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Human Medicines Division
Veterinary Medicines Division

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

The below table does not include EU/EEA country codes, which can be found from page 14 onwards.

Abbreviation[1]	
1S1A	One substance, one assessment (see EU chemicals assessment reform)
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
ADA	Antidrug antibody
ACT EU initiative	Accelerate Clinical Trials in the EU (see ACT EU)
ADI	Acceptable Daily Intake
ADR	Adverse Drug Reaction (see GVP annex I)
AE	Adverse Event (see GVP annex I)
AEFI	Adverse Event Following Immunisation (see GVP annex I)
AER	Adverse Event Report
AESI	Adverse Event of Special Interest
AHEG	(EMA) Ad Hoc Expert Group
AI	Acceptable Intake
AI	Artificial Intelligence
AICG	(EMA) Artificial Intelligence Coordination Group
AM	Additional Monitoring
AMA	African Medicines Agency
AMEG	(EMA CHMP/CVMP) Antimicrobial Advice Ad Hoc Expert Group (see AMEG)
AMR	Antimicrobial resistance (see Antimicrobial resistance)
ANVISA	Brazilian health regulatory agency (see International agreements)
API	Active Pharmaceutical Ingredient (see International collaboration on GMP inspections)

[1] 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')

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API	Application Programming Interface (see Substance and product data management under SPOR)
AR	Assessment Report
ARSP	Assessment Report Summary for the Public (see EU herbal monographs)
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 Access to documents)
ATD	Anti-Tampering Device (see Falsified medicines: overview)
ATMP	Advanced Therapy Medicinal Product (i.e. gene, cell and tissue engineering products)
AWP	(EMA CVMP) Antimicrobials Working Party (see AWP)
BA	Bioavailability
BE	Bioequivalence
BEMA	Benchmarking of European Medicines Agencies (see Integrated quality management system)
BCP	(EMA) Business Continuity Planning
BDSG	(HMA-EMA) Big Data Steering Group (see HMA-EMA joint BDSG)
BMWP	(EMA CHMP) Biosimilar Medicinal Products Working Party
BPG	Best Practice Guide
B/R	Benefit/Risk (in B/R assessment, B/R balance, B/R profile…)
BWP	(EMA CHMP) Biologics Working Party
CAMD	Competent Authority for Medical Devices (see CAMD)
CAP	Centrally Authorised Product
CAPA plan	Corrective and preventive action plan
CAR-T cell	Chimeric antigen receptor T cell
CAS	Chemical Abstracts Service
CAT	(EMA) Committee for Advanced Therapies
CBMP	Cell-based Medicinal Product
CBRN	Chemical, Biological, Radiological and Nuclear (see EU CBRN risk mitigation)
CCDS	Company Core Data Sheet (see GVP 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)
CDM	Common Data Model (see Data in regulation)
CDP	(EMA) Clinical Data Publication (see Clinical data publication)
CdT	Centre de Traduction (see Translation Centre for the bodies of the EU)
CDx	Companion Diagnostics
CE mark	Conformité Européenne = European conformity mark (see Medical Devices)
CECP	Clinical Evaluation Consultation Procedure (see Medical Devices)
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia (see EDQM- Certification of suitability)
CHMP	(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
ClinRO	Clinician-Reported Outcome
CM	Continuous Manufacturing
CMA	Conditional Marketing Authorisation
CMC	Chemistry Manufacturing and Controls
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
CMO	Contract Manufacturing Organisation
CMS	Concerned Member State
CNSWP	(EMA CHMP) Central Nervous System Working Party (see CNSWP)
CoA	Certificate of Analysis
COMP	(EMA) Committee for Orphan Medicinal Products
Corr.	Corrigendum
CP	Centralised Procedure (see Applying for EU marketing authorisation)
CP	Concept Paper (see Scientific guidelines)
CPAR	Consultation Procedure public Assessment Report (see CHMP opinions on consultation procedures)
CPMP	*Committee for Proprietary Medicinal Products, former name of CHMP*
CQA	Critical Quality Attribute
CQI	Core Quality Information
CR	Complete response
CRDF	Controlled-release Dosage Form
CRM	Customer Relationship Management
CRR	Complete response rate
CRO	Contract Research Organisation
CSP	Core Safety Profile
CSR	Clinical Study Report
CT	Clinical Trial (see Clinical trials)
CTA	Clinical Trial Application
CTCG	Clinical Trial Coordination Group (see HMA CTCG)
CTD	Common Technical Document – see eCTD
CTIS	Clinical Trials Information System (see CTIS)
CTR	Clinical Trial Regulation (see Clinical trials human medicines)
CTS	Communication and Tracking System (see HMA – CMDh CTS Working Group)
CTU	Clinical Trial Unit
CV	Curriculum vitae
CVMP	(EMA) Committee for Veterinary Medicinal Products
CVSWP	(EMA CHMP) Cardiovascular Working Party (see CVSWP)
DARWIN EU®	Data Analysis and Real World Interrogation Network (see DARWIN EU)
DCP	Decentralised Procedure (see Applying for EU marketing authorisation)
DCO	Data cut-off
DDC	Drug-Device Combination
DDD	Defined Daily Dose (see ATC)

