16 July 2026
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Cover note on revision of Guideline on Veterinary Good Pharmacovigilance Practices (VGVP) Module: Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files (PSMFs)

Background or context of the revision

Revision 1 of the Guideline on Veterinary Good Pharmacovigilance Practices (VGVP) Module on Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files (PSMFs) is based on pharmacovigilance inspectors experience, common inspection findings and questions and requests for clarification from marketing authorisation holders (MAHs). No concept paper was created for this revision since it does not constitute either a new guideline or a significant revision of the existing one. The scope of the public consultation is limited to the proposed changes which are provided in track-changes mode to facilitate review.

Summary of changes and explanation of revised text

Section 1. Introduction, text on applicability of the Module aligned with the text in the other VGVP Modules.

Section 2. Pharmacovigilance, text revised to provide guidance in case of Partial MAH Transfer, e.g. marketing authorisation of the same Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) is transferred at national level only in, at least, one Member State without being transferred in all CMSs, based on pharmacovigilance inspectors experience [Guidance for Management of Post-Authorisation Procedures and Pharmacovigilance Activities after Partial Marketing Authorisation Transfer at National Level Following Mutual Recognition or Decentralized Procedure or subsequent Recognition Procedure (so-called Partial MAH Transfer) makes cross-reference to inspection guidance].

Section 2.1 Qualified Person responsible for Pharmacovigilance, to provide guidance on back-up arrangements based on inspection experience and questions received by MAHs.

Section 2.2.2. Performance Indicators, to provide guidance based on inspection experience and questions received by MAHs.

Section 2.2.3 Audits, text added to clarify the requirements for the PSMF main body and respective Annex in accordance also with the published Q&A.

Section 2.2.7 Quality management system requirements for pharmacovigilance tasks contracted/subcontracted by the marketing authorisation holder, text to clarify the information expected for MAHs entities (being under same Headquarter or not) and highlight that MAH entities and

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/or third parties involved in the pharmacovigilance system should be clearly stated and roles and responsibilities should be clearly defined, including the case of co-marketing of separately authorised VMPs, which are identical in all aspects apart from their invented names.

Appendix providing additional guidance based on EU inspectors PSMF checklist and pharmacovigilance inspection experience to date. The focus is on PSMF content - mainly annexes: Annex V of the PSMF (i-iii) with the different lists (contracts, delegation of tasks, etc.) for which marketing authorisation holders requested more guidance on what to include in each Annex /list.

EUROPEAN MEDICINES AGENCY
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Guideline on veterinary good pharmacovigilance practices (VGVP)

Module: Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files (Rev 1)

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Start of public consultation	27 July 2026
End of consultation (deadline for comments)	24 September 2026

Comments should be provided using the template. The completed comments form should be sent to phvins@ema.europa.eu; cc: Vet-Guidelines@ema.europa.eu

Keywords	***Quality management system; PSMF: pharmacovigilance system master file***

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1. Introduction

This module of the guidelines on veterinary good pharmacovigilance practices (VGVP) addresses the basic requirements on the pharmacovigilance system, its integral quality management system and the pharmacovigilance system master file (PSMF) that marketing authorisation holders for veterinary medicinal products authorised in the European Union (EU) should establish and maintain.

This module is applicable to authorised veterinary medicinal products in the EU/EEA irrespective of the authorisation procedure (centralised or national authorisation, including mutual recognition, decentralised and subsequent recognition procedures) and registered homeopathic veterinary medicinal products. For the scope of this module, the responsibilities of registration holders of homeopathic veterinary medicinal products are the same as those for marketing authorisation holders. This module should be read in conjunction with 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 and Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021, in particular Article 17(5), 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.

This module should also be read in conjunction with the other modules of the guideline on veterinary good pharmacovigilance practices (VGVP), pharmacovigilance inspection procedures and national legislations, as applicable.

~~This guidance is applicable to any veterinary medicinal product in the EU, authorised via any marketing authorisation procedure including registered homeopathic veterinary medicinal products [Regulation (EU) 2019/6, Article 87(5)].~~

2. Pharmacovigilance system

According to Article 77 of Regulation (EU) 2019/6, marketing authorisation holders shall establish and maintain a system for collecting, collating and evaluating information on the suspected adverse events concerning their authorised veterinary medicinal products ('pharmacovigilance system'), enabling them to fulfil all their pharmacovigilance obligations.

The overall objectives of a pharmacovigilance system are:

promoting the safe and effective use of veterinary medicinal products, in particular through providing timely information about the safety of veterinary medicinal products and their impact to public health, animal health, animal welfare and the environment;

detecting and taking measures to prevent harm to animals and humans from adverse events and harm to the environment arising from the use of or exposure to authorised veterinary medicinal products within or outside the terms of the marketing authorisations; and

complying with the legal requirements for pharmacovigilance tasks and responsibilities.

The pharmacovigilance system of the marketing authorisation holder shall be fully functional [Commission Implementing Regulation (EU) 2021/1281, Article 2(2)(a)] and described clearly and unambiguously in the pharmacovigilance system master file [Commission Implementing Regulation (EU) 2021/1281, Article 2(2)(f)]. The marketing authorisation holder may, where appropriate, use separate pharmacovigilance systems for different categories of veterinary medicinal products [Commission Implementing Regulation (EU) 2021/1281, Article 21(3)]. For example, a single

marketing authorisation holder may establish more than one pharmacovigilance systems specific for particular types of veterinary medicinal products (vaccines, pharmaceuticals, etc.). Each such system shall be described in a separate pharmacovigilance system master file [Commission Implementing Regulation (EU) 2021/1281 Article 21(3)]. For each veterinary medicinal product, the marketing authorisation holder or marketing authorisation holders belonging to the same parent company, shall not have more than one pharmacovigilance system [Regulation (EU) 2019/6, Article 77(2)] described in a pharmacovigilance system master file. In case the PSMF also covers VMPs which were subject to a so-called Partial MAH Transfer (marketing authorisation of the same MRP/DCP/SRP VMP is transferred at national level only in, at least, one MS without being transferred in all concerned Member States (CMSs)) the respective arrangements have to be covered by the PSMFs of the different MAHs in ANNEX V unless the MAHs share the same PSMF (e.g. companies belonging to the same parent company) [For further information please see respective Guidance EMA/CMDv/240372/2023].

