EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

← Pharmacovigilance: post-authorisation

Good pharmacovigilance practices (GVP)

Good pharmacovigilance practices (GVP) are a set of measures drawn up to facilitate the performance of pharmacovigilance in the European Union (EU). GVP apply to marketing-authorisation holders, the European Medicines Agency (EMA) and medicines regulatory authorities in EU Member States. They cover medicines authorised centrally via the Agency as well as medicines authorised at national level.

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Guideline on GVP

The guideline on GVP was a key deliverable of the 2010 pharmacovigilance legislation.

Each chapter and revisions are developed by a team consisting of experts from EMA and from EU Member States.

The guideline on GVP is divided into chapters that fall into two categories:

- modules covering major pharmacovigilance processes;
- product- or population-specific considerations.

Modules covering major pharmacovigilance processes

GVP modules I to XVI cover major pharmacovigilance processes and the development of this set of guidance is concluded.

The **module numbers XI, XII, XIII and XIV** stay void, as their planned topics have been addressed by other guidance documents on the Agency's website (see bullet points below Final GVP modules table).

Product- or population-specific considerations

The **chapters on product- or population-specific considerations** are available for vaccines, biological medicinal products and the paediatric population.

A chapter on pharmacovigilance for the use of medicines during **pregnancy** and **breastfeeding** has been subject to public consultation and is currently being finalised.

GVP modules and considerations are regularly reviewed for revision needs and schedules.

Planned updates

Amendments to Commission Implementing Regulation (EU) No 520/2012, by means of Commission Implementing Regulation (EU) 2025/1466 of 22 July 2025, are applicable and the guidance in GVP will be updated accordingly in upcoming revisions of the modules.

GVP modules impacted by the recently adopted ICH-E2D(R1) and ICH-M14 guidelines will also be revised.

In the interim, the guidance and definitions provided in these ICH guidelines should be applied as far as they impact on GVP guidance; With regard to the ICH-E2D(R1) guideline, the recommendations detailed in the EU implementation strategy document and the additional further supportive information published on EMA's ICH-E2D webpage should also be followed.

Also on this topic

Archive of development of good pharmacovigilance practices

Superseded pharmacovigilance guidance documents

Introduction

Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with final considerations on pregnant and breastfeeding women and their children exposed in utero or via breastmilk

Reference Number: EMA/358327/2025

English (EN) (200.43 KB - PDF)

First published: 06/02/2026

View

Final GVP modules

Guideline on good pharmacovigilance practices: Module I – Pharmacovigilance systems and their quality systems

Adopted

Consultation dates: 21/02/2012 to 18/04/2012

Reference Number: EMA/541760/2011

Legal effective date: 02/07/2012

English (EN) (213.14 KB - PDF)

First published: 25/06/2012

Last updated: 25/06/2012

View

Guideline on good pharmacovigilance practices: Module II – Pharmacovigilance system master file (Rev. 2)

Adopted

Reference Number: EMA/816573/2011

Legal effective date: 31/03/2017

English (EN) (340.71 KB - PDF)

First published: 25/06/2012

Last updated: 30/03/2017

View

Guideline on good pharmacovigilance practices: Module III – Pharmacovigilance inspections

Adopted

Reference Number: EMA/119871/2012 Rev 1

Legal effective date: 16/09/2014

English (EN) (189.47 KB - PDF)

First published: 13/12/2012

Last updated: 15/09/2014

View

Guideline on good pharmacovigilance practices (GVP) - Module IV – Pharmacovigilance audits (Rev. 1)

Adopted

Reference Number: EMA/228028/2012 Rev 1

English (EN) (154.02 KB - PDF)

First published: 12/12/2012

Last updated: 11/08/2015

View

Guideline on good pharmacovigilance practices: Module V – Risk management systems (Rev. 2)

Adopted

Consultation dates: 21/02/2012 to 18/04/2012

Reference Number: EMA/838713/2011

Legal effective date: 31/03/2017

English (EN) (568.8 KB - PDF)

First published: 25/06/2012

Last updated: 30/03/2017

View

Guideline on good pharmacovigilance practices (GVP) - Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev. 2)

Adopted

Reference Number: EMA/873138/2011 Rev. 2

Legal effective date: 22/11/2017

English (EN) (2.02 MB - PDF)

First published: 25/06/2012

Last updated: 02/08/2017

View

Guideline on good pharmacovigilance practices (GVP) - Module VI Addendum I – Duplicate management of suspected adverse reaction reports