DDI	Drug-Drug Interaction
DER	Drug Extract Ratio (see HMPC scientific guidelines)
DG	Directorate-General (at the European Commission)
DG	(EMA) Drafting Group (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)
DILI	Drug Induced Liver Injury
DFS	Disease-free survival
DLP	Data Lock Point
DM	Decentralised Manufacturing
DMCS	Description Manufacturing Control Storage
DME	Designated Medical Event (see Signal Management)
DMP	Development Medicinal Product (see EudraVigilance medicinal product dictionary)
DoI	Declaration of Interests (see Handling competing interests)
DoC	Declaration of Conformity
DOR	Duration of response
DP	Drug Product
DPC	Data Protection Coordinator
DPO	Data Protection Officer
DS	Drug Substance
DSJ	Development Summary and Justification
DSMB	Data Safety Monitoring Board
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 eSubmission website's section on eCTD)
EDPB	European Data Protection Board (see EDPB)
EDPS	European Data Protection Supervisor (see Data protection and privacy)
EDQM	European Directorate for the Quality of Medicines (see EDQM of the Council of Europe)
EEA	European Environment Agency (https://www.eea.europa.eu/)
EEA-EFTA states	European Economic Area – European Free Trade Association states
EIF	Emerging Infectious Disease
EFS	Event-free survival
EFSA	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)
EHR	Electronic Health Record
EM	Education Material (see GVP Module XVI Addendum I)