The marketing authorisation holder shall be responsible for the pharmacovigilance of the veterinary medicinal product(s) for which it holds a marketing authorisation and shall continuously evaluate by appropriate means the benefit-risk balance of their veterinary medicinal product(s) and, if necessary, take appropriate measures to minimize the risk. The marketing authorisation holder's risk management system consists of all procedures and processes for monitoring the benefit-risk balance of veterinary medicinal products and performing signal management and includes communication, as referred to in Articles 16 to 20 of the Commission Implementing Regulation (EU) 2021/1281. Marketing authorisation holders shall ensure continuous assessment and document the risk management measures and the outcome of risk minimisation measures in the pharmacovigilance system master file [Commission Implementing Regulation (EU) 2021/1281, Article 16(3)] for the veterinary medicinal products for which specific safety monitoring requirements exist.

Where the pharmacovigilance tasks have been contracted/subcontracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in detail in the pharmacovigilance system master file [Commission Implementing Regulation (EU) 2021/1281, Articles 21(2) and 22(3e)]. The marketing authorisation holder shall retain full responsibility for all pharmacovigilance obligations contracted/subcontracted to third parties as laid down in the Regulation (EU) 2019/6 and in the Commission Implementing Regulation (EU) 2021/1281, Article 2(7), and therefore the arrangements with third parties should cover how oversight and compliance with legal requirements can be ensured. Contracted/subcontracted person(s) or any other third party carrying out pharmacovigilance activities in whole or in part, on behalf of or in conjunction with marketing authorisation holders, shall accept to be audited by or on behalf of marketing authorisation holders.

The marketing authorisation holder shall comply with good pharmacovigilance practice for veterinary medicinal products. In addition to this Module and the Module on Controls and Pharmacovigilance Inspections, for key pharmacovigilance processes dedicated Modules are included in veterinary good pharmacovigilance practice guidance, as follows:

Module on Collection and recording of suspected adverse events for veterinary medicinal products.

Module on Signal management.

Module on Communication.

2.1. Qualified person responsible for pharmacovigilance (QPPV)

The QPPV designated by the marketing authorisation holder should have oversight of the pharmacovigilance system in terms of structure and performance and be in a position to ensure the

fulfilment of the tasks described in Article 78 of Regulation (EU) 2019/6, continuously (24/7), either directly or through delegation and supervision in accordance with Articles 77 and 78 of Regulation (EU) 2019/6. The oversight referred to above should cover the functioning of the marketing authorisation holder's pharmacovigilance system in all relevant aspects, including:

- quality control and assurance procedures;
- standard operating procedures;
- PSMF preparation and maintenance;
- database operations;
- safety reporting;
- signal management;
- post-marketing surveillance studies;
- communication to stakeholders;
- contractual/subcontractual arrangements, compliance data (e.g. in relation to the quality, completeness and timelines for safety reporting and signal management), audit reports;
- preventive or corrective action plan preparation and implementation; and
- training of personnel in relation to pharmacovigilance.

It is recognised that this role of the QPPV may impose extensive tasks on the QPPV, depending on the size and nature of the pharmacovigilance system and the number and type of veterinary medicinal products covered by the marketing authorisation holder's pharmacovigilance system. The QPPV may therefore delegate specific tasks, with appropriate oversight, to appropriately qualified and trained individuals, e.g. acting as experts on the safety aspects of certain veterinary medicinal products, provided that the QPPV maintains system oversight and overview of the safety profiles of all veterinary medicinal products. Such delegation should be documented in the PSMF. In case the QPPV has not completed veterinary surgeon training, marketing authorisation holders shall make arrangements to ensure that the QPPV is assisted by a veterinary surgeon on a continuous basis [Commission Implementing Regulation (EU) 2021/1281, Article 3(2)].

The hierarchical relationship of the QPPV shall be defined in an organisational chart together with those of other managerial and supervisory staff. In case the tasks of the QPPV are outsourced to a third party those arrangements shall be specified in detail in the contract and included in the PSMF [Regulation (EU) 2019/6, Article 77(9)].

Usually the QPPV will be designated to a single pharmacovigilance system and respective PSMF. It is acceptable for the same QPPV to provide services for more than one marketing authorisation holder, for a shared or for separate pharmacovigilance systems (e.g. in the case of subcontractor QPPV) or, if required, to fulfil the role of QPPV for more than one pharmacovigilance system of the same marketing authorisation holder, provided that the QPPV is able to fulfil duly all obligations.

Back-up arrangements that apply in the absence of the QPPV or of the veterinary surgeon, assisting the QPPV, if applicable, as referred to in Commission Implementing Regulation (EU) 2021/1281, Article 2(6), should be in place and clearly described in the PSMF. Back-up procedures should be accessible via the QPPV's usual contact details and if this is not the case, the relevant alternative contact information must also be supplied. The QPPV must ensure that, where the back-up

arrangements involve a deputy or a team, the individual(s) designated as back-up have the necessary information, training, and qualifications to undertake the role since the same responsibilities and regulatory obligations that apply to the QPPV also apply, by analogy, to the deputy.

