

5 December 2023 EMA/899164/2022 Rev.1 Human Medicines Division Veterinary Medicines Division

# Abbreviations used in EMA scientific committees & CMD documents and in relation to EMA's regulatory activities

Abbreviation <sup>1</sup>					
3Rs	3Rs principles -Replace, Reduce and Refine- for the ethical use of animals in				
	medicine testing across the European Union (see also Joint 3Rs WP)				
AA	Accelerated Assessment				
ACT EU initiative	Accelerate Clinical Trials in the EU (see <u>ACT EU</u> )				
ADI	Acceptable Daily Intake				
ADR(s)	Adverse Drug Reaction(s) (see GVP annex I)				
AE(s)	Adverse Event(s) (see GVP annex I)				
AEFI(s)	Adverse Event(s) Following Immunisation (see GVP annex I)				
AER	Adverse Event Report				
AESI	Adverse Event of Special Interest				
AHEG	(EMA) Ad Hoc Expert Group				
AI	Artificial Intelligence				
AM	Additional Monitoring				
AMEG	(EMA CHMP/CVMP) Antimicrobial Advice Ad Hoc Expert Group (see AMEG)				
AMR	Antimicrobial resistance (see <u>Antimicrobial resistance</u> )				
ANVISA	Brazilian health regulatory agency (see <u>International agreements</u> )				
API	Active Pharmaceutical Ingredient (see <u>International collaboration on GMP</u>				
	inspections)				
AR(s)	Assessment Report(s)				
ARSP	Assessment Report Summary for the Public (see <u>EU herbal monographs</u> )				
ASMF WG	(Joint EMA/HMA) Active Substance Master File Working Group (see ASMF WG)				
ASU	Antimicrobial sales and use				
ATC(/DDD)	Anatomical Therapeutic Chemical classification system, maintained by WHO				
	(with Defined Daily Doses)				
ATD	(EMA) Access to Documents (see <u>Access to documents</u> )				

 $<sup>^{1}</sup>$  Acronyms are abbreviations that can be pronounced as a word (e.g. 'CAT') whereas initialisms are abbreviations for which each letter is pronounced separately (as in 'SME')

ATD	Anti-Tampering Device (see <u>Falsified medicines: overview</u> )				
ATMP(s)	Advanced Therapy Medicinal Product(s) (i.e. gene, cell and tissue engineering				
	products)				
AWP	(EMA CVMP) Antimicrobials Working Party (see <u>AWP</u> )				
ВА	Bioavailability				
BE	Bioequivalence (see also Country codes: BE = Belgium)				
BEMA	Benchmarking of European Medicines Agencies (see <u>Integrated quality</u>				
	management system)				
ВСР	(EMA) Business Continuity Planning				
BMWP	(EMA CHMP) Biosimilar Medicinal Products Working Party				
B/R	Benefit/Risk (in B/R assessment, B/R balance, B/R profile)				
BWP	(EMA CHMP) Biologics Working Party				
CAMP	Competent Authority for Medical Devices				
CAP(s)	Centrally Authorised Product(s)				
CAPA plan	Corrective and preventive action plan				
CAR-T cell	Chimeric antigen receptor T cell				
CAT	(EMA) Committee for Advanced Therapies				
СВМР	Cell-based Medicinal Product				
CCDS	Company Core Data Sheet (see <u>GVP</u> annex I)				
CCI	Commercially Confidential Information				
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods (see Codex				
	Alimentarius)				
CCSI	Company Core Safety Information (see GVP annex I)				
CdT	Centre de Traduction (see <u>Translation Centre for the bodies of the EU</u> )				
CDx	Companion Diagnostics				
CDP	(EMA) Clinical Data Publication (see <u>Clinical data publication</u> )				
CE mark	Conformité Européenne = European conformity mark (see <u>Medical Devices</u> )				
CECP	Clinical Evaluation Consultation Procedure (see Medical Devices)				
CEP(s)	Certificate(s) of Suitability to the monographs of the European Pharmacopoeia				
	(see EDQM- Certification of suitability)				
СНМР	(EMA) Committee for Medicinal Products for Human Use (previously: CPMP)				
CI	Confidence interval				
CI	Contraindication				
CIA	Critically Important Antimicrobials				
CIOMS	Council for International Organizations of Medical Sciences				
CMA	Conditional Marketing Authorisation				
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures (human)				
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures for				
	Veterinary Medicinal Products				
CMDS	Critical Medical Devices Shortage				
CMS(s)	Concerned Member State(s)				
CNSWP	(EMA CHMP) Central Nervous System Working Party (see <u>CNSWP</u> )				
СОМР	(EMA) Committee for Orphan Medicinal Products				
Corr.	Corrigendum				
СР	Centralised Procedure (see <u>Applying for EU marketing authorisation</u> )				
СР	Concept Paper (see <u>Scientific guidelines</u> )				
CPAR	Consultation Procedure public Assessment Report (see <u>CHMP opinions on</u>				

