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# Highlights from the 20th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 13 November 2025

The following records announcements and action points from the 20th Pharmacovigilance Industry Platform meeting.

## *Welcome and matters arising*

- E. Korakianiti and U. Wändel Liminga welcomed the participants to the EMA Industry Platform, including the PRAC members, EMA and all industry associations.

## *Real World Evidence update*

- As a FU to the 19th EMA industry meeting the regulators summarised three main pathways for generating RWE studies, including by the DARWIN EU network, namely (1) in clinical context (orphan designation, scientific advice, PIP, MAA, post-authorisation), (2) to support the planning and validity of studies and (3) to investigate associations and the impact of regulatory decisions. At present, the network has 31 data partners, and an annual report on RWE experience is published here. Among the finalised studies, the PRAC (and safety evaluation) rank highest in terms of study requests, while studies of effectiveness are also being explored. Anti-infectives, anti-cancer and nervous system medicines are the most frequent classes for RWE study investigations. Presented examples of DARWIN studies included doxycycline and suicidality, RSV disease burden and the use patterns of GLP-1 agonists.

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- Responding to industry question on data cleaning, the regulators explained that data partners are selected based on their relevance to the study question and data completeness. In addition, they clarified that studies are deemed not feasible if after exploring the available sources, the capture of data, or the outcome(s) of interest are deemed too rarely reported to achieve the desired sample size (and power) or based on the required timelines for completion of the analysis.
- The regulators presented the **HMA-EMA Catalogues of real-world data sources and studies** designed to enhance transparency, discoverability, and support the use of RWD in regulatory decision-making. The EMA and HMA launched electronic catalogues in 2024 to promote good



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practices in non-interventional research. The catalogues serve as a centralised, publicly accessible repository of RWD sources, studies, institutions and networks from across the globe. They feature standardised metadata structure, enhanced search functionality and linkage between data sources and studies. Industry associations are encouraged to use this resource to register any type of RWD study and consult it at design stage for identifying suitable sources and for streamlining study document preparation using standardised metadata.

- **Action:** Industry associations to encourage data holders and study investigators are invited to contribute information on data sources and studies to improve transparency and collaboration.

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## *Guidance update*

- The regulators presented the annual **update on the EU-Good Pharmacovigilance Practices** with two guidelines published in 2025, the Product- or Population-Specific Considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk, and the Addendum I to GVP Module XVI on risk minimisation measures (RMM) for medicinal products with embryo-fetal risks. They followed up with the revisions planned for 2026, incl. GVP I, III, VII ADD I, VIII and IX which will not be sent for public consultation, instead GVP II, IV and VI will be subject to public comments.

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- MfE presented their proposal for **modernising GVP Modules VI and IX**. The regulators clarified that some suggestions made for module IX revisions have been already included in the Q&A, see here. Considering industry questions regarding a federated ADR database, the regulators clarified the legal framework for pharmacovigilance in the EU and the importance of EudraVigilance database. In addition, they suggested that industry may consider creating reporting consortia of MAHs to reduce duplication of ICSRs in the context of generic medicinal products and case reports published in medical literature.

- As a follow-up to the 17th EMA industry meeting, MfE presented the **off-patent sector perspective on additional risk minimisation measures (aRMMs)**. The association acknowledged the initiatives directed at increasing transparency for generic medicinal products, including EMA's publication of the risk management plans (RMPs) for centrally authorised medicines, as well as the 'Guidance on specific adverse reaction follow-up questionnaires (Specific AR FUQs)'. Some challenges remaining included the implementation of aRMMs, the need for harmonisation with revised GVP XVI, aspects related to digitalisation (e.g. electronic Product Information (PI)), and the European medicines web portal (EMWP).

**Post-meeting notes:**

1. EMA recognises the opportunities of digitalisation to benefit public health. Providing PI in a harmonised electronic format will facilitate wider dissemination to patients and healthcare professionals (HCP) in their chosen format and platforms, as well as integration with e-Health systems. Currently, the ePI initiative is focusing on harmonised electronic SmPC, package leaflet and labelling documents only. However, the harmonised standard in use (the EU ePI Common Standard based on HL7 FHIR) can be extended in future to include other materials, such as aRMMs. The 'Draft Reflection paper on linking to electronic product information (ePI) from EU medicine packages' envisages how patients and HCPs could access ePI in future, in addition to other relevant materials such as aRMMs. Industry will have a driving role in making

electronic information available to patients and HCPs. Currently, the focus is on go live of ePI and roll out across the Member States. Once the product is sufficiently mature, future developments could include harmonised electronic aRMMs. Industry's Subject Matter Experts are involved in the development of the product through the Stakeholder participation in information management platform.

2. Regulators are making progress towards development of an EMWP. EMA has recently updated the vision and high-level approach to take account of technical developments with its digital portfolio since the publication of the Reflection paper on the development of the EMWP (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/reflection-paper-development-european-medicines-web-portal_en.pdf). The next step towards realisation is exploratory user research and user-experience (UX) design, which will ensure that the first public version of EMWP (its minimal viable product) meets user needs. EMA plans to conduct this research and design in 2026. In the meantime, EMA's corporate website continues to serve as the EMWP for the dissemination and publication of information as defined in the 2010 pharmacovigilance legislation, from a legal-compliance perspective (see https://www.ema.europa.eu/en/about-us/about-website/legal-notice#european-medicines-web-portal-10877).

- As a follow-up to the 19th EMA industry meeting EFPIA updated on the mapping of regulatory guidance considered relevant for topic of **pharmacovigilance for non-fixed drug combinations**, encompassing broadly areas of RMP (GVP V rev 2, GVP XVI rev 3 and the RMP template), PSUR (GVP VII rev 1, ICH E2C (R2) and associated Q&A), safety surveillance (GVP IX rev 1) and several documents relating to SmPC labelling. EFPIA workstream proposed definition of non-fixed drug combination medicinal product is as follows: "concurrent use of two (or more) separate medicinal products - investigational or approved - to treat a specific indication, a new stage or subgroup of an existing disease indication, and/or as add-on therapy to an existing treatment".
- **Action**: Regulators to consider presented mapping at the next revision of the relevant guidance(s) of the GVP Modules.

**Post-meeting notes**:

1. The RMP template Checklist for assessors' sections updated with the suggestions pertinent to safety specifications, pharmacovigilance planning, and the alignment of risk minimisation measures.

2. GVP V rev 2 to be updated with the points pertinent to SIII "Clinical trial exposure", SVII "Identified and potential risks", SVIII "Summary of the safety concerns"

## *Update on AI initiatives in the field of pharmacovigilance*

- EMA updated on the progress made with use of AI and data analytics in pharmacovigilance, guided by the Network Data Steering Group (NDSG) workplan (2025–2028). Key workstreams include strategy, data analytics, AI, data interoperability, stakeholder engagement, and international guidance. EMA has been experimenting with AI at several levels of the signal detection workflow: Literature screening for ICSRs (OWLS), Literature screening for signals (ERATO), EurEKA (ADR data extraction), AI-enhanced case adjudication (AERGIA), Insight generation from signal historical reviews (MNEMOSiNE). These projects are at various stages, from user testing to ongoing development. EMA referred to three collaborative initiatives relevant to AI and pharmacovigilance:

SMART Methods, the knowledge mining and AI use case collection within the regulatory network and the CIOMS Working Group XIV.

Update on AI in pharmacovigilance at EMA

Industry presented several use cases of successful implementation of AI tools in pharmacovigilance. For example, a purpose-built AI redaction tool deployed for the redaction of patient personal identifiable information from source documents in line with global privacy regulations. The solution delivers large time savings allowing staff to focus on higher-value tasks. The tool supports seven languages and was developed and validated in a short time allowing also for audit logs, role-based access control, document retention policies, and ongoing quality monitoring. Future enhancements may add more languages and image recognition capabilities. Other tools have been used to extract data from safety reports, with high accuracy and efficiency, with all outputs reviewed by humans before final processing. Large language models (LLMs) helped automate the drafting of safety case narratives, increasing consistency and allowing experts to focus on clinical judgment. Challenges remain around data privacy, regulatory compliance, and algorithmic bias, but ongoing innovation promises safer medicines and better patient outcomes.