In addition to the QPPV, the marketing authorisation holder shall designate a local or regional representative for the purpose of receiving reports of suspected adverse events who is able to communicate in the languages of the relevant Member States [Regulation (EU) 2019/6, Article 77(3)]. The local or regional representative should report to the QPPV in relation to the pharmacovigilance tasks and responsibilities. The QPPV may also act as the local representative. The marketing authorisation holder shall ensure that the QPPV has sufficient authority to influence the performance of the quality management system with regard to pharmacovigilance and the pharmacovigilance activities of the marketing authorisation holder. The marketing authorisation holder should therefore ensure that the QPPV has authority over and access to the PSMF and approves/authorises any changes to it. The authority over the pharmacovigilance system and the PSMF allows the QPPV to implement changes to the system as well as to initiate regulatory action in response to emerging safety concerns. Furthermore, the marketing authorisation holders shall ensure that there is an appropriate procedure in place to identify and deal with any conflicts of interest of the QPPV [Commission Implementing Regulation (EU) 2021/1281, Article 2(3)].

When a marketing authorisation holder intends to expand its veterinary medicinal product portfolio, for example by acquisition of another company or by purchasing individual marketing authorisations from another marketing authorisation holder, the QPPV should be notified well before the transfer of pharmacovigilance activities in order to ensure that the potential impact on the pharmacovigilance system can be assessed and the system can be adapted accordingly. The QPPV should be involved in determining what pharmacovigilance data is to be requested from the other marketing authorisation holder, either pre- or post-acquisition. In this situation, the QPPV should review the sections of the contractual arrangements that relate to responsibilities for pharmacovigilance activities and safety data exchange (either as part of a general template or on a case by case) and have the authority to request amendments.

When a marketing authorisation holder intends to establish a partnership with another marketing authorisation holder, organisation or person that has a direct or indirect impact on the pharmacovigilance system, the QPPV should be informed in sufficient time to allow for required changes to the pharmacovigilance system to be made and be involved in the preparation of the corresponding contractual arrangements so that all necessary provisions relevant to the pharmacovigilance system are included to enable the QPPV to fulfil the responsibilities listed in Article 78 of Regulation (EU) 2019/6.

2.2. Quality management system

Marketing authorisation holders shall establish and use quality management systems that are adequate and effective for the performance of their pharmacovigilance activities.

Quality management system means a formalised system that provides for comprehensive processes, procedures, and responsibilities for achieving quality policies and objectives to coordinate and direct an organisation's activities and improve its effectiveness and efficiency in this regard on a continuous basis [Commission Implementing Regulation (EU) 2021/1281, Article 1(a)].

While there has to be compliance with these legal requirements, the implementation of a quality system should be adapted to the respective organisation. The application of the quality system should be adapted to how crucial each pharmacovigilance task is for fulfilling the objectives for each

veterinary medicinal product covered by a pharmacovigilance system. The quality system shall be based on all the following activities [Commission Implementing Regulation (EU) 2021/1281, Article 4(6)]:

- Quality planning: establishing structures and planning integrated and consistent processes.
- Quality adherence: carrying out tasks and responsibilities in accordance with quality requirements.
- Quality control and assurance: monitoring and evaluating how effectively the structures and processes have been established and how effectively the processes are being carried out.
- Quality improvements: correcting and improving the structures and processes where necessary.

Processes to monitor the performance and effectiveness of a pharmacovigilance system and its quality system include:

- reviews of the systems by those responsible for management;
- audits;
- compliance monitoring;
- inspections;
- evaluating the effectiveness of actions taken with veterinary medicinal products for the purpose of minimising risks and supporting their safe and effective use.

The quality management system shall be described in the pharmacovigilance system master file [Commission Implementing Regulation (EU) 2021/1281, Article 4]. Relevant documents include:

- documents on assignment of roles, responsibilities and authorities to all personnel directly involved in pharmacovigilance tasks;
- job descriptions defining the duties of the managerial and supervisory staff;
- training plans and records;
- instructions for the compliance management processes;
- appropriate instructions on the processes to be used in case of urgency, including business continuity;
- performance indicators where they are used to continuously monitor the good performance of pharmacovigilance activities;
- reports of audits and follow-up audits, including their dates and results;
- the methods of monitoring the efficient operation of the quality system and, in particular, its ability to fulfil the quality objectives;
- records to demonstrate that deficiencies and deviations from the established quality system are monitored, that corrective and preventive actions have been taken, that solutions have been applied to deviations or deficiencies and that the effectiveness of the actions taken has been verified.

2.2.1. Written procedures

An essential element of any pharmacovigilance system is that there are clear written procedures in place. The quality management system shall include detailed policies, processes and procedures, documented in the PSMF, for at least, but not necessarily limited to, pharmacovigilance activities listed in Chapter 4 of Commission Implementing Regulation (EU) 2021/1281:

1. Initial recording of suspected adverse event.
2. Collection of additional data.
3. Collation of reports of suspected adverse events and additional data.
4. Data handling other than mentioned in points (1) to (3) of this list.
5. Evaluation of data.
6. Monitoring the quality, integrity and completeness of all information registered in the pharmacovigilance system including, but not restricted to, the information reported to the Union pharmacovigilance database and management of duplicates.
7. Recording of adverse event in the Union pharmacovigilance database.
8. Archiving of all relevant documents.
9. Risk management system including processes for:
    - 9.1. signal management [Commission Implementing Regulation (EU) 2021/1281, Article 17];
    - 9.2. continuous monitoring of the benefit-risk balance of veterinary medicinal products [Commission Implementing Regulation (EU) 2021/1281, Articles 18 and 19];
    - 9.3. overarching communication plan [Commission Implementing Regulation (EU) 2021/1281, Article 20].
10. Document management system [Commission Implementing Regulation (EU) 2021/1281, Article 5].
11. Training [Commission Implementing Regulation (EU) 2021/1281, Article 6].
12. Audit [Commission Implementing Regulation (EU) 2021/1281, Article 8].

