regulation (EC) No 45/2001).

For the Agency the provisions set out in Regulation (EC) No 45/2001 apply; for medicines regulatory authorities in EEA Member States and MAHs the rules set out in Regulation (EU) No 679/2016 the General Data Protection Regulation apply.

5.2.4. Methods of providing access to AER data held in EVVET

Access to EVVET data is provided through easy to use query and data retrieval functions based on the EVVET system components described in chapter 5.1. Table 2. provides an overview of the system components applied to provide access to AER data for each stakeholder group and outlines the overall format of the data outputs.

237 **Table 2.** EVVET system components with AER data outputs by stakeholder group

EudraVigilance System Component	Data Outputs
Medicines regulatory authorities in EEA Member States, the European Commission and the Agency	
• EV Gateway for the electronic re-routing of AERs to medicines regulatory authorities in EEA Member States based on primary source country for regulatory purposes	• AER electronic (XML) format
• EVWEB including AER Export Manager	• AER electronic (XML) format • AER forms
• EVVET DWH	• Data outputs based on predefined and customisable query and signal detection functionalities • AER line listings • AER forms
Healthcare Professionals and the Public	
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • AER line listings (based on core AER data elements) • AER forms (for individual case review)
Marketing Authorisation Holders	
• EVWEB including AER Export Manager	• AERs electronic (XML) format • AER forms
• EVVET DWH	• Data outputs based on predefined query and signal detection functionalities • AER line listings • AER forms
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • AER line listings (based on core AER data elements) • AER forms (for individual case review)
Academia + Medicines regulatory authorities in third countries	
• Adrreports.eu portal	• Aggregated data outputs based on predefined queries • AER line listings (based on core AER data

EudraVigilance System Component	Data Outputs
	elements) • AER forms (for individual case review)
• Not applicable	• Ad-hoc preparation of data set by the Agency based on receipt of a research request; data format will depend on research request

5.2.5. Detailed description of access to AER data held in EVVET by Stakeholder Group

5.2.5.1. Medicines regulatory authorities in the EEA, the European Commission and the Agency

5.2.5.1.1. Reports of suspected adverse reactions in EVVET

In accordance with (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVVET is provided for all AER data elements for all medicinal products authorised in the EEA.

For further details refer to Table 3.

Table 3. Access to AER data by Medicines regulatory authorities in the EEA, the Agency and the European Commission

Stakeholder	Disclosure	Access Authorisation
• Medicines regulatory authorities in EEA Member States • Agency • European Commission	• AER Level 3: – All data elements for AERs reported to EVVET (for details refer to Annex A)	Authorised Personnel

5.2.5.1.2. Methods of Access

A description of how access is provided to these stakeholders including the main data outputs is given in chapter 5.2.4.

5.2.5.1.3. Access Authorisation

Access is granted to authorised personnel of the European Commission, the Agency and Medicines regulatory authorities in the EEA. The identification of 'authorised personnel' is based on the EVVET registration process. In Member States, where regional pharmacovigilance centres are established, the responsible medicines regulatory authority determines the level of access, which should be granted to these centres.

5.2.5.1.4. Personal data protection requirements

The AER data access provisions (Level 3) apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The fundamental right to protection of personal data has to be fully and effectively guaranteed in all pharmacovigilance activities.

Hence, the data shall only be used for the purpose of the pharmacovigilance responsibilities identified by the relevant legislative requirements (e.g. signal detection).

More specifically stakeholder group I is responsible for ensuring that:

- Information on EudraVigilance Veterinary is included in the privacy statements on their pharmacovigilance activities.
- Confidentiality of AERs and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EVVET.

5.2.5.2. Healthcare Professionals and the Public

5.2.5.2.1. Reports of suspected adverse reactions in EVVET

In accordance with the provisions of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVVET is provided for a defined set of AER data elements in compliance with Regulation (EC) No 45/2001 on personal data protection. This applies to AE reports for all veterinary medicinal products authorised in the EEA independent of the authorisation procedure. General explanations and guidance on the nature and the interpretation of the accessible data will be provided on the adrreports.eu portal.

For further details refer to Table 4.

