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Annual report of the Pharmacovigilance Inspectors' Working Group for 2024

Adopted by the PhV IWG on 25 September 2025

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List of Abbreviations

ADR	Adverse drug reactions
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 (DHW)
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 fifteenth 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 [H]), and the Pharmacovigilance Working Party (Veterinary Medicinal Products) (PhV WP [V]).

This annual report for 2024 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:

- 07-08 March 2024 (virtual meeting);
- 13-14 June 2024 (hybrid meeting);
- 26-27 September 2024 (virtual meeting);
- 21-22 November 2024 (hybrid 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.

On 22 November 2024 part of the plenary meeting was dedicated to a meeting with industry stakeholder representatives.

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, extent of use, 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.

In 2024, a project was launched to revamp the procedure for preparing and maintaining the risk-based programme for routine pharmacovigilance inspections of MAHs of CAPs for both human and veterinary medicines.

The results presented in Tables 1 and 2 show the number of inspections conducted in relation to the human and veterinary pharmacovigilance inspection programmes for 2024, respectively, and split by the type of site inspected.

Table 1 - Human pharmacovigilance inspections conducted in 2024 in the context of the programme for the pharmacovigilance inspection of companies with CAPs

2024	QPPV/PSMF (MAH) site	Global PhV site	Subcontractor/ Licensing partner/affiliate site	Total
CHMP requested	7	0	3	10
National inspection programmes	45	1	3	49
Total	52	1	6	59

Table 2 - Veterinary pharmacovigilance inspections conducted in 2024 in the context of the programme for the pharmacovigilance inspection of companies with CAPs

2024	QPPV/PSMF (MAH) site	Global PhV site	Subcontractor/ Licensing partner/affiliate site	Total
CVMP requested	4	0	1	5
National inspection programmes	2	0	0	2
Total	**6**	**0**	**1**	**7**

3.2. Categorisation of findings for CHMP requested inspections conducted in 2024

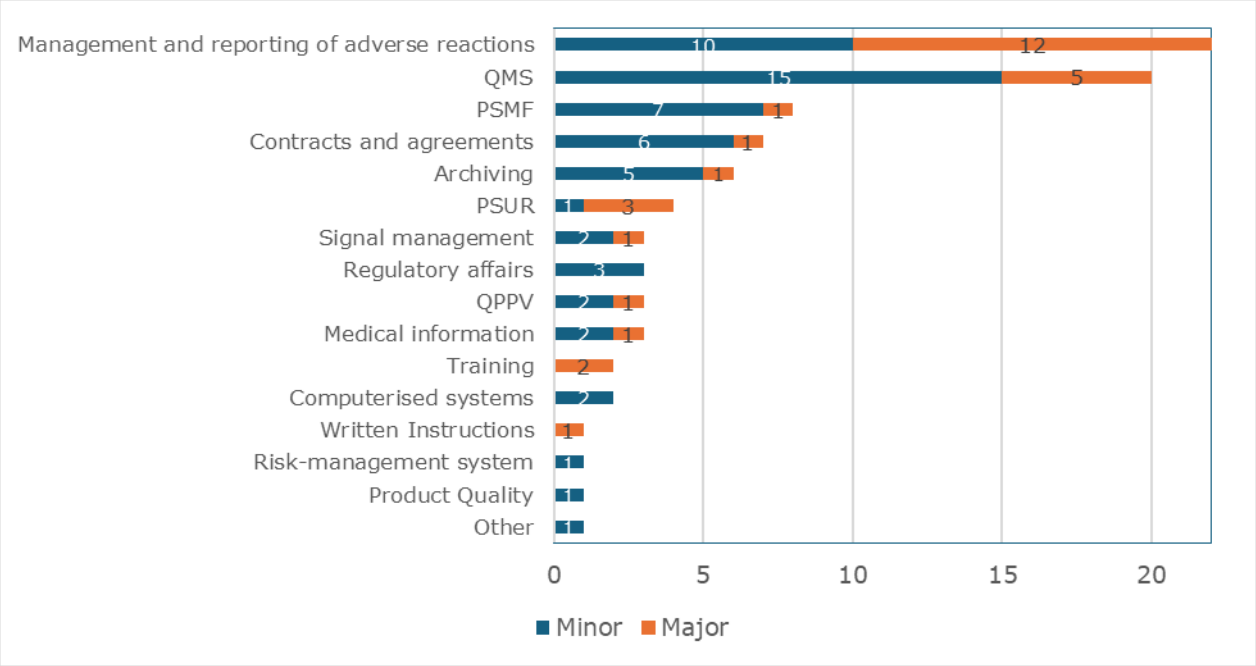
A total of 87 deficiencies, comprising 0 critical (0%), 29 major (33.33%) and 58 minor (66.67%) findings were recorded for the CHMP requested human medicines pharmacovigilance inspections conducted in 2024 (period covered from 01/01/2024 until 31/12/2024).

The main findings observed during inspections conducted in 2024 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 2024 were the following:

- Management and reporting of adverse reactions
- QMS
- PSMF

Figure 1 - Number of findings related to the main categories graded as critical, major, and minor for CHMP requested inspections conducted in 2024



In 2024, a total of 22 findings were identified in the area of adverse reaction management and reporting. Of these, twelve were classified as major findings: three related to submission and follow-up processes, two to medical review and MedDRA coding, two to literature screening, and two to the receipt and collation of ICSRs from all sources at a single collection point within the EU.

The remaining ten findings were classified as minor and were associated mainly (3 findings) with the submission and follow-up processes, and the rest are in the following categories: literature screening and the receipt and collation of ICSRs from all sources at a single point within the EU.

3.3. Categorisation of findings for CVMP requested inspections conducted in 2024

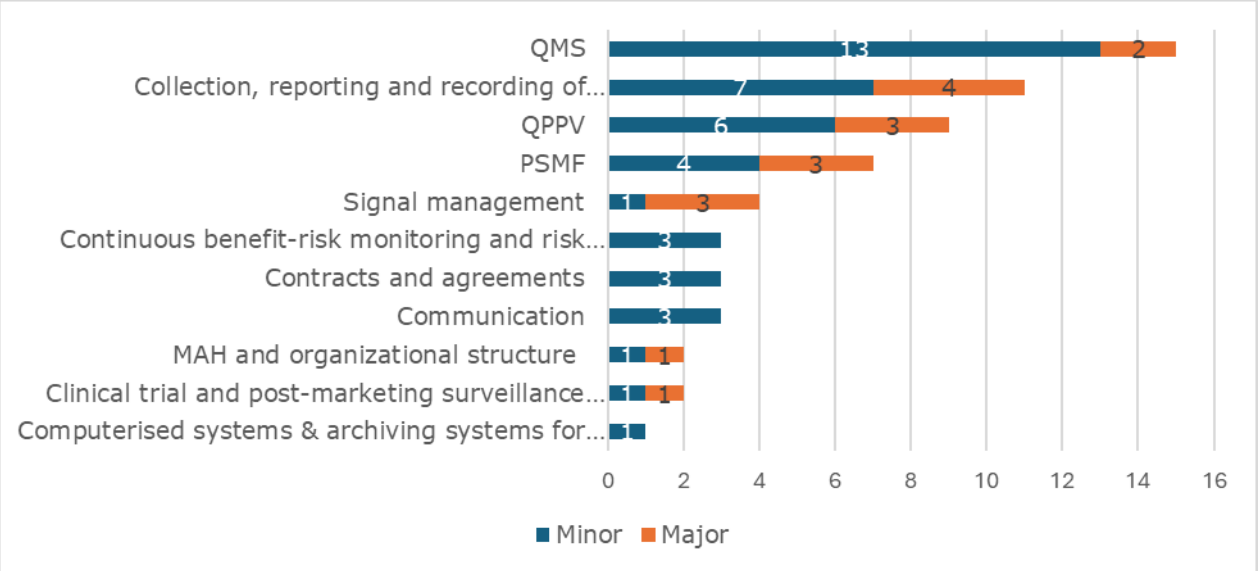
A total of 60 deficiencies, comprising 0 (0%) critical, 17 major (28.33%) and 43 minor (71.67%) findings were recorded for the CVMP requested veterinary medicines pharmacovigilance inspections conducted in 2024 (period covered from 01/01/2024 until 31/12/2024).

The main findings observed during inspections conducted in the 2024 are detailed in Figure 2 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 2024 were the following:

- QMS
- Collection, reporting and recording of suspected adverse events
- QPPV

Figure 2 - Number of findings related to the main categories graded as critical, major, and minor for CVMP requested inspections conducted in 2024



In 2024, a total of 15 findings were identified within the Quality Management System (QMS). Of these, two were classified as major findings, specifically related to the Audit and CAPA processes, as well as written instructions (such as SOPs and manuals). The remaining 13 findings were considered minor. Among these, three were associated with the Audit and CAPA processes, three with the Document Management System, three with SOPs, three with Training, and one with key performance indicators (KPIs).

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 2024 the group was involved in the revision of the:

- Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level.
- GVP Module XVI – Risk minimisation measures (Rev 3) and its new Addendum II.

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 2024 the group continued working on the development of pharmacovigilance compliance monitoring reports for inspectors.

4.3. Joint inspections

From the total of 10 CHMP pharmacovigilance site inspections conducted in 2024, 4 inspections were joint inspections involving more than one MS (see Table 1 in Section 3).

From the total of 5 CVMP pharmacovigilance site inspections conducted in 2024, 2 inspections were joint inspections involving more than one MS (see Table 2 in Section 3).

4.4. Training and development

No Pharmacovigilance Inspectors Working Group training course took place during 2024.

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 recommendation(s) to the PRAC in relation to pharmacovigilance inspections or related assessment issues.
- During the PhV IWG meetings held in 2024, 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;

- Use of automation and AI in pharmacovigilance;
- Risk-based inspection planning;
- 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 2024 discussions on the following topics took place
  - Inspection findings: harmonisation and information sharing;
  - Pre-inspection requests guidance/simplification;
  - PSMF Expectations;
  - Expectations for the "intracompany" PV agreements;

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 2024, 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;
  - EudraVigilance -Veterinary (EV-Vet) and Data Warehouse (DWH);
  - Digital Business Transformation - EMA inspection co-ordination;
  - Risk-based inspection planning;
  - Queries on guidance/legislation interpretation;
  - PIC/S activities in the field of PhV inspections (GVP Best Practices and Artificial Intelligence-Machine Learning Working Groups).

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:

- 2024 KIDS-APEC PV Coed Training, South Korea 05 - 06 September 2024;
- DIA Global Forum for QPPV, Amsterdam 05 - 07 November 2024;
- 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.