FORUM

Abbreviation list Pharmacovigilance/Drug Safety

A

ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Events Following Immunization
AF	Application Form
AI	Artificial Intelligence
AMG	German Medicines Act (ger. ArzneiMittelGesetz)
API	Active Pharmaceutical Ingredient
AR	Assessment Report
AR	Adverse Reaction
ARD	Applicant's Response Document
ASMF	Active Substance Master File
ASR	Annual Safety Report
ATC-Code	Anatomical Therapeutic Chemical Code (WHO)
ASR	Annual Safety Report
ATMP	Advanced Therapeutic Medicinal Product

B

BfArM	Federal Institute for Pharmaceuticals and Medical Products in Germany (ger. Bundesinstitut für Arzneimittel und Medizinprodukte)
BMG	Federal Ministry of Health in Germany (ger. BundesMinisterium für Gesundheit)
BMWP	Biosimilar Medicinal Products Working Party
BPG	Best Practice Guide
BPWP	Blood Products Working Party
BVL	Federal Institute for Consumer Protection and Food Safety
BWP	Biotechnology Working Party

C

CA	Competent Authority
CAB	Change Advisory Board
CAP	Centralised Authorised/Approved Product
CAPA	Corrective and Preventive Action
CAT	Committee for Advanced Therapies
CCDS	Company Core Data Sheet
CCSI/CSI	Company Core Safety Information
CD	Commission Decision
CDS	Core Data Sheet
CEP	Certification of suitability to the monographs of the European Pharmacopoeia
CESP	Common European Submission Platform
CESSP	Common European Single Submission Portal
CHMP	Committee for Medicinal Products for Human Use
CI	ContraIndication
CIOMS	Council for International Organisations of Medical Sciences
CMA	Conditional Marketing Authorisation
CMC	Chemistry, Manufacturing, and Control
CMD(h)	Coordination group for Mutual recognition and Decentralised procedures – human
CMD(v)	Coordination group for Mutual recognition and Decentralised procedures - veterinary
CMS	Concerned Member States
CO	Clinical Overview
CoE	Council of Europe
COS	Certification Of Suitability
CP	Centralised Procedure
CPP	Certificate of Pharmaceutical Product
CPP	Critical Process Parameter
CR	Controlled Release
CRA	Clinical Research Associate
CRD	Common Renewal Date
CRF	Case Report Form
CRO	Clinical Research Organisation

CSDB	Corporate Serial number DataBase
CSI/CCSI	Core Safety Information
CSP	Core Safety Profile
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTD	Common Technical Document
CTIS	Clinical Trial Information System
CTS	Communication Tracking System
CVMP	Committee for Medicinal Products for Veterinary use

D

D	Day
DAR	Draft Assessment Report
DARWIN	Data Analysis and Real World Interrogation Network (EU)
DC	DeCentralised
DCP	DeCentralised Procedure
DDL	Dear Doctor Letter
DDPS	Detailed Description of the Pharmacovigilance System
DHPC	Direct Healthcare Professional Communication
DIMDI	German Institute for Medical Documentation and Information (ger. Deutsches Institut für Medizinische Dokumentation und Information)
DLP	Data Lock Point
DMC/DSMB	Data Monitoring Committee
DME	Designated Medical Event
DMF	Drug Master File
DP	Drug Product
DRA	Drug Regulatory Affairs
DSMB/DMC	Data and Safety Monitoring Board
DSUR	Development Safety Update Report
DUS	Drug Utilisation Study

E

E2B	Guideline for electronic transmission of ICSRs
EAEPC	European Association of Euro-Pharmaceutical Companies
eAF	Electronic Application Form
EC	European Commission
EC	Ethics Committee
ECC	Error Correction Code
ECDC	European Centre for Disease Prevention and Control
eCTD	Electronic Common Technical Document
EDBMS	EudraVigilance DataBase Management System
EDI	Electronic Data Interchange
EDMF	European Drug Master File
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area (EU + Iceland, Liechtenstein, Norway)
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System
EN	European Norm
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EoP	End of Procedure
EPAR	European Public Assessment Report
ePI	Electronic Product Information
EPITT	European Pharmacovigilance Issues Tracking Tool (EMA)
EPL	EMA Product Lead
ERA	Environmental Risk Assessment
ERMS	EU Risk Management Strategy
eRMR	Electronic Reaction Monitoring Report
ERP	European Reference Medicinal Product
ETL	Extract, Transform, and Load
EU	European Union
EU-PAS	EUropean electronic register of Post-Authorisation Studies (EMA; ENCePP)
EudraCT	European Clinical Trials database