Table 4. Access to EudraVigilance data by healthcare professionals and the public

Stakeholders	Disclosure	Access Authorisation
Healthcare Professionals and the Public	• AER Level 1: – Subset of AER data elements for substances/veterinary medicinal products authorised in the EEA (for details refer to Annex A)	Not required

5.2.5.2.2. Methods of Access

A description of how access is provided to these stakeholders including the main data outputs is given in chapter 5.2.4.

5.2.5.2.3. Access Authorisation

No authorisation for accessing the data by means of the adrreports.eu portal will be required i.e. all healthcare professionals and the public can access adverse reaction data of interest.

5.2.5.2.4. Personal data protection requirements

Data access and provision is based on a defined AER data set (Level 1) in compliance with Regulation (EC) No 45/2001. A statement on data privacy will be included under the section "Background" of the adrreports.eu portal. The Agency is also operating a procedure for access and rectification in line with the aforementioned Regulation.

5.2.5.3. . Marketing Authorisation Holders

5.2.5.3.1. Reports of suspected adverse reactions in EVVET

In accordance with the provisions of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EV is provided to MAHs for a defined set of AER data elements in compliance with Regulation (EC) No 45/2001 and Regulation (EU) No 679/2016, the General Data Protection Regulation.

For further details refer to Table 5.

Table 5. Access to EudraVigilance data by Marketing Authorisation Holders

Stakeholder	Disclosure	Access Authorisation
Marketing Authorisation Holders	• AER Level 1: – Subset of AER data elements for substances/medicinal products authorised in the EEA (for details refer to Annex A) made available through EVVET DWH – In addition, access to the following fields via the restricted EVVET system:	EU Qualified Person Responsible for Pharmacovigilance (EU QPPV) (headquarter level), appointed Deputy and authorised personnel under the strict responsibility of the EU QPPV.
	• AER Level 2: – Extended subset of AER data elements for their products including case narrative (for details refer to Annex A)	EU QPPV (headquarter level) /appointed Deputy and authorised personnel under the strict responsibility of the EU QPPV.
	• AER Level 3: – All data elements for AERs that MAH submitted ("Sender-based") to EVVET	EU QPPV (headquarter level)/appointed Deputy and authorised personnel under the strict responsibility of the EU QPPV.

5.2.5.3.2. Methods of access

A description of how access is provided to these stakeholders including the main data outputs is given in chapter 5.2.4.

5.2.5.3.3. Access Authorisation

Access to AER data elements Level 1 is granted to authorised personnel of a MAH at headquarter level. The identification of authorised personnel under the strict responsibility of the EU QPPV is based on the EVVET registration process. The EU QPPV of the MAH (headquarter level) or their registered Deputy nominates the authorised personnel in line with the EVVET registration process and is responsible for updating the user registration for their organisation accordingly. Additionally, AER Level 2 access is granted to the EU QPPV/registered Deputy and any other personnel under the strict responsibility of the EU QPPV of a MAH at headquarter level.

5.2.5.3.4. Personal data protection requirements

The access provisions apply without prejudice to regulation (EU) No 679/2016, the General Data Protection Regulation. The fundamental right to protection of personal data have to be fully and effectively guaranteed in all pharmacovigilance activities. More specifically, MAHs are responsible for ensuring that:

- With regard to the processing of personal data, for the purpose of pharmacovigilance activities, information on the transfer of data to EVVET is included in their privacy statements.
- Confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- Appropriate technical and organisational measures are implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EVVET.

5.2.5.4. Group IV: Academia

5.2.5.4.1. Reports of suspected adverse reactions in EVPM

In the context of this Access Policy the following definition applies:

'Academia' or 'Academic sector' should be understood as consisting of public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations[2].

'Non-profit organisation' or 'non-profit legal entity' should be understood as a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members[3].

[2] MSCA Standard Eligibility Conditions: Extract from the MSCA part of the main Work Programme" of 10 December 2013

[3] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

'Legal entity' should be understood as any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations[4].

`**International European interest organisation'** should be understood as an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe[5].

In accordance with the provisions of Regulation (EC) No 726/2004, access to individual cases of suspected adverse reactions reported to EVVET is provided for a defined set of AER data elements (Level 1) in compliance with Regulation (EC) No 45/2001.