In each area, the marketing authorisation holder should be able to provide evidence of a system that supports appropriate and timely decision making and action. The list of written procedures should also be available and should comprise the procedural document reference number, title, effective date and document type (for all standard operating procedures, work instructions, manuals, etc.) and details on how the procedures can be accessed. Procedures belonging to service providers and other third parties should be clearly identified. Documents relating to specific local/country procedures need not be listed, but a list may be requested on a per country basis.

2.2.2. Performance indicators

The organisation shall use relevant performance indicators [Commission Implementing Regulation (EU) 2021/1281, Article 7] to continuously monitor the performance of pharmacovigilance activities in relation to the quality requirements in accordance with legislation and guidance. The items of information that can be collected at regular intervals to track the performance of the system should be realistic and measurable, such as submission timeliness or quality of reports / reports free of errors.

~~A~~Section E of the PSMF should include a high level description of the performance indicators used to continuously monitor the performance of pharmacovigilance activities and the outcome of risk minimisation measures whereas Annex 4, point (iii) of the PSMF should include a list with further details on the ~~list of these~~ performance indicators, including the reason why they have been chosen, if applicable, and a description on how to use them. Results of (actual) performance measurements should be ~~included in Section E.3 of the PSMF~~available, either as part of the Annex or upon request, to evidence continuous monitoring and that the respective corrective and preventive action process is initiated if the performance indicators are not met.

2.2.3. Audits

Marketing authorisation holders shall perform audits of the pharmacovigilance system at regular risk-based intervals to ensure that it complies with the requirements set out in Commission Implementing Regulation (EU) 2021/1281 and to determine the pharmacovigilance system effectiveness. Audits of the pharmacovigilance system should ensure that it complies with the legal requirements, the human resource management, the compliance management, the record management and data retention and to ensure its effectiveness. A report shall be drawn up on the results for each audit and any follow-up audits and these shall be sent to the QPPV and management responsible for the matters audited, as applicable, to ensure that management cooperates with the QPPV to address the findings. The report should include the results of audits of organisations or persons the marketing authorisation holder has delegated tasks to, as these are part of the marketing authorisation holder's pharmacovigilance system. The risk-based audit schedule and the report on each audit and follow-up audit, including their dates and results shall be documented in Section E and Annex 4 of the PSMF, as applicable. The process for risk-based planning shall be described and the rationale documented in the PSMF [Commission Implementing Regulation (EU) 2021/1281 Article 8(3)]. Section E should include a list of audits associated with unresolved critical or major findings, for which the due date to implement the corrective and preventive action plan (CAPA) has already passed.

Annex 4 of the PSMF should include a more comprehensive list of scheduled and completed audits, including critical and major findings for which the due date to implement the CAPA has not passed yet (outstanding critical and major findings). The list of completed audits should cover a period of five years as associated corrective and preventative actions shall be documented for the last 5 years in accordance with Commission Implementing Regulation (EU) 2021/1281 Article 9(1).

Contracted/subcontracted person(s) or any other third party carrying out pharmacovigilance activities in whole or in part, on behalf of or in conjunction with marketing authorisation holders, shall accept to be audited by or on behalf of marketing authorisation holders [Commission Implementing Regulation (EU) 2021/1281, Article ~~6~~8(2)].

2.2.4. Corrective and Preventive Action Plan

The marketing authorisation holder's corrective and preventive action plan shall document in writing a robust, effective and useful process systematically addressing and minimizing identified risks or defects. It shall be clear and precise and address timelines for action [Commission Implementing Regulation (EU) 2021/1281, Article 9]. Marketing authorisation holders shall monitor the implementation and assess the effectiveness of corrective and preventive actions. If there are changes associated with the corrective and preventive actions, those changes shall be evaluated and be part of a controlled process of change (change management) and communicated to relevant stakeholders.

In particular as a consequence of audits, corrective action(s), including a follow-up audit on deficiencies identified, shall be taken where necessary. Additionally, corrective and preventive actions should be drawn for non-compliance identified during inspections by the competent authorities aiming at monitoring the compliance of marketing authorisations holders with legally required pharmacovigilance tasks and responsibilities. Associated corrective and preventive actions shall be documented for the last 5 years.

2.2.5. Training of personnel for pharmacovigilance

Achieving the required quality for the conduct of pharmacovigilance processes and their outcomes by an organisation is intrinsically linked with the availability of a sufficient number of competent and appropriately qualified and trained personnel.

All personnel involved in the performance of pharmacovigilance activities shall receive initial and continued training [Commission Implementing Regulation (EU) 2021/1281, Article 6(1)]. For marketing authorisation holders, this training shall relate to the roles and responsibilities of the personnel.

The organisation shall keep training plans and records for documenting, maintaining and developing the competences of personnel [Commission Implementing Regulation (EU) 2021/1281, Article 6(2)]. Training plans should be based on training needs assessment and should be subject to monitoring.

The training should support continuous improvement of relevant skills, the application of scientific progress and professional development and ensure that staff members have the appropriate qualifications, understanding of relevant pharmacovigilance requirements as well as experience for the assigned tasks and responsibilities. All staff members of the organisation should receive and be able to seek information about what to do if they become aware of a safety concern.

There should be a process in place within the organisation to check training results in the appropriate levels of understanding and conduct of pharmacovigilance activities for the assigned tasks and responsibilities, or to identify unmet training needs, in line with professional development plans agreed for the organisations as well as the individual staff members.

Adequate training should also be considered by the organisation for those staff members to whom no specific pharmacovigilance tasks and responsibilities have been assigned but whose activities may have an impact on the pharmacovigilance system or the conduct of pharmacovigilance. Such activities include but are not limited to those related to clinical trials, technical product complaints, medical information, sales and marketing, regulatory affairs, legal affairs and audits.

Appropriate instructions on the processes to be used in case of pharmacovigilance-related urgency, including business continuity, shall be provided by the organisation to their personnel.

2.2.6. Document management system

The organisation shall record all pharmacovigilance information and ensure that it is handled, stored, saved and archived to allow accurate reporting, interpretation and verification of that information.