EudraGMDP	An EU database of GMP and GDP information (EMA)
EUDRANET	European Union Drug Regulatory Authorities Network (EMA)
EUnetHTA	EU network for Health Technology Assessment
EURD-List	EUropean Reference Dates List
EV	EudraVigilance
EVCTM	EudraVigilance Clinical Trial Module
EVDAS	EudraVigilance Data Analysis System
EVMPD	EudraVigilance Medicinal Product Dictionary
EVPM	EudraVigilance Post-authorisation Module
EVWEB	EudraVigilance WEB application
EWG	Expert Working Group
EWP	Efficacy Working Party
EXCiPACT	International Certification Scheme for pharmaceutical excipient manufacturers/distributors

F

FAERS	FDA Adverse Event Reporting System
FAIR	Findable, Accessible, Interoperable, and Reusable
FAR	Final Assessment Report
FDA	Food and Drug Administration
FDC	Fixed-Dose Combination
FMD	Falsified Medicines Directive
FMEA	Failure Mode and Effects Analysis
FP	Finished Product
FPP	Finished Pharmaceutical Product
FRAR	Final Renewal Assessment Report
FUM	Follow-Up Measure
FVAR	Final Variation Assessment Report

G

GCC	Gulf Cooperation Council
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GDPR	General Data Protection Regulation
Ger	German
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GS	Global Standards
GS1	Organisation and collaboration platform for a common language of business worldwide; GS1 standards are the most widely used system of standards in the world (Example: GTIN)
GSL	General Sale List
GTIN	Global Trade Identifier Number (GS1)
GVP	Good Pharmacovigilance Practice

H

HA	Health Authority
HBD	Harmonised Birth Day
HCP	HealthCare Professional
HLGT	High-Level Group Term (MedDRA)
HLT	High-Level Term (MedDRA)
HMA	Heads of Medicines Agencies
HMP	Herbal Medicinal Products
HPC	High Performance Computing
HQ	Head Quarter
HTA	Health Technology Assessment
HWG	Medicinal Advertising Act in Germany (ger. HeilmittelWerbeGesetz)

IB	Investigators Brochure
IBD	International Birth Date
IC	Informed Consent
ICH	International Conference on Harmonisation
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	Individual Case Safety Report
IDMP	Identification and Description of Medicinal Products
IGDRP	International Generic Drug Regulators Pilot/Programme
IIT	Investigator Initiated Trial
IME	Important Medical Event
IMPACT	International Medicinal Products Anti-Counterfeiting Taskforce (WHO)
IMPD	Investigational Medicinal Product Dossier
INN	International Non-proprietary Name (WHO)
IPEC Federation	International Pharmaceutical Excipients Council Federation
IPRF	International Pharmaceutical Regulators Forum
IPRP	International Pharmaceutical Regulators Programme
IRB	Institutional Review Board
IRIS	EMA's online regulatory and scientific information management platform
IRN	Incident Review Network
ISE	Integrated Summary of Efficacy
ISO	International Organisation for Standardization
ISRB	Integrated Summary of Risk Benefit
ISS	Integrated Summary of Safety
ITIL	Information Technology Infrastructure Library
ITF	Innovation Task Force (EMA)

K

KOL	Key Opinion leader
KPI	Key Performance Indicator

L

LCM	LifeCycle Management
LLM	Large Language Model
LLT	Lowest Level Term (MedDRA)
LoQI	List of Outstanding Issues
LoQ	List of Questions

M

MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MB	Management Board
MDM	Master Data Management
MedDRA	Medical Dictionary for Drug Regulatory Activities
MedWatch	Safety information and adverse event reporting program der FDA
MERS	Multi-agency Electronic Regulatory System
MFA	Multi Factor Authentication
MI	Machine Intelligence
ML	Machine Learning
MR	Mutual Recognition
MRP	Mutual Recognition Procedure
MS	Member States

N

NAP	Nationally Authorised Product
NAP	National Action Plan
NCA	National Competent Authority
NeeS	Non eCTD Electronic Submission
NfG	Note for Guidance
NHRN	National Healthcare Reimbursement Number
NIS	Non-Interventional Study
NIST	National Institute of Standards and Technology
NMVO	National Medicines Verification Organisation
NMVS	National Medicines Verification System
NOAEL	No Observed Adverse Effect Level
NOC	No Objection Certificate
NOEL	No Observed Effect Level
NP	National Procedure
NtA	Notice to Applicants
NTIN	National Trade Item Number
NUI	Non-Urgent Information
NUIS	Non-Urgent Information System

O

OE/OPEX	Operational Excellence
OE	Oral Explanation
OH	Oral Hearing
OMS	Organisation Management Service
OOS	Out Of Specification
OOT	Out Of Trend
OPEX/OE	OPerational EXcellence
OS	Operating System
OTC	Over-The-Counter

P

P	Pharmacist
PAC	Post-Approval Changes
PAES	Post Authorisation Efficacy Study
PaedPAR/PdPAR	Paediatric Public Assessment Report
PAI	Pre-Approval Inspection
PAM	Post Authorisation Measures
PAR	Public Assessment Report
pAR	Preliminary Assessment Report
PAS	Prior Approval Supplement
PASS	Post Authority Safety Study
PBRER	Periodic Benefit-Risk Evaluation Report
PC	Product Code
PdAR	Paediatric Assessment Report
PdPAR/PaedPAR	Paediatric Public Assessment Report
PEI	Paul Ehrlich Institute (Agency of the German Federal Ministry of Health)
Ph.Eur.	Euopean Pharmacopoeia
PhVIWG	PharmacoVigilance Inspectors Working Group
PhVWP	PharmakoVigilance Working Part
PI	Product Information
PI1	Principal Investigator
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIL/PL	Patient Information Leaflet
PIP	Pediatric Investigation Plan
PL/PIL	Package Leaflet
PL	Product Licence
PL1	Private Label
PLM	Product Lifecycle Management
PMF	Plasma Master File
PMS	Product Management Service
POM	Prescription-Only Medicines
PPN	Pharmaceutical Product Number
PRAC	Pharmacovigilance Risk Assessment Committee
PRAR	Preliminary Renewal Assessment Report

PSMF	PharmacoVigilance System Master File
PSRPH	Potential Serious Risk to Public Health
PSUR	Periodic Safety Update Report
PSUSA	EU PSUR Single Assessment
PT	Preferred Term (MedDRA)
PV	PharmacoVigilance
PVAR	Preliminary Variation Assessment Report
PVS	PharmacoVigilance System

Q

Q&A	Questions and Answers
QA	Quality Assurance
QC	Quality Control
QM	Quality Management
QMS	Quality Management System
QOS	Quality Overall Summary
QP	Qualified Person
QPPV	Qualified Person for Pharmacovigilance
QPR	Quality Product Review
QRD	Quality Review of Documents
QWP	Quality Working Party

R

R&D	Research & Development
RA	Rapid Alert
RA	Regulatory Affairs
RA	Risk Assessment
RAR	Rapid Assessment and Response
RAR	Renewal Assessment Report
RAS	Rapid Alert System
RBA	Risk-Based Approach

RCA	Root Cause Analysis
RCT	Randomised Clinical Trial
REMS	Risk Evaluation and Mitigation Strategy (FDA)
RFI	Request for Information
RFID	Radio Frequency Identification
RMM	Risk Minimisation Measure
RMP	Reference Medicinal Product
RMP	Risk Management Plan
RMS	Reference Member State
ROR	Reporting Odds Ratio
RSI	Request for Supplementary Information
RSI	Reference Safety Information
RUT	Readability User Test
Rx	Medical prescription / Only available on prescription

S

SA	Scientific Advice
SAE	Serious Adverse Event
SAG	Scientific Advisory Group
SAR	Serious Adverse Reaction
SAWP	Scientific Advice Working Party
SCM	Supply Chain Management
SD	Signal Detection
SDS	Safety Data Sheet
SF	Safety Factor
SLA	Service Level Agreement
SmAR	Summary Assessment Report
SME	Small and Medium enterprises
SmPC	Summary of Product Characteristics
SMS	Substance Management Services
SMQ	Standardised MedDRA Queries
SOC	System Organ Class
SOP	Standard Operation Procedure
SPC	Supplementary Protection Certificate

SPOR	Substance, Product, Organisation, and Referential (ISO)
SRP	Subsequent Recognition Procedure
SRS	Safety Reporting System
SSO	Single Sign-On
StB	Local QPPV in Germany (ger. Stufenplanbeauftragte(r))
STAMP	Expert group on Safe and Timely Access to Medicines for Patients
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWI	Standard Working Instruction
SWP	Safety Working Party

T

TF	Task Force
TME	Targeted Medical Event
TOC	Table of Content

U

UAR	Unexpected Adverse Reaction
UI	Unique Identifier
USR	Urgent Safety Restriction
UUP	Urgent Union Procedure

V

VAERS	Vaccine Adverse Event Reporting System
VAMF	Vaccine Antigen Master File
VAR	Variation Assessment Report
vet	Veterinary
VICH	Veterinary International Council for Harmonisation

VigiBase	Database of reported potential side effects of medicinal products (WHO)

W

WEU	Well-Established Use
WHO	World Health Organisation
WI	Work Instruction
WL	Warning Letter (FDA)
WS	Work Sharing
WTO	World Trade Organisation

X

XEVMPD	Extended Eudravigilance Medicinal Product Dictionary
XEVPRM	EudraVigilance Product Report Message
XML	Extensible Markup Language

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