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Update on the EU-Good Pharmacovigilance Practices (EU-GVP)

21st EMA Industry Stakeholder Platform – Operation of EU Pharmacovigilance

20 October 2026

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2026: New GVP Product- or Population-Specific Considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk - *published*

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2 February 2026
EMA/653036/2019 corr 1*

Guideline on good pharmacovigilance practices (GVP)

Product- or Population-Specific Considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk

Draft finalised by the Agency in collaboration with Member States	27 November 2019
Draft agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	29 November 2019
Draft adopted by Executive Director	4 December 2019
Release for public consultation	6 December 2019
End of consultation	28 February 2020
Revised draft agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	5 January 2026
Revised draft agreed by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – human (CMDh)	26 January 2026
Revised agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	2 February 2026
Date for coming into effect	9 February 2026

* Correction 1 includes clarifications of the gestational periods in the examples of potential impact of timing of exposure for different pregnancy outcomes in Section P.III.A.1.3..

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2026: Revised GVP Module III: Pharmacovigilance inspections - *published*

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4 September 2026
EMA/119871/2012 Rev 2*

Guideline on good pharmacovigilance practices (GVP)

Module III – Pharmacovigilance inspections (Rev 2)

Date for coming into effect of first version	13 December 2012
Date for coming into effect of Revision 1	16 September 2014
Draft Revision 2 reviewed by the Agency's Pharmacovigilance Inspectors' Working Group (PhVIWG)	2 June 2026
Draft Revision 2 agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	6 July 2026
Draft Revision 2 agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)	16 July 2026
Draft Revision 2 agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	4 September 2026
Date for coming into effect of Revision 2*	10 September 2026

* Revision 2 includes the following:

- Incorporating the new legal provisions as per Articles 6(3) and (4) and Article 13(1a) of Implementing Regulation (EU) No 520/2012 as amended by Commission Implementing Regulation (EU) 2025/1466 of 22 July 2025 in relation to subcontracting in III.A. and III.B.3.;
- Deleting the mention of clinical trials, now under governed by Regulation (EU) No 536/2014, in III.B.1.4.;
- Updating legal references to Regulation (EU) 2024/568 in relation to fees in III.C.6.;
- Updating references and information on web access to referenced documents in III.B.5. and throughout the Module;
- Alignments with the referenced Union procedures throughout the Module;
- Clarifications in the light of experience with remote inspections in III.B.1.7.;
- Strengthening of a risk-based inspection cycle in III.C.4.3.;
- Providing a clarification regarding timing of document provision in III.C.5.;
- Overall editorial improvements, specifying legal references for clarity, and alignments with revisions of this and other GVP Modules.

Note: As the Implementing Regulation (EU) 2025/1466 was subject to public consultation in the EU, Revision 2 of GVP Module III was not subject to public consultation.