	consultation procedures)				
СРМР	Committee for Proprietary Medicinal Products, former name of CHMP				
CRM	Customer Relationship Management				
CRO	Contract Research Organisation				
CSP(s)	Core Safety Profile(s)				
CSR					
	Clinical Study Report				
CTCC	Clinical Trial				
CTCG	Clinical Trial Coordination Group (see HMA CTCG)				
CTD	Common Technical Document – see eCTD				
CTTG	Clinical Trial Facilitation Group (see HMA CTFG)				
CTIS	Clinical Trials Information System (see CTIS)				
CTR	Clinical Trial Regulation (see Clinical trials human medicines)				
CV	Curriculum vitae				
CVMP	(EMA) Committee for Veterinary Medicinal Products				
CVSWP	(EMA CHMP) Cardiovascular Working Party (see <u>CVSWP</u> )				
DARWIN EU®	Data Analysis and Real World Interrogation Network (see <u>DARWIN EU</u> )				
DCP	Decentralised Procedure (see <u>Applying for EU marketing authorisation</u> )				
DDCs	Drug-Device Combination(s)				
DER	Drug Extract Ratio (see <u>HMPC scientific guidelines</u> )				
DG	Directorate-General (at the European Commission)				
DG(s)	(EMA) Drafting Group(s) (see Working parties and domains)				
DHPC	Direct Healthcare Professional Communication (see GVP annex I)				
DIA	Drug Information Association				
DIBD	Development International Birth Date (see GVP annex I)				
DLP	Data Lock Point				
DoI	Declaration of Interests (see <u>Handling competing interests</u> )				
DPO	Data Protection Officer				
DPC	Data Protection Coordinator				
DSUR	Development Safety Update Report (see GVP annex I)				
DUS	Drug Utilisation Study				
eAF	electronic Application Form				
EC	European Commission (http://ec.europa.eu/index_en.htm)				
ECDC	European Centre for Disease Prevention and Control				
	(https://www.ecdc.europa.eu/en)				
ECHA	European Chemicals Agency (https://echa.europa.eu/)				
eCTD	electronic Common Technical Document (see <u>eSubmission website's section on</u>				
	eCTD)				
EDPS	European Data Protection Supervisor (see <u>Data protection and privacy</u> )				
EDQM	European Directorate for the Quality of Medicines (see <u>EDQM of the Council of</u>				
	<u>Europe</u> )				
EEA	European Environment Agency (https://www.eea.europa.eu/)				
EEA-EFTA states	European Economic Area – European Free Trade Association states				
EFSA EFFA States	European Food Safety Authority (http://www.efsa.europa.eu)				
EHDS	European Health Data Space (https://health.ec.europa.eu/ehealth-digital-health-				
	and-care/european-health-data-space en)				
EMA/CAT-NB	Ad hoc European Medicines Agency/Committee for Advanced Therapies and				
Medical Devices Notified Body Collaboration Group – see <u>EMA/CAT-NB</u>					
	Ficultia Devices Notified Dody Collaboration Group - See Lina/CAT-ND				

