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Union procedure on the preparation, conduct and reporting of EU veterinary pharmacovigilance inspections

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This guideline replaces EMEA/INS/PhV/85058/2008 "Procedure for conducting pharmacovigilance inspections requested by the Committee for Medicinal Products for Veterinary Use (CVMP)" and EMA/INS/PhV/226163/2014 "Procedure for reporting of pharmacovigilance inspections requested by the CVMP".

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Union procedure on the preparation, conduct and reporting of EU veterinary pharmacovigilance inspections

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1. Introduction

The pharmacovigilance regulatory obligations placed on marketing-authorisation holders (MAH) of veterinary medicinal products are laid down in Regulation (EC) No 2019/6, and the Commission Implementing Regulation (EU) No 2021/1281. Guidelines on the interpretation of legislative pharmacovigilance requirements are published in the adopted guideline on Veterinary Good Pharmacovigilance Practices (VGVPs) Module: Controls and pharmacovigilance inspections replacing Eudralex Volume 9b Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use.

In accordance with Article 126(1) of Regulation 2019/6, the competent authorities of the Member States (MSs) shall, in cooperation with the Agency, ensure that all pharmacovigilance systems master files in the Union are regularly checked and that the pharmacovigilance systems are correctly applied. Inspections may be carried out as part of the controls of the pharmacovigilance systems [Regulation (EU) 2019/6, Article 123(6); Commission Implementing Regulation (EU) 2021/1281, Article 27]. The Module: Controls and pharmacovigilance inspections of the VGVP states that pharmacovigilance inspections should be planned, coordinated, conducted, reported on, followed-up and documented in accordance with inspection procedures consistent with agreed Union procedures on EU veterinary pharmacovigilance inspections developed by the European Union (EU) Pharmacovigilance Inspectors Working Group (PhV IWG) to support harmonisation for the mutual recognition of pharmacovigilance inspections within the EU. This Union procedure should be read in conjunction with the other Union procedures on EU veterinary pharmacovigilance inspections published to compliment VGVP Module: Controls and pharmacovigilance inspections.

2. Scope

This procedure constitutes a guideline on the preparation, conduct, reporting and follow up of national competent authority (NCA) pharmacovigilance inspections and outlines the steps taken for the Committee for Veterinary Medicinal Products (CVMP) requested pharmacovigilance inspections. Addition of particulars or modifications may be applied to meet the objectives of the different types of inspections, e.g. routine and targeted inspections (see VGVP Module: Controls and pharmacovigilance inspections 2.7). The responsibility for conducting and reporting lies with the inspectorate involved, i.e. the inspector(s) selected with the specified roles. Preparation of a risk-based programme for pharmacovigilance inspections is presented in the Union procedure on the coordination of EU veterinary pharmacovigilance inspections.

3. Preparation

Preparation encompasses those activities undertaken after the selection of an MAH, or third party, for a pharmacovigilance inspection and prior to inspection conduct. It involves prospective planning to ensure inspection objectives are achieved. Activities include but are not limited to:

- allocating resources to conduct the inspection;
- announcing the inspection to the inspected entity;
- making the necessary logistical arrangements;
- collecting inspection and assessment information relevant to MAH and their product(s) from the EU Network;
- defining the inspection scope and agenda (i.e. the inspection plan).

These activities are undertaken by the Member State competent authority(ies) responsible for conducting the inspection and involve interaction with the inspected entity as needed. Interaction with the body requesting the inspection, if different to the Member State competent authority conducting the inspection (e.g. CVMP and /or its Pharmacovigilance Working Party (PhV WP), another Member State competent authority), may also be necessary.

3.1. Resource allocation

- Inspector(s) should be appointed for an inspection, taking into consideration national procedures, as well as the Union procedures entitled "Recommendations on the training and experience of inspectors performing pharmacovigilance inspections", as appropriate. For the selection of involved parties for CVMP requested inspections, refer to the Union procedure on the coordination of EU veterinary pharmacovigilance inspections.
- Expert(s) should be appointed to join the inspection team when and as necessary, depending on the inspection scope and objectives. The experts may be joining from an NCA of another Member State, if needed.
- The definitions, and duties of the involved parties (reporting inspector, lead inspector, etc.) are provided under the "Definitions" section of the Union procedure for coordinating veterinary pharmacovigilance inspections, in the section on inspections requested by the CVMP.
- The combination of inspectors and inspection days should be sufficient to ensure the inspection objectives are achieved.