Adopted

Reference Number: EMA/405655/2016

Legal effective date: 22/11/2017

English (EN) (359.92 KB - PDF)

First published: 28/07/2017

Last updated: 02/08/2017

View

Guideline on good pharmacovigilance practices (GVP) - Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance

Adopted

Reference Number: EMA/178902/2025

Legal effective date: 25/07/2025

English (EN) (334.9 KB - PDF)

First published: 24/07/2025

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Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report

Adopted

Consultation dates: 21/02/2012 to 18/04/2012

Reference Number: EMA/816292/2011 Rev.1*

Legal effective date: 13/12/2013

English (EN) (1.45 MB - PDF)

First published: 25/06/2012

Last updated: 12/12/2013

View

Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev. 3)

Adopted

Reference Number: EMA/813938/2011

Legal effective date: 13/10/2017

English (EN) (235.42 KB - PDF)

First published: 25/06/2012

Last updated: 12/10/2017

View

Guideline on good pharmacovigilance practices (GVP): Module VIII Addendum I - Requirements and recommendations for the submission of information on non-interventional post-authorisation safety studies (Rev. 3)

Adopted

Reference Number: EMA/395730/2012 Rev. 3

English (EN) (86.49 KB - PDF)

First published: 23/06/2020

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Guideline on good pharmacovigilance practices (GVP): Module IX – Signal management (Rev. 1)

Adopted

Reference Number: EMA/827661/2011

Legal effective date: 22/11/2017

English (EN) (283.21 KB - PDF)

First published: 25/06/2012

Last updated: 12/10/2017

View

Guideline on good pharmacovigilance practices (GVP): Module IX Addendum I – Methodological aspects of signal detection

from spontaneous reports of suspected adverse reactions

Adopted

Reference Number: EMA/209012/2015

Legal effective date: 22/11/2017

English (EN) (133.95 KB - PDF)

First published: 12/10/2017

Last updated: 12/10/2017

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Guideline on good pharmacovigilance practices: Module X – Additional monitoring

Adopted

Consultation dates: 27/06/2012 to 24/08/2012

Reference Number: EMA/169546/2012

Legal effective date: 25/04/2013

English (EN) (271.91 KB - PDF)

First published: 25/04/2013

Last updated: 25/04/2013

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Guideline on good pharmacovigilance practices: Module XV – Safety communication (Rev. 1)

Adopted

Reference Number: EMA/118465/2012

Legal effective date: 13/10/2017

English (EN) (188.52 KB - PDF)

First published: 24/01/2013

Last updated: 12/10/2017

View

Guideline on good pharmacovigilance practices (GVP) Module XVI – Risk minimisation measures (Rev 3)

Reference Number: EMA/204715/2012

Legal effective date: 06/08/2024

English (EN) (937.46 KB - PDF)

First published: 28/02/2014

Last updated: 05/08/2024

View

Guideline on good pharmacovigilance practices (GVP) - Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks

Adopted

Reference Number: EMA/608947/2021

Legal effective date: 29/08/2025

English (EN) (254.73 KB - PDF)

First published: 28/08/2025

View

Guideline on good pharmacovigilance practices (GVP): Module XVI Addendum II – Methods for evaluating effectiveness of risk minimisation measures

Reference Number: EMA/419982/2019

Legal effective date: 06/08/2024

English (EN) (624.08 KB - PDF)

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View

- Where GVP chapters refer to Modules XI or XIV, consult the Agency's page on partners and networks.
- Where GVP chapters refer to Module XII, consult the Agency's page on post-marketing authorisation: regulatory and procedural guidance for human medicinal products.
- Where GVP chapters refer to Module XIII, consult the Agency's page on the incident management plan.
- In relation to the GVP VII module please note that an explanatory note and a question and answer guidance document for assessors have been developed to clarify certain aspects of the single assessment that are specific to nationally authorised products. These documents should be considered as interim guidance until the GVP VII module is revised as per the established process. Once the updated GVP module is published, this guidance will be removed. These documents can be found on the Periodic safety update reports: questions and answers page.
- Where GVP modules refer to the European Medicines Agency's and the Heads of Medicines Agencies' procedural advice on referral procedures for safety reasons, consult referral procedures page.