EMCDDA	European Manitoring Centre for Drugs and Drug Addiction				
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction				
ΓΜΓΛ	( <a href="http://www.emcdda.europa.eu">http://www.emcdda.europa.eu</a> )  Old acronym for: European Medicines Agency; use: EMA				
EMEA					
EMR	Electronic Medical Records				
EMRN	European Medicines Regulatory Network (see <u>EMRN</u> )				
EMT	(EMA) Experts Management Tool (see <u>European experts</u> )				
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance ( <a href="https://www.encepp.eu/">https://www.encepp.eu/</a> )				
Enpr-EMA	European network of paediatric research at EMA (see Enpr-EMA)				
EP	European Parliament ( <u>http://www.europarl.europa.eu/</u> )				
EPAR	European Public Assessment Report				
e-PI	electronic Product Information				
EPITT	European Pharmacovigilance Issues Tracking Tool				
EPMAR	European Public MRL Assessment Report (see <u>Maximum residue limit assessment reports</u> )				
ERA	Environmental Risk Assessment				
ERAWP	(EMA CVMP) Environmental Risk Assessment Working Party (see <u>ERAWP</u> )				
ERMS	European Risk Management Strategy (see <u>ERMS</u> )				
eRMR	electronic Reaction Monitoring Report				
ESEC(s)	(EMA) European Specialised Expert Community(ies) (see Working parties and				
, ,	domains)				
ESMP	European Shortages Monitoring Platform (see <u>Availability of medicines</u> )				
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicine (see <u>ESUAvet</u>				
	Working Group)				
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption (see <u>ESVAC</u> )				
ETF	(EMA) Emergency Task Force (see <u>ETF</u> )				
EU	European Union				
EU-ADR Project	Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (formerly known as ALERT)				
EUDAMED	European database on medical devices (see <u>EUDAMED</u> )				
Eudra-	European Union Drug Regulating Authorities				
EudraCT	European Union Drug Regulating Authorities Clinical Trials database:				
	see <u>EudraCT</u> and <u>EU Clinical Trials Register</u>				
EU-IN	(Joint HMA/EMA) EU Innovation Network (see <u>EU-IN</u> )				
EU-M4all	EU Medicines for all: see Medicines for use outside the European Union (formerly				
	known as 'Article 58 procedure')				
EUnetHTA	European Network for Health Technology Assessment				
EU-NTC	EU Network Training Centre (see <u>EU-NTC</u> )				
EU PAS Register	EU Post-Authorisation Study register				
EURD list	List of EU Reference Dates and frequency of PSUR submission (see <u>EURD list</u> )				
EURL ECVAM	European Union Reference Laboratory for alternatives to animal testing (see				
	Ethical use of animals in medicine testing)				
EURORDIS	European Organisation for Rare Diseases (http://www.eurordis.org/)				
EUTCT	European Union Telematics Controlled Terms – has been replaced by RMS				
EU IVMAB	EU Immunisation and Vaccine Monitoring Board				
EV	EudraVigilance (see <u>EudraVigilance</u> : <u>electronic reporting</u> )				
EVVet	EudraVigilance Veterinary				
_ , , , ,	<u> </u>				

EV-EWG	EudraVigilance Expert Working Group (see <u>EV-EWG</u> )				
EVMPD	EudraVigilance Medicinal Products Dictionary				
EWP-V	(EMA CVMP) Efficacy Working Party (see <u>EWP-V</u> )				
fAR	final Assessment Report				
FDA	Food and Drug Administration (US) (see <u>International agreements</u> )				
FDC	Fixed Dose Combination  (OS) (see <u>International agreements</u> )				
FDHA					
FMD	Federal Department of Home Affairs (Switzerland) (see <u>International agreements</u> )  Falsified Medicines Directive (see <u>Falsified medicines: overview</u> )				
fvAR	final variation Assessment Report				
FWG	(EMA CHMP) Formulation Working Group (see FWG)				
GACP	Good Agricultural and Collection Practice (see HMPC GACP quideline)				
GCG	(EMA CHMP) Guideline Consistency Group (see GCG)				
GCP	Good Clinical Practice (see GCP)				
GCP IWG	Good Clinical Practice Inspectors Working Group (see Compliance: overview)				
GDP	Good Distribution Practice (see GDP)				
GDPR	General Data Protection Regulation (see Workshop on GDPR and secondary use of				
ODI K	data for medicines and public health purposes)				
GEG	(EMA CHMP) Geriatric Expert Group (see GEG)				
GLP	Good Laboratory Practice (see GLP)				
GMA	Global Marketing Authorisation				
GMO	Genetically Modified Organism				
GMP	Good Manufacturing Practice (see GMP)				
GMDP IWG	Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group				
	(see Compliance: overview)				
GPAG	(EMA PRAC) Granularity and Periodicity Advisory Group				
GSPR	General Safety and Performance Requirements (see Medical Devices)				
GTMP	Gene Therapy Medicinal Product				
GVP	Good Pharmacovigilance Practices (see GVP)				
HAEMWP	(EMA CHMP) Haematology Working Party (see <u>HAEMWP</u> )				
HBD	Harmonised Birth Date				
НС	Health Canada (see <u>International agreements</u> )				
HCP(s)	Healthcare Professional(s)				
HCPWP	(EMA) Healthcare Professionals' Working Party (see HCPWP)				
HERA	Health Emergency Preparedness and Response Authority				
НМА	Heads of Medicines Agencies (formerly: HoA) – see HMA				
- HMA-Joint	with three groups: HMA-Joint, HMA-Human and HMA-Veterinary				
- HMA(h)					
- HMA(v)					
НМР	Herbal Medicinal Product (see <u>EU herbal monographs</u> )				
НМРС	(EMA) Committee on Herbal Medicinal Products				
НоА	was: Heads of Agencies, use: HMA				
HP	Herbal preparation (see <u>EU herbal monographs</u> )				
	equivalent to 'Herbal drug preparation' in Ph. Eur. monographs				
HR	Hazard Ratio				
HS	Herbal substance (see <u>EU herbal monographs</u> )				
1	equivalent to 'Herbal drug' in Ph. Eur. monographs				
	equivalence to the control and grant				