A document management system shall be put in place for all documents related to pharmacovigilance activities, ensuring their retrievability as well as traceability of the measures taken to investigate safety concerns, of the timelines for those investigations and of decisions on safety concerns, including their date and the decision-making process. The document management system referred to in Article 5 of Commission Implementing Regulation 2021/1281 shall include a record management system for

receiving, recording, collating and assessing information on adverse events [Commission Implementing Regulation 2021/1281, Article 10(1)].

All information technology (IT) systems, (electronic) storage spaces and record management systems including database systems used as part of pharmacovigilance activities should be located, designed, constructed, adapted and maintained to suit their intended purpose in line with the quality objectives for pharmacovigilance. These systems should be subject to appropriate checks, qualification and/or validation activities to prove their suitability for the intended purpose. Evidence on validation status of the system(s) used should be available upon request, if applicable. There should be appropriate structures and processes in place to ensure that pharmacovigilance data and records are protected from destruction during the applicable record retention period.

As part of a record management system, specific measures should be taken at each stage in the storage and processing of pharmacovigilance data to ensure data security, integrity and confidentiality. This should involve strict limitation of access to records and to databases to authorised personnel respecting the confidentiality of the data. For systems critical for the conduct of pharmacovigilance it should be ensured to build into the system the creation of a record of all pharmacovigilance data changes and deletions (a system generated "audit trail"). For change or deletion of pharmacovigilance data the reason should be documented. Audit trails need to be available.

2.2.7. Quality management system requirements for pharmacovigilance tasks contracted/subcontracted by the marketing authorisation holder

Where a marketing authorisation holder has contracted/subcontracted part or all of its pharmacovigilance tasks, it shall retain full responsibility for ensuring that an effective quality management system is applied in relation to those tasks. All legislative and guidance requirements are also applicable to the other organisation (third party) to which the tasks have been contracted/subcontracted even if it is located outside the EU.

When contracting/subcontracting tasks to a third party, the marketing authorisation holder shall conclude contract(s) with the third party and these should be detailed, up-to-date and clearly document the allocation of tasks and responsibilities between the marketing authorisation holder and the third party. A description of the contracted/subcontracted activities and/or services and a list of the contracts with contractors/subcontractors, specifying the veterinary medicinal product(s) and territory(-ies) concerned, shall be included in the PSMF [Commission Implementing Regulation (EU) 2021/1281, Article 22(3)(e)(iii)]. The third party may be subject to inspection at the discretion of the competent or supervisory authority in the relevant Member State depending on the location of the contractor/subcontractor organisation and /or the tasks and responsibilities delegated to them.

Contractual arrangements should be prepared with the aim of enabling compliance with the legal requirements by each party involved. The third party may not subcontract any task assigned to it by the marketing authorisation holder without the marketing authorisation holder’s written consent. When preparing contractual arrangements, the marketing authorisation holder should include sufficiently detailed descriptions of the delegated tasks, the related interactions and data reconciliation, together with, for example, agreed definitions, tools, assignments and timelines. The contractual arrangements should also contain clear information on the practical conduct of the outsourced tasks, including those for the maintenance of pharmacovigilance databases, if applicable. Further, they should indicate which processes are in place for verifying whether the agreed arrangements are being adhered to on an ongoing basis. In this respect, e.g. regular risk-based audits of the third party by the marketing

authorisation holder are required. In cases of contractual arrangements between MAHs in relation to co-marketing of separately authorised VMPs, which are identical in all aspects apart from their invented names, these arrangements should include measures to avoid the duplicate submission of adverse events to EudraVigilance Veterinary (EVVet). Where aspects of the system such as the organisational arrangements are particular to the product rather than the main system of the MAH/company this should also be indicated in the relevant PSMF Annexes, as applicable.

2.3. Pharmacovigilance system master file (PSMF)

2.3.1. Summary of the pharmacovigilance system master file

Article 8(1)(c) of Regulation EU 2019/6 requires a summary of the applicant's pharmacovigilance system master file to be included in the marketing authorisation application, which, in accordance with Article 23 of Commission Implementing Regulation 2021/1281, shall include the following elements:

- The pharmacovigilance system master file reference number.
- The pharmacovigilance system master file location.
- Name, contact details and place of operation of the QPPV.
- A signed statement from the marketing authorisation holder and the QPPV that the QPPV has the necessary means to fulfil the tasks and responsibilities requested by Regulation (EU) 2019/6.
- The type of record management system used for adverse events reports including the name of the database, if applicable.

At the time of the granting of a marketing authorisation, the information from the summary of the applicant's pharmacovigilance system master file (QPPV name, contact details and location, PSMF reference number and location) will be stored in the Union product database and communicated to the Union pharmacovigilance database by means of the interconnection as foreseen in Article 74(2) of Regulation (EU) 2019/6. Information on all pharmacovigilance system master files must be registered in the database and while each PSMF and QPPV will be linked to one or more veterinary medicinal products, each product authorised under Regulation (EU) 2019/6 should be linked to a single PSMF and the respective designated QPPV.

Marketing authorisation holders shall ensure that the entries in the Union product database for veterinary medicinal products are always up-to-date, including the information about the QPPV, name and contact details (telephone numbers for continuous availability, email address, postal address and operational location of the QPPV) and PSMF reference number and location information. Upon a change in any of the information in the summary of the applicant's pharmacovigilance system master file, the relevant variation not requiring assessment [Regulation (EU) 2019/6, Article 61] shall be submitted to the database in accordance with the list provided in the Annex of Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council and within 30 days following the implementation of that variation. Readily available up to date information will facilitate identification of the competent authorities of the Member States responsible to carry out inspections of the pharmacovigilance system master files located in their Member State and any changes to those (i.e. the Supervisory Authorities, see the VGVP Module on Controls and Pharmacovigilance Inspections, section 2.3).