## *EudraVigilance update*

- As a follow-up to the 19th EMA industry meeting EFPIA jointly with EUCOPE, AESGP, EuropaBio, and MfE reiterated their questions about the possibility of taking a risk proportionate approach to **case follow-up activities**. GVP VI is not explicit that every single case should be followed, and practices have been developed over the years which may not be optimal and are reinforced through inspections. Industry estimates that approximately 65% of initially received ICSRs lack sufficient information for meaningful assessment. Most companies have a similar process that dictates all serious cases require three follow-up attempts, for non-serious and unexpected cases two attempts. There is no differentiation between well-established and newly authorised products. In industry's view the Guideline on specific adverse reaction follow-up questionnaires (Specific AR FUQ) advises that FU should only be sent if necessary and should be short in nature. The associations have suggested a meeting with relevant parties including EMA, and Pharmacovigilance Inspectors' Working Group (PhVIWG) and PRAC representatives.
- The regulators acknowledged the several challenges described by industry associations. They have commented that the upcoming revision of GVP Module VI with a planned E2D(R1) alignment may address some of the issues and highlighted the importance of continued dialogue with all stakeholders on this topic.

**Actions:**

1. The regulators to address the concerns raised by industry associations. **Post-meeting note**: The Pharmacovigilance Inspectors' Working Group will discuss the concerns at their 2026 meetings.

2. The regulators to consider the possibilities to integrate, in line with the existing EU legal framework, additional guidance in GVP Module VI for ADR cases follow-up activities based on a risk proportionate approach.

- Regulators have announced the **termination of the pilot of continuous monitoring in EudraVigilance** by MAHs under the amended IR EU 520/2012, clarifying reporting expectations. MAHs should continue using EV data for signal management and report actions via PSURs,

variations, or safety issue notifications - not as standalone signal notifications. Regulators clarified that most standalone notifications received during the pilot period were outside of its scope, highlighting the low added value of such process. The upcoming GVP IX revision will reflect this update.

presentation-termination-pilot-signal-detection-eudravigilance-marketing-authorisation-holders-mahs-s-eleni-ema_en.pdf

- Industry has been informed about **ICSR compliance reports** (for 7/15/90-day timelines) by EVDAS. QPPVs/RPs of all sender organizations will be automatically contacted. This initiative was launched on 3 Sep 2025 and is planned for every month with compliance reports covering the submissions made to EV the previous month. Next notification will be sent on 3 Dec 2025.

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## *A.O.B*

- Europharm SMC presented industry's **pharmacovigilance questions related to drug-device products** legally framed by the Medical Devices Regulation (EU) 2017/745 (EU MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (EU IVDR. For drug-device combinations (DDCs), there are specific provisions in the EU MDR, which outline how to handle them based on whether the device and drug form a single integral product or are separate. Key features include stricter safety controls, a comprehensive database (EUDAMED), unique device identification (UDI), and new responsibilities for manufacturers. Industry sought to clarify whether any interlinking between EUDAMED and EudraVigilance have been foreseen.
- The regulators clarified that at present, the COMBINE program has a specific working group (project group 2) discussing the challenges and alignment opportunities in relation to the safety reporting for combined medicinal products and medical devices / in vitro diagnostic medical devices used in the context of clinical trials, clinical evaluation and clinical performance studies. In November 2025, EMA established a multidisciplinary operational group for combination products (COMBO) that include representatives from authorities of medical devices, medicinal products, notified bodies, and the European Commission. Any learnings from the COMBINE program in relation to the safety reporting could support enhancing some alignment in the post authorisations setting. The newly constituted groups could serve a platform for any discussion involving the relevant stakeholders.

## *Conclusions and next steps*

Regulators and Industry stakeholders acknowledge the benefit and importance of continued dialogue noting the progress achieved since the pharmacovigilance platforms were set up initially to support pharmacovigilance regulation implementation.