HTABs	Health Technology Assessment Bodies (see <u>HTA Bodies</u> )				
IBD	International Birth Date (see GVP annex I)				
ICH	International Conference on Harmonisation of Technical Requirements for				
	Registration of Pharmaceuticals for Human Use				
ICMRA	International Coalition of Medicines Regulatory Authorities (see ICMRA)				
ICSR(s)	Individual Case Safety Report(s) (see GVP annex I)				
ICTPR	(WHO) International Clinical Trials Registry Platform				
IGDRP	International Generic Drug Regulators Programme				
IDWP	(EMA CHMP) Infectious Diseases Working Party (see IDWP)				
im	intramuscular				
IMP	Investigational Medicinal Product				
IMP	(EU Regulatory Network) Incident Management Plan (see IMP)				
INN	International Non-proprietary Name (see WHO/INN)				
IPs	Interested Parties				
IPRP	International Pharmaceutical Regulators Programme (see IPRP)				
IR	Inspection Report				
IRCH	International Regulatory Cooperation for Herbal Medicines (under WHO)				
IIR					
IRIS	Integrated Inspection Report				
IKIS	Not an abbreviation. Refers to the regulatory & scientific information management platform between EMA and stakeholders (NCAs, industry)				
IRN	(EU Regulatory Network) Incident Review Network (see IMP)				
ISO IDMP	Internal Organization for Standardization for the Identification of Medicinal				
130 10111	Products (see <u>ISO IDMP standards</u> ) – implementation through the following EMA				
	services:				
	- OMS = Organisation Management Service				
	- PMS = Product Management Service				
	- RMS = Referentials Management Service				
	- SMS = Substance Management Service				
ITF	(EMA) Innovation Task Force (see <u>Innovation in medicines</u> )				
ITT	Intention-To-Treat (analysis)				
iv	intravenous				
IVD	In vitro Diagnostics				
IVDR	In vitro Diagnostic medical devices Regulation (see Medical Devices)				
IVMAB	(ECDC/EMA) Immunisation and Vaccine Monitoring Advisory Board				
IVMP	Immunological Veterinary Medicinal Product				
IWP	(EMA CVMP) Immunologicals Working Party (see <u>IWP</u> )				
JAP	(HMA/EMA) Joint Audit Plan				
JECFA	Joint FAO/WHO Expert Committee on Food Additives				
JIACRA	Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (see				
_	Analysis of antimicrobial consumption and resistance)				
Joint 3Rs WP	(EMA CHMP/CVMP) Joint 3Rs Replacement, Reduction and Refinement Working				
	Party (see <u>3Rs principles</u> )				
KPI	Key Performance Indicator				
LE	List entry (see <u>EU herbal monographs and list entries</u> )				
LM	Limited Markets				
LoI	Letter of Intent				
LoOI	List of Outstanding Issues				