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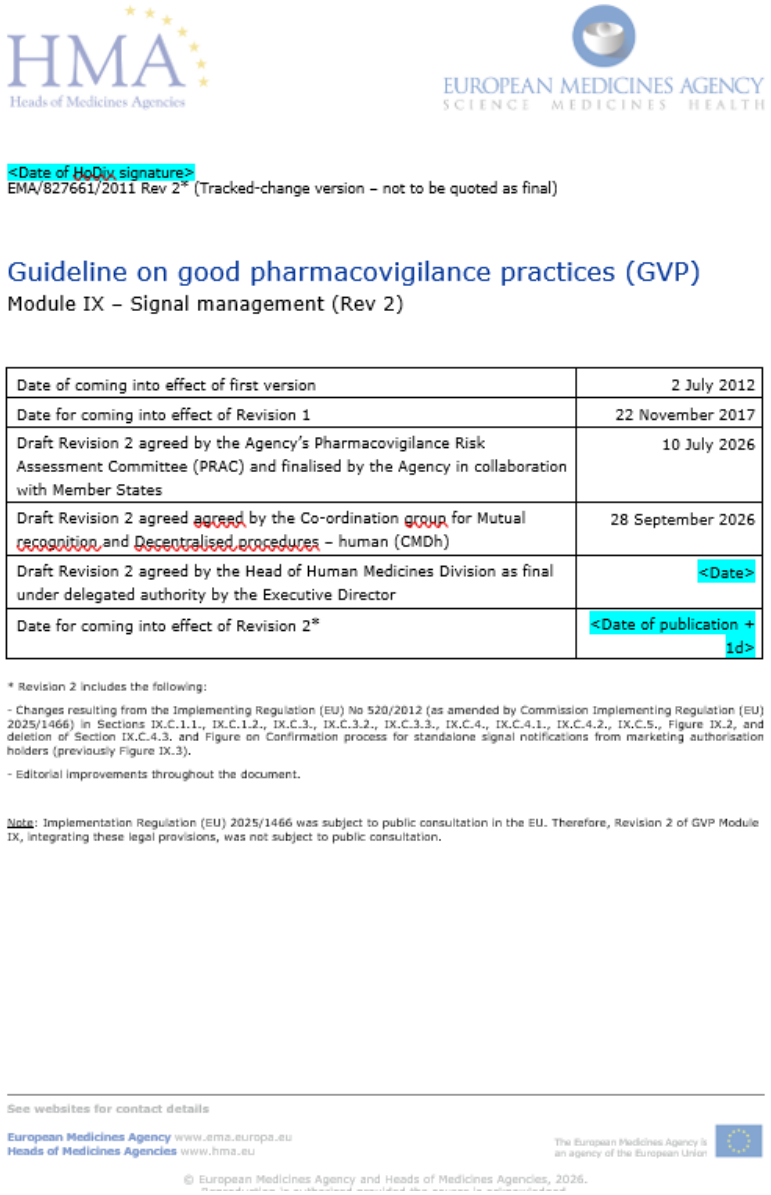
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2026: Revised GVP Module IX: Signal management - *under sign-off for publication*



<Date of HoDix signature>
EMA/827661/2011 Rev 2* (Tracked-change version – not to be quoted as final)

Guideline on good pharmacovigilance practices (GVP)

Module IX – Signal management (Rev 2)

Date of coming into effect of first version	2 July 2012
Date for coming into effect of Revision 1	22 November 2017
Draft Revision 2 agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	10 July 2026
Draft Revision 2 agreed agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)	28 September 2026
Draft Revision 2 agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	<Date>
Date for coming into effect of Revision 2*	<Date of publication + 1d>

* Revision 2 includes the following:

- Changes resulting from the Implementing Regulation (EU) No 520/2012 (as amended by Commission Implementing Regulation (EU) 2025/1466) in Sections IX.C.1.1., IX.C.1.2., IX.C.3., IX.C.3.2., IX.C.3.3., IX.C.4., IX.C.4.1., IX.C.4.2., IX.C.5., Figure IX.2, and deletion of Section IX.C.4.3. and Figure on Confirmation process for standalone signal notifications from marketing authorisation holders (previously Figure IX.3).

- Editorial improvements throughout the document.

Note: Implementation Regulation (EU) 2025/1466 was subject to public consultation in the EU. Therefore, Revision 2 of GVP Module IX, integrating these legal provisions, was not subject to public consultation.

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2026: Revised GVP Annex I: Definitions - *under sign-off for publication*

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HoDiv Sign off date
EMA/876333/2011 Rev 6*

Guideline on good pharmacovigilance practices (GVP)

Annex I - Definitions (Rev 6)

Date for coming into effect of first version	2 July 2012
Date for coming into effect of Revision 1	13 December 2012
Date for coming into effect of Revision 2	8 January 2014
Date for coming into effect of Revision 3	28 April 2014
Date for coming into effect of Revision 4	13 October 2017
Date for coming into effect of Revision 5	6 August 2024
Draft Revision 6 agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	6 October 2026
Draft Revision 6 agreed agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)	9 October 2026
Draft Revision 6 agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	<Date of HoDiv sign off>
Date for coming into effect of Revision 6*	<Day of publication +1d>

*Note: Revision 6 includes the following:

