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Human Division

Highlights from the 21st EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 20 October 2026

The following records announcements and action points from the 21st Pharmacovigilance Industry Platform meeting.

Welcome and matters arising

- P. Mas and G. Genov welcomed the participants to the EMA Industry Platform, including the PRAC and CMDh members, EMA and all industry associations. Questions concerning the new pharmaceutical legislation were confirmed as outside the scope of this meeting and should be addressed through the dedicated communication channels.

EudraVigilance updates

- EMA marked 25 years since establishment of the EudraVigilance Gateway in November 2001. The system has evolved from paper-based reporting to electronic ICSR submission, EVDAS analytics, broader stakeholder access and centralised SUSAR reporting. As of August 2026, EudraVigilance contained 18.5 million individual cases, corresponding to more than 32 million case transactions, and received approximately 7,400 ICSR transactions per day in 2025. Since 2012, more than 900 signals have been prioritised and assessed by PRAC; 54 resulted in product information changes and 50 in direct healthcare professional communications. EMA announced the Second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection which will take place on 1 December 2026 with remote participation options.

  https://www.ema.europa.eu/en/media/75838

- EMA reviewed the first year of monthly ICSR compliance reports generated through EVDAS. Reports cover the applicable 7-, 15- and 90-day reporting timelines and are sent to registered QPPVs and responsible persons of sender organizations that submitted ICSRs in the preceding month. The reports support compliance monitoring, root-cause analysis and identification of late reporting patterns. EMA described corrections made during the first year, including the treatment of the first downgrade from serious to non-serious and a data-load control introduced after incomplete data affected the March report. Common issues identified included missing or late QPPV registration, uncertainty about sender identifiers within industry, differences between internal submission counts and EudraVigilance records, and insufficient communication between QPPVs,

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case-processing functions, CROs and IT teams. An EVDAS query to support reconciliation of submitted ICSRs is under development. Average industry compliance for 1 October 2025 to 30 September 2026 was reported as 96.57% for EVPM 15-day reporting, 98.17% for EVPM 90-day reporting, 97.31% for EVCTM fatal or life-threatening cases and 98.3% for EVCTM non-fatal and non-life-threatening cases.

- **Action**: At the upcoming second HMA/EMA multi-stakeholder forum EMA to provide a more detailed breakdown of industry compliance performance, including an appropriate distributional view.

  https://www.ema.europa.eu/en/media/75839

CMDh Work Plan 2026–2028, including transparency measures related to pharmacovigilance

- The regulators presented the CMDh multi-annual objective to improve the transparency and accessibility of safety outcomes for nationally authorised products. Planned work includes publication of important safety-variation outcomes, PRAC advice to Member States, lists of safety concerns and guidance on additional risk-minimisation measures in mutual-recognition and decentralised procedures. PRAC advice to Member States will be published in a structured table on the CMDh pharmacovigilance procedures outcomes webpage, showing the active substance or product, the request for advice, links to CMDh minutes and the outcome. The aim is to make information currently available through meeting minutes easier to find and follow. For important safety variations, CMDh intends to publish an NCA-prepared safety summary and clean product-information changes prepared by the marketing authorisation holder. Supporting guidance for preparation of the publication-ready product-information changes is planned. A dedicated webpage integrated with the Communication and Tracking System is planned for lists of safety concerns. Technical work remains a dependency for this and other transparency initiatives. CMDh has started work on guidance for additional risk-minimisation measures in MRP and DCP procedures, initially focusing on patient cards and greater consistency at European level.
- Industry welcomed the initiatives and offered support in reviewing future guidance.