1.0	List of Overtions					
LoQ	List of Questions					
LTT	Lines to take [internal EMA document usually not for publication]					
MA	Marketing Authorisation					
MAA	Marketing Authorisation Application					
MAH	Marketing Authorisation Holder					
MAWP	Multi-annual Work Plan					
МВ	(EMA) Management Board					
MD	Medical Device					
MDCG	(EU) Medical Device Coordination Group					
MDIG	(EMA) Medical Devices Implementation Group					
MDR	Medical Devices Regulation (see <u>Medical Devices</u> )					
MDSSG	(EMA) Medical Devices Shortages Steering Group					
MedDRA	Medical Dictionary for Regulatory Activities – organised in a hierarchical structure					
	characterised by different levels:					
	- SOC = System Organ Class					
	- HLGT = High Level Group Term					
	- HLT = High Level Term					
	- PT = Preferred Term					
	- LLT = Lowest Level Term					
MIC	Minimum Inhibitory Concentration					
MLM	Medical literature monitoring					
MLWP	Monographs and List entries Working Party (former HMPC working party)					
MNAT	Multinational Assessment Team (see <u>Multinational assessment team concept</u> )					
МО	Major Objection					
MoU	Memorandum of Understanding					
MR	Mutual Recognition					
MRA	Mutual Recognition Agreement (see <u>MRA</u> )					
MRL	Maximum Residue Limit (see <u>Maximum residue limits</u> )					
MRP	Mutual Recognition Procedure (see <u>Applying for EU marketing authorisation</u> )					
MS(s)	Member State(s) of the European Union					
MSSG	(EMA) Medicines Shortages Steering Group (see MSSG)					
MUMS	Minor Use, Minor Species					
MWP	(EMA CHMP) Methodology Working Party (see <u>MWP</u> )					
NAMs	New Approach Methodologies					
NAP(s)	Nationally Authorised Product(s)					
NAS	New Active Substance					
NcWP	(EMA) Non-clinical Working Party (see NcWP)					
NCA(s)	National Competent Authority(ies)					
NfG	Note for Guidance					
NRG	(EMA) [Invented] Name Review Group (see NRG)					
NtA	Notice to Applicants (see <u>Eudralex – Volume 2</u> )					
NTWP	(EMA CVMP) Novel Therapies and Technologies Working Party (see NTWP)					
NUI	Non-Urgent Information (see also RA/NUI System)					
OD	Orphan Designation (see Orphan designation: Overview)					
OE	Oral Explanation					
OEG(s)	(EMA) Operational Expert Group(s) (see <u>Working parties and domains</u> )					
	- BOEG = Biostatistics Operational Expert Group					

	- MSOEG = Modelling and Simulation Operational Expert Group			
	- RWDOEG = Real World Data Operational Expert Group			
OIE	World Organisation for Animal Health, based on its original name Office			
	International des Epizooties – see also WOAH  European Anti-Fraud Office			
OLAF	European Anti-Fraud Office			
OMCL(s)	Official Medicines Control Laboratory(ies) (https://www.edqm.eu/en/omcl-			
	<u>background-and-mission</u> )			
OMS	see ISO IDMP			
ONCWP	(EMA CHMP) Oncology Working Party (see ONCWP)			
OPEN initiative	Opening our Procedures at EMA to Non-EU authorities - see OPEN Pilot: one-year			
	review and recommendations			
ORGAM	Organisational Matters (see PROM; see also <u>HMPC</u> )			
OTC	Over-the-counter			
PA	Protocol Assistance (see <u>Scientific advice and protocol assistance</u> )			
PaedPAR	Paediatric Public Assessment Report			
PAES	Post-Authorisation Efficacy Study (see PAES Q&A)			
PAM(s)	Post Authorisation Measure(s) categorised as follows in EMA's product and			
	procedure tracking database – see PAMs Q&A			
	ANX = Annex II condition			
	LEG = Legally Binding Measure			
	MEA = Additional PhV activity in the RMP			
	SOB = Specific Obligation			
	REC = Recommendation			
pAR	preliminary Assessment Report			
PASS	Post-Authorisation Safety Study (see <u>GVP</u> annex I)			
PBRER	Periodic Benefit-Risk Evaluation Report			
PBT	Persistent Bioaccumulative Toxic (chemical)			
PCWP	(EMA) Patients' and Consumers' Working Party (see PCWP)			
PCU	Population Correction Unit			
PD	Pharmacodynamic(s)			
PD	(EMA) Parallel Distribution (see <u>Parallel distribution</u> )			
PdAR	Paediatric Assessment Report			
PDCO	(EMA) Paediatric Committee			
PECP	Performance Evaluation Consultation Procedure (see Medical Devices)			
PEM (study)	Prescription-Event Monitoring (study)			
PHE	Public Health Emergency			
Ph.Eur.	European Pharmacopoeia (https://www.edqm.eu/en/european-pharmacopoeia)			
PhV	Pharmacovigilance			
PhV IWG	Pharmacovigilance Inspectors Working Group (see Compliance: overview)			
PhVWP	Pharmacovigilance Working Party (working party that preceded the PRAC)			
PhVWP-V	(EMA CVMP) Pharmacovigilance Working Party (see PhVWP-V)			
PI	Product Information (see <u>Product Information requirements for human medicines</u>			
	and Product Information requirements for veterinary medicines)			
PIC/S	Pharmaceutical Inspection Co-operation Scheme (see PIC/S)			
PIL	Patient Information Leaflet			
PIP(s)	Paediatric Investigation Plan(s) (see PIPs)			
PK	Pharmacokinetic(s)			
i	i narmaconiicuc(3)			