- Addition of the definition of Outcome of the (suspected) adverse reaction in accordance with ICH-E2B(R3);
- Addition of the definitions of Feasibility assessment, Patient experience data, Real-world data, Real-world evidence, Target population (non-interventional study) and Study population in accordance with ICH-M14;
- Update of the definition of Primary data collection in accordance with ICH-E8(R1);
- Updates of the definitions of Confirmed signal, Non-confirmed signal, Refuted signal, Signal confirmation by the PRAC Rapporteur or Lead Member State and Validated signal in accordance with GVP Module IX rev 2;
- Updates to the explanatory notes to the definition of Signal management process with deletion of reference to GVP Module VIII App1.1.1. and related update of the definition;
- Updates of the explanatory notes to the definition of Signal in accordance with Article 19(1) of Implementation Regulation 520/2012 as amended by Implementing Regulation (EU) 2025/1466 (addition of 'suspected') and ICH-E2D(R1) (replacement of 'gender' by 'sex');
- Editorial improvements of the definitions of Emerging safety issue and Signal analysis and prioritisation by the PRAC in accordance with GVP Module IX rev 2;
- Update of the reference to ICH-M14 for the definition of Secondary use of data;
- Reference to GVP Annex IV with regard to references to the ICH-E2F Guideline;
- Updated weblink to the SCOPE Best Practice Guide on Signal Management.

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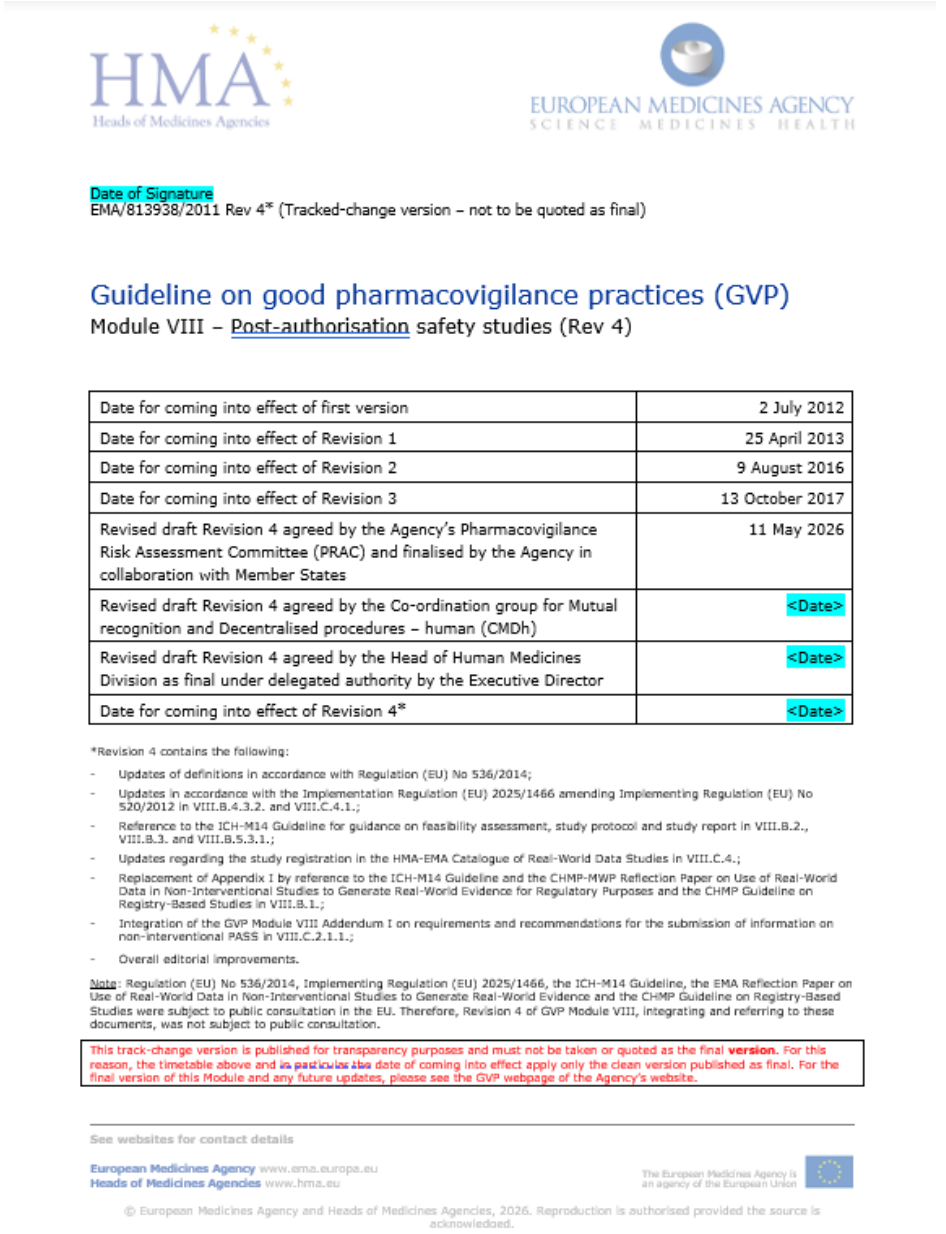
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2026: Revised GVP Module VIII: Post-authorisation safety studies - *under finalisation*



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Date of Signature
EMA/813938/2011 Rev 4* (Tracked-change version – not to be quoted as final)

Guideline on good pharmacovigilance practices (GVP)

Module VIII – Post-authorisation safety studies (Rev 4)

Date for coming into effect of first version	2 July 2012
Date for coming into effect of Revision 1	25 April 2013
Date for coming into effect of Revision 2	9 August 2016
Date for coming into effect of Revision 3	13 October 2017
Revised draft Revision 4 agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States	11 May 2026
Revised draft Revision 4 agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)	<Date>
Revised draft Revision 4 agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director	<Date>
Date for coming into effect of Revision 4*	<Date>

*Revision 4 contains the following:

- Updates of definitions in accordance with Regulation (EU) No 536/2014;
- Updates in accordance with the Implementation Regulation (EU) 2025/1466 amending Implementing Regulation (EU) No 520/2012 in VIII.B.4.3.2. and VIII.C.4.1.;
- Reference to the ICH-M14 Guideline for guidance on feasibility assessment, study protocol and study report in VIII.B.2., VIII.B.3. and VIII.B.5.3.1.;
- Updates regarding the study registration in the HMA-EMA Catalogue of Real-World Data Studies in VIII.C.4.;
- Replacement of Appendix I by reference to the ICH-M14 Guideline and the CHMP-MWP Reflection Paper on Use of Real-World Data in Non-Interventional Studies to Generate Real-World Evidence for Regulatory Purposes and the CHMP Guideline on Registry-Based Studies in VIII.B.1.;
- Integration of the GVP Module VIII Addendum I on requirements and recommendations for the submission of information on non-interventional PASS in VIII.C.2.1.1.;
- Overall editorial improvements.

Note: Regulation (EU) No 536/2014, Implementing Regulation (EU) 2025/1466, the ICH-M14 Guideline, the EMA Reflection Paper on Use of Real-World Data in Non-Interventional Studies to Generate Real-World Evidence and the CHMP Guideline on Registry-Based Studies were subject to public consultation in the EU. Therefore, Revision 4 of GVP Module VIII, integrating and referring to these documents, was not subject to public consultation.

This track-change version is published for transparency purposes and must not be taken or quoted as the final **version**. For this reason, the timetable above and ~~in particular the~~ date of coming into effect apply only the clean version published as final. For the final version of this Module and any future updates, please see the GVP webpage of the Agency's website.

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2026 – GVP documents under revision **-> 2027**

- GVP Module II: Pharmacovigilance System Master File – Release for public consultation in Q1 2027
- GVP Module IV: Pharmacovigilance audits – For public consultation
- GVP Module V: Risk management systems – For public consultation
- GVP Module IV: Collection, management and submission of reports of suspected adverse reactions to medicinal products – For public consultation
- GVP Module XV: Safety communication – For public consultation?
- Considerations P.I: Vaccines: For public consultation
- GVP Annex I: Definitions

Thank you!

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2027 – GVP documents to be developed

- Module VII ADD I on RMM implementation updates in PSURs

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