3.2. Announcing the inspection

- NCAs have the right to inspect at any time. In exceptional circumstances, an inspection may be performed without prior notice [Regulation (EU) 2019/6, Article 123(6)]. This could arise, for example, in the conduct of a "targeted" inspection to investigate an immediate public health or compliance concern.
- However, routine practice is for advance notice of the intent to inspect a pharmacovigilance system to be given to a company (MAH and/or third parties). The period of notice served should be sufficient to enable organisation of logistical arrangements and review of relevant data. Unnecessarily long notice periods should be avoided. As guidance, a period of six to eight weeks is considered sufficient for a routine inspection. However, national procedures may apply different time periods, as appropriate.
- The Member State competent authority should prepare the announcement of the inspection following national procedures. Announcement communications could include, for example, the name of the inspector(s), MAH, the objectives and nature of the inspection (i.e. routine systems, product specific, targeted inspection) and if known, the proposed address of the inspection site(s). Additional information, including the pharmacovigilance system master file (PSMF) reference number, any specific product authorisations to be reviewed, or the intention to perform the inspection remotely, if applicable, can be added, as appropriate.
- The announcement should be issued to the relevant contact person, requesting confirmation of the inspected entity's availability, and that access to all required documents/databases will be provided. If the relevant contact person is not the EU qualified person responsible for pharmacovigilance (QPPV) that contact person should be requested to inform the EU QPPV.

- A request for the inspected entity to submit information for the purposes of inspection preparation should be made. The inspection type (e.g. systems or product specific) and objectives will determine the pre-inspection documentation required, however, requests will routinely include at least submission of the pharmacovigilance system master file or the relevant parts of it. Additional supportive data demonstrating how the pharmacovigilance system operates or, describing specific issues of interest may also be requested, as appropriate (e.g. list of annual statements for compliance verification). The timeline and method of submission of documentation should be clearly defined for the inspected entity.

  - The timeline provided should be adapted by the lead inspector, as needed.

  The intent to perform an inspection at a site, located in a third country, or in a Member State different to the competent authority performing the inspection, should be communicated to the local authorities or Member State competent authority, as appropriate. When the site is located in another Member State, the inspectorate of that Member State must be notified of the inspection. In such cases, a joint inspection may be performed, or the requesting Member State could ask the competent authority in that Member State to conduct the inspection on their behalf i.e. may submit a targeted inspection request. If a national inspection is to be conducted in a third country, then the Agency should be notified, in accordance with the Union procedure on the coordination of EU veterinary pharmacovigilance inspections. For details on the announcement (including timelines) of CVMP requested inspections, refer to the Union procedure on the coordination of EU veterinary pharmacovigilance inspections.

3.3. General considerations for preparation

- Inspector(s) should familiarise themselves with the pharmacovigilance system and any relevant product specific issues, prior to the inspection. Information submitted by the inspected entity, as well as data available through the EU regulatory network, may be considered, as follows:

  - Data submitted by the inspected entity as outlined in section 3.2.
  - Prior pharmacovigilance inspection history, e.g. information on pharmacovigilance inspection outcomes communicated by Member State competent authorities in the Union Pharmacovigilance database [Regulation (EU) 2019/6, Article 74 (1)].
  - Prior GxP ("good practice") inspection history, where appropriate both originating from the Member State competent authority conducting the inspection and from other sources including other Member State competent authorities and the Agency.
  - Information concerning the functioning of the pharmacovigilance system, e.g. compliance data available from the Agency, such as Union Pharmacovigilance Database reporting metrics and data quality issues.
  - Feedback from other competent authority functions, in particular pharmacovigilance assessors.

- The scope of the inspection (i.e. aspects of the pharmacovigilance system that will be inspected) should be defined, based on the inspection type, objectives, the information reviewed and VGVP guidance. The scope should be documented in accordance with national procedures and described in the inspection report.

- The scope of supervisory authority inspections should be in line with the requirements outlined in section 2.7.1. of VGVP Module: Controls and pharmacovigilance inspections. The areas listed in this VGVP section should be considered for the scope of an initial supervisory authority inspection. Additional areas may be examined, as appropriate. The scope of supervisory authority re-

inspections may be adjusted, as appropriate, depending on, for example, previous findings, changes to the system/company and any new safety or compliance issues that have been identified. Other routine inspections should also be conducted taking into account the scope defined in section 2.7 of VGVP Module: controls and pharmacovigilance inspections. Consideration should be given to avoid duplication of inspections conducted by a supervisory authority, or other Member State competent authority, when feasible. In that regard, there may be circumstances when a more limited scope, or more detailed inspection of specific aspects, can be performed. For example, when appropriate, national inspections of a local affiliate office may focus on review of local processes, including but not limited to collection of safety data in that Member State, interface with the QPPV and communication with the local Member State competent authority.