Each PSMF can be declared only in one location in the applicant's summary of pharmacovigilance system master file and subsequently in the Union product database and this single location should be registered as part of controlled organisation data. The address of the location of the PSMF provided should be a physical office address which reflects either the site in the EU where the main pharmacovigilance activities of the marketing authorisation holder are performed or the site where the QPPV operates. This address may be different to that of the applicant/marketing authorisation holder, for example it may be a different office of the marketing authorisation holder or the address of a third party undertaking the main activities. Where the PSMF is held in electronic form, the location stated must be a site where the data stored can be directly accessed, and this is sufficient in terms of a practical electronic location. When determining the main site of pharmacovigilance activity, the marketing authorisation holder should consider the most relevant EU site for the pharmacovigilance system since the relative importance of particular activities may vary according to the veterinary medicinal products and fluctuate in the short term. The marketing authorisation holder should have an appropriate rationale for the location decision. In the situation where the main activities take place outside the EU, or where a main site cannot be determined, the location should default to the site where the QPPV operates. If one PSMF covers the veterinary medicinal products of more than one marketing authorisation holders (e.g. different subsidiaries of one parent company act as marketing authorisation holder and are all covered by one PSMF) the Summary of the pharmacovigilance system master file should list all marketing authorisation holders concerned.

2.3.2. Pharmacovigilance system master file content

The PSMF is a legal requirement in the EU and is applicable for any veterinary medicinal product authorised in the EU, irrespective of the marketing authorisation procedure. The required content and management of the PSMF in accordance with the Commission Implementing Regulation (EU) 2021/1281 applies irrespective of the organisational structure of a marketing authorisation holder, including any contracting/subcontracting or delegation of activities, or their location. Irrespective of the location of other activities, the QPPV's residence, the location at which he/she carries out his/her tasks and the PSMF location must be within the EU. Following European Economic Area (EEA) agreements, the QPPV may also reside and operate in Norway, Iceland or Liechtenstein. The content of the pharmacovigilance system master file should reflect availability of global safety information for veterinary medicinal products authorised in the EU, presenting information on the pharmacovigilance system applied at global, regional and national level, as applicable. The content shall be indexed to allow for efficient navigation in the document and follow the structure described in the Commission Implementing Regulation (EU) 2021/1281, Article 22, on the format and content of the pharmacovigilance system master file. The PSMF shall describe the pharmacovigilance system in place at the current time.

The PSMF shall consist of a main part and Annexes containing the information described in the Commission Implementing Regulation (EU) 2021/1281, Article 22, and as shown in Table 1. The sections in the main part of the PSMF should be self-sufficient and contain information that is fundamental for the description of pharmacovigilance system whereas the corresponding Annexes should include supplementary information for each section that may change frequently. Changes in main part of the PSMF (Section A-F) should be listed in the logbook in Annex 1, whereas changes in the Annexes should not be covered in the logbook (see 2.3.3.).

Table 1. PSMF content overview

PSMF section	Main Part	Annexes
Information on the PSMF	Section A	Annex 1 – Logbook
QPPV, Assisting veterinary surgeon, and back up procedures	Section B	Annex 2
Marketing Authorisation holder information	Section C	Annex 3
Document management system (including record management system for adverse event recording)	Section D	
Quality management system for pharmacovigilance activities	Section E	Annex 4
Contractual arrangements between marketing authorisation holders and third parties concerning pharmacovigilance activities	Section F	Annex 5

2.3.3. Pharmacovigilance system master file location, availability and maintenance

The requirements for the location, availability and maintenance of the PSMF are provided in Article 79(6) of Regulation (EU) 2019/6 and in Articles 24 and 25 of the Commission Implementing Regulation (EU) 2021/1281.

Where a pharmacovigilance system is shared by several marketing authorisation holders each marketing authorisation holder is responsible ensuring that the common PSMF describes adequately the pharmacovigilance system applicable for its own products. When pharmacovigilance activities are shared between marketing authorisation holders it is advised that the partners agree on how to mutually maintain the relevant sections within their own pharmacovigilance system master files. Accessibility of the PSMF to all the applicable marketing authorisation holder(s), and its provision to competent authorities should be defined in written agreements. It is vital that marketing authorisation holder(s) can gain assurance that the pharmacovigilance system used for its veterinary medicinal products is appropriate and compliant.

According to Article 24(3) of Commission Implementing Regulation 2021/1281 the PSMF itself shall be subject to version control and indicate the date(s) when it was last updated. Any alteration to the content of the main part of the PSMF made within the last 5 years shall be recorded in a logbook, indicating

- the changed section;
- the kind of change;
- the date of change;
- the person responsible for the change;
- where appropriate, the reason for the alteration [Commission Implementing Regulation (EU) 2021/1281, Article 24(4)].

Changes to the information in the Annexes do not need to be tracked in the form of a logbook and version control should be adjusted to the type of information. For example, information in the Annexes of the PSMF that is being regularly updated, such as veterinary medicinal product lists or compliance

figures, may include outputs from controlled systems (such as electronic document management systems or regulatory databases). The information and superseded versions of such content may be managed outside of the PSMF content itself, provided that the history of changes is maintained and available to competent authorities and the Agency on request. Marketing authorisation holders need to ensure that the obligations concerning the timely provision of an up-to-date PSMF can be met. [Regulation (EU) 2019/6, Article 79 (6), Commission Implementing Regulation (EU) 2021/1281, Articles 21(1) and 24(5)].

Definitions

Please refer to the VGVP Glossary for relevant definitions.

Appendix 1

This appendix provides practical guidance on the content of the Pharmacovigilance System Master File (PSMF) for veterinary medicinal products in accordance with Commission Implementing Regulation (EU) 2021/1281 and specifically with Article 22 and is intended to support Marketing Authorisation Holders (MAHs), Qualified Persons Responsible for Pharmacovigilance (QPPVs), and regulatory authorities in ensuring compliance with regulatory requirements.