EMA/CAT-NB	Ad hoc European Medicines Agency/Committee for Advanced Therapies and Medical Devices Notified Body Collaboration Group – see EMA/CAT-NB
EMACOLEX	European Medicines Agencies Cooperation of legal and legislative issues (see EMACOLEX)
EMANS	European Medicines Agencies Network Strategy (see EMANS)
EMCDDA	*Old acronym for: European Monitoring Centre for Drugs and Drug Addiction*; see: EUDA
EMEA	*Old acronym for: European Medicines Agency; use: EMA*
EMR	Electronic Medical Records
EMRN	European Medicines Regulatory Network (see EMRN)
EMT	(EMA) Experts Management Tool (see European experts)
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (https://www.encepp.eu/)
Enpr-EMA	European network of paediatric research at EMA (see Enpr-EMA)
ENPRS	European Network for Partnership in Regulatory Science
EoI	Extension of Indication
EP	European Parliament (http://www.europarl.europa.eu/)
EPAR	European Public Assessment Report
e-PI	electronic Product Information
EPITT	European Pharmacovigilance Issues Tracking Tool
EPMAR	European Public MRL Assessment Report (see Maximum residue limit assessment reports)
ERA	Environmental Risk Assessment
ERAWP	(EMA CVMP) Environmental Risk Assessment Working Party (see ERAWP)
ERMS	European Risk Management Strategy (see ERMS)
eRMR	electronic Reaction Monitoring Report
ESEC	(EMA) European Specialised Expert Community (see Working parties and domains)
ESI	Emerging Safety Issue (see GVP)
ESMP	European Shortages Monitoring Platform (see Availability of medicines)
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicine (see ESUAvet Working Group)
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption (see ESVAC)
ETF	(EMA) Emergency Task Force (see ETF)
EU	European Union
EUAN	European Union Agencies Network (see EUAN)
EU-ADR Project	Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge *(formerly known as ALERT)*
EUDA	European Union Drugs Agency (*formerly known as European Monitoring Centre for Drugs and Drug Addiction* – see EUDA)
EUDAMED	European database on medical devices (see EUDAMED)
EUDPR	EU Data Protection Regulation (see Regulation (EU) 2018/1725)
Eudra-	European Union Drug Regulating Authorities
EudraCT	European Union Drug Regulating Authorities Clinical Trials database: see EudraCT and EU Clinical Trials Register
EU-IN	(Joint HMA/EMA) EU Innovation Network (see EU-IN)
EU IVMAB	EU Immunisation and Vaccine Monitoring Board

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 EU NTC)
EURD list	List of EU Reference Dates and frequency of PSUR submission (see EURD list)
EURL ECVAM	European Union Reference Laboratory for alternatives to animal testing (see Ethical use of animals in medicine testing)
EUTCT	*European Union Telematics Controlled Terms – has been replaced by RMS*
EV	EudraVigilance (see EudraVigilance: electronic reporting)
EVDAS	EudraVigilance Data Analysis System
EVIP	European Vaccination Information Portal (see EVIP)
EVVet	EudraVigilance Veterinary (see EudraVigilance Veterinary)
EV-EWG	EudraVigilance Expert Working Group (see EV-EWG)
EVMPD	EudraVigilance Medicinal Products Dictionary
EWG	(ICH) Expert Working Group
EWP-V	(EMA CVMP) Efficacy Working Party (see EWP-V)
FAIR (data)	Findable, Accessible, Interoperable and Reusable
fAR	final Assessment Report
FDA	Food and Drug Administration (US) (see International agreements)
FDC	Fixed Dose Combination
FDHA	Federal Department of Home Affairs (Switzerland) (see International agreements)
FIH	First-In-Human
FIM	First-In-Man
FMD	Falsified Medicines Directive (see Falsified medicines: overview)
FP	Finished Product
FUQ	Follow-up questionnaire
fvAR	final variation Assessment Report
FWG	(EMA CHMP) Formulation Working Group (see FWG)
GACP	Good Agricultural and Collection Practice (see HMPC GACP guideline)
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 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
GRDF	(VICH) Global Regulatory Dossier Framework
GSPR	General Safety and Performance Requirements (see Medical Devices)
GTMP	Gene Therapy Medicinal Product