Furthermore, an extended AER data set (Level 2) for substances or substance classes for medicinal products authorised in the EEA can be made available to academia by the Agency based on the following principles:

- The Agency supports efforts that aim to directly advance public health and work which is intended to improve procedures for protecting public health.
- The data to be provided should be sufficient to carry out work aimed at achieving either of the objectives named above and should observe EU legislation on protection of personal data.
- A research request should be submitted to the Agency using the form "Send a question to the European Medicines Agency[6]".
- The research request should address as a minimum the primary research question, the methodology to be used, the way that the results will impact on public health and the name and contact details of the person nominated by the academic institution to safeguard the EVVET data for the research purpose. These details should not exceed 1500 words and should be provided in English. A panel with representatives from the Agency's Pharmacovigilance Department will review the research request for the purpose of preparing the AER data set required for the research. The data quality will be the best available to the Agency at the time of request. Metadata (i.e. explanations on how to interpret the data e.g. comparisons to baselines) essential for the interpretation of the EudraVigilance data set for which access is provided, will be also made available by the Agency where applicable.
- The Agency will not review the validity or soundness of the research proposal and will apply a standard timescale for response to requests.
- The academic researchers should make all possible efforts to publish their research outcome. A copy of any associated articles should be provided to the Agency at least 5 business days ahead of publication. This is for information purposes only.

Table 6. Access to EVVET data by Academia

Stakeholder Group IV	Disclosure	Access Authorisation

[4] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[5] REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp; a template will be made available at the dedicated webpage "Access to EudraVigilance data" of the Agency's corporate website

Stakeholder Group IV	Disclosure	Access Authorisation
Academia	• AER Level 1: – Subset of AER data elements for substances/medicinal products authorised in the EEA (for details refer to Annex A)	Not required.
	• AER Level 2: – Extended set of AER data elements (for details refer to Annex A)	Nominated person by the academic institution following submission of a research request

5.2.5.4.2. Methods of access

A description of how access is provided to these stakeholders including the main data outputs is given in chapter 5.2.4.

5.2.5.4.3. Access Authorisation

No authorisation for accessing the AER (Level 1) data set by means of the adrreports.eu portal will be required i.e. all academic researchers can access adverse reaction data of interest.

Access to an extended data set (AER Level 2) will be provided by the Agency to a person nominated by the academic institution to safeguard the EVVET data following submission of a research request.

5.2.5.4.4. Personal data protection requirements

The personal data protection requirements for AER level are identical to those outlined in chapter 5.2.5.3.4.

5.2.5.5. Group VI: Medicines regulatory authorities in third countries

5.2.5.5.1. Reports of suspected adverse reactions in EVVET

Access to individual cases of suspected adverse reactions occurring in the EEA and reported to EVVET is provided for a defined set of AER data elements (Level 1 and Level 2) in compliance with Regulation (EC) No 45/2001.

For further details refer to Table 7.

Table 7. Access to EVVET data by Medicines regulatory authorities in third countries

Stakeholder Group VI	Disclosure	Access Authorisation
Medicines regulatory authorities in third countries	• AER Level 1: – Subset of AER data elements for substances/medicinal	Not required

Stakeholder Group VI	Disclosure	Access Authorisation
	products authorised in the EEA (for details refer to Annex A)	
	• AER Level 2: – Subset of AER data elements for substances/medicinal products authorised in the EEA (for details refer to Annex A)	Nominated contact of medicines regulatory authority in the third country

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397 **5.2.5.5.2. Methods of access**

398 A description of how access is provided to these stakeholders including the main data outputs is given
399 in chapter 5.2.4.

400 **5.2.5.5.3. Access authorisation**

401 Access to the AER data set Level 2 is provided where the Agency receives a request from a medicines
402 regulatory authority in a third country e.g. in the context of the evaluation of a safety issue related to
403 a medicine. Access is provided to the nominated contact of the medicines regulatory authority.

404 **5.2.5.5.4. Personal data protection requirements**

405 Transfer of data to medicines regulatory authorities in third countries will in any case comply with
406 applicable data protection legislation.

407 6. Entry into force of the EudraVigilance Access Policy

408 This Access Policy will enter into force six months following the announcement by the Management
409 Board of the Agency that the EudraVigilance Veterinary 3 database has achieved full functionality.

