EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines and Product Data Management

Checklist on information/elements that should be provided by marketing authorisation holders in their detailed descriptions of the pharmacovigilance system for competent authorities' assessment

Veterinary medicinal products

Introduction for assessors of the DDPS (the PhVWP, the IWG and other PhV assessors):

The attached checklist is to be used by all competent authorities for assessing the "Detailed description of the pharmacovigilance system" from marketing authorisation holders. However, it is subject to some individual member state-specific requirements that are due to national legislation/requirements. Some member states may wish to ask additional questions not listed below. Nevertheless, it should be made clear to the marketing authorisation holder concerned that these are at the request of the competent authority and should not be considered to be part of the "Detailed description of the pharmacovigilance system". The required information should be supplied in a separate document to the competent authority.

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Scope of the pharmacovigilance system

Description of required data element	What is acceptable	What is not acceptable	Comments
Does the DDPS apply to the proposed MAH for the product being authorised by the current procedure? For example: does the DDPS describe the arrangements for a product that is marketed in countries where the MAH does not have an office; or if the MAH is a subsidiary of the Parent company, is it described in the DDPS?	The organisations controlled by the system are clearly identified.	It is not acceptable for the name of the MAH requesting the MAA to be different from the name listed in the DDPS, unless an explanation is provided.	The company should provide an explanation if the DDPS does not cover the MAA in question. Details should be provided in the product specific addendum if appropriate. In cases where the MAH uses a third party (e.g. contractor or other company) for processing pharmacovigilance information, this must be explained in the DDPS. However, the responsibility for PhV remains with the MAH.

Evidences

Description of required data element	What is acceptable	What is not acceptable	Comments
1) Was a signed statement provided by the MAH and the QPPV regarding having the services of a QPPV and the necessary means to collect and notify any adverse reaction (adverse event) occurring either in the Community or in a third country?	Statement provided and signed by a suitable representative of the MAH and by the appropriate QPPV for the MAA.	Statement not signed by both the QPPV and the proposed MAH; or statement does not mention the applicant (MAH listed in the MAA); or the wording of the statements deviates significantly from the one in Volume 9B.	In general there should be 2 signatures, that of the QPPV, and one from the representative of the applicant entity/MAH. Note: It is preferable for the 2 signatures to be on 1 statement. However, 2 separate statements would be acceptable as long as the wording is in accordance with Volume 9B. The person signing on behalf of the MAH should not be the same person as the QPPV except in 1-person MAHs.
2) Was the name of the QPPV and their contact details provided in the MAA form?	The location is included in the MAA, and is within the EEA.	Located outside the EEA.	The EMA legal opinion is that the location in the EEA is based on the personal address of the QPPV, but this is not required in the MAA at present.

Description of required data element	What is acceptable	What is not acceptable	Comments
3) Was a summary of the CV of the QPPV provided with key information relevant to the role e.g. main qualifications, training and experience?	Summary of the CV of the QPPV provided with details of PhV experience.	Document not provided.	Most MSs are flexible as to how long the QPPV has been in the job; however, some MSs request experience of at least 1 year. MSs should consider assessing QPPV experience and qualifications on a case by case basis taking into account MAH size, and number and type of products covered by the DDPS. Long lists of scientific publications are not required.
4) Does the QPPV have veterinary qualifications or access to a veterinarian?	The QPPV has veterinary qualifications or access to a veterinarian.		Note: Most MSs are flexible as to the qualifications of the QPPV, but some MSs require qualification of veterinarian or pharmacist etc.

Description of required data element	What is acceptable	What is not acceptable	Comments
5) Has a summary of the job description of the QPPV been provided?	List of PhV responsibilities, for example: the establishment and maintenance of a PhV system; recording of AEs: preparation of AE reports and PSURs for CAs; conducting continuous PhV evaluation; and timely provision of information to CAs and EMA as necessary regarding benefits/ risks of a veterinary medicinal product or on request. Where PhV responsibilities or roles are delegated, these should be indicated together with the job title/section of the person(s)/section that is responsible.	Some QPPV responsibilities neither referred to nor delegated (e.g. PSUR preparation).	For a full list, see responsibilities of the QPPV as listed in Volume 9B. Individual names are not required in the DDPS.
6) Has a description of the back-up procedure to be applied in the absence of the QPPV been provided?	Procedure described with post/position of back-up e.g. other Regulatory Affairs staff.	No back-up procedure described.	Names of back-up QPPV/other person are not required in the DDPS, but MSs may request these separately or on inspection.
7) Has a copy of the online registration or a letter from the EMA confirming registration with EVVet been provided?	Copy of online registration form to be provided (with password masked) or satisfactory explanation with regards to electronic reporting.	Only a EudraVigilance training attendance certificate is provided.	The requirement varies between MSs and according to size of MAH/no of reports received.