GVP	Good Pharmacovigilance Practices (see GVP)
HaDEA	European Health and Digital Executive Agency (see HaDEA)
HAEMWP	(EMA CHMP) Haematology Working Party (see HAEMWP)
HBD	Harmonised Birth Date
HC	Health Canada (see International agreements)
HCP	Healthcare Professional
HCPWP	(EMA) Healthcare Professionals' Working Party (see HCPWP)
HERA	Health Emergency Preparedness and Response Authority (see HERA)
HLGT	High Level Group Term (see MedDRA)
HLT	High Level Term (see MedDRA)
HMA - HMA-Joint - HMA(h) - HMA(v)	Heads of Medicines Agencies *(formerly: HoA)* – see HMA with three groups: HMA-Joint, HMA-Human and HMA-Veterinary
HMP	Herbal Medicinal Product (see EU herbal monographs)
HMPC	(EMA) Committee on Herbal Medicinal Products
HoA	*was: Heads of Agencies, use: HMA*
HP	Herbal preparation (see EU herbal monographs) *equivalent to 'Herbal drug preparation' in Ph. Eur. monographs*
HR	Hazard Ratio
HRQoL	Health-related quality of life
HS	Herbal substance (see EU herbal monographs) *equivalent to 'Herbal drug' in Ph. Eur. monographs*
HTA	Health Technology Assessment
HTAb	Health Technology Assessment body (see HTA Bodies)
HTACG	Member State Coordination Group on HTA (see HTACG)
HTAR	Health Technology Assessment Regulation (EU) 2021/2282
HTD	Health Technology Developer
IBD	International Birth Date (see GVP annex I)
IC	Information Component
ICF	Informed Consent Form
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	Individual Case Safety Report (see GVP annex I)
ICTPR	(WHO) International Clinical Trials Registry Platform
iDDC	integral Drug-Device Combination
IDWP	(EMA CHMP) Infectious Diseases Working Party (see IDWP)
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
IFU	Instructions For Use (see Medical Devices)
IGDRP	International Generic Drug Regulators Programme
IHSI	International Horizon Scanning Initiative (see IHSI)
IIR	Important Identified Risk
IIR	Integrated Inspection Report
im	intramuscular
IME	Important Medical Event

IMP	Investigational Medicinal Product
IMP	(EU Regulatory Network) Incident Management Plan (see IMP)
IND	(US) Investigational New Drug
INN	International Nonproprietary Name (see WHO/INN)
IPC	In-process Control
IPD	Individual Patient Data
IPs	Interested Parties
IPR	Important Potential Risk
IPRP	International Pharmaceutical Regulators Programme (see IPRP)
IR	Inspection Report
IRB	Institutional Review Board
IRCH	International Regulatory Cooperation for Herbal Medicines (under WHO)
IRIS	*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)
IRP	Integrated Research Platform
ISE	Independent Scientific Expert (see EMA scientific committees)
ISO IDMP	Internal Organization for Standardization for the Identification of Medicinal Products (see ISO IDMP standards) – implementation through the following EMA services: - OMS = Organisation Management Service - PMS = Product Management Service - RMS = Referentials Management Service - SMS = Substance Management Service
ISRR	Immunisation Stress-Related Response
ITF	(EMA) Innovation Task Force (see Innovation in medicines)
ITT	Intention-To-Treat (analysis)
iv	intravenous
IVD	In vitro Diagnostics
IVDR	(EU) 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 IWP)
JAMS	Joint Action on Market Surveillance of Medical Devices (see JAMS)
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 3Rs principles)
JSA	Joint Scientific Assessment
JSC	Joint Scientific Consultation (see Parallel joint scientific consultation with regulators and HTA bodies)
KPI	Key Performance Indicator
LE	List entry (see EU herbal monographs and list entries)
LEG	Legally Binding Measure (see PAMs Q&A)
LLFG	(EMA) Listen and Learn Focus Group (see Quality Innovation Group)

