EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

ANNEX III Acronyms and abbreviations used in the PRAC (Pharmacovigilance Risk Assessment Committee) Minutes

ADR(s)	**Adverse Drug Reaction(s)**
PhVIWG	Ad Hoc Pharmacovigilance Inspectors Working Group
AE(s)	Adverse Event(s)
AEFI(s)	Adverse Event(s) Following Immunisation
AR(s)	Assessment Report(s)
ARITMO	The acronym for the "Arrhythmogenic potential of drugs" project, which "claims to analyse **the arrhythmic potential of drugs** in the following classes of **study drugs** (> 250 compounds): **antipsychotics**, **anti-infectives** (antibacterials, antimycotics and antivirals) and **H1-antihistamines**, globally and in specific subgroups (age, co-morbidity, genetically)".
ART	Anti-Retroviral Therapy
ATC(/DDD)	Anatomical Therapeutic Chemical classification system (with Defined Daily Doses)
ATMP(s)	Advanced Therapy Medicinal Product(s) (i.e. gene, cell and tissue engineering products)
BMWP	Biosimilar Medicinal Products Working Party
BPWP	Blood Products Working Party
BWP	Biologics Working Party
CAP(s)	Centrally Authorised Product(s)
CAPA plan	Corrective and preventive action plan
CCDS	Company Core Data Sheet
CHMP	Committee for Medicinal Products for Human Use *(previously: CPMP)*
CI	Contraindication
CIOMS	Council for International Organizations of Medical Sciences
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures (human) (*previously: MRFG*)
CMS(s)	Concerned Member State(s)
COMP	Committee for Orphan Medicinal Products
CPMP	*Was: Committee for Proprietary Medicinal Products, use: CHMP*

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8668
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

CPWP	Cell-based Products Working Party (retired working party)
CSP(s)	Core Safety Profile(s)
CSR	Clinical Study Report
CTD	Common Technical Document
CTFG	Clinical Trial Facilitation Group
D:A:D	Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) is a prospective multi-cohort study of HIV-infected persons under active follow-up.
DCP	Decentralised Procedure
DDPS(s)	Detailed Description of the Pharmacovigilance System(s)
DG	Directorate-General (at the EC)
DHPC	Direct Healthcare Professional Communication
DIA	Drug Information Association
DLP	Data Lock Point
DRAs	Drug Regulatory Authorities – *non-EU only, see CAs*
DSRU	Drug Safety Research Unit
EC	European Commission (http://ec.europa.eu/index_en.htm)
eCTD	electronic Common Technical Document
EFA	European Federation of Allergy and Airways Diseases Patients' Associations (http://www.efanet.org)
EFPIA	European Federation of Pharmaceutical Industries and Associations (http://www.efpia.eu)
EFSA	European Food Safety Authority (http://www.efsa.europa.eu)
EGA	European Generic Medicines Association (http://www.egagenerics.com)
EMA	European Medicines Agency (http://www.ema.europa.eu/ema)
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction (http://www.emcdda.europa.eu)
EMEA	*Old acronym for: European Medicines Agency; use: EMA*
ENTIS	European Network of Teratology Information Services (http://www.entis-org.com)
EP	European Parliament (http://www.europarl.europa.eu/)
EPAR	European Public Assessment Report
EPITT	European Pharmacovigilance Issues Tracking Tool
ERMS	EU Risk Management Strategy
eRMR	electronic Reaction Monitoring Report
EU	European Union
EU-ADR Project	**E**xploring and **U**nderstanding **A**dverse **D**rug **R**eactions by Integrative Mining of Clinical Records and Biomedical Knowledge *(formerly known as ALERT)*
Eudra-	European Drug Regulatory Authorities
EudraNet	- Network
EudraSmPC	- Summary of Product Characteristics
EUROCAT	A European network of population-based registries for the epidemiologic surveillance of congenital anomalies. *The acronym EUROCAT is derived from its original name "European Concerted Action on Congenital Anomalies and Twins".*
EURORDIS	European Organisation for Rare Diseases (http://www.eurordis.org/)
EUTCT	European Union Telematics Controlled Terms
EV	EudraVigilance
EV-EWG	EudraVigilance Expert Working Group