Organisations

Description of required data element	What is acceptable	What is not acceptable	Comments
8) Have the company units or other organisations where the principal EEA and global PhV activities are undertaken been identified and their location given?	Location of head office and subsidiaries/affiliates or others who might receive reports directly from users e.g. distributors or wholesalers.		Specific affiliates should not be listed in the DDPS, but MSs may request these separately.
9) Have the sites where the main databases are located been identified? Note: See also section on databases for further clarification and information.	Location of database server or site(s) of storage of original reports.	No or partial information provided.	Databases based outside the EEA are accepted as long as the information is available in the EEA.
10) Has a high level organisation chart or description been provided giving an overview of the global and EEA PhV units and organisations?	Chart/description gives the main relationships between the units, the affiliates/parent company and contractors.		
11) Have the positions of the QPPV and any local PhV contact(s) within the company units been identified in the description or a chart?	Location of QPPV etc identified.	No or partial information provided.	It should be clear whether the QPPV is directly employed by the MAH or is a contractor.

Description of required data element	What is acceptable	What is not acceptable	Comments
12) Are reporting interactions within the company clearly described? For example: links between the QPPV and other departments that may receive AE reports.	Reporting interactions clearly described.	Reporting interactions not clearly described.	
13) Has a summary of the PhV activities conducted at each unit been provided and are all important activities covered in the text and/or in a flowchart?	List of activities included (as well as identification and location of unit(s) responsible for each).	Responsibilities for activities not defined.	Examples of PhV activities to be included: receipt of AEs (collection and follow-up of AE information); seriousness classification; veterinary review; causality coding; recording/ storing of AEs; reporting to CAs; collation of PSURs; literature searches; and benefit-risk review.
14) Has the flow of safety information from spontaneous reports and PSURs from the source to the CAs been adequately described in the text and flowchart?	Description and diagram detailing flow, including time frames for serious/non-serious AEs and PSURs.	No explanation provided or type of document (e.g. PSUR) not included.	MSs would like to see time frames given for the submission of serious AEs and PSURs, but this is not mandatory.
15) Has reference been made to the capture of external reference numbers e.g. the CA case reference number and/or the worldwide reference number?	Recording of external reference numbers captured.	External reference numbers not recorded or not mentioned.	

Description of required data element	What is acceptable	What is not acceptable	Comments
16) Have agreements with third parties (e.g. contracted QPPV/deputy or distributors) been described, including responsibilities for PhV activities?	Brief description of allocation of responsibilities for PhV activities e.g. where third parties distribute products and receive reports directly from users.	Not described.	Only PhV-related details are required. Diagrams/flowcharts explaining the responsibilities between the third parties and the MAH would be helpful, but these would be optional.

Databases

Description of required data element	What is acceptable	What is not acceptable	Comments
17) Has the means of PhV data storage been identified and briefly described (e.g. is it on paper/ electronic database or spreadsheet)?	The type of data (paper and/or electronic) and its storage should be clearly identified and briefly described.	No system implemented or described for storage of PhV data.	
18) What kind of database is used by the applicant for PhV purposes (e.g. for compilation of AEs, for control of submission of PSURs, for product information, for sales, etc)?	Databases or electronic files (e.g. Excel) for compilation of AEs.	No databases or record of AEs and PSURs.	Most MSs are flexible as to whether a MAH has an electronic database or not depending on the number of AEs the MAH received. Note: Some MSs also require MAHs to have databases or electronic files for control of submission of PSURs, for product information, for sales etc.
19) Is the electronic database or system validated?	A statement indicating the validation status should be provided (if a MAH has an electronic database).	No validation statement (or explanation) provided.	
20) Have the sites where the main databases are located been identified?	Sites identified.	Sites not identified.	Note: This information may already have been included in the Organisation section.
21) Have the sites in which data may be accessed been identified?	Check that the sites where data can be accessed (electronically and on paper) have been identified.	Access only outside the EEA is not acceptable.	Note: This information may already have been included in the Organisation section.
22) Has the main site of data storage been identified?	The main site where data is stored (electronically and on paper) should be identified.	No information provided.	Note: This may be included in the Data Storage section.

Description of required data element	What is acceptable	What is not acceptable	Comments
23) Has the applicant/MAH described a signal detection programme or system?	The MAH should describe the tools or approaches used for detecting signals.	No signal detection system implemented or no mention of any tools or approaches relating to signal detection.	Note: Some MSs would prefer larger MAHs to have an electronic signal detection system.
24) Has a statement regarding the compliance of the systems with internationally agreed standards for electronic submission been provided (e.g. VeDDRA)?	The MAH should provide a statement informing of their compliance with the standards for electronic submission.	No statement or explanation (e.g. if the MAH has no database) provided.	
25) Has a method of reporting to the CAs been identified?	Reporting of AEs should be done electronically, unless in exceptional circumstances. The method should be in accordance with Legislation, Reporting Schemes and Volume 9B.	Paper reporting is not acceptable, unless in exceptional circumstances.	Electronic reporting for serious AEs is required by most MAHs, but there might be some flexibility for MAHs with very few reports per year in accordance with individual CA requirements. For example, the acceptability of the SEF should be taken into account.
26) Has the post holder or group responsible for the operation and management of the database been identified?	Post holder(s) or group identified.	No post holder or group indicated as being responsible.	

Training

Description of required data element	What is acceptable	What is not acceptable	Comments
27) Has the type and frequency of training been briefly described?	A general description is provided on how the training is conducted, the position of the person who provides the training and how often personnel are trained.	No information provided.	Examples of how training is conducted: the QPPV provides training for all relevant personnel, or personnel attend external PhV training etc. Examples of how often personnel are trained: upon commencing employment, refresher training, training on updated SOPs, etc.
28) Have the people/staff trained been identified?	A general statement is provided regarding categories of personnel that are trained, e.g. members of PhV team, sales personnel, receptionists, etc, as applicable.		
29) Has the location of training records and CV storage been identified?	A statement is provided in relation to where the training record is located and the position of the person responsible for updating it.	Not information provided.	Only the storage location of the CV of the PhV trainer is required.

Documents storage and archiving

Description of required data element	What is acceptable	What is not acceptable	Comments
30) Have the locations where different types of documents are archived been identified?	Sites are identified.	No information provided.	Examples of locations for short-term and long-term storage: - at the local affiliate, - at the headquarters, - at a contract archive company.
31) Have the types of documents stored been identified (e.g. original AE reports, QC records relating to AE processing, queries from CAs, SOPs, training records and source records)?	The type of documents stored is provided.	No information provided.	Note: It is not an EU requirement, but some MSs require the following: the person(s) (title) responsible for the archiving operations, the standards used for archiving activities and whether the archiving systems in use are fully validated. These may be requested by the MS concerned, but they should not form part of the DDPS.

Quality management system

Description of required data element	What is acceptable	What is not acceptable	Comments
32) Has a brief description of the quality management system and quality assurance procedures used to assess the PhV system been given?	Description includes: a) the elements that are covered, e.g. applicable SOPs, validation of the PhV computer applications and archiving audit reports; b) the organisational roles and responsibilities for the activities; and c) procedures for ensuring that corrective and preventive action is taken to improve the quality management system, if necessary.	Description not provided.	Detail is not a requirement of the DDPS, but additional questions can be raised outside the DDPS or during inspections.

Written procedures (SOPs should not be included in the DDPS)

Description of required data element	What is acceptable	What is not acceptable	Comments
33) Have the following activities been listed as being covered by the SOPs/written procedures?			Note: A SOP or written procedure may cover one or more topics, or one topic may be included in one or more SOPs/written procedures.
33a) The role of the QPPV and the back-up procedure to be applied in the absence of the QPPV.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33b) The collection from all sources, follow-up, processing, QC (including duplicate detection), assessment, classification, veterinary/ scientific review and reporting (including expedited and electronic reporting) of SARs/AEs.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33c) The collation, preparation, review and reporting of data in PSURs.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33d) Global PhV activities including continuous monitoring of safety profiles of products, signal detection and benefit-risk assessment.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	

Description of required data element	What is acceptable	What is not acceptable	Comments
33e) Communication with national competent authorities and animal health professionals regarding changes to the benefit-risk balance of products and requests for information.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33f) Handling of urgent safety issues, product defects, safety restrictions and variations.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33g) Management and use of databases (or other recording systems if appropriate).	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33h) Staff training.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33i) Internal audit of the PhV system.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33l) Archiving of PhV information.	Covered by SOP/written procedure.	Not included in SOP/written procedure or not mentioned.	
33m) Has any exclusion been explained or justified?	Yes.	No.	

Product specific addendum

Description of required data element	What is acceptable	What is not acceptable	Comments
34) Has sufficient information been supplied to describe the differences between the MAH's standard system description and that for the PhV monitoring of this product?	Identification of the organisation and description of their PhV activities/responsibilities or type of agreement, as applicable, should be provided to indicate differences in PhV procedures.		
35) Has the product specific information regarding sub-contracting of major PhV activities, and/or co-licensing or co-marketing arrangements been provided in the product specific addendum?	A description or table that outlines the product-specific contracts is provided. It is also acceptable to provide a table indicating the sub-contracting, co-licensing and co-marketing agreements in place for all products of the same MAH, including the concerned product.	Not identifying the sub-contracting, co-licensing and/or co-marketing partners in the text or in an addendum, if applicable.	Alternatively, the MAH should include a clear statement that there are no sub-contracting, co-licensing or co-marketing arrangements within the EEA for the product that is the subject of the product-specific MAA.

Annex

List of Abbreviations

AE	Adverse event
CA	Competent authorities
DDPS	Detailed descriptions of the pharmacovigilance system
EEA	European economic area
EMA	European medicines agency
EU	European union
EVVet	EudraVigilance veterinary
IWG	Pharmacovigilance Inspectors Working Group
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MS	Member state
PhV	Pharmacovigilance
PhVWP	CVMP Pharmacovigilance Working Party
PSUR	Periodic safety update report
QC	Quality control
QPPV	Qualified person responsible for pharmacovigilance
SAR	Serious adverse reaction
SEF	Simple electronic form
SOP	Standard operating procedure
VeDDRA	Veterinary dictionary for drug related affairs