- It is recommended that inspectors prepare an inspection plan, which may include:
  - The objectives and scope of the inspection;
  - Identification of the inspection team members and their respective roles, if more than one inspector/expert is going to conduct the inspection;
  - The date and place, where the inspection is to be conducted;
  - Identification of the functional units to be inspected;
  - Identification of documents/electronic tools which will be reviewed, and to which access is required, in so far as is possible;
  - The expected time and duration for each major inspection activity (premises, processes etc.), as applicable;
  - The schedule for the final meeting;
  - Relevant aspects of the inspection plan, for example the agenda and document access requirements, may be shared with the inspected entity in advance, to ensure the availability of relevant personnel and documentation.
- Other logistical/general considerations are, as follows:
  - It should be verified that the site(s) selected for inspection, and included in the inspection announcement, are appropriate with respect to ensuring the objectives of the inspection can be achieved. Where additional sites or a change in site is necessary, an amended announcement should be issued, in accordance with Section 3.2;
  - If teleconference(s) are planned during the inspection with experts, assessors, MAH personnel located off site etc., this should be identified in advance, in so far as is possible;
  - If upon agreement from the body commissioning the inspection, it is decided to conduct a remote inspection, the inspected entity should be contacted to make the necessary arrangements. The inspected entity should be requested to provide a description of the electronic tools available to facilitate inspection conduct. Consideration should be given to any compatibility issues that may arise, and where feasible, testing should be performed in advance. Back up arrangements should also be considered.
- Inspections conducted outside of routine programmes such as those arising from within the Member State competent authority responsible for conducting that inspection should follow national procedures. Any communication between competent authorities and/or the Agency should be documented.

4. Conduct of the inspection

The inspection activities will be carried out according to the details set up in the inspection plan. The inspection plan can be amended during the inspection, for example, to ensure that the inspection's objectives are achieved. Any amendment to the plan should be documented.

Information to fulfil the inspection can be collected by, for example:

- review of relevant documents;
- examination of facilities in place to determine their compliance with regulatory pharmacovigilance obligations;
- examination of computer systems;
- conduct of interviews;
- review of internal and external communication e.g. log books, communication with authorities etc.

Any refusal of access to records and retrieval of documentation to which the inspector(s) has/have a legal right to access, should be documented in the inspection report. This should then be communicated with the authority requesting the inspection for further action and decision on consequences. The steps described below for the conduct of the inspection may not be always applicable for all types of inspection.

4.1. Opening meeting

Prior to start of the inspection, an opening meeting must take place between the inspection team and the company being inspected. The chair of the meeting should be the lead inspector.

The purpose of the opening meeting is to:

- introduce the inspection team;
- explain the regulatory framework for the conduct of the inspection;
- provide information about the scope and the objectives of the inspection;
- clarify logistics, timeframes and other references included in the inspection plan;
- introduce the MAH representatives attending the inspection;
- allow the company to present an overview of the pharmacovigilance system and how this relates to their organisational structure including roles, responsibilities, reporting lines and information on third parties delegated pharmacovigilance activities, as applicable.
- clarify with the MAH representatives whether there are any anticipated difficulties foreseen in relation to the conduct of the inspection.

4.2. Review of documentation, processes and systems

The documents and processes to be reviewed during an inspection will depend on the type, scope and focus of the inspection, for example a "targeted" inspection may focus on particular issues of concern, or defined parts of the pharmacovigilance system and inspections at local affiliates may have a different scope to inspection of global pharmacovigilance sites. Appendix 1, section C provides a list of items that could be reviewed during an inspection. However, this list is not exhaustive and should be amended as necessary to ensure the scope of the inspection is met.

4.3. Inspection observations

All inspection observations should be documented. If appropriate, copies should be made of records containing inconsistencies or illustrating non-compliance.

