

BADI | ANALYTICAL REPORT – MEETING SUMMARY – KEY HIGHLIGHTS

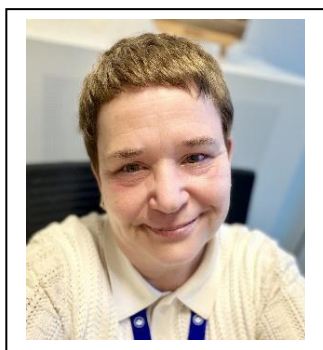
Module 1 | 9 October 2026 | Online (Webex)

Drug Regulatory Affairs Update 2026 | Meeting summary, thematic analysis and action items

1. Scope, basis and limitations

This summary covers Module 1 of the online training course “Drug Regulatory Affairs Update 2026” organised by the Bulgarian Association for Drug Information (BADI) and held on 9 October 2026. It was prepared from the Webex notes provided and four presentations: Viola Macolic Sarinic, Galyna Cordero, Valentin Kopanarov and Dessislava Ilieva-Tonova.

The purpose of this summary is to outline the key points of the meeting of 9 October. The information was compiled by a team of the Association without interpreting the results themselves. The sessions were moderated by Tatyana Benisheva, Chair of BADI, and Margarita Strokova, Member of the BADI Management Board – both with many years of experience in medicines regulation.



Presentation 1

2. Viola Macolic Sarinic, PRAC Scientific Committee Lead, Pharmacovigilance Office, Quality and Safety of Medicines Department at EMA – European Medicines Agency (EMA)

2.1. The EU pharmacovigilance regulatory system

Viola Macolic Sarinic of EMA presented the European pharmacovigilance network, comprising the 27 Member States, Iceland and Norway, EMA, the national competent authorities, PRAC, CHMP and CMDh. The involvement of patients and healthcare professionals in the regulatory process was highlighted.

EudraVigilance collects reports of suspected adverse drug reactions. Slide 15 of the presentation reports 31,253,245 ICSRs as of 31.12.2025, relating to 17,898,709 individual cases. A report of a suspected reaction does not in itself prove a causal relationship.

PRAC assesses signals, PSURs/PSUSAs, PASS, referral procedures and risk minimisation measures. Recommendations and decisions are adopted by PRAC monthly and through the applicable approval and national implementation pathways; marketing authorisation holders are responsible for timely updates to the product information and the related variations, and these reports are followed on the EMA website by all marketing authorisation holders – of both innovative and generic medicines.

The presentation also included Bulgarian data: 23,894 reports in VigiBase as of September 2026 (slides 34–39). This is an indicator of reported volume, not a stand-alone measure of the quality or completeness of reporting. The use of artificial intelligence at EMA was also presented (Figure 1).



Figure 1. Artificial intelligence used by EMA.

2.2. From regulatory decision to real-world safety

Viola also discussed risk minimisation measures, Direct Healthcare Professional Communications (DHPC), product information and impact assessment. The EMA study presented shows that unclear responsibilities and limited time can reduce the reach and use of additional educational materials. The practical conclusion is to measure not only whether information has been published, but whether it has reached the right audience, been understood and been applied.

From information to decision (slides 31–52).

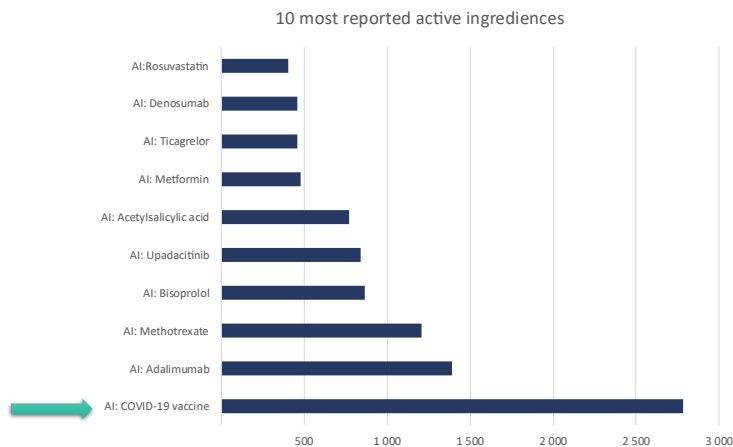
- **Signals in 2025:**
 - 68% of potential signals come from EudraVigilance screening (76% in 2024), around 27% from the literature and 4% from cooperation with other regulators.
 - Around 3% of the signals reviewed are validated for assessment by PRAC.
 - Of the closed signals, 26 led to a change in the product information, 12 to routine pharmacovigilance and 1 to a referral procedure.
- **Tools:** RMP, PSUSA/PSUR, PASS (categories 1, 2 and 3) and referral procedures under Articles 20, 31 and 107i.

