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Annual report of the Pharmacovigilance Inspectors Working Group for 2025

Adopted by the PhV IWG on 01 October 2026



List of Abbreviations

ADR	Adverse drug reactions
AE	Adverse Event
CAP	Centrally Authorised Product
CAPA	Corrective And Preventive Actions
CHMP	Committee for Medicinal Products for Human Use
CVMP	Committee for Veterinary Medicinal Products
DWH	Data Warehouse
EEA	European Economic Area
EU	European Union
EVCTM	EudraVigilance Clinical Trial Module
EVDAS	EudraVigilance Data Analysis System
EVPM	EudraVigilance Post-Authorisation Module
EV-Vet	EudraVigilance-Veterinary
GCP	Good Clinical Practices
GVP	Good Pharmacovigilance Practices
ICSR	Individual Case Safety Report
KPI	Key Performance Indicators
MAH	Marketing Authorisation Holder
MS	Member State
NCA	National Competent Authority
PhV IWG	Pharmacovigilance Inspectors Working Group
PhVWP-V	Pharmacovigilance Working Party (Veterinary Medicinal Products)
PIC	Pharmaceutical Inspection Co-operation Scheme
PRAC	Pharmacovigilance Risk Assessment Committee (Human Medicinal Products)
PSMF	Pharmacovigilance System Master File
QMS	Quality Management System
QPPV	Qualified Person responsible for Pharmacovigilance
VGVP	Guideline on Veterinary Good Pharmacovigilance Practices

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1. Introduction

This document is the sixteenth annual report of the Pharmacovigilance Inspectors Working Group (PhV IWG). The PhV IWG was established by the European Medicines Agency (hereinafter "the Agency") within the scope of Article 57(1)(i) of Regulation (EC) No 726/2004. Following a report on its first year of operation, the PhV IWG [mandate](#) was endorsed by the Heads of Medicines Agencies on 18-19 May 2009 and by the Agency's Management Board on 1 October 2009, thereby formally establishing the PhV IWG.

The PhV IWG focuses on the harmonisation and coordination of pharmacovigilance-related activities at EU (hereinafter the "Union") level. The group's role and activities are described in more detail in its [work plan](#). The group supports the coordination of the provision of pharmacovigilance inspection-related advice and provides a link to other groups such as the Committee for Medicinal Products for Human Use (CHMP), the Committee for Veterinary Medicinal Products (CVMP), the Pharmacovigilance Risk Assessment Committee (Human Medicinal Products) (PRAC), and the Pharmacovigilance Working Party (Veterinary Medicinal Products) (PhVWP-V).

This annual report for 2025 has been drawn up in line with the format and objectives of the [2024-2026 work plan](#).

2. Meetings

The plenary meetings, involving pharmacovigilance inspectors working with human medicinal products and pharmacovigilance inspectors working with veterinary medicinal products, were held on the following dates:

- 06-07 March 2025 (virtual meeting);
- 05-06 June 2025 (hybrid meeting);
- 25-26 September 2025 (hybrid meeting);
- 13 November 2025 (virtual meeting).

Meetings included a joint session of relevance to both human and veterinary matters, and two separate sessions which dealt with human and veterinary matters separately.

A hybrid meeting between industry stakeholder representatives for veterinary medicinal products, the Pharmacovigilance Working Party (PhVWP-V) and the PhV IWG was held at EMA on 21 May 2025.

On 26 September 2025 part of the PhV IWG plenary meeting was dedicated to a meeting with industry stakeholder representatives for human medicinal products. In addition, several virtual meetings took place using teleconferencing or equivalent settings:

- For human medicinal products: *ad hoc* presentations on pharmacovigilance inspection topics have been delivered to the PRAC meetings, as necessary.
- For veterinary medicinal products: *ad hoc* presentations on pharmacovigilance inspection topics were organised for the PhVWP-V meetings, as necessary.

3. Pharmacovigilance inspections relating to centrally authorised medicinal products

3.1. General overview

For human medicinal products, the CHMP with input from the PRAC and in conjunction with the competent authority of the Member State in whose territory the pharmacovigilance system master file is located (hereafter known as the supervisory authority) and the inspectors' working group, have created and maintained a programme for inspection in relation to CAPs, in accordance with GVP Module III on pharmacovigilance inspections and the Union procedure on the coordination of EU pharmacovigilance inspections.