4.4. Closing meeting with the inspected entity

At the end of the inspection, the inspector(s) should conduct a closing meeting with the company being inspected. The QPPV should ensure his/her team attends the meeting. The purpose of the closing meeting is to:

- present a summary of the inspection findings to ensure that the results of the inspection are clearly understood;
- provide the inspected party with an opportunity to correct misconceptions and misunderstandings in response to the findings.
- explain the grading definitions for findings;
- explain the procedures and timelines for distribution of the report, response and any follow-up measures;

An inspection may consist of visits to more than one location. If appropriate, a closing meeting may be held at each location inspected.

Exceptional circumstances may occur which require premature termination of inspection. In such event the deviations from the inspection plan and the reason for early termination should be documented in the inspection report.

5. Reporting of the inspection

5.1. Preparing inspection reports

For each site inspected an inspection report (IR) should be prepared. The inspection reporting process should follow a Member State competent authority procedure. For CVMP requested inspections, the specific additional provisions noted in this procedure should be complied with.

During the conduct of the inspection or preparation of the reports the inspectors may decide to inform the Agency on particularly urgent critical findings in advance of the circulation of the inspection reports.

There could be circumstances where it may be appropriate to generate only one report for two or more sites, even though these represent separate inspections. Such circumstances can occur, for example if different sites were inspected but it is useful to combine the findings in the report. For CVMP requested inspections the reporting inspector will communicate this to the Agency as soon as this decision is taken so that it is documented and, if possible, it is also indicated in the CVMP adopted inspection request.

5.2. The inspection report (IR)

The inspection report should be prepared by the members of the inspection team and usually coordinated by the lead inspector or, reporting inspector in the case of CVMP requested inspections. Appendix 1 gives an example of the format for an IR of a pharmacovigilance site. This format should be used for CVMP requested inspections. For other inspections, national formats may be

used but harmonisation of content is recommended. The content of the IR should be reviewed/agreed by the members of the inspection team. For CVMP requested inspections, the IR will be signed by the lead inspector and other inspectors/expert(s) as required. Signatures may be scanned /electronic and sent to the reporting inspector, if appropriate.

The IR should be issued in a timely manner after the end of the inspection. For CVMP requested inspections, the preliminary version of the IR should be issued within 30* working days. Where a combined IR is prepared, the time is calculated from the last day of the last inspection (or from when the last post-inspection document has been received). The IR and cover letter/e-mail should be sent to the MAH by the inspectorate/NCA prior to finalisation, with a request for comments, including for example, comments on major factual errors, points of disagreement and corrective and preventive actions (CAPA). For CVMP requested inspections, the CAPA should be provided by the MAH within a defined time period of 30* working days after receiving the report, and in accordance with the dates outlined on the CVMP adopted inspection request. If a response is not received within the stipulated time frame, the absence of a reply should be recorded in the IR.

The MAH response should be assessed by the inspectors, including the impact of comments on the inspection findings, if any, and the adequacy of the proposed CAPA in accordance with the requirements of Commission Implementing Regulation (EU) 2021/1281, Article 9. For CVMP requested inspections, this assessment should be included in the final version of the IR and issued within 10* working days of receipt of the MAH response. The final adopted IR will be signed by the lead inspector and other inspectors as required by national legal requirements and national competent authority standard operating procedures (SOPs). If the proposed CAPA or the timelines of requested actions are not accepted, additional follow up action should be taken in accordance with section 6.3 of this procedure.

When the CAPA proposed by the MAH is acceptable, the inspection may be closed. For actions not completed at the time of the inspection report sign off, prior to closure of the inspection the MAH should commit in writing that all CAPA actions will be completed as scheduled. Thereafter a confirmation on inspection completion and/or any other follow up recommendation will be issued by the inspection team.

The results of pharmacovigilance inspections shall be recorded in the pharmacovigilance database as referred to in Articles 74 and 126(6) of Regulation (EU) 2019/6. For those inspections conducted under the national programme, the national inspectorate should provide with the result of the inspection, the inspection report or a summary of the inspection report when the inspection report is not written in English including any critical findings and/or major findings, and information on how these issues are being addressed (e.g. summary of the CAPA for critical and major findings). Appendix 2 provides a template for collecting information on pharmacovigilance issues for the attention of the inspectors or assessors, as applicable.

In the case of CVMP requested inspections, the report prepared by the lead inspector/ reporting inspector will be sent to the Agency Inspections Office. When the inspection of more than one site is applicable, for each site inspected, the lead inspector prepares an IR and forwards it to the reporting inspector (if different person) within 70* working days after the completion of the inspection.

The target dates for the availability of the inspection reports are agreed and stated in the inspection request adopted by the CVMP.

* The time shown should be considered as an indication and can be modified if necessary.