  https://www.ema.europa.eu/en/media/75841

AI initiatives in the field of PhV

EMA perspective

- EMA presented artificial intelligence as a strong potential fit for pharmacovigilance because of high data volumes, repetitive and structured workflows, extensive text-based information and established human quality-control steps. They emphasised human accountability, validation against curated datasets, attention to false negatives, auditability, and protection of patient data. Some examples of currently explored and future use cases include literature screening for reportable ICSRs and potential signals, duplicate detection, ADR extraction from product information, case adjudication and analysis of historical signal records. EurEKA (European Union Product Information Entity Extraction and Knowledge Acquisition) and ERATO (Enhanced Review of Abstracts using Transformer mOdels.) are in pilot deployment; EurEKA has mapped more than 150,000 ADRs for centrally authorised products, while ERATO has reduced substantially the literature abstracts requiring manual review.

  https://www.ema.europa.eu/en/media/75842

- EMA described an internal regulatory-network framework and catalogue to support transparent sharing and potential reuse of AI tools across the European medicines regulatory network, including information on intended purpose, performance, development, and support. EMA will participate in a five-year Innovative Health Initiative public-private project on AI-powered signal detection, starting in January 2027. The project is expected to test models and data sources, address signal detection and risk prediction, develop implementation recommendations and human oversight approaches, and produce tools, templates, and training materials. For guidance on the use of AI across the medicinal-product lifecycle, EMA referred to the 2024 reflection paper, jointly published EMA: FDA principles for good AI practice and a coordinated guidance roadmap. A Q&A on AI in pharmacovigilance, whose scope has been informed by a survey of stakeholders, is being drafted; a draft for public consultation is anticipated in spring 2027.

Industry perspective

- Industry contrasted traditional AI and machine-learning approaches with generative AI, noting that generative models are non-deterministic, less fully explainable, and subject to performance drift. Published experiments showed task-dependent performance and continuing need for human review, business context, and technical guardrails. Examples included 78% accuracy in mapping signs and symptoms to MedDRA preferred terms, significant improvement in translating natural-language prompts into database queries when pharmacovigilance business context was provided, and 73% consistency for a retrieval-augmented interface to pharmacovigilance process documentation. Narrative-generation experiments demonstrated hallucination risks that required controls to prevent critical errors. Key risks discussed were apparently plausible but incomplete outputs, hallucination and its effect on reviewer memory, complacency when errors are infrequent, and over-interpretation of context-dependent questions. A proposed path forward comprised risk-based experimentation, proportionate guardrails and explainability, trained human oversight, governance and regulatory alignment, and continuous monitoring for drift, bias, hallucination, and threshold deviations.

Real World Evidence update

- EMA reported that DARWIN EU now includes 40 data partners from 18 European countries, covering more than 250 million people. More than 100 studies have been completed, and the total number of completed and ongoing studies is close to 150. In the latest reporting period, just over 100 research topics and potential study requests were received, with feasibility close to 80% while study volume increased by almost 50%. RWE is being used across the medicinal-product lifecycle for drug-utilisation, epidemiology, safety and effectiveness questions. Standardised analytics using a common data model support delivery in approximately three months for drug-utilisation studies and five to six months for more complex safety or effectiveness studies. Examples included a doxycycline and suicidality study that supported the conclusion that there was no association; a clozapine and agranulocytosis study contributing to revised blood-monitoring recommendations; GLP-1 receptor agonist utilisation and adverse-reaction studies; work on women's health; venous thromboembolism with oral contraceptives and non-steroidal anti-inflammatory medicines; and real-world effectiveness of first-line immunotherapy for non-small-cell lung cancer.

  EMA clarified that RWE is not expected to replace pivotal randomised studies or MAH's obligations for post-authorisation studies. It can complement traditional evidence and may support selected settings such as external comparator arms or specialised populations.

  https://www.ema.europa.eu/en/media/75844

PSUR updates

News items published in 2026

- EMA presented the updates to the Q&A guidance document on PSUSAs for assessors (rev. 1), intended for NCAs, PRAC Rapporteurs/Alternates/members, and EMA staff, as well as minor updates to the explanatory note to GVP Module VII (rev. 4), intended for all stakeholders. The updated Q&A, covers centrally and nationally authorised products; provides section-by-section guidance for completion of the assessment report; aligns with the amended Commission IR 520/2012 (Commission IR 2025/1466 of 22 Jul 25) to include the need of EudraVigilance monitoring by MAH and new aspects related to the effectiveness of risk-minimisation measures); refers to the GVP guidance 'Pregnant and breastfeeding women and their children exposed in utero or via breastmilk' for pregnancy and breastfeeding related aspects in PSURs; and the potential use of real-world evidence/Darwin EU studies. The updated explanatory note reinforces, in line with the amended Commission IR 520/2012 the continued assessment of additional risk-minimisation measures, particularly in relation to the entry of generics and biosimilars, the use of EudraVigilance data alongside other sources by MAHs in PSURs, and the application of GVP guidance 'Pregnant and breastfeeding women and their children exposed in utero or via breastmilk'.

Proposed pilot for pre-filling PSUSA assessment report templates

- EMA provided heads up to Industry on the proposal to conduct a voluntary pilot in 2027 under which certain MAHs would be asked to pre-fill specified factual sections of PSUSA assessment report templates. The objectives are to reduce administrative work for assessors, allow greater focus on scientific evaluation, improve efficiency and quality, and enable companies to e.g. highlight in the AR specific information for due assessors' consideration. The pilot is intended to cover all PSUSA CAPs-only procedures and PSUSA NAPs-only procedures involving a single marketing authorisation holder. Sections identified by assessors' feedback as most useful include Annex section 1: PSUR data, Annex section 2: signal and risk evaluation, Annex section 3: benefit evaluation or RMP update, and Annex section 4 (if applicable): benefit evaluation. Subject to PRAC endorsement in November 2026 on conducting such proposed pilot in 2027, EMA intends to publish the PSUSA AR templates and pilot information by December 2026 on the PSUR Repository webpage and tentatively start the one-year pilot in February 2027 (TBC). In relation to the PSUSA NAPs only procedures involving a single MAH, EMA would aim to contact these QPPVs individually. Separately from the pilot, EMA intends to request summary tabulations and relevant case tables in Excel format for all PSUSA procedures from early 2027, with specific submission instructions to be published on the PSUR repository webpage.

- **Action:** Marketing authorisation holders of PSUSA CAPs only and selected Marketing authorisation holders of PSUSA NAPs only will be encouraged to participate in the voluntary pilot once launched in 2027.

  https://www.ema.europa.eu/en/media/75845

Industry associations' 2025 PSUR survey

- EFPIA presented a survey of 19 companies covering 418 PSURs and PSUSA procedures with assessment reports received between 2022-2024. The analysis examined outcomes of monitoring requests for safety topics, cumulative review and requests in the RSI, individual case narratives, causality reassessment, and requests on marketing status information. Industry pointed out based on the survey outcomes that many topics remained open across assessment cycles and recommended that requests set out the supporting evidence or hypothesis, focused data scope, intended patient-safety decision, evidence gaps, target date and follow-up ownership. Industry also asked that unresolved or urgent concerns be considered through the most appropriate

regulatory route rather than remaining open over long PSUR cycles. Industry asked for clearer targeting and rationale where these data are scientifically necessary. Regulators indicated that updated Q&A guidance document on PSUSAs for assessors (rev. 1) already address several concerns highlighted in this survey in particular in relation to requests in the RSI and on individual case narratives and reminded companies on their role in proactively suggesting closure of monitoring of specific safety topics with appropriate justification in the PSUR. The discussion recognised that marketing status and local exposure may also be relevant to contextualising benefit-risk in particular settings, while not necessarily being equally relevant to every safety concern.

Actions:

1. The regulators to provide a brief update to PRAC on the industry survey findings.

2. Industry associations and regulators to continue monitoring the impact of the updated assessor guidance and training.

Post-meeting note:

The results of the industry survey were presented to the PRAC at its **November 2026 plenary** for information.

Guidance update

Good Pharmacovigilance Practices overview

- EMA presented recently published and forthcoming GVP work. Published documents included new guidance on data collection and risk assessment of medicines use in pregnant and breastfeeding women and the effects on their children exposed in utero or via breastmilk (EU-GVP P. III) and the revised pharmacovigilance inspection guidance (EU-GVP M III). EMA clarified that in the context of pharmacovigilance systems and their quality management, a third party is currently understood as any organisation to which a pharmacovigilance task is subcontracted, with oversight applied through a risk-based approach. A definition is intended to be developed in 2027, to be included in next year's revision of EU-GVP Annex I. EU-GVP Module VIII on post-authorisation safety studies is being finalised, to implement the ICH-M14 guideline and the recently amended Implementing Regulation. Work is also progressing on EU-GVP Modules II, IV, V, VI and XV as the vaccine-specific Considerations Chapter P.I. A new Addendum to EU-GVP Module VII is planned to address reporting on the implementation status of risk minimisation measures in PSURs. A broader revision of Module VII to start in 2028 in the context of the new pharmaceutical legislation. EMA indicated that public consultations will be staggered and review periods will take typical holiday periods into account.
- In response to a question regarding the DIS-aRMM study, EMA clarified that the study results have been considered by PRAC for follow-up and that it is expected that the fuller application of the implementation-science based revision 3 of EU-GVP Module XVI issued in 2024 will remedy current deficiencies seen in the dissemination of aRMM materials. It was also clarified that work on a PRAC paper concerning digital support to risk minimisation is ongoing, also in the context of latest developments such the need for AI-readable information and strengthening of engagement with stakeholders beyond industry.

  https://www.ema.europa.eu/en/media/75847

GVP IX rev. 2

- EMA presented the rev. 2 driven by the termination of the EudraVigilance signal-monitoring pilot and the amended IR 520/2012. MAHs are no longer required to continuously monitor EudraVigilance or submit standalone validated-signal notifications to EMA and national competent authorities. They can monitor EudraVigilance as a primary source for signal detection or use its data during validation and full assessment of signals detected from other sources. The monitoring frequency must be risk-proportionate and documented. PSURs and variations remain the principal regulatory tools for signals. Where a MAH concludes that product information should be updated following its signal assessment, the variation should be notified no later than three months after the signal validation.

  https://www.ema.europa.eu/en/media/75849

GVP V rev. 3

- EMA reported that the draft GVP Module V and RMP template have returned to the drafting group to better align the RMP assessment process with the expected new pharmaceutical legislation. The revision will simplify the safety specification, reduce duplication with the clinical safety assessment and focus RMP content on additional pharmacovigilance activities and additional risk-minimisation measures. This additional drafting cycle is expected to delay public consultation by approximately six months. ATMP-specific guidance remains advanced and will be included in the consultation.

  https://www.ema.europa.eu/en/media/75848

Revision of "Guideline on Risk assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling"

- The revised joint CHMP-PRAC guideline will address fertility, pregnancy and breastfeeding, integrating non-clinical and clinical evidence into recommendations for healthcare professionals and patients. It will include standard wording for both the summary of product characteristics and package leaflet, including new statements for fertility and for females who can become pregnant. The revision expands guidance on animal-to-human exposure margins, weight-of-evidence approaches and new approach methodologies; provides a more detailed framework for adverse pregnancy outcomes, including neurodevelopmental disorders; and substantially expands assessment of breastfeeding, including medicine levels in breast milk and estimated infant exposure. Adoption by PRAC and CHMP was anticipated for November or December 2026, followed provisionally by a three-month public consultation.

- **Action:** Industry associations are encouraged to participate actively in the forthcoming public consultation.

  https://www.ema.europa.eu/en/media/75850

Conclusions and next steps

Regulators and industry stakeholders acknowledged the value of continued dialogue and information exchange on the operation of EU pharmacovigilance. Follow-up will focus on the agreed actions concerning in the participation in the PSUSA pre-filling pilot, an update to PRAC on the industry PSUR survey findings, continued monitoring of the updated assessor guidance and training, and engagement in forthcoming public consultations.