EVM	European Vaccine Manufacturers
EVMPD	EudraVigilance Medicinal Products Dictionary
EWP	Efficacy Working Party (retired working party)
fAR	final Assessment Report
FDA	Food and Drug Administration (US)
FUM	Follow-up Measures
fvAR	final variation Assessment Report
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GPRD	General Practice Research Database (UK)
GTWP	Gene Therapy Working Party (retired working party)
GVP	Good Pharmacovigilance Practice
HAART	Highly Active Anti-Retroviral Therapy
HBD	Harmonised Birth Date
HCP(s)	Healthcare Professional(s)
HCPWG	Healthcare Professionals' Working Group
HMA - HMA-Joint - HMA(h) - HMA(v)	Heads of Medicines Agencies *(formerly: HoA)* with three groups: HMA-Joint, HMA-Human and HMA-Vet
HMPC	Committee on Herbal Medicinal Products
HoA	*was: Heads of Agencies, use: HMA*
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR(s)	Individual Case Safety Report(s)
INN	International Non-proprietary Name
IRN	Incident Review Network
iv	Intravenous
KPNC	Kaiser Permanente Northern California
LoOI	List of Outstanding Issues (authored by the CxMP and addressed to the Applicant at ca Day 180)
LoQ	List of Questions (authored by the CxMP and addressed to the Applicant at Day 120)
LoU	Letter of Undertaking
LTT	Lines to take [document usually not for publication]
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MB	Management Board
MedDRA	Medical Dictionary for Regulatory Activities
MR	Mutual Recognition
MRFG	*Was: Mutual Recognition Facilitation Group, use: CMDh*
MRP	Mutual Recognition Procedure
MS(s)	Member State(s)
NAP(s)	Nationally Authorised Product(s)
NCA(s)	National Competent Authority(ies)
NfG	Note for Guidance

NICE	National Institute of Clinical Excellence (UK)
NNRTI	Non-Nucleoside analogues Reverse Transcriptase Inhibitor
NRG	Invented Name Review Group
NRTI	Nucleoside analogue Reverse Transcriptase Inhibitor
NtA	Notice to Applicants
NUI	Non-Urgent Information (sometimes called "Infofax"); see also RA/NUI System
OE	Oral Explanation
ORGAM	Organisational Matters
OTC	Over-the-counter
pAR	preliminary Assessment Report
PASS	Post-authorisation Safety Study
PCG	Product Coordination Group
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee *(previously: PEG)*
PEG	*Was: Paediatric Working Party; use: PDCO* *(was: Paediatric Expert Group; no acronym change)*
PEM (Study)	Prescription-Event Monitoring (Study)
PgWP	Pharmacogenomics Working Party
PHARMO	Institute for Drug Outcomes Research (NL)
PhRMA	Pharmaceutical Research and Manufacturers of America
PhV	Pharmacovigilance
PhVIWG	Pharmacovigilance Inspectors Working Group
PhVWP	Pharmacovigilance Working Party (retired working party)
PhEur	European Pharmacopoeia
PI	Product Information
PIL	Patient Information Leaflet
PIP(s)	Paediatric Investigation Plan(s)
PIs	Protease Inhibitors
PL	Package Leaflet
PMS	Post-Marketing Surveillance
POM	Prescription-only Medicine
PPP	Pregnancy Prevention Programme
PRR	Proportional Reporting Ratio
PRAC	Pharmacovigilance Risk Assessment Committee
PREG	Pandemic Response Expert Group
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Single Assessment
PT(s)	Preferred Term(s)
PTL	Product Team Leader (EMA)
QPPV	Qualified Person for Pharmacovigilance
QRD	Quality Review of Documents
QWP	Quality Working Party
RA	Rapid Alert; see also RA/NUI System
RA/NUI System	Rapid Alert/Non-Urgent Information System
RCT(s)	Randomised Controlled Trial(s)
Re	Regarding
REMS	Risk Evaluation & Mitigation Strategies

RMM(s)	Risk Minimisation Measure(s)
RMP(s)	Risk Management Plan(s)
RMR	Reaction Monitoring Report
RMS(s)	Reference Member State(s)
RSI	Request for Supplementary Information
SAE	Serious Adverse Event
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
sc	subcutaneous
SmPAR	Summary Pharmacovigilance Assessment Report
SMQs	Standardised MedDRA Queries
SOC	System Organ Class
SOP	Standard Operating Procedure
SmPC	Summary of Product Characteristics
SUSAR	Suspected Unexpected Serious Adverse Reactions
SWP	Safety Working Party
TC	Teleconference
USR	Urgent Safety Restriction
VAESCO	Vaccine Adverse Event Surveillance & Communication
VC	Videoconference
VWP	Vaccine Working Party
WHO	World Health Organization
WHO-UMC	WHO-Uppsala Monitoring Centre

Country codes of EU/EEA Countries[1]

Country (short name in English)	ISO Country Code	Agency	Acronym
Austria	AT	European Union Telematics Controlled Terms	AGES
Belgium	BE	Federal agency for medicines and health products	FAMHP
Bulgaria	BG	Bulgarian Drug Agency	BDA
Croatia	HR	Agency for medicinal products and medical devices of Croatia	ALMP
Cyprus	CY	Ministry of Health Pharmaceutical Services	MOH
Czech Republic	CZ	State Institute for Drug Control	SUKL
Denmark	DK	Danish Health and Medicines Agency	DKMA
Estonia	EE	State Agency of	

		Medicines	
Finland	FI	Finnish Medicines Agency	FIMEA
France	FR	The French National Agency for Medicines and Health Products Safety	ANSM
Germany	DE	Federal Institute for Drugs and Medical Devices	BfArM
Greece	GR	National Organization for Medicines	EOF
Hungary	HU	National Institute of Pharmacy	OGYI
Iceland	IS	Icelandic Medicines Agency	IMA
Italy	IT	Italian Medicines Agency	AIFA
Ireland	IE	Irish Medicines Board	IMB
Latvia	LV	State Agency of Medicines of Latvia	ZVA
Liechtenstein	LI	Office of Health/ Medicinal Products Control Agency	LLV
Lithuania	LT	State Medicines Control Agency	VVKT
Luxembourg	LU	Ministry of Health	MS
Malta	MT	Medicines Authority	
Netherlands	NL	Medicines Evaluation Board	CBG-MEB
Norway	NO	The Norwegian Medicines Agency	NOMA
Poland	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	URPL
Portugal	PT	National Authority of Medicines and Health Products	INFARMED
Romania	RO	National Agency for Medicines and Medical Devices	ANM
Slovakia	SK	State Institute for Drug Control	SUKL
Slovenia	SL	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke	

Spain	ES	Spanish Agency of Medicines and Medical Devices	AEMPS
Sweden	SE	Medical Products Agency	MPA
United Kingdom	UK	Medicines and Healthcare Products Regulatory Agency	MHRA

Country Codes of Accession/Candidate Countries (Observers)[1]

Country	ISO Country Code
Former Yugoslav Republic of Macedonia	MK
Turkey	TR

Country Codes of Other European Countries[1]

Country	ISO Country Code
Albania	AL
Andorra	AD
Armenia	AM
Azerbaijan	AZ
Belarus	BY
Bosnia and Herzegovina	BA
Georgia	GE
Holy See (Vatican City State)	VA
Moldova	MD
Monaco	MC
Montenegro	ME
Russia	RU
San Marino	SM
Serbia	RS
Switzerland	CH
Ukraine	UA
Vatican City State	See *Holy See*

Other Country Codes used in PRAC Minutes[1]

Country	ISO Country Code
Australia	AU
Canada	CA
China	CN
Japan	JP
New Zealand	NZ

United States (of America)	US(A)

[1] Sources: http://publications.europa.eu/code/en/en-370100.htm and http://www.iso.ch/iso/en/prods-services/iso3166ma/02iso-3166-code-lists/list-en1.html).