5.3. Content of IR

An IR template of a pharmacovigilance inspection report is provided in appendix 1. This could be used as an example for national inspection reports but should always be used for CVMP requested inspections.

The classification of inspection findings is provided in appendix 3. Each finding should refer to the regulatory requirement to which it relates.

Furthermore, comments from the inspectors may be described as appropriate.

The IR can contain an overall conclusion on whether the pharmacovigilance system complies in general or in relation to the inspected sections, with the relevant regulations within the EU or in accordance with local requirements, as appropriate.

In the case of CVMP requested inspections, the following additional points should be taken into consideration:

1. Language of the IR

This IR is prepared according to a common standard in English, unless required by local regulations to be in local language. In the latter case the IR will be translated into English under the responsibility of the lead inspector.

2. Content of the IR

The IR will contain an evaluation of the significance of any non-compliance and provide a summary of the major and critical findings. It will also contain an overall conclusion regarding compliance of the pharmacovigilance system with EU/local regulations and the potential subsequent risk for public health and especially when several sites are inspected.

Any questions related to the reports are handled by the reporting inspector, who is responsible for the necessary communication with the lead inspectors, if applicable, Agency Inspections Office, CVMP, (co)- rapporteur and the assessors.

3. Review of the format of the IR

A review of the reports is conducted on behalf of the CVMP by the Agency Inspections Office, within 5 calendar days from receiving the report. The Agency will check the format of the IR for adherence to:

- the procedures established by the PhV IWG;
- the inspection request adopted by the CVMP;
- citation of applicable regulations and guidelines.

Non-adherence(s) encountered by this review will be notified to the reporting inspectorate in writing, with a deadline for revision or other remedial action.

The reporting inspectorate shall provide a revised version or other remedial action within the timeframe agreed, and if not, an explanation for the non-adherence(s) should be provided. If the explanation for non-adherence is not agreed by the Agency, the rapporteur/co- rapporteur and CVMP will be sent the report and a document describing the point(s), as appropriate.

In the event of outstanding issues relating to non-adherence, the report, issues identified and reporting inspector explanation are circulated to the PhV IWG, for peer review, by written procedure. Seven calendar days will be allowed for response, after which the responses will be collated and appended to a final recommendation made by the Agency Inspections Office, which will be communicated to the rapporteur/co- rapporteur, CVMP and the reporting inspectorate.

4. Communication between inspectors, (co)-rapporteur and assessors

Direct communication is encouraged between the reporting inspector, the lead inspectors, (co)-rapporteur and assessors and Agency Inspections Office as early as possible in the process of preparing reports. After the reports are finalised and signed the discussion on matters such as evaluation and interpretation of findings described in the report may continue (see section 6 of this procedure).

For an overview of the timelines of CVMP requested inspections refer to Annex 2 of the Union veterinary procedure on the coordination of EU pharmacovigilance inspections.

5. Forwarding the IR to (co)-rapporteur and marketing authorisation holder/QPPV and inspection follow-up

The Agency Inspections Office will circulate the final IR to the (co)-rapporteur and thereafter to marketing authorisation holder and their QPPV. The IR conclusions should recommend any follow-up to be requested by the MAH. The conclusion should recommend further inspection or any other action, if and as considered necessary.

5.4. Record management and archiving

The principles and requirements to be followed will be described in the Union procedure on record keeping and archiving of documents obtained or resulting from the pharmacovigilance inspections.

6. Inspection follow up and inspection outcome sharing

6.1. Communication of pharmacovigilance inspection results between Member State inspectors, (co)-rapporteur and assessors

The results of the pharmacovigilance inspections shall be recorded in the pharmacovigilance database as referred to in Regulation (EU) 2019/6, Article 74 for access by the Agency, Member States national competent authority inspectors, rapporteurs and assessors.

6.2. Forwarding the IR to (co)-rapporteur and marketing authorisation holder/QPPV

The rapporteur/co-rapporteur and, if applicable, the CVMP consider the content and findings of the report and may ask for clarification or additional information from the inspection team. The Agency Inspection Office will promptly inform the reporting inspector of the need for clarifications/additional information, or any recommendation/conclusion decided at the CVMP. The Agency Inspection Office will forward the final IR to the MAH and their QPPV. In case the inspection report has been previously forwarded to the MAH directly by the reporting inspector according to national procedures the reporting inspectorate should copy EMA to keep it informed.

6.3. Follow-up of the inspection outcome

Some inspection outcomes will require follow-up due to the major and/or critical findings. The IR conclusions should recommend any follow-up action to be requested of the MAH and recommendation(s) for national competent authorities (e.g. further inspection), if and as necessary, and those should be clearly captured in the pharmacovigilance database.

Consideration should be given to whether the MAH has proposed adequate corrective action(s) to rectify the identified non-compliance and adequate preventive action(s) to eliminate the underlying

root cause of the non-compliance in order to prevent recurrence. The inspector(s) should also establish whether the MAH has undertaken a further assessment to determine the extent to which the non-compliance exists within the pharmacovigilance system and what impact it may have for all products. Action(s) proposed within a CAPA plan should be SMART (i.e. Specific, Measurable, Achievable, Realistic and Time driven), and the inspector(s) should assess whether the deliverables and timeframes specified in the CAPA plan are clear and reasonable, in accordance with Commission Implementing Regulation (EU) 2021/1281, Article 9.

The inspector(s) should seek further information and/or clarification from the MAH if the responses do not adequately address the non-compliances. This may include seeking clarification over proposed timeframes for specific actions. In this instance, consideration should be given to the seriousness of the issue, the nature of the proposed action(s) and whether any interim measures will be put in place to mitigate identified risks. The clarifications/updates required should be documented in writing and a timeframe should be proposed for the receipt of the updated responses. The number of attempts to obtain satisfactory responses should be determined by the inspector(s) using professional judgement and, where necessary, the lead/reporting inspector can request a meeting with the MAH to discuss the responses.

Upon receipt of an acceptable CAPA plan proposed by the MAH, the inspection can be closed according to national procedures. The MAH should be instructed that, if the timelines for corrective and preventive actions for critical or major findings change, or if the MAH is no longer able to implement the proposed corrective and preventive actions as intended, the lead/reporting inspector should be promptly notified. Changes to proposed corrective and preventive actions should be provided in writing to the lead/reporting inspector.

If, after further clarification has been sought, the responses to the inspection findings are not deemed acceptable, or there is persistent non-compliance this should be escalated according to national procedures or via the Agency for inspections of MAHs with CAPs. Escalation of the inspection outcome may be necessary to the CVMP's PhVWP for information and/or discussion and agreement of the most appropriate follow up action (e.g. periodic CAPA progress update reports by the MAH, submission of specific safety data for assessment, re-inspection, warning letter/enforcement action). Consultation with the concerned rapporteur/co-rapporteur will be necessary for product specific issues.

Where there are follow-up documents to be reviewed, this review should be led by the reporting inspector in conjunction with the rapporteur/co-rapporteur, the Agency's PhV inspection coordinator and the Agency's product lead, as applicable. In case the documentation to be reviewed is product specific the rapporteur/co-rapporteur may take the lead, if necessary. The reporting inspector and lead inspectors, and expert(s) if applicable, should ensure, to the extent possible, that deputies are nominated to provide input where they are not available themselves.

References

- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC
- Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products
- Guideline on Veterinary good pharmacovigilance practices (VGVP) – Module: Controls and Pharmacovigilance inspections.

- Union procedure on coordination of EU veterinary pharmacovigilance inspections
- Union recommendations on the training and experience of inspectors performing pharmacovigilance inspections.
- Union guidance on record keeping and archiving of documents obtained or resulting from pharmacovigilance inspections

Appendix 1 –Pharmacovigilance inspection report template

Click here for the template.

Appendix 2- Template for collecting information on Pharmacovigilance issues for the attention of the inspectors/assessors

Click here for the template.

Appendix 3- Classification of inspection findings

Critical: a fundamental deficiency in one or more pharmacovigilance processes or practices that represents a serious violation of applicable legislative requirements and /or guidance and/or leads to a seriously deficient pharmacovigilance system with a high level of risk to animal or public health. Critical findings require immediate action.

Remark: deficiencies classified as critical may include a pattern of deviations classified as major.

Major: a non-critical deficiency in the pharmacovigilance system, practices or processes that represents a violation of applicable legislative requirements and/or guidance and could potentially adversely influence or pose a risk to animal or public health.

Remark: deficiencies classified as major may include a pattern of deviations classified as minor.

Minor: a deficiency in the pharmacovigilance system, practices or processes that represents a deviation from applicable legislative requirements and/or guidance and would not be expected to adversely affect or pose a risk to animal or public health.

Comments and/or recommendations: Observations that might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future. This is not a deviation.