9 October 2017
EMA/135814/2013 Rev 1*

Guideline on good pharmacovigilance practices (GVP)

Annex V – Abbreviations (Rev 1*)

* Revision 1 includes a revision to the abbreviation SDR and the following additional abbreviations: Add, ADME, aRMM, BSA, CAT, DCP, EDI, EMA, Enpr-EMA, eRMR, EudraCT, EU-POG, EV EWP, GPG, HLGT, ID, ME, MRP, No, PDCO, PEM, PhV, PIP, PUMA, RCT, RMM, SCOPE and US FDA.

See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

The European Medicines Agency is an agency of the European Union

Abbreviation	
A-CASI	Audio computer-assisted self-interviewing
ACK	Acknowledgement
Add	Addendum (in GVP reference numbers)
ADME	Absorption, distribution, metabolism and excretion
ADR	Adverse drug reaction (preferred term: Adverse reaction)
AE	Adverse event
AEFI	Adverse event following immunisation
AESI	Adverse event of special interest
App	Appendix (in GVP reference numbers)
AR	Assessment report
aRMM	Additional risk minimisation measure
Art	Article
ATC	Anatomical- therapeutic-chemical (in Anatomical Therapeutic Chemical Classification System)
ATMP	Advanced therapy medicinal product
BSA	Body surface area
CAP	Centrally authorised medicinal product
CAT	Committee for Advanced Therapies (at the European Medicines Agency)
CCDS	Company core data sheet
CCSI	Company core safety information
CHMP	Committee for Medicinal Products for Human Use (at the European Medicines Agency)
CIOMS	Council for International Organizations of Medical Sciences
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures – Human (at the European Medicines Agency)
COSO	Committee of Sponsoring Organizations of the Treadway Commission
DB	Database
DCP	Medicinal product authorised through the decentralised authorisation procedure
DDPS	Detailed description of the pharmacovigilance system
DHPC	Direct healthcare professional communication

Abbreviation	
DIBD	Development international birth date
DIR	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended
DLP	Data lock point
DP	Decentralised authorisation procedure
DSUR	Development safety update report
DUS	Drug utilisation study
EC (in reference numbers of legislation)	European Community
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECG	Electrocardiogram
eCTD	Electronic common technical document
EDI	Electronic data interchange
EEA	European Economic Area
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
ENS	Early Notification System
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
EPPV	Early post-marketing phase vigilance (e.g. in Japan)
ePSUR	Periodic safety update report in structured electronic format
eRMR	Electronic reaction monitoring report
ERMS FG	European Risk Management Strategy Facilitation Group (of the Heads of Medicines Agencies)
ESTRI	ICH electronic standards for the transfer of regulatory information
EU	European Union
EudraCT	European Clinical Trials Database
EU-POG	EU Network Pharmacovigilance Oversight Group

Abbreviation	
EURD	EU reference date
EV	EudraVigilance
EV EWG	EudraVigilance Expert Working Group (at the European Medicines Agency)
EVCTM	EudraVigilance Clinical Trial Module
EVDAS	EudraVigilance Data Analysis System
EVMPD	EudraVigilance Medicinal Product Dictionary
EVPM	EudraVigilance Post-Authorisation Module
FAERS	FDA Adverse Event Reporting System (of the US FDA)
GCP	Good clinical practice
GDP	Good distribution practice
GLP	Good laboratory practice
GMP	Good manufacturing practice
GPG	Good practice guide
GPP	ISPE Guidelines for good pharmacoepidemiology practices
GVP	Good pharmacovigilance practices (for the European Union)
HLGT	Higher level group term (in MedDRA)
HLT	High-level term (in MedDRA)
HMA	Heads of Medicines Agencies
IBD	International birth date
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	Individual case safety report
ID	Identifier
IIA	Chartered Institute of Internal Auditors
IME	Important medical event
INN	International non-proprietary name
IR	Commission Implementing Regulation (EU) No 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC
ISO	International Organization for Standardization
ISPE	International Society for Pharmacoepidemiology

Abbreviation	
IT	Information technology
IVRS	Interactive voice response systems
MA	Marketing authorisation
MAH	Marketing authorisation holder
MaxSPRT	Maximised sequential probability ratio test
ME	Medication error
MedDRA	ICH Medical Dictionary for Regulatory Activities
MR	Mutual recognition authorisation procedure
MRP	Mutually recognised medicinal product, i.e. medicinal product authorised through the mutual recognition authorisation procedure
MS	Member State
NAP	Nationally authorised medicinal product
NCA	National competent authority
NIMP	Non-investigational medicinal product
No	Number
O/E	Observed-versus-expected analysis
P.	Product- or Population-Specific Considerations (in GVP)
PAES	Post-authorisation efficacy study
PAS	Post-authorisation study
PASS	Post-authorisation safety study
PBRER	Periodic benefit-risk evaluation report
PCG	Project Co-ordination Group (of the governance structure set up by the European Medicines Agency and national competent authorities for the implementation of the new pharmacovigilance legislation)
PDCO	Paediatric Committee Committee (at the European Medicines Agency)
PEM	Prescription event monitoring
PhV	Pharmacovigilance
PhV DB	Pharmacovigilance database
PhVIWG	Pharmacovigilance Inspectors Working Group (at the European Medicines Agency)
PIP	Paediatric investigation plan
PL	Package leaflet

Abbreviation	
PPP	Pregnancy prevention programme
PRAC	Pharmacovigilance and Risk Assessment Committee (at the European Medicines Agency)
PrAR	Preliminary assessment report
PRR	Proportional reporting ratio
PSMF	Pharmacovigilance system master file
PSUR	Periodic safety update report
PT	Preferred term (in MedDRA)
PUMA	Paediatric use marketing authorisation
QPPV	Qualified person responsible for pharmacovigilance in the EU
QRD	Quality Review of Documents (at the European Medicines Agency)
RCT	Randomised clinical trial
REG	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency as amended
Rev	Revision
RMM	Risk minimisation measure
RMP	Risk management plan
SCCS	Self-controlled case series design
SCOPE (short for SCOPE Joint Action)	Strengthening Collaboration for Operating Pharmacovigilance in Europe Joint Action (of EU Member States)
SDR	Signal of disproportionate reporting
SmPC	Summary of product characteristics
SMQ	Standardised MedDRA query
SOC	System organ class (in MedDRA)
SUSAR	Suspected unexpected serious adverse reaction
TT	Timetable
URD	Union reference date (preferred term: EU reference date)
US FDA	United States Food & Drug Administration
WHO	World Health Organization
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

Abbreviation	
XEVPRM	eXtended EudraVvigilance Product Report Message