LLT	Lowest Level Term (see MedDRA)
LM	Limited Markets
LMS	Lead Member State (see Signal Management)
LoI	Letter of Intent
LoOI	List of Outstanding Issues
LoQ	List of Questions
LTFU	Long Term Follow-Up
LTL	Less than lifetime
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
MB	(EMA) Management Board
MCMN (trial)	Multicenter/multinational (trial)
MD	Medical Device
MDCG	(EU) Medical Device Coordination Group
MDIG	(EMA) Medical Devices Implementation Group
MDR	(EU) Medical Devices Regulation (see Medical Devices)
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
MI	Missing Information
MIC	Minimum Inhibitory Concentration
MIDD	Model-Informed Drug Development
MLM	Medical literature monitoring
MLWP	*Monographs and List entries Working Party (former HMPC working party)*
MNAT	Multinational Assessment Team (see Multinational assessment team concept)
MO	Major Objection
MoA	Mechanism of Action
MoU	Memorandum of Understanding
MR	Mutual Recognition
MRA	Mutual Recognition Agreement (see MRA)
MRL	Maximum Residue Limit (see Maximum residue limits)
MRP	Mutual Recognition Procedure (see Applying for EU marketing authorisation)
MS	Member State of the European Union
MSP	Multi-stakeholder Platform (see ACT-EU)
MSSG	(EMA) Medicines Shortages Steering Group (see MSSG)
MUMS	Minor Use, Minor Species
MWP	(EMA CHMP) Methodology Working Party (see MWP)
NAMs	New Approach Methodologies
NAP	Nationally Authorised Product

NAS	New Active Substance
NB	Notified Body (see High-risk medical devices: consultation procedures and advice | European Medicines Agency (EMA))
NcWP	(EMA) Non-clinical Working Party (see NcWP)
NCA	National Competent Authority
NCD	Non-communicable disease (see EU Public Health NCDs)
NfG	Note for Guidance
NITAG	National Immunisation Technical Advisory Group (see ETF)
NMI	Non-mutagenic Impurity
NRA	(WHO) National Regulatory Authority
NRG	(EMA) [Invented] Name Review Group (see NRG)
NtA	Notice to Applicants (see Eudralex – Volume 2)
NTWP	(EMA CVMP) Novel Therapies and Technologies Working Party (see NTWP)
NUI	Non-Urgent Information (see also RA/NUI System)
OCS	Overall Control Strategy
OD	Orphan Designation (see Orphan designation: Overview)
OE	Oral Explanation
OECD	Organisation for Economic Co-operation and Development
OEG	(EMA) Operational Expert Group (see Working parties and domains) - 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
OLAF	European Anti-Fraud Office, based on its name in French *Office européen de lutte antifraude*
OMCL	Official Medicines Control Laboratory (https://www.edqm.eu/en/omcl-background-and-mission)
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 HMPC)
ORR	Overall response rate
OS	Overall survival
OTC	Over-the-counter
PA	Protocol Assistance (see Scientific advice and protocol assistance)
PaedPAR	Paediatric Public Assessment Report
PAES	Post-Authorisation Efficacy Study (see PAES Q&A)
PAM	Post Authorisation Measure 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

PAS	Post-Authorisation Safety
PASS	Post-Authorisation Safety Study (see GVP annex I)
PBRER	Periodic Benefit-Risk Evaluation Report
PBT	Persistent Bioaccumulative Toxic (chemical)
PCO	Patients' and Consumers' Organisations
PCWP	(EMA) Patients' and Consumers' Working Party (see PCWP)
PCU	Population Correction Unit
PD	(EMA) Parallel Distribution (see Parallel distribution)
PD	Personal Data
PD	Pharmacodynamic(s)
PD	Progressive Disease
PdAR	Paediatric Assessment Report
PDCO	(EMA) Paediatric Committee
PECP	Performance Evaluation Consultation Procedure (see Medical Devices)
PED	Patient Experience Data
PEM (study)	Prescription-Event Monitoring (study)
PFS	Progression-free survival
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 Product Information requirements for human medicines and Product Information requirements for veterinary medicines)
PI	Product Intermediate
PICO	Population, Intervention, Comparator, Outcome
PIC/S	Pharmaceutical Inspection Co-operation Scheme (see PIC/S)
PIL	Patient Information Leaflet
PIP	Paediatric Investigation Plan (see PIPs)
PK	Pharmacokinetic(s)
PL	Package Leaflet
PL	(EMA) Product Lead
PLCM	Product Lifecycle Management
PLD	Patient Level Data
PLM	Product Lifecycle Management
PMDA	Pharmaceuticals and Medical Devices Agency (Japan) (see International agreements)
PMF	Plasma Master File (see PMF certification)
PMS	Post-Marketing Surveillance (see also under ISO IDMP)
PMSF	Principal Molecular Structural Feature (see Orphan similarity)
POC-M	Point-of-Care Manufacturing
POM	Prescription-only Medicine
PP	Per Protocol (analysis)
PPD	Protected Personal Data
PPP	Pregnancy Prevention Programme
PPP	Public-Private Partnership