410

Annex A - AER data elements accessible by stakeholder group

This chapter provides a list of all data elements for AERs defined in the guidelines "VICH GL42: Pharmacovigilance: data elements for submission of adverse event reports (AERs)" and "VICH GL35: Pharmacovigilance: electronic standards for transfer of data".

It further outlines the access of AER data elements provided for each stakeholder group as defined in chapter5.2.1.

Access to AER data elements by stakeholder group

VICH GL35 Data Elements		**NCAs**	**PUBLIC**	**MAH**	**MAHs/Academia/NCAs in 3rd countries**	**MAHs**
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
VICH	GL 42 Contents					
A.	Administrative and Identification Information					
A.1	Regulatory Authority (RA)					
A1.1	RA name	Y	Y	Y	Y	Y
A1.2	Street address	Y	N	N	N	Y
A1.3	City	Y	N	N	N	Y
A1.4	State/county	Y	N	N	N	Y
A1.5	Mail/zip code	Y	N	N	N	Y
A1.6	Country (3 character country codes ISO 3166)	Y	Y	Y	Y	Y
A.2	Marketing Authorisation Holder (MAH)					
A.2.1	MAH Information					
A.2.1.1	Business name	Y	Y	Y	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
A.2.1.2	Street address	Y	N	N	N	Y
A.2.1.3	City	Y	N	N	N	Y
A.2.1.4	State/county	Y	N	N	N	Y
A.2.1.5	Mail/zip code	Y	N	N	N	Y
A.2.1.6	Country (3 characters country codes ISO 3166)	Y	N	N	N	Y
A.2.2	Person Acting on Behalf of MAH					
A.2.2.1	Title	Y	N	N	N	Y
A.2.2.2	First name	Y	N	N	N	Y
A.2.2.3	Last name	Y	N	N	N	Y
A.2.2.4	Telephone	Y	N	N	N	Y
A.2.2.5	Fax	Y	N	N	N	Y
A.2.2.6	e-mail	Y	N	N	N	Y
A.3	Persons Involved in the AER					
A.3.1	Primary Reporter					
A.3.1.1	Primary Reporter Category	Y	Y	Y	Y	Y
A.3.1.2	Last name	Y	N	N	N	Y
A.3.1.3	First name	Y	N	N	N	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
A.3.1.4	Telephone	Y	N	N	N	Y
A.3.1.5	Fax	Y	N	N	N	Y
A.3.1.6	e-mail	Y	N	N	N	Y
A.3.1.7	Business name	Y	N	N	N	Y
A.3.1.8	Street address	Y	N	N	N	Y
A.3.1.9	City	Y	N	N	N	Y
A.3.1.10	State/county	Y	N	N	N	Y
A.3.1.11	Mail/zip code	Y	N	N	N	Y
A.3.1.12	Country (3 characters country codes ISO3166)	Y	Y	Y	Y	Y
A.3.2	Other Reporter					
A.3.2.1	Primary Reporter Category	Y	Y	Y	Y	Y
A.3.2.2	Last name	Y	N	N	N	Y
A.3.2.3	First name	Y	N	N	N	Y
A.3.2.4	Telephone	Y	N	N	N	Y
A.3.2.5	Fax	Y	N	N	N	Y
A.3.2.6	e-mail	Y	N	N	N	Y
A.3.2.7	Business name	Y	N	N	N	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
A.3.2.8	Street address	Y	N	N	N	Y
A.3.2.9	City	Y	N	N	N	Y
A.3.2.10	State/county	Y	N	N	N	Y
A.3.2.11	Mail/zip code	Y	N	N	N	Y
A.3.2.12	Country (3 characters country codes ISO 3166)	Y	Y	Y	Y	Y
A.4	AER Information					
A.4.1	Unique AER Identification Number	Y	Y	Y	Y	Y
A.4.2	Original received date	Y	N	Y	Y	Y
A.4.3	Date of Current Submission	Y	N	Y	Y	Y
A.4.4	Type of Report					
A.4.4.1	Type of Submission & Code	Y	N	N	N	Y