Deviations should be avoided and if necessary, they should be clearly explained and duly justified.

Table 2 below provides an overview of the pharmacovigilance system master file (PSMF) sections /annexes and corresponding information.

Table 2. PSMF sections /annexes and corresponding information

PSMF Part Section/ Annex	Requirement	Reference
Main part **Section A**	General Information: PSMF reference number (allocated by the QPPV) PSMF location The address of the location of the PSMF should be a physical office address which reflects either the site in the EU where the main pharmacovigilance activities of the marketing authorisation holder are performed or the site where the QPPV operates. Version The PSMF shall be subject to version control and indicate the date when it was last updated The name of the concerned MAH(s) (list of MAHs sharing the pharmacovigilance system), as applicable. The list of PSMFs for the MAH (concerning products with a different pharmacovigilance system), if applicable.	IR Art 22 (2.a) IR Art 22 (2.a) VGVP QMS 2.3.1 IR Art 25 (1) IR Art 24 (3)
Main part **Section B**	QPPV QPPV, including name, contact details and a signed statement from the MAH and the QPPV confirming that the QPPV concerned has the necessary means to fulfil the tasks and responsibilities required by Regulation (EU) 2019/6; Veterinary surgeon Arrangements concerning the veterinary surgeon referred to in Article 3(2), applicable when the QPPV has not completed	IR Art 22 (2.b)

PSMF Part Section/ Annex	Requirement	Reference
	veterinary surgeon training, including the assistant veterinary surgeon contact details. Back -up A description of the back-up arrangements of the QPPV and the veterinary surgeon.	
Main part **Section C**	Organisational structure Detailed description of the organisational structure of the marketing authorisation holder, including a parent company or group of companies associated. This should include organizational chart showing parent/group of companies, departments, as applicable, and reporting lines. Description of QPPV's position in organisation hierarchy (e.g. reports directly to Head of Regulatory Affairs) should also be included.	IR Art 22 (2.C)
Main part **Section D**	Document Management System Description of the document management system, including archiving and access/retrievability during retention period. IT systems Description of the information technology (IT) systems, (electronic) storage spaces and record management systems including database systems used. Validation Description of the checks, qualification and/or validation activities to prove the suitability of the IT systems for the intended purpose. Data security Description of how data security, integrity and confidentiality is ensured. Record management system Description of the record management system for receiving, recording, collating and assessing information on adverse events; including: (a) type of record management system used for adverse event reports, including the name of the database used, if applicable; (b) location where the record management system is kept;	IR Art 22 (2.d) IR Art 5 IR Art 22 (2.d) IR Art 5, Art 10 VGVP QMS 2.2.6

PSMF Part Section/ Annex	Requirement	Reference
	(c) description of functionality of the record management system; (d) operational responsibility of the personnel responsible for the record management system; (e) summary of the assessment of its fitness for purpose. Information on system security, access limitations, retention periods, and audit trail functionality must be provided to demonstrate compliance with regulatory standards.	
Main part **Section E**	Quality Management System description: Adverse Event (AE) management A description of the processes used for (a) initial recording of any suspected adverse event; (b) collection of additional data; (c) collation of reports of suspected adverse events and additional data; (d) data handling other than mentioned in points (a) to (c); (e) evaluation of data; (f) monitoring of quality, integrity and completeness of all information registered in the pharmacovigilance system including information reported to the Union pharmacovigilance database and management of duplicates; (g) recording of any adverse event in the Union pharmacovigilance database; (h) archiving of all relevant documents. Risk and signal management A description of the processes used for risk management, monitoring of the benefit-risk balance, signal management and communication to all relevant stakeholders. PSMF maintenance A description of the processes used for the maintenance and availability of the pharmacovigilance system master file. Training Description of the training management system	IR Art 22 (2.e)i) IR Art 22 (2.e)i) IR Art 16(1) IR Art 22 (2.e)i) IR Art 22 (2.e)ii)

PSMF Part Section/ Annex	Requirement	Reference
	Archiving Description of the system used for documenting or archiving information, including the use of version control, as appropriate Performance indicators A description of the system for monitoring the performance of the pharmacovigilance activities and the outcome of risk minimisation measures. Audit A description of the responsibilities for quality assurance auditing (risk-based intervals, cover all pharmacovigilance activities, contracted partners). Open findings A list of audits associated with unresolved critical or major findings. CAPA A description of the corrective and preventive action plan management and change management in place and monitoring and assessing the effectiveness of these.	IR Art 22 (2.e)iii) IR Art 22 (2.e)iv) IR Art 22 (2.e)v) IR Art 22 (2.e)vi) IR Art 22 (2.e)vii)
Main part **Section F**	**Contractual Arrangements**: A description of the contractual arrangements concerning pharmacovigilance activities.	**IR Art 22 (2.f)**
Annexes **Annex I**	Logbook Any alteration to the content of the main part of the PSMF made within the last 5 years shall be recorded in a logbook, indicating • the changed section; • the kind of change; • the date of change; • the person responsible for the change; • where appropriate, the reason for the alteration	IR Art 22 (3.a) IR Art 24(4) VGVP QMS 2.3.3
Annex II (Section B)	Curriculum vitae	IR Art 22 (3.b)