2.3. For Bulgaria, the need for more active reporting of adverse reactions, including by pharmacists, was discussed, since the reports from Bulgaria in EMA's VigiBase up to September 2026 number only 23,894.

Bulgaria in detail (slides 34–39)

- **Volume:** 23,894 reports in EMA's VigiBase up to September 2026, around **0.29%** of all reports for the EU/EEA (8.29 million).
- **Reporters:** physicians 51%, patients and consumers 46%. The total exceeds 100% because a report may have more than one reporter.
- **Seriousness:** 45% serious, 29% non-serious, 26% unknown. The most frequent criteria are other medically important conditions (30%) and hospitalisation (18%). A fatal outcome is recorded in 4.7% of reports.
- **Trend:** steady growth, peaking in 2021 (21% of all reports) due to COVID-19 vaccines. By 2025 the annual share is around 10%.
- **Most frequently reported substances:** COVID-19 vaccines (2,781), adalimumab (1,388), methotrexate (1,208), bisoprolol (863) and upadacitinib (840).
- **Most frequent reactions:** general disorders and administration site conditions (35%), investigations (19.5%), gastrointestinal disorders (19.4%) and nervous system disorders (18.9%).

Bulgaria



23 894 reports in VigiBase
by September 2026



Substance	Reports
COVID-19 vaccines	2,781
Adalimumab	1,388
Methotrexate	1,208
Bisoprolol	863
Upadacitinib	840
Acetylsalicylic acid	771
Metformin	480
Ticagrelor	458
Denosumab	458
Rosuvastatin	404

Figure 2. The ten most frequently reported active substances in EMA's VigiBase up to September 2026 (23,894 reports from Bulgaria in total).

2.4. From decision to safe practice (slides 53–59). This is followed by updates to the SmPC and package leaflet, educational materials, DHPCs (for example on meningioma with desogestrel and etonogestrel, dated 06.08.2026) and communication.

According to the EMA IMPACT study, only 30% of centrally authorised medicines from 2010–2015 had additional risk minimisation measures at the time of authorisation. Patients often do not receive these materials because of unclear responsibilities and lack of time.

2.5. DARWIN EU, real-world data and legislative outlook

Viola presented DARWIN EU as a European network for the analysis of real-world healthcare data that supports regulatory questions and signal assessment. Spontaneous reports remain the foundation but are complemented by real-world data (health records, registries, dispensing data). DARWIN EU uses a common data model and federated analysis, in which the data remain local. AI can assist with case processing, literature screening, duplicate detection and signal detection. Accountability and scientific judgement remain human. DARWIN EU complements, but does not replace, mandatory post-authorisation safety studies (PASS).

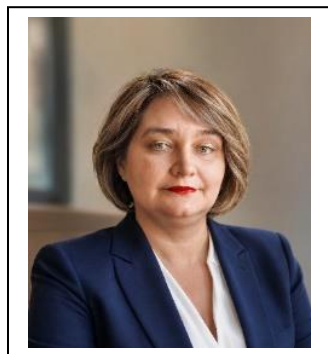
2.6. The new pharmaceutical legislation

Regarding the 2023 pharmaceutical legislative package, the provisionally agreed text was discussed, which provides for limiting *the routine submission of a separate RMP for certain generic products and the removal of the additional monitoring symbol*. These proposals/provisional agreements require subsequent verification against the final legislative text and dates of application. Core signal and PSUR activities remain essential.