PL	Package Leaflet				
PL	(EMA) Product Lead				
PLD	Patient Level Data				
PMDA	Pharmaceuticals and Medical Devices Agency (Japan) (see <u>International</u>				
וווטא	agreements)				
PMF	Plasma Master File (see <u>PMF certification</u> )				
PMS	Post-Marketing Surveillance (see also under ISO IDMP)				
POM	Prescription-only Medicine				
PP	Per Protocol (analysis)				
PPD	Protected Personal Data				
PPP	Pregnancy Prevention Programme				
PRA	Preliminary Risk Analysis (see IMP)				
PRAC	(EMA) Pharmacovigilance Risk Assessment Committee				
PRIME	(EMA) Priority Medicines scheme (see PRIME)				
PROM	Preparatory and Organisational Matters (see <u>CHMP</u> – formerly known as ORGAM)				
PRP	Preliminary Risk Profiling				
PRR	Proportional Reporting Ratio				
PSA	Parallel Scientific Advice				
PSMF Pharmacovigilance System Master File (for human medicines: see GVP for veterinary medicines: see VGVP)					
PSUFU	PSUSA Follow-Up				
PSUR	<del> </del>				
PSUSA	Periodic Safety Update Report (see <u>GVP</u> annex I)				
PUMA	PSUR Single Assessment  Paediatric Use Marketing Authorisation (see PUMA)				
QIG	<del>-</del>				
QoL	(EMA CHMP/CVMP) Quality Innovation Group (see QIG)  Ouglity of Life				
QP	Quality of Life Qualified Person				
QPPV	Qualified Person for Pharmacovigilance				
QRD-WG	(EMA) Working Group on Quality Review of Documents (see QRD)				
QWP	(EMA CHMP/CVMP) Quality Working Party (see QWP)				
RA	Rapid Alert – see also RA/NUI System				
Raav	recombinant adeno-associated viral vector				
RA/NUI System	Rapid Alert/Non-Urgent Information System				
RCT(s)	Randomised Controlled Trial(s)				
R&D	Research and Development				
REA	Relative Effectiveness Assessment				
REMS	Risk Evaluation & Mitigation Strategies				
RFI					
RfR	(EMA) Request for Information  Report for Release				
RIWP	(EMA CHMP) Rheumatology/Immunology Working Party (see RIWP)				
RMAT	Regenerative Medicine Advanced Therapy				
RMM(s)	Risk Minimisation Measure(s) / Risk Mitigation Measure(s)				
RMP or RefMP	Reference Medicinal Product				
RMP					
RMR	Risk Management Plan (see <u>GVP</u> annex I)  Reaction Monitoring Report				
RMS or RefMS	Reference Member State (see also 'RMS' under ISO IDMP)				
ROG	Regulatory Optimisation Group (see HMA ROG)				
roo   regulatory optimisation group (see <u>link roo</u> )					

RPCs	Regional Pharmacovigilance Centres					
RPI						
RRR	Research Product Identifier (see <u>Requesting SA or PA from EMA</u> )  Relative Risk Reduction					
RSI						
RSS	Request for Supplementary Information					
RUP	Regulatory Science Strategy (see RSS)					
	Repeat Use Procedure (see CMDh MRP/RUP)					
RWD	Real World Data					
RWE	Real World Evidence Scientific Advice					
SA						
SAE	Serious Adverse Event					
SAG(s)	(EMA) Scientific Advisory Group(s)					
SAP	Statistical Analysis Plan					
SAWP	(EMA CHMP) Scientific Advice Working Party (see SAWP)					
SAWP-V	(EMA CVMP) Scientific Advice Working Party (see <u>SAWP-V</u> )					
SB	Significant Benefit					
SBP(s)	Similar Biotherapeutic Product(s) (WHO term for biosimilars)					
SC	subcutaneous					
SFDA	State Food and Drug Authority (China) (see <u>International agreements</u> )					
SmAR	Summary Assessment Report					
SMEs	Small and Medium-sized Enterprises (see <u>Support to SMEs</u> )					
SmPAR	Summary Pharmacovigilance Assessment Report					
SmPC	Summary of Product Characteristics (see <u>How to prepare and review a SmPC</u> )					
SMQs	Standardised MedDRA Queries					
SMS	See ISO IDMP					
SNSA	Simultaneous National Scientific Advice (see HMA/EMA EU-IN)					
SoC	Standard of care					
SOC	System Organ Class – see MedDRA					
SOH	Scientific Opinion Holder (related to <u>EU-M4all</u> )					
SoHo	Substance of Human origin					
SOP	Standard Operating Procedure					
SPC	Supplementary Protection Certificate					
SPOC	Single Point of Contact					
	- EO-SPOC = (EMA) Economic Operators Single Point of Contact					
	- SPOC WP = (EMA) Medicines Shortages Single Point of Contact Working Party					
	(see <u>SPOC WP</u> )					
	- MD-SPOC WP = (EMA) Medical Device Shortages Single Point of Contact Working					
	Party					
SPOR	Substance, product, organisation and referential (see SPOR master data)					
SRLM	Strategic Review & Learning Meeting					
SSR	Summary Safety Reports					
SUSAR	Suspected Unexpected Serious Adverse Reactions					
Swissmedic	Swiss Agency for Therapeutic Products (see <u>International agreements</u> )					
SWP-V	(EMA CVMP) Safety Working Party (see <u>SWP-V</u> )					
TCM	Traditional Chinese Medicine					
tDGs	(EMA) temporary Drafting Groups (see Working parties and domains)					
TDD	Total Daily Dose					
TGA	Therapeutic Goods Administration (Australia) (see <u>International agreements</u> )					

TMF	Trial Master File				
ToC	Table of Conclusions				
ToC	Table of Contents				
ToD	Table of Decisions				
THMP	Traditional Herbal Medicinal Product (see <u>EU herbal monographs</u> )				
TU	Traditional Use (see <u>EU herbal monographs</u> )				
TUR	Traditional Use Registration (see <u>EU herbal monographs</u> )				
UDI	Unique Device Identifier (see <u>Medical Devices</u> )				
UI	Unique Identifier (see <u>Falsified medicines: overview</u> )				
UMN	Unmet Medical Need				
UPD	Union Product Database (see <u>UPD</u> )				
UPhV	Union Pharmacovigilance Database (see <u>EudraVigilance Veterinary</u> )				
USR	Urgent Safety Restriction				
VarWP	(EMA) Working Party on Variation Regulation (see <u>Variations for human</u>				
	medicines)				
VICH	International Cooperation on Harmonisation of Technical Requirements for				
	Registration of Veterinary Medicinal Products				
VeDDRA	Veterinary Dictionary for Drug Regulatory Activities				
VMP	(ECDC/EMA) Vaccine Monitoring Platform (see <u>Vaccine Monitoring Platform</u> )				
VMP	Veterinary Medicinal Product				
VNeeS	Veterinary Non-eCTD Electronic Submission				
VNRA	Variation Not Requiring Assessment				
VRA	Variation Requiring Assessment				
VWP	(EMA CHMP) Vaccines Working Party (see <u>VWP</u> )				
WEU	Well-established use				
WG	Working Group				
WHO	World Health Organization				
WHO-UMC	WHO-Uppsala Monitoring Centre				
WOAH	World Organisation for Animal Health				
WP	Working party (see Working parties and domains)				
WS	Work Sharing				

#### Country codes of EU/EEA Countries<sup>2</sup>

Country (short name in English)	Country Code	Agency	Acronym
Austria	AT	Austrian Agency for Health and Food Safety	AGES
Belgium	BE	Federal Agency for Medicines and Health Products	FAMHP
Bulgaria	BG	Bulgarian Drug Agency	BDA

 $<sup>^2 \ \, \</sup>text{Sources: } \underline{\text{http://publications.europa.eu/code/en/en-370100.htm}} \ \, \text{and } \underline{\text{http://www.iso.ch/iso/en/prods-services/iso3166ma/02iso-3166-code-lists/list-en1.html)}};$ 

https://ec.europa.eu/environment/enlarg/candidates.htm#:~:text=Albania%2C%20Moldova%2C%20the%20Republic%20 of,possible%20request%20for%20transition%20periods.

Bulgaria (V)	BG	Bulgarian Food Safety Authority	BFSA
Croatia	HR	Agency for medicinal products and	HALMED
		medical devices of Croatia	
Croatia (V)	HR	Ministry of Agriculture - Veterinary	MPS
		and food safety directorate	
Cyprus	CY	Ministry of Health -Pharmaceutical	МОН
		Services	
Cyprus (V)	CY	Veterinary Services, Ministry of	MOA
		Agriculture, Natural Resources and	
0 1:	07	Environment	CUITA
Czechia	CZ	State Institute for Drug Control	SUKL
Czechia (V)	CZ	Institute for State Control of	USKVBL
Denmark	DK	Veterinary Biologicals and Medicines	DKMA
	EE	Danish Medicines Agency	
Estonia Finland	FI	State Agency of Medicines	SAM FIMEA
	FR FR	Finnish Medicines Agency  National Agency for the Safety of	ANSM
France	FK	Medicines and Health Products	AINOIN
France (V)	FR	French Agency for Food,	ANSES
Traffee (V)		Environmental and Occupational	ANGES
		Health & Safety	
Germany (H+V)	DE	Federal Institute for Drugs and	BfArM
, , ,		Medical Devices	
Germany (H+V)	DE	Paul Ehrlich Institute	PEI
Greece	GR (ISO)	National Organization for Medicines	EOF
	EL <sup>2</sup>		
Hungary	HU	National Institute of Pharmacy and	OGYI
		Nutrition	
Hungary (V)	HU	Directorate of Veterinary Medicinal	NEBIH
Tables	16	Products	TAGA
Iceland	IS	Icelandic Medicines Agency	IMA
Italy	IT	Italian Medicines Agency	AIFA
Italy (V)	IT	Ministry of Health	HDDA
Ireland	IE	Health Products Regulatory Authority	HPRA
Latvia	LV	State Agency of Medicines	ZVA
Latvia (V)	LV	Food and Veterinary Service	PVD
Liechtenstein	LI	Office of Health/ Department of	LLV
Licensensen		Pharmaceuticals	
Lithuania	LT	State Medicines Control Agency	VVKT
Lithuania (V)	LT	State Food and Veterinary Service	VMVT
Lithuania (V)	LT	National Food and Veterinary Risk	NMVRVI
. ,		Assessment Institute	
Luxembourg	LU	Ministry of Health	MS
Malta	MT	Malta Medicines Authority	MMA
Malta	MT	Veterinary and Phytosanitary	
		Regulation Department	

Netherlands	NL	Medicines Evaluation Board	CBG-MEB
Norway	NO	Norwegian Medicines Agency	NOMA
Poland	PL	Office for Registration of Medicinal	URPL
		Products, Medical Devices and	
		Biocidal Products	
Portugal	PT	National Authority of Medicines and	INFARMED
		Health Products	
Portugal (V)	PT	National Authority for Animal Health	DGAV
Romania	RO	National Agency for Medicines and	ANM
		Medical Devices	
Romania (V)	RO	Institute for Control of Biological	ICBMV
		Products and Veterinary Medicines	
Slovakia	SK	State Institute for Drug Control	SUKL
Slovakia (V)	SK	Institute for State Control of	USKVBL
		Veterinary Biologicals and	
		Medicaments	
Slovenia	SI	Agency for Medicinal Products and	JAZMP
		Medical Devices of the Republic of	
		Slovenia	
Spain	ES	Spanish Agency of Medicines and	AEMPS
		Medical Devices	
Sweden	SE	Medical Products Agency	MPA

#### **Country Codes of Accession/Candidate Countries<sup>2</sup>**

Country	Country Code
Albania	AL
Moldova	MD
The Republic of North Macedonia	MK
Montenegro	ME
Serbia	RS
Turkey	TR
Ukraine	UA

## Country Codes of Other European Countries<sup>2</sup>

Country	ISO Country Code
Andorra	AD
Armenia	AM
Azerbaijan	AZ
Belarus	BY
Bosnia and Herzegovina	BA
Georgia	GE
Holy See (Vatican City State)	VA
Monaco	MC
Russia	RU
San Marino	SM

Switzerland	СН
Vatican City State	See Holy See

### Other Country Codes<sup>2</sup>

Country	ISO Country Code
Australia	AU
Canada	CA
China	CN
Japan	JP
New Zealand	NZ
United States (of America)	US(A)