PSMF Part Section/ Annex	Requirement	Reference
	Curriculum vitae includes information on qualifications and training of the qualified person responsible for pharmacovigilance and, if applicable, the assistant veterinary surgeon. Job description A description of the tasks and responsibilities of the qualified person responsible for pharmacovigilance Proof of registration Proof of registration with the pharmacovigilance database. Delegated activities A list of the pharmacovigilance activities that have been delegated by the qualified person responsible for pharmacovigilance to third parties.	
Annex III (Section C)	List of products A list of all veterinary medicinal products covered by the pharmacovigilance system master file, including the international non-proprietary name (INN) of the active substances, if applicable, the Member States in which the product is authorised or registered, the type of procedure for authorisation and the authorisation numbers in each Member State where the product is authorised. Where applicable, if the list includes veterinary medicinal products authorised or registered outside the EU/EEA, it should preferably allow filtering between EEA and non-EEA products. This ensures that all products can be viewed for adequate oversight while also enabling region-specific review. This aspect should be considered when selecting the list format. Other PSMF(s) A list of reference numbers for other pharmacovigilance system master files held by the same marketing authorisation holder, where applicable. Local representatives A list of local or regional representatives for the purpose of receiving reports of suspected adverse events, including their contact details, responsibilities and territories, where applicable. Sites	IR Art 22 (3.c)

PSMF Part Section/ Annex	Requirement	Reference
	A list of the sites where pharmacovigilance activities are carried out: document management, training, audits, change management, recording and management of AE's, risk-management, monitoring of the benefit-risk balance, signal management and communication to all relevant stakeholders, maintenance and availability of the pharmacovigilance system master file.	
Annex IV (Section E)	Standard Operating Procedures (SOPs) A list of documents, policies, procedures and processes used for the pharmacovigilance activities: document management, training, audits, change management, recording and management of AE's, risk management, monitoring of the benefit-risk balance, signal management and communication to all relevant stakeholders, maintenance and availability of the pharmacovigilance system master file.	IR Art 22 (3.d)i)
	Audits A list of all scheduled and completed audits including outstanding critical and major findings.	IR Art 22 (3.d)ii) IR Art 8
	Performance indicators A list of the performance indicators (monitor the performance of pharmacovigilance activities and the outcome of risk minimisation measures) including the reason why they have been chosen and a description on how to use them. It is recommended to keep results of (actual) performance measurements as evidence of compliance with this requirement.	IR Art 22 (3.d)iii) IR Art 7 IR Art 22 (3.d)iv)
	Training Information on training plans and records for pharmacovigilance activities and a reference to their location.	IR Art 6 (2) IR Art 22 (3.d)v)
	Factor The methodology to calculate the factor for each of the veterinary medicinal products covered by the PSMF according to country, target species and pack size. According to the posology of the product, the factor will determine how many animals can be treated with one package of a given pack size, regardless of the formulation. The Agency shall publish guidance on the mathematical formula to calculate the factor. Marketing authorisation holders shall record their assumptions on distribution of sales per target species and treatment regimen per target species that they use for the calculation of the factor in the	IR Art 14 (2) IR Art 14 (3)

PSMF Part Section/ Annex	Requirement	Reference
	pharmacovigilance system master file. Marketing authorisation holders shall update the factor, when necessary. Risk management measures A list of risk management measures and the outcome of risk minimisation measures.	IR Art 22 (3.d)vi)
Annex V (Section F)	Contractual arrangements Service providers A list of the activities or services subcontracted by the marketing authorisation holder to third parties to fulfil pharmacovigilance obligations and information on who the activities or services are subcontracted to, including the name and address any subcontractors, where applicable. QPPV activities A list of the tasks of the qualified person responsible for pharmacovigilance referred to in Article 78 of Regulation (EU) 2019/6 that have been totally or partially outsourced and the information on who the activities or services are subcontracted to, including the name and address of the subcontractor(s), where applicable. Partners A list of existing contracts and agreements with third parties, where applicable, including the products and territories concerned.	IR Art 22 (3.e)i) IR Art 22 (3.e)ii) IR Art 22 (3.e)iii)

Section C – Organisation of the Marketing Authorisation Holder

- The organisational structure of the MAH must be fully and clearly presented, preferably including an organisational chart that identifies parent company or group of companies associated, as applicable, relevant departments, subsidiaries, and reporting lines relating to pharmacovigilance activities.
- In situations where multiple national MAHs operate within a global structure and share one PSMF, Section C must explicitly list all national MAHs covered by the PSMF. A generic statement such as "several MAHs share this PSMF" is not sufficient. The signed statement per MAH entity in section B does not replace the need for a comprehensive list.
- The description must delineate the operational interface between global and local PV functions, clarifying roles, responsibilities, and communication pathways.
- Contact details of the national MAHs or affiliates involved in pharmacovigilance should be included where applicable.

- The section should deliver a full, self-contained description of how the PSMF applies to the different organisational entities and thus reference to other documents or procedures should be avoided.

Annex IV (Linked to Sections D and E) – Quality Management System Documentation and Performance Information

- The performance indicators should be a way to continuously monitor the pharmacovigilance system and ensure operational efficiency and regulatory compliance.
- The methodologies for monitoring pharmacovigilance performance indicators shall be described, including the list of the performance indicators, the reason why they have been chosen, if applicable, a description on how to use them and the confirmation that the respective corrective and preventive action is initiated if the key performance indicator is not met.
- Results of (actual) performance measurements should be available, either as part of the Annex or upon request, to evidence continuous monitoring and that the respective corrective and preventive action process is initiated if the key performance indicators are not met.
- This is separate from the audit contact and follow up.

Lists and Use of Links within the PSMF

- All lists contained within the PSMF and its annexes (e.g., product listings, representatives, subcontractors, training records, audits) must be maintained in formats that enable clarity, comprehension, filterability, and search functionality, as necessary and applicable. Such maintenance supports effective system oversight and facilitates regulatory compliance.
- The QPPV must ensure that these lists are periodically reviewed, verified for accuracy, and updated as needed, with appropriate version control, to reflect the current state of the pharmacovigilance system.
- For documents/information required in the PSMF main part and annexes in accordance with Commission Implementing Regulation 2021/1281, any hyperlinks embedded within the main Part or annexes must direct to documents provided within or submitted alongside the PSMF when the reviewer has no access to the content/system linked.
- Where electronic document management systems are employed, it is essential to provide downloadable or printable versions of referenced documents together with the PSMF.