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Human Medicines Division

Work plan for the Pharmacovigilance Inspectors' Working Group for 2024-2026

Name of Working Party:	**Pharmacovigilance Inspectors Working Group (PhV IWG)**
Chairperson:	Calogero Cannavo’
Vice chair:	n/a

Work plan period: June 2024 – December 2026 (Revision of the 2021 -2024 work plan)

The Pharmacovigilance Inspectors' Working Group (PhV IWG) was established by the European Medicines Agency (EMA) within the scope of Article 57(1)(i) of Regulation (EC) No. 726/2004 and its mandate was endorsed by the Heads of Medicines Agencies and the EMA Management Board in 2009, thereby formally establishing the PhV IWG. It is a group comprising pharmacovigilance inspectors working with human medicinal products (H) and pharmacovigilance inspectors working with veterinary medicinal products (V).

The PhV IWG focuses on the harmonisation and coordination of pharmacovigilance related activities at the EU level.

The current three-year rolling workplan is the revision of 2021-2024 workplan considering the current activities of the PhV IWG and the role of the group towards the goals and recommendations of the European medicines regulatory network (EMRN) strategy to 2025. Activities/objectives in each section appear in order of priority (high to low and short/medium to long term objectives) and the domain of the activity, human (H) and/or veterinary (V) medicinal products is shown when necessary.

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1. Strategic goals:

- Harmonisation and coordination of pharmacovigilance inspection related activities at EU level ***RSS Goal 2: Driving collaborative evidence generation —improving the scientific quality of evaluations*** **(HV)**
- Strengthen the link with (pharmacovigilance) assessors; diversify and integrate the inspection process and compliance management along the product lifecycle. ***RSS Goal 1. Catalysing the integration of science and technology in medicines development*** **(HV)**
- Develop capacity building opportunities for inspectors from the EU/EEA as well as countries outside the EU/EEA and contribute to information sharing international initiatives and international initiatives, including joint inspections, as applicable. ***RSS Working together: international regulatory science cooperation*** **(HV)**
- Provide expert support to PhV inspection related matters and in relation to the implementation of the Veterinary Regulation (EU) 2019/06 **(V)**
- Maintain a close link and two-way dialogue with other groups such as CHMP, PRAC, CVMP and its PhV WP, GCP IWG, GMP/GDP IWG, CMDh, CMDV, etc. in areas of common interest. ***RSS Goal 1. Catalysing the integration of science and technology in medicines development*** **(HV)**
- Develop external engagement and communication to promote trust and confidence in the EU regulatory system and compliance monitoring ***RSS Goal 3. Advancing patient-centred access to medicines in partnership with healthcare systems*** **(H)**
- Develop new and improved communication and engagement channels and methods to reach out to stakeholders. ***RSS Goal 2. Driving collaborative evidence generation - improving the scientific quality of evaluations*** **(V)**
- Disseminate and exchange knowledge, expertise, and innovation across the network and to stakeholders. ***RSS Goal 4. Enabling and leveraging research and innovation in regulatory science*** **(HV)**
- Develop an understanding of, and regulatory response to new technologies and materials in pharmaceuticals and integrate this into the pharmacovigilance inspection process. ***RSS Goal 1. Catalysing the integration of science and technology in medicines development*** **(HV)**

2. Tactical goals: activities/projects to deliver the strategic goals

- PhV IWG – Pharmacovigilance Risk Assessment Committee (PRAC) assessors' interaction
  - Organise a Workshop/session between safety/pharmacovigilance assessors and inspectors.
  - Discuss the methods for inspection of risk management plan implementation and measurement of effectiveness of risk minimisation measures.
  - Prepare a joint action plan (inspectors/ assessors) to target specific studies for inspection, and potentially collaborate with GCP inspectors, to gain experience on inspection of PASS/PAES. Based on the lessons learnt, develop a process for future triggered inspections on PASS/PAES, guidance documents, and training material.
- Continue supporting the implementation of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6) in close collaboration with the Agency's Veterinary department and stakeholders (development of good pharmacovigilance guidelines, training on new ways of working and topics of interest).
- Liaise with assessors, the GCP and GMDP IWGs on the following topics:
  - Transparency of inspections and inspection outcomes.
  - Personal data protection.
  - Pharmacovigilance inspection in the benefit-risk evaluation and a uniform system of non-compliance follow-up (harmonise escalation of follow-up actions).
- Engage with the EU NTC, EU network and stakeholders, as appropriate, to identify experts/trainings and events and make an action plan to
  - keep inspectors aware of new technologies and latest IT tools and equip EU inspectors and assessors with the skills and relevant tools to inspect and assess new technologies;
  - inform and train the group on the latest developments on big data, Member States' uptake of electronic health records, registries, genomics data, and secure data availability.

2.1. Guideline activities:

- Concerning human medicinal products, the group will focus on
  - the revision of GVP Module I on Pharmacovigilance systems and their quality systems, as necessary;
  - the revision of GVP Module II on the Pharmacovigilance system master file, as necessary;
  - Union guidance on pre-authorisation pharmacovigilance inspections;
  - guidance on triggers for inspection, the inspection request process and conduct of PASS/PAES pharmacovigilance inspections;
  - contribution to the development of questions and answers (Q&A) on topics of interest, as necessary.

- Concerning veterinary medicinal products, the group will focus on
  - good pharmacovigilance guidance on pharmacovigilance inspections and pharmacovigilance system master file revision and related topics to support the implementation of the new Veterinary Regulation 2019/6;
  - Union procedure on the coordination of veterinary pharmacovigilance inspections;
  - the revision and drafting of Union procedures, as applicable;
  - contribution to the development of questions and answers (Q&A) on topics of interest, as necessary.

2.2. Training activities:

- Conduct a Pharmacovigilance Inspectors' training course with the participation of EU/EEA and third-country inspectors to promote training, harmonisation, and capacity building for the EU and the global network.
- Training on new and improved tools used by inspectors, as required:
  - EudraVigilance (EV) and EudraVigilance data analysis system (EVDAS)/data warehouse training for pharmacovigilance inspectors (human and veterinary).
  - Extended EudraVigilance medicinal product dictionary (XEVMPD) and the generation and use of Article 57/XEVMPD reports for human medicinal products pharmacovigilance inspectors, as necessary.
  - Organise expert presentations and information days to equip EU inspectors and assessors with the skills and relevant tools to inspect and assess new technologies, as required.
- Develop training for Assessors on PhV inspections.
- Develop a basic online course for pharmacovigilance inspectors.
- Maintain close communication with pharmacovigilance assessors and facilitate training and workshops for inspectors and assessors, including the *ad-hoc* attendance of assessors at PhV IWG meetings and of inspectors at PRAC (for specific topics, MAH/product[s]).
- Develop opportunities for lectures/workshops in the margins of PhV IWG meetings, on specialised topics, by members of the group and by invited guests, including interaction with industry on topics of common interest.
- Training on new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database. (V)
- Training and discussion on new technologies — such as veterinary practice management systems and mobile phone apps — to increase the reporting rates of adverse events. (V)
- Follow up on the proposals for training within the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S Working Group[s] [WGs]) on GVP Best Practices and Artificial Intelligence — Machine Learning (AI-ML) in accordance with the agreed mandate.

2.3. Communication and Stakeholder activities:

- Develop a communication plan with stakeholders aiming to

- raise awareness on the work of the PhV IWG, inspection outcomes, and inspection follow-up;
- communicate new requirements and developments;
- discuss topics of common interests (risk management plan implementation and measurement of effectiveness of risk minimisation measures, pharmacovigilance, and social media);
- Improve communication of veterinary pharmacovigilance to the general public. (V)

2.4. Cross-domain activities:

- Maintain a dialogue with the inspectors of good clinical practice (GCP) and good manufacturing practice (GMDP) on topics of common interest or areas of shared expertise to be proposed by the PhV IWG members.

3. Operational goals: medicinal product-specific activities

Pharmacovigilance inspections are conducted to ensure that requirements for monitoring the safety of medicines are met. The pharmacovigilance inspections scope covers the MAH pharmacovigilance system (fully or partly depending on the type of inspections) and any relevant product specific issues, as applicable. A strong link between pharmacovigilance inspectors and assessors is essential especially for pharmacovigilance inspection planning and inspection outcome follow-up (*see section 3.2*).

3.1. Pre-Authorisation activities

Discuss pre-authorisation pharmacovigilance inspections, triggers, process, and inspection follow-up between PhV IWG, CHMP and PRAC assessors, as necessary.

3.2. Evaluation and supervision activities

- Implementation and improvements of the risk-based programme for routine pharmacovigilance inspections of marketing authorisation holders of human and veterinary centrally authorised products (CAPs).
- For cause inspections at the request of the scientific committees for human and/or veterinary medicinal products (PRAC, CHMP and CVMP).
- Continue the implementation of the Agency's Managing Meeting Documents system (MMD) to facilitate the sharing of the following between the Agency, the Members States (inspectors and assessors) and the European Commission:
  - Pharmacovigilance inspections information on MAHs of human medicinal products (planned and conducted inspections, third country inspections and inspection outcome and non-compliance identified during inspections, corrective and preventive actions agreed).
  - Pharmacovigilance assessment information on MAHs of human medicinal products (MAH/product specific concerns, non-compliance, delays and inconsistencies in submissions, "for cause" inspection requests).
- Support the sharing of the outcome of pharmacovigilance inspections of MAHs of veterinary medicinal products in relation to the implementation of the new Veterinary Medicines Regulation (IRIS platform).
- Support collaboration with assessors on data quality issues and signal management activities for veterinary medicinal products.

4. Expertise required

Harmonisation, coordination and sharing of information on inspections within the Union is one of the main roles of the group and therefore experts nominated by the relevant national authority for human and/or veterinary medicinal products from each Member State is essential. One member from each of the EEA Member States, with senior responsibility and broad experience in pharmacovigilance inspections should be nominated. One additional member from each Member State where there is a separate pharmacovigilance inspectorate for human and veterinary medicinal products may be nominated. A replacement delegate, who would participate in those exceptional cases where the nominated member is unable to attend the meeting, may also be nominated.

The composition of the group should remain as currently is. Additional staff of the authorities may attend with the chairman's agreement, in particular, where their participation is needed for a specific topic. Experts will be identified depending on the topic of interest.

Participation in a subgroup of the PhV IWG should be possible for any Subject Matter Expert (SME) from NCAs, who are registered in EMA's Expert Management Tool.

5. Work modalities/Architecture

The PhV IWG shall meet at least four times per year, face-to-face and by teleconference according to the proposed plan. The dates of the meetings shall be communicated to the members and alternate members in advance. Some meetings or parts of the meetings may involve joint activities with other working groups, workshops, and training in order to make best use of the time and resources. Additional meetings may be held when planned for specific reasons, such as training. The group will agree on the priorities and adjust this yearly.

Drafting groups will conduct the majority of their business by correspondence and teleconference but upon reasoned request meetings will be organised by EMA usually in the margins of the plenary meeting of the PhV IWG.

Trainings and workshops should be broadcast and/or recorded, when possible, so that they can become available to non-members/a broader audience.