Presentation 2

3. Artificial intelligence (AI) in audits: methodology and control

Galyna Cordero, an experienced auditor from Ukraine, presented a step-by-step model: risk-based audit planning, automated PSMF review, ICSR analysis, verification of signal detection, and control of database integrity and migrations.



AI can detect gaps and inconsistencies in documentation; machine learning can detect anomalies; generative AI can support drafting and structured queries – but she repeatedly stressed that in-depth pharmacovigilance expertise is required for experts to be able to identify the non-conformities.

The critical limitations of AI – hallucinations, algorithmic bias, opaque models, inconsistent outputs and confidentiality risks – still exist.

Validated systems, version control, documented acceptance criteria, audit trail, human review, GDPR/cybersecurity compliance and competent independent auditors are required.

The future of artificial intelligence in audits (slides 13–15)

- **Competencies:** the auditor must combine PV expertise, knowledge of ML, AI governance and ethics, and critical evaluation of outputs.
- **Towards continuous compliance:** instead of periodic audits, AI agents monitor data and processes in real time, for example for late ICSRs or SOP deviations. The auditor becomes more of a strategist who manages the systems that detect deviations.

Particularly valuable were the points on vendor qualification, data migration verification, business continuity exercises and the involvement of QPPV, QA, IT, legal and local teams. The situation in Ukraine showed why backup power, the use of VPN and practically tested plans are essential.

Roadmap Phase 2: AI-Assisted Document Review and PSMF Analysis

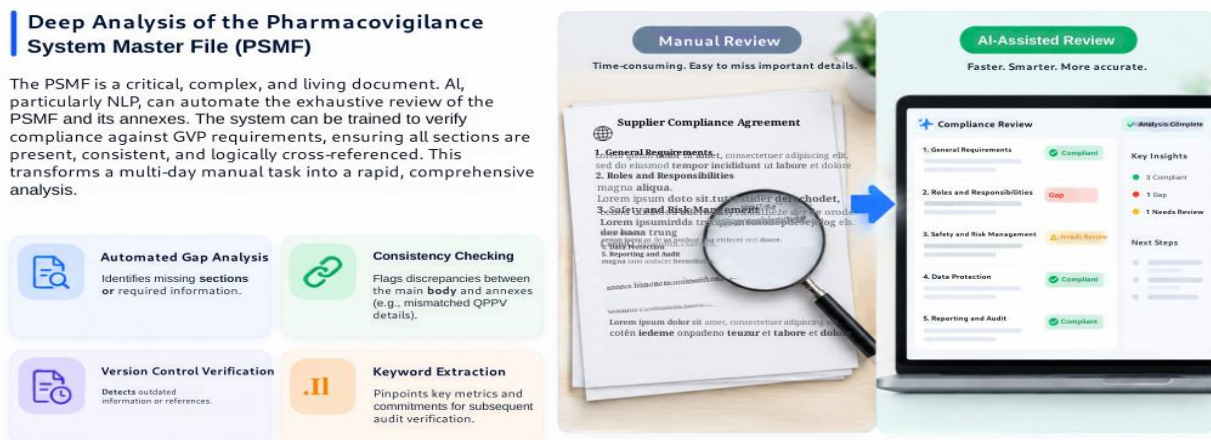


Figure 3. AI-assisted PSMF analysis, Cordero, slide 5.

A 5-phase roadmap was presented (slides 4–8)

1. **Pre-audit planning:** AI analyses historical findings, CAPAs, inspection reports, ICSR volumes and risk profiles. The output is a prioritised list of sites and processes with a rationale, so that the audit scope is defensible.
2. **Document and PSMF review:** NLP checks the Pharmacovigilance System Master File against GVP requirements. It finds missing sections, inconsistencies between the main body and the annexes (for example different QPPV details) and outdated information. A multi-day manual task becomes a rapid analysis.
3. **ICSR audit:** instead of a random sample, 100% of cases are analysed. Illogical dates (for example death before reaction onset), inconsistent MedDRA coding and workflow delays are identified.
4. **Signal detection audit:** the focus shifts from “what” the signal is to “how” it is detected. The auditor checks whether the algorithm is scientifically sound and GxP-validated, whether the

input data are complete and whether there is documented human review. The auditor also checks how model drift is monitored and how algorithm changes are managed.