For veterinary medicinal products, the CVMP supported by the Pharmacovigilance Working Party, in conjunction with the supervisory authority and the inspectors' working group, have created and maintained a programme for inspection in relation to CAPs, in accordance with VGVP Module on Controls and pharmacovigilance Inspections and the Union procedure on the coordination of veterinary pharmacovigilance inspections.

The inspections covered by these programmes are prioritised based on the potential risk to public health, the nature of the products, the extent of use, the number of products that the MAH has on the EEA market and other risk factors listed in GVP Module III on pharmacovigilance inspections and VGVP Module on Controls and pharmacovigilance Inspections.

The focus of these inspections is to determine whether the MAH has the personnel, systems, and facilities in place to meet its regulatory pharmacovigilance obligations for CAPs in the EEA. These inspections are requested as system inspections with one or more specific products selected as examples, for which specific information can be traced and verified through the various processes. This provides practical evidence for the functioning of the MAH's pharmacovigilance system in the Union and its compliance with the regulatory requirements.

In general, it is anticipated that national inspection programmes will fulfil the need for the routine inspections included in this programme and therefore it is expected that the inspection programme is achieved mainly through the national programmes. However, there are situations where these inspections might be specifically requested by the CHMP or CVMP, as applicable (e.g. global pharmacovigilance sites in third countries; additional sites within the Union are identified for inspection and require joint inspections involving the Member State concerned by that site and the supervisory authority). For-cause inspections are also reflected in this programme as they may replace the need for routine inspections.

Since September 2022, the coordination of pharmacovigilance inspections requested by EMA's committees for human and veterinary medicines under the centralised procedure has been managed through the IRIS platform, a secure online platform for handling product-related scientific and regulatory procedures, that EMA launched in 2018, as part of EMA's digital transformation programme.

The project to redesign the procedure for preparing and maintaining the risk-based programme for routine pharmacovigilance inspections of MAHs of CAPs for both human and veterinary medicines, launched in 2024, was finalised in 2025.

The results presented in Tables 1 and 2 show, respectively, the number of inspections conducted in relation to the human and veterinary pharmacovigilance inspection programmes in 2025, broken down by the type of site inspected.

Table 1 - Human pharmacovigilance inspections conducted in 2025 in the context of the programme for the pharmacovigilance inspection of companies with CAPs

2025	QPPV/PSMF (MAH) site	Global PhV site	Subcontractor/ Licensing partner/affiliate site	Total
CHMP requested	2	0	5	7
National inspection programmes	42	0	10	52
Total	44	0	15	59

Table 2 - Veterinary pharmacovigilance inspections conducted in 2025 in the context of the programme for the pharmacovigilance inspection of companies with CAPs

2025	QPPV/PSMF (MAH) site	Global PhV site	Subcontractor/ Licensing partner/affiliate site	Total
CVMP requested	2	0	1	3
National inspection programmes	3	0	0	3
Total	5	0	1	6

3.2. Categorisation of findings for CHMP requested inspections conducted in 2025

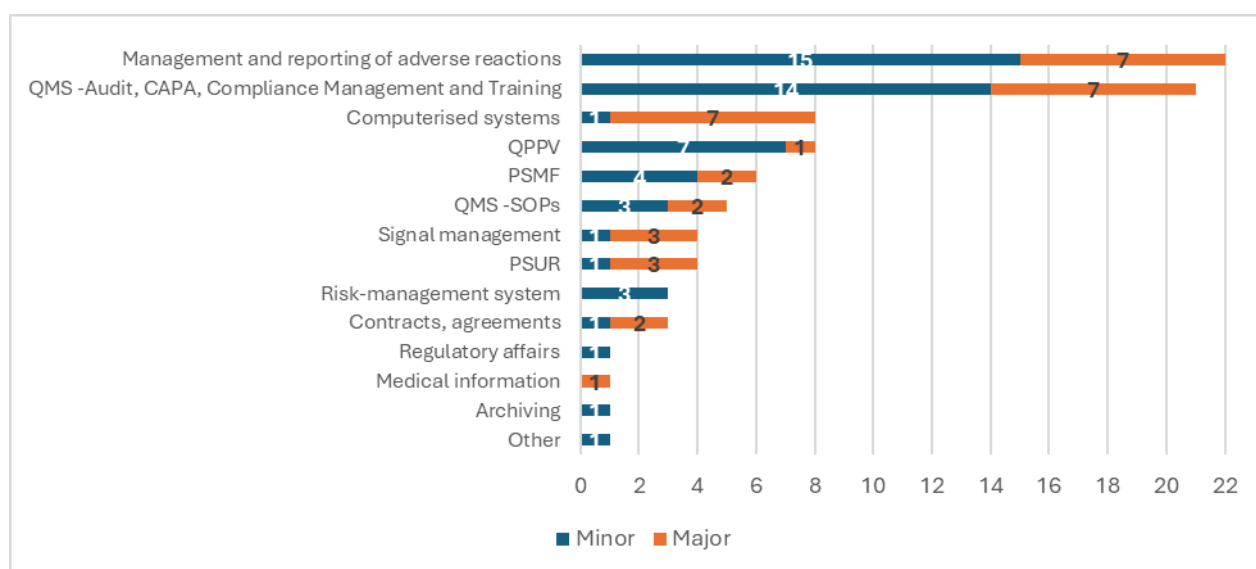
A total of 88 deficiencies, comprising 0 critical, 35 major (39.8%) and 53 minor (60.2%) findings were recorded for the CHMP requested human medicines pharmacovigilance inspections conducted in 2025 (period covered from 01/01/2025 until 31/12/2025).

The main findings observed during inspections conducted in 2025 are detailed in Figure 1 in accordance with the categorisation of pharmacovigilance inspection findings agreed by the PhV IWG.

The three most common areas with findings identified during inspections conducted in 2025 were the following:

- Management and reporting of adverse reactions;
- Quality Management System (QMS);
- Computerised systems.

Figure 1 - Number of findings related to the main categories graded as critical, major, and minor for CHMP requested inspections conducted in 2025



A total of 22 findings were identified in the area of management and reporting of adverse reactions. Of these, seven were classified as major findings, related to quality control process, submissions and follow-up processes, assessment of seriousness, causality and expectedness, medical review and MedDRA coding, as well as the receipt of Individual Case Safety Reports (ICSRs) from all sources and their collation at a single point within the EU.

The remaining fifteen findings were classified as minor and were associated mainly with the submission and follow-up processes, and the rest with literature screening, quality control process, medical review and MedDRA coding, as well as the receipt of ICSRs from all sources and collection and collation at a single point within the EU.

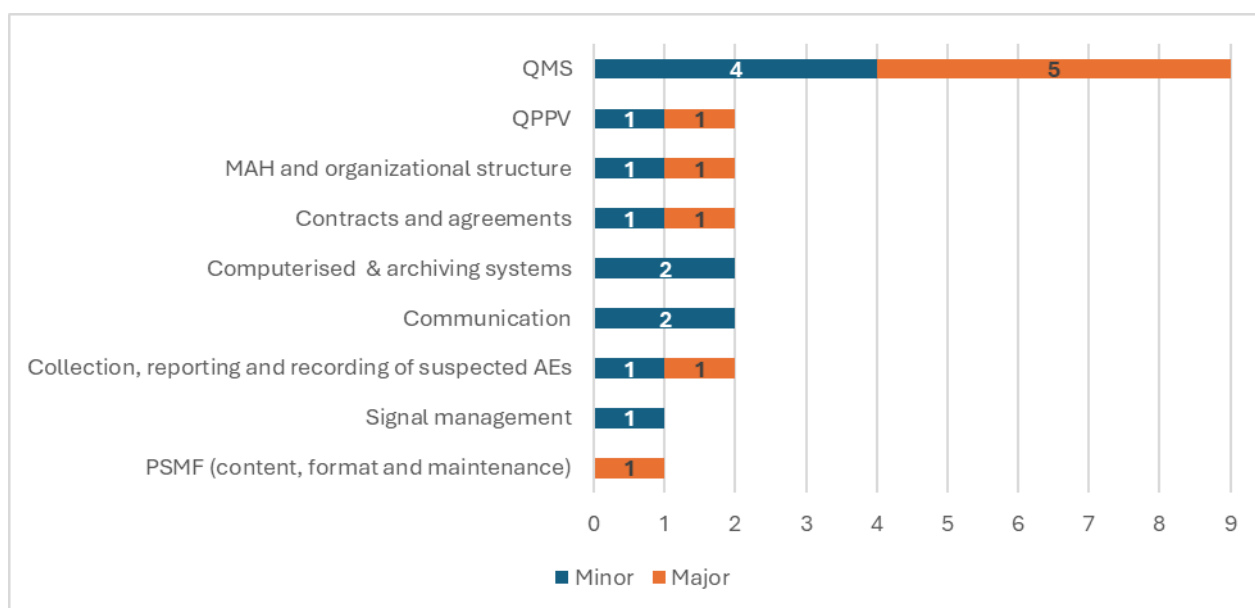
3.3. Categorisation of findings for CVMP requested inspections conducted in 2025

A total of 23 deficiencies, comprising 0 critical, 10 major (43.48%) and 13 minor (56.52%) findings were recorded for the CVMP requested veterinary medicines pharmacovigilance inspections conducted in 2025 (period covered from 01/01/2025 until 31/12/2025).

The main findings observed during inspections conducted in 2025 are detailed in Figure 2 in accordance with the categorisation of pharmacovigilance inspection findings agreed by the PhV IWG.

The most common area with findings identified during inspections conducted in 2025 was Quality Management System (QMS).

Figure 2 - Number of findings related to the main categories graded as critical, major, and minor for CVMP requested inspections conducted in 2025



QMS deficiencies represented the most frequently cited inspection findings, accounting for a total of nine findings. Of these, five were classified as major findings, including three related to audit and CAPA processes and two related to document management systems. The remaining four were classified as minor findings, comprising two related to training, one related to KPIs, and one related to document management systems.

4. Harmonisation topics

4.1. Human pharmacovigilance legislation

To support further harmonisation for the mutual recognition of pharmacovigilance inspections within the Union and in connection with human medicinal products, in 2025 the group was involved in the revision of the:

- [GVP Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks](#)
- [GVP Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance](#)
- [GVP Product- or population-specific considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk](#)

4.2. Implementation of the new veterinary pharmacovigilance legislation

To support the implementation of the new pharmacovigilance legislation and in connection with veterinary medicinal products in 2025 the group continued supporting the development of pharmacovigilance compliance monitoring reports for inspectors.

The group was also involved in the revision of existing guidance and Q&A:

- Guideline on veterinary good pharmacovigilance practices (VGVP) Module on Pharmacovigilance systems, their Quality Management Systems and pharmacovigilance system master files (ongoing)
- [Veterinary pharmacovigilance inspections: Q&As](#)

4.3. Joint inspections

From the total of 7 CHMP pharmacovigilance site inspections conducted in 2025, 5 inspections were joint inspections involving more than one MS (see Table 1 in Section 3).

The 3 CVMP pharmacovigilance site inspections conducted in 2025 were joint inspections involving more than one MS (see Table 2 in Section 3).

4.4. Training and development

A hybrid Pharmacovigilance Inspectors' Working Group training course took place, 27-28 November 2025. The training organisation was supported by the programme committee Germany (BVL), Denmark (Danish Medicines Agency) and Austria (AGES). Participants included inspectors and assessors from both veterinary and human units of Member States (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Iceland, Italy, Latvia, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden) as well as inspectors, assessors/experts from non-EU countries (Albania, Australia, Azerbaijan, Barbados, Brazil, Bosnia and Herzegovina, Canada, Moldova, Montenegro, Mozambique, Peru, Republic of North Macedonia, Serbia, Thailand, Türkiye, Ukraine, UK).

- Key objectives of the training:
 - to promote awareness and better understanding of legislation and/or guidance, as applicable, with focus on good pharmacovigilance practices (GVP) and Union procedures on

pharmacovigilance inspections and their implementation in relation to human medicinal products;

- to promote awareness and better understanding of the New Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/1281) and guidance, as applicable, and its implementation in relation to veterinary medicinal products;
 - to share experiences from inspections (human and veterinary) conducted by individual MS to promote further harmonisation of inspection approaches and sharing best practices;
 - to build understanding, promote further interaction between assessors and inspectors and improve the coordination of inspection and the verification of pharmacovigilance compliance.
- The following topics were presented and/or discussed in the human and veterinary medicinal products related workshops:
 - Signal management;
 - Special features of big and small companies and their inspection.
 - The following topics were presented and/or discussed in the human medicinal products related workshops:
 - Guideline on good pharmacovigilance practices (GVP) Module XVI – Risk minimisation measures – implementation of Rev 3;
 - Guideline on good pharmacovigilance practices (GVP) Module II - Pharmacovigilance System Master File (PSMF) findings and harmonisation of expectations;
 - Extended EudraVigilance medicinal product dictionary (XEVMPD);
 - Harmonisation in grading of findings.
 - The following topics were presented and/or discussed in the veterinary medicinal products related workshops:
 - Signal management process & EudraVigilance Veterinary Data Warehouse (EV-Vet DWH);
 - PSMF expectations and harmonisation of findings;
 - Harmonisation in grading of findings.

4.5. Medicinal products for human use

- The PhV IWG has prepared and is maintaining the risk-based programme for routine pharmacovigilance inspections of MAHs related to human CAPs.
- Pharmacovigilance inspectors also provided recommendations to the PRAC in relation to pharmacovigilance inspections or related assessment issues.
- During the PhV IWG meetings held in 2025, discussions on the following topics took place:
 - Revision of the PhV IWG work plan for 2024-2026;
 - Sharing and discussion of inspection report findings;
 - Sharing of pharmacovigilance inspection information;
 - Development of peer review of case studies;

- EudraVigilance and EudraVigilance Data Analysis System (EVDAS);
- Digital Business Transformation - EMA inspection coordination;
- Risk-based inspection planning;
- Use of automation and AI applications in pharmacovigilance;
- Queries on guidance/legislation interpretation;
- PIC/S activities in the field of PhV inspections (GVP Best Practices and Artificial Intelligence-Machine Learning Working Groups).
- During the stakeholder meeting in 2025, discussions on the following topics took place:
 - Inspection and information sharing;
 - PSMF Expectations and harmonisation;
 - Harmonisation of data points to be included in routine ICSR line listings generated for inspections;
 - Inspection of AI.

4.6. Medicinal products for veterinary use

- The PhV IWG has prepared and is maintaining the risk-based programme for routine pharmacovigilance inspections of MAHs related to veterinary CAPs. These programmes (human and veterinary) are not publicly available as they contain confidential information.
- During the PhV IWG meetings held in 2025, discussions on the following topics took place:
 - Revision of the PhV IWG work plan for 2024-2026;
 - Regulation (EU) 2019/6 on veterinary medicinal products, corresponding implementing and delegated acts and guidance, as applicable;
 - Development of peer review of case studies;
 - Sharing and discussion of inspection report findings;
 - EV-Vet DWH;
 - Digital Business Transformation - EMA inspection coordination;
 - Risk-based inspection planning;
 - Use of automation and AI applications in pharmacovigilance;
 - Queries on guidance/legislation interpretation;
 - PIC/S activities in the field of PhV inspections (GVP Best Practices and Artificial Intelligence-Machine Learning Working Groups).
- During the Pharmacovigilance Working Party (PhVWP-V)-PhV IWG Interested Parties meeting held in 2025, inspectors shared the experiences gained from pharmacovigilance inspections performed under the new veterinary Regulation (EU) 2019/6.

5. Liaison with other groups

5.1. Interaction with the PRAC

- The PhV IWG interacted with assessors on topics related to:
 - Issues identified during inspections and follow-up, as necessary;
 - Preparation and maintenance of the risk-based programme for routine pharmacovigilance inspections of MAHs connected with human CAPs.

5.2. Interaction with the CVMP Pharmacovigilance Working Party

- The PhV IWG interacted with assessors on topics related to:
 - Regulation (EU) 2019/6 on veterinary medicinal products, corresponding implementing and delegated acts and guidance, as applicable;
 - Updates on inspections planned and conducted;
 - Follow-up of pharmacovigilance inspections;
 - Preparation and maintenance of the risk-based programme for routine pharmacovigilance inspections of MAHs connected with veterinary CAPs.

5.3. Communication with the public and external bodies

- Delegates from the PhV IWG have participated and/or given presentations on behalf of the group in different European conferences and meetings covering different topics of public interest:
 - DIA Global Forum for QPPV, Amsterdam 19-20 November 2025;
 - EudraVigilance Expert Working Group (EV-EWG) on an *ad hoc* basis as additional domain experts on pharmacovigilance areas of common interest to the PhV IWG and EV-EWG;
 - PIC/S meetings: GVP Best Practices and Artificial Intelligence-Machine Learning Working Groups.