Final GVP product- or population-specific considerations

Guideline on good pharmacovigilance practices (GVP): Product- or population-

specific considerations I: Vaccines for prophylaxis against infectious diseases

Adopted

Reference Number: EMA/488220/2012

Legal effective date: 13/12/2013

English (EN) (460.19 KB - PDF)

First published: 12/12/2013

Last updated: 12/12/2013

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Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations II: Biological medicinal products

Adopted

Reference Number: EMA/168402/2014

Legal effective date: 16/08/2016

English (EN) (377.05 KB - PDF)

First published: 15/08/2016

Last updated: 15/08/2016

View

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

Adopted

Reference Number: EMA/653036/2019

Legal effective date: 09/02/2026

English (EN) (488.58 KB - PDF)

First published: 06/02/2026

View

Guideline on good pharmacovigilance practices (GVP): Product- or Population-Specific Considerations IV: Paediatric population

Adopted

Reference Number: EMA/572054/2016

Legal effective date: 08/11/2018

English (EN) (206.02 KB - PDF)

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Final GVP annex I - Definitions

Guideline on good pharmacovigilance practices: Annex I - Definitions (Rev. 5)

Reference Number: EMA/876333/2011

Legal effective date: 06/08/2024

English (EN) (335.04 KB - PDF)

First published: 25/06/2012

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Final GVP annex II - Templates

Guideline on good pharmacovigilance practices: Annex II – Templates: Cover page of periodic safety update report (PSUR)

Adopted

Consultation dates: 21/02/2012 to 18/04/2012

Reference Number: EMA/170043/2013

Legal effective date: 25/04/2013

English (EN) (176.08 KB - PDF)

First published: 25/06/2012

Last updated: 25/04/2013

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Guideline on good pharmacovigilance practices: Annex II – Templates: Direct Healthcare Professional Communication (DHPC) (Rev. 1)

Adopted

Reference Number: EMA/36988/2013

Legal effective date: 13/10/2017

English (EN) (61.21 KB - PDF)

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Guideline on good pharmacovigilance practices (GVP): Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication (CP DHPC)

Adopted

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View

For other templates developed outside the GVP process, see:

Risk management plans

Pharmacovigilance: Regulatory and procedural guidance

Final GVP annex III - Other pharmacovigilance guidance

Other pharmacovigilance guidance developed outside the GVP process:

Pharmacovigilance: regulatory and procedural guidance

Guideline on specific adverse reaction follow-up questionnaires (Specific AR FUQ)

Reporting requirements of marketing authorisation holders in the EU regarding suspected adverse reactions occurring with medicinal products they donate outside the EU to public health programmes against neglected tropical diseases

Signal management

EudraVigilance

Access to EudraVigilance data

Incident management plan

Periodic safety update reports (PSURs)

Guideline on registry-based studies - Scientific guideline

ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Guideline on key aspects for the use of pharmacogenomics in the pharmacovigilance of medicinal products

Good practice guide on recording, coding, reporting and assessment of medication errors

Good practice guide on risk minimisation and prevention of medication errors

Risk minimisation strategy for high-strength and fixed-combination insulin products, addendum to the good practice guide on risk minimisation and prevention of medication errors

Guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products - Scientific guideline

PRAC rules of procedure

Final GVP annex IV - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for pharmacovigilance

ICH E2A Clinical safety data management: definitions and standards for expedited reporting - Scientific guideline

ICH E2B (R3) Electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide - Scientific guideline

ICH E2C (R2) Periodic benefit-risk evaluation report - Scientific guideline

ICH E2D post-approval safety data management - Scientific guideline

ICH E2E Pharmacovigilance planning (Pvp) - Scientific guideline

ICH E2F Development safety update report - Scientific guideline

ICH M1 Medical Dictionary for Regulatory Activities (MedDRA)

MedDRA support documentation

Standardised MedDRA Queries (SMQs)

ICH M2 electronic standards for the transfer of regulatory information (ESTRI)

ICH guideline E19 on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials - Scientific guideline

ICH M14 guideline on general principles on plan, design and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines - Scientific guideline

Final GVP annex V - Abbreviations

Guideline on good pharmacovigilance practices: Annex V – Abbreviations (Rev. 1)

Adopted

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GVP under public consultation

No document under public consultation at present.

Related content

Privacy statement

Page update history

An update log is available to show the date and summary of changes to this webpage. It does not include updates to linked documents or minor edits like typos or broken link fixes.

The tracking of updates begins in February 2026.

See update history

Topics

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Pharmacovigilance

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