5. **Database integrity and migration:** *AI compares every critical field across millions of records between the legacy and the new system. It detects truncated or corrupted data, checks narratives and attachments, and produces a discrepancy report before go-live.*

Risks and controls (slides 11–12)

- **Hallucinations:** *always verify claims against the primary source.*
- **Bias:** *evaluate the training data and fairness across demographic groups.*
- **“Black box”:** *insist on explainability (XAI), test inputs and outputs, and review the validation documentation.*
- **GxP requirements:** *the AI tool is treated as a computerised system. GAMP 5 validation, anonymised or pseudonymised data, immutable audit trails and vendor qualification are required.*

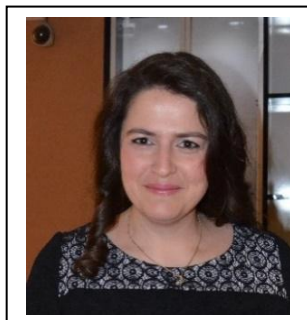
Six key takeaways from the presentation

1. *AI complements rather than replaces.*
2. *The audit focus shifts from “what” to “how”.*
3. *Implementation must be phased.*
4. *Competence is a prerequisite.*
5. *Vigilance towards AI risks is needed.*
6. *The future is proactive.*

Note: *the slides also contain example charts and data, such as risk scores and percentages. These appear to be illustrative and have therefore not been included as facts.*

Presentation 3

4. The Bulgarian inspection perspective



Dessislava Ilieva-Tonova of the BDA (Head of Division “Pharmacovigilance and Clinical Trials Control and Inspection”, Department “Market Supervision and Inspection” at the Bulgarian Drug Agency – BDA) presented the BDA’s approach under GVP Module III: routine and ad hoc inspections; system and targeted inspections; inspections of marketing authorisation holders and contractual partners. The presentation indicates approximately 2–4 weeks of preparation, 2 working days of inspection and a post-inspection process of 3 months or more (slide 5).

In the pre-inspection phase, the PSMF, documents on the responsible persons, SOPs, contracts and adverse reaction data are requested. The documents must reflect the processes actually applied.

After the inspection, an analysis of findings, corrective and preventive actions (CAPA) and evidence of implementation are expected. For each non-conformity, the inspector expects **a root cause analysis, corrective actions (where applicable), mandatory preventive actions, expected outcomes and a deadline for each of them**. The response must be submitted within 30 days. If the inspectors consider the proposed actions irrelevant or insufficient, detailed instructions will be given in the final report.

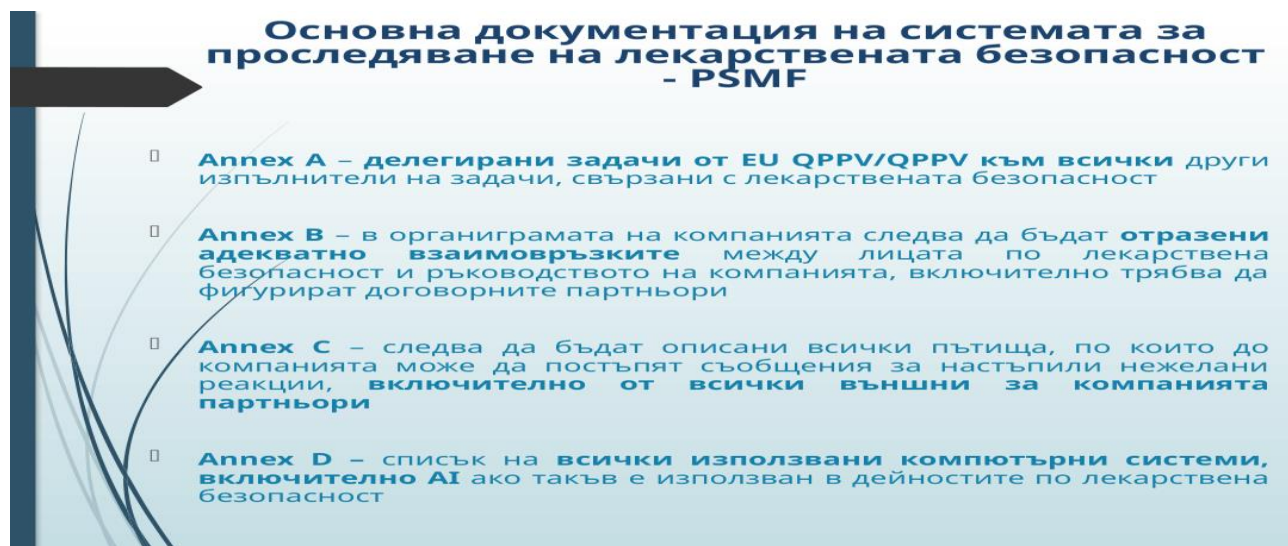


Figure 4. PSMF checkpoints, Ilieva-Tonova, slide 17.

Slides 15–24 list common problem areas identified by the regulatory authorities during inspections, for example:

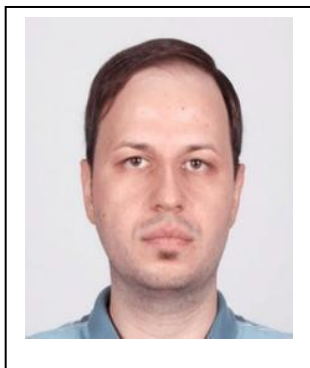
Pharmacovigilance persons (slides 15–16)

- **Notification of the regulator:** a change of the EU QPPV or the local contact person must be notified under Article 191 of the Medicinal Products in Human Medicine Act (ZLPHM) without delay and no later than 30 calendar days. The change must also be reflected in the Article 57 database.
- **Training:** lack of regular specialised training (XEVMPPD, EudraVigilance, MedDRA) and of training following changes in legislation, SOPs or guidelines.
- **Job descriptions:** must reflect the actual activities and roles.
- **Deputising:** no written procedure for deputising between the person and their deputy, and no records of handover of tasks.
- **EU QPPV – local persons communication:** no defined procedure, type and frequency of communication, and no records of it.

Other weaknesses were also pointed out, such as changes to and competencies of the QPPV/local persons, inconsistencies in the PSMF annexes, incomplete SOPs, traceability of reports, unclear allocation of responsibilities in contracts and insufficient documentation of audits. These are specific checkpoints for companies' self-assessment, which should be taken into account for future inspections by the regulatory authorities. See these slides for more detail.

Presentation 4

5. Practical applications and the PV technology market



Valentin Kopanarov, a long-standing expert in pharmacovigilance, distinguished three modes: automation of deterministic tasks, AI assistance with human confirmation, and decisions that must remain with the expert. This distinction is useful for assigning responsibility for case intake, triage, literature, duplicates, signal assessment and aggregate analyses.

The presentation cited specific, context-dependent results: a pilot vendor comparison with F1 of 0.52–0.74 (slide 8); a French evaluation of 11,633 reports from 27 centres, with AUC 0.97 and F1 0.80 for ADR identification (slide 9); vigiMatch with a positive predictive value of 86% in the UK, 64% in Denmark and 33% in Spain (slide 10); approximately 85% sensitivity for

automated and 83% for manual literature monitoring (slide 11). These data are not a universal guarantee of performance.

The market is segmented into core safety platforms, intake/workflow tools, specialised literature systems and signal/public health products.

Oracle, IQVIA, Veeva, ArisGlobal, RxLogix, Ennov, UMC and others were mentioned, without any claim of equivalence. The recommendation is to choose according to the task, the evidence, data access, costs and the possibility of independent validation.

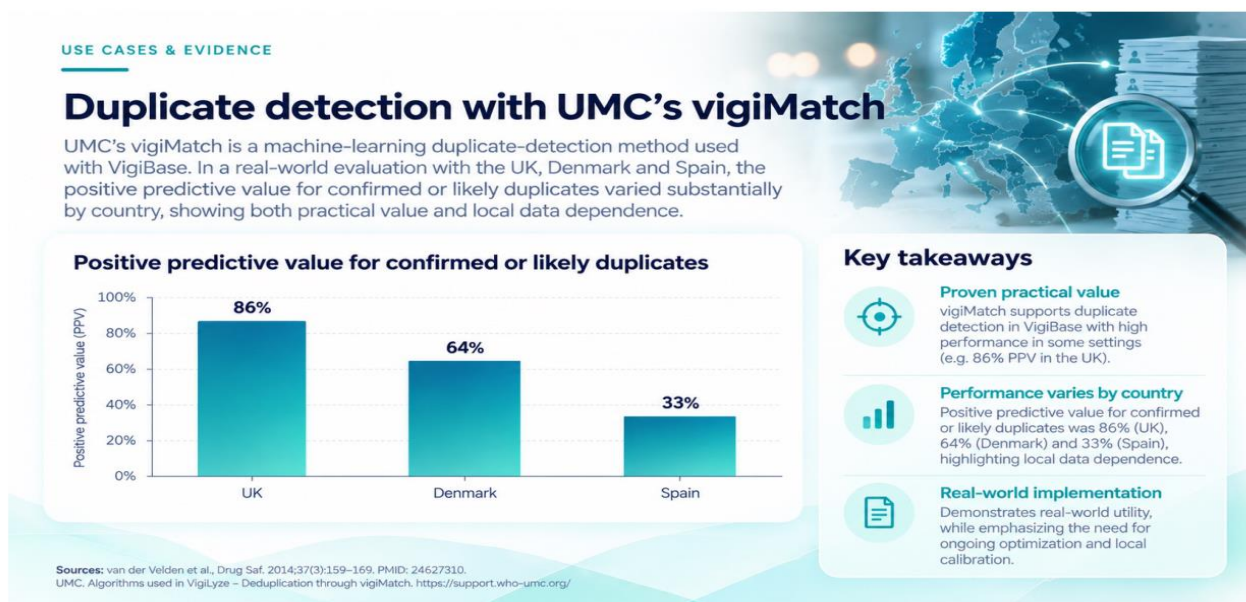


Figure 5. Example results for duplicate detection, Kopanarov, slide 10.

6. Discussion and critical analysis

Participants discussed differing organisational readiness for AI, inconsistent national inspection practices, GDPR compliance, the conditions for working with external vendors and the need for auditors to acquire technological literacy. It was emphasised that a good strategy starts with simplifying and mapping processes, not with buying software.

Analytical conclusion 1: documentary compliance without operational evidence is not sufficient. Conclusion 2: the usefulness of AI is assessed against a specific task, a predefined risk threshold and an independently verified result. Conclusion 3: regulatory communication should have measurable indicators of reach and impact. Conclusion 4: small companies need proportionate implementation models.

7. Conclusion

Module 1 linked regulatory principles with real-world decisions in pharmacovigilance systems. The overall message is that AI can support efficiency and quality, but accountability for decisions, patient safety and demonstrable compliance remains with competent professionals and organisations.

8. Follow-up actions and responsible parties

The status of each item distinguishes between a stated commitment, an idea and a recommendation. No deadlines have been set, as none were reliably established in the notes provided.

9. Sources and methodology

- Webex meeting summary and action items, supplied by the organiser, 09.10.2026.
- Viola Macolic Sarinic, “From Safety Reporting to Regulatory Decision-Making”, 71 slides (PowerPoint).
- Galyna Cordero, “AI as a Tool for Pharmacovigilance Audits”, 16 slides.
- Valentin Kopanarov, “Artificial Intelligence in Pharmacovigilance: Moving from Concepts to Practice”, 24 pages.
- Dessislava Ilieva-Tonova, “Pharmacovigilance Inspections from the BDA’s Perspective” (in Bulgarian: “Инспекциите по лекарствена безопасност от позицията на ИАЛ”), 26 slides.

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