PPS	Patient Preference Studies
PQBR	Product Quality Benefit Risk
PQS	Pharmaceutical Quality System
PR	Partial Response
PRA	Preliminary Risk Analysis (see IMP)
PRAC	(EMA) Pharmacovigilance Risk Assessment Committee
PRIME	(EMA) Priority Medicines scheme (see PRIME)
PRISMA	(EMA) PRAC Risk Minimisation Alliance
PRO	Patient-Reported Outcome (see HTA)
PROM	Patient-Reported Outcome Measure (see HTA)
PROM	(EMA CHMP) Preparatory and Organisational Matters (see CHMP – *formerly known as ORGAM*)
PRP	Preliminary Risk Profiling (see Use of antimicrobials in animals)
PRR	Proportional Reporting Ratio
PSA	(FDA/EMA) Parallel Scientific Advice
PSMF	Pharmacovigilance System Master File (for human medicines: see GVP annex I; for veterinary medicines: see VGVP)
PSUFU	PSUSA Follow-Up
PSUR	Periodic Safety Update Report (see GVP annex I)
PSUSA	PSUR Single Assessment
PT	Platform Trial
PT	Preferred Term (see MedDRA)
PUMA	Paediatric Use Marketing Authorisation (see PUMA)
QIG	(EMA CHMP/CVMP) Quality Innovation Group (see QIG)
QMS	Quality Management System
QoL	Quality of Life
QoNM	Qualification of Novel Methodologies
QP	Qualified Person
QPPV	Qualified Person responsible for Pharmacovigilance
QRD-WG	(EMA) Working Group on Quality Review of Documents (see QRD)
QTPP	Quality Target Product Profile
QWP	(EMA CHMP/CVMP) Quality Working Party (see QWP)
RA	Rapid Alert – see also RA/NUI System
RA	Reference Authority
RA	Regulatory Affairs
rAAV	recombinant adeno-associated viral vector
RAN	Rapid Alert Network
RA/NUI System	Rapid Alert/Non-Urgent Information System
RCT	Randomised Controlled Trial
R&D	Research and Development
REA	Relative Effectiveness Assessment
REMS	Risk Evaluation & Mitigation Strategies
RFI	(EMA) Request for Information
RfM	Request for Modification
RfR	Report for Release
RIWP	(EMA CHMP) Rheumatology/Immunology Working Party (see RIWP)
RM	Raw Material

RMAT	Regenerative Medicine Advanced Therapy
RMM	Risk Minimisation Measure / Risk Mitigation Measure
RMP or RefMP	Reference Medicinal Product
RMP	Risk Management Plan (see GVP annex I)
RMR	Reaction Monitoring Report
RMS or RefMS	Reference Member State (see also 'RMS' under ISO IDMP)
RMS	Risk Management System
ROG	Regulatory Optimisation Group (see HMA ROG)
ROR	Reporting Odds Ratio
RPC	Regional Pharmacovigilance Centre
RPI	Research Product Identifier (see Requesting SA or PA from EMA)
RRR	Relative Risk Reduction
RS	Reference Standard
RSI	Request for Supplementary Information
RSS	(EMA) Regulatory Science Strategy (see RSS)
RUP	Repeat Use Procedure (see CMDh MRP/RUP)
RWD	Real World Data
RWE	Real World Evidence
RWS	Real World Study
SA	Scientