PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

PvPI TRAINING MODULE

Indian Pharmacopoeia Commission,
National Coordination Centre – PvPI
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Abbreviations

ACSoMP	Advisory Committee on Safety of Medicinal Products (WHO)
ADE	Adverse drug event/effect
ADR	Adverse drug reaction
AEFI	Adverse event following immunisation
API	Active pharmaceutical ingredient (WHO)
ART	Antiretroviral therapy
ARV	Antiretrovirals
ATC	Anatomical, Therapeutic, Chemical classification
CDC	Centers for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organization
CEM	Cohort Event Monitoring
CIOMS	Council for International Organizations of Medical Sciences
CRO	Contract research organisation
DDD	Defined Daily Dose
DIA	Drug Information Association
DTC	Direct to consumer
DTP	Direct to patient
E2B	The current international standard for ADR reporting developed by ICH
FIC	(WHO) Family of International Classifications
FOI	Freedom of information
FTP	File transfer protocol
GACVS	Global Advisory Committee on Vaccine Safety (WHO)
GCP	Good clinical practice.
GLP	Good laboratory practice
GMP	Good manufacturing practice
IB	Investigators brochures.
ICD	International Classification of Diseases
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	Individual case safety report

IPC	Indian Pharmacopoeia Commission
ISO	International Organization for Standardization
ISoP	International Society of Pharmacovigilance
ISPE	International Society for Pharmacoepidemiology
MAH	Market authorisation holder
MedDRA	Medical Dictionary for Drug Regulatory Affairs
NCC	National coordination centre (for pharmacovigilance) Prepared by the Uppsala Monitoring Centre
NCE	New chemical entity
NDA	New Drug Application
NGO	Non-governmental organisation
NME	New molecular entity
NSAID	Non-steroidal anti-inflammatory drug
OTC	Over-the-counter
PCC	Poison Control Centre
PDR	Physicianôs Desk Reference
PDS	Pharmacoepidemiology and Drug Safety (journal)
PD	Pharmacodynamics
PK	Pharmacokinetics
po	per oral
PEM	Prescription event monitoring
PIL	Package insert leaflet
PMS	Post-marketing surveillance
POM	Prescription only medicine
PPI	Proton Pump Inhibitor
PSM	Procurement and supply management
PSUR	Periodic safety update report
PV	Pharmacovigilance
PvPI	Pharmacovigilance Programme of India
QA	Quality Assurance
QOS	Quality Overall Summary
QSM-WHO	Quality Assurance and Safety of Medicines (WHO)
RCA	Root-cause analysis
SAE	Serious Adverse Event

SAR	Serious Adverse Drug Reaction
SOC	System organ class
SOP	Standard operating procedure
SUSAR	Suspected unexpected serious adverse reaction
UAR	unexpected adverse reaction
UMC	The Uppsala Monitoring Centre
UNITAID	Organization cooperating with WHO and others on the WHO millennium goals
VAERS	Vaccine adverse event reporting system
WHO	World Health Organization
WHO-ART	WHO Adverse Reaction Terminology
WHO-CC	WHO Collaborating Centre, Prepared by the Uppsala Monitoring Centre.
WHO-DD	WHO Drug Dictionary
WHO-DDE	WHO Drug Dictionary Enhanced
WHO-UMC	World Health Organization- Uppsala Monitoring Centre