A.4.4.2	Reason for Nullification Report	Y	N	N	N	Y
A.4.4.3	Type of Information in Report & Code	Y	Y	Y	Y	Y
B.	Description of Animal Data Information					
B.1	Animal Data					
B.1.1	Number of Animals Treated	Y	Y	Y	Y	Y
B.1.2	Number of Animals Affected	Y	Y	Y	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.1.2.1	Attending Veterinarian's assessment of animal health status prior to VMP use & Code	Y	Y	Y	Y	Y
B.1.3	Species (Type of Species) & Code	Y	Y	Y	Y	Y
B.1.4	Breed & Code					
B.1.4.1.1	Breed (Purebreed)	Y	Y	Y	Y	Y
B.1.4.2.1	Breed (Crossbred)	Y	Y	Y	Y	Y
B.1.5	Gender & Code	Y	Y	Y	Y	Y
B.1.6	Reproductive Status & Code	Y	Y	Y	Y	Y
B.1.7	Female Physiological Status & Code	Y	Y	Y	Y	Y
B.1.8	Animal Weight					
B.1.8.1	Weight Measured, Estimated or Unknown & Code	Y	Y	Y	Y	Y
B.1.8.2	Minimum Weight	Y	Y	Y	Y	Y
B.1.8.2.1	Minimum Weight Unit	Y	Y	Y	Y	Y
B.1.8.3	Maximum Weight	Y	Y	Y	Y	Y
B.1.8.3.1	Maximum Weight Unit	Y	Y	Y	Y	Y
B.1.9	Animal Age					
B.1.9.1	Age Measured, Estimated or Unknown & Code	Y	Y	Y	Y	Y
B.1.9.2	Minimum Age	Y	Y	Y	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.1.9.2.1	Minimum Age Units (code)	Y	Y	Y	Y	Y
B.1.9.3	Maximum Age	Y	Y	Y	Y	Y
B.1.9.3.1	Maximum Age Units (code)	Y	Y	Y	Y	Y
B.2	VMP(s) Data and Usage					
B.2.1	Registered Name or Brand Name	Y	Y/N	Y	Y	Y
B.2.1.1	Product Code	Y	Y	Y	Y	Y
B.2.1.2	Registration Identifier	Y	N	N	Y	Y
B.2.1.3	Anatomical Therapeutic Chemical Vet (ATCvet) Code	Y	N	N	Y	Y
B.2.1.4	Company or MAH	Y	N	N	Y	Y
B.2.1.5	MAH Assessment	Y	N	N	Y	Y
B.2.1.6	RA Assessment	Y	N	N	Y	Y
B.2.1.6.1	RA Assessment Term	Y	N	N	Y	Y
B.2.1.6.1.1	Explanation Relating to Assessment	Y	N	N	Y	Y
B.2.1.7	Route of Exposure (Route of Administration)	Y	Y	Y	Y	Y
B.2.1.7.1	Dose Per Administration	Y	Y	Y	Y	Y
B.2.1.7.1.1	Numeric Value for Dose (Numerator)	Y	Y	Y	Y	Y
B.2.1.7.1.1.1	Units of Value for Dose (Numerator)	Y	Y	Y	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.2.1.7.1.2	Numeric Value for Dose (Denominator)	Y	Y	Y	Y	Y
B.2.1.7.1.2.1	Units of Value for Dose (Denominator)	Y	Y	Y	Y	Y
B.2.1.7.1.3	Interval of Administration	Y	Y	Y	Y	Y
B.2.1.7.1.3.1	Numeric Value for Interval of Administration	Y	Y	Y	Y	Y
B.2.1.7.1.3.1.1	Units of Value for Interval of Administration	Y	Y	Y	Y	Y
B.2.1.7.1.3.2	Date of First Exposure	Y	N	Y	Y	Y
B.2.1.7.1.3.3	Date of Last Exposure	Y	N	Y	Y	Y
B.2.2	Active Ingredient(s)					
B.2.2.1	Active Ingredient(s)	Y	Y	Y	Y	Y
B.2.2.1.1	Numeric Value for Strength (Numerator)	Y	N	N	Y	Y
B.2.2.1.1.1	Units for Numeric Value for Strength (Numerator)	Y	N	N	Y	Y
B.2.2.1.2	Numeric Value for Strength (Denominator)	Y	N	N	Y	Y
B.2.2.1.2.1	Units for Numeric Value for Strength (Denominator)	Y	N	N	Y	Y
B.2.2.1.3	Active Ingredient Code	Y	Y	Y	Y	Y
B.2.2.2	Dosage Form & Code	Y	Y	Y	Y	Y
	Lot Number					
B.2.3	Lot Number	Y	N	N	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.2.3.1	Expiry Date	Y	N	N	Y	Y
	Administration					
B.2.4	Who Administered the VMP & Code	Y	Y	Y	Y	Y
	Label Usage					
B.2.5	Use According to Label	Y	Y	Y	Y	Y
B.2.5.1	Explanation for Off-Label Use	Y	Y	Y	Y	Y
B.2.5.1.1	Explanation for Off-Label Use – Was the target species Off-Label?	Y	Y	Y	Y	Y
B.2.5.1.2	Explanation for Off-Label Use – Was the route of administration Off-Label?	Y	Y	Y	Y	Y
B.2.5.1.3	Explanation for Off-Label Use – Was the animal overdosed?	Y	Y	Y	Y	Y
B.2.5.1.4	Explanation for Off-Label Use – Was the animal underdosed?	Y	Y	Y	Y	Y
B.2.5.1.5	Explanation for Off-Label Use – Was the treatment regimen Off-Label?	Y	Y	Y	Y	Y
B.2.5.1.6	Explanation for Off-Label Use – Was the indication Off-Label?	Y	Y	Y	Y	Y
B.2.5.1.7	Explanation for Off-Label Use – Was the storage condition Off-Label?	Y	Y	Y	Y	Y
B.2.5.1.8	Explanation for Off-Label Use – Was the product expired?	Y	Y	Y	Y	Y
B.2.5.1.9	Explanation for Off-Label Use – Was there any other Off-Label issue?	Y	Y	Y	Y	Y
B.3	Adverse Event Data					
B.3.1	Narrative of AE	Y	N	N	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.3.2	Adverse Clinical Manifestations (AER Term Name(s) & Code(s))	Y	Y	Y	Y	Y
B.3.2.1	Number of Animal	Y	Y	Y	Y	Y
B.3.2.1.1	Accuracy of the Number of Animals	Y	Y	Y	Y	Y
B.3.3	Date of Onset of AE (AE Start Date)	Y	Y	Y	Y	Y
B.3.4	Length of Time Between Exposure to VMP and Onset of AE	Y	Y	Y	Y	Y
B.3.5	Duration of AE					
B.3.5.1	Duration (Time)	Y	Y	Y	Y	Y
B.3.5.1.1	Duration Time Units	Y	Y	Y	Y	Y
B.3.6	Serious AER	Y	Y	Y	Y	Y
B.3.7	Treatment of AE	Y	Y	Y	Y	Y
B.3.8	Outcome to Date					
B.3.8.1	Ongoing	Y	Y	Y	Y	Y
B.3.8.2	Recovered/Normal	Y	Y	Y	Y	Y
B.3.8.3	Recovered with Sequela	Y	Y	Y	Y	Y
B.3.8.4	Died	Y	Y	Y	Y	Y
B.3.8.5	Euthanized	Y	Y	Y	Y	Y
B.3.8.6	Outcome Unknown	Y	Y	Y	Y	Y

VICH GL35 Data Elements		NCA	PUBLIC	MAH	MAHs/Academia/NCAs in 3rd countries	MAHs
ICH/EU	**DATA ELEMENT NAME**	**Level 3**	**Level 1**	**Level 1**	**Level 2**	**Level 3***
B.3.9	Previous Exposure to VMP	Y	Y	Y	Y	Y
B.3.10	Previous AE to VMP	Y	Y	Y	Y	Y
B.4	Dechallenge-Rechallenge Information					
B.4.1	Did AE Abate After Stopping the VMP?	Y	Y	Y	Y	Y
B.4.2	Did AE Reappear After Re-introduction of the VMP?	Y	Y	Y	Y	Y
B.5	Assessment of AE					
B.5.1	Attending Veterinarian's Assessment of AE	Y	N	N	Y	Y
B.6	Report Number(s) of Linked Report(s)					
B.6.1	Unique Adverse Event Report Identification Number	Y	N	N	Y	Y
B.6.2	Explanation for Linkage	Y	N	N	Y	Y
B.7	Supplemental Documents					
B.7.1	Attached Document Filename	Y	N	N	N	Y
B.7.1.1	Attached Document Type	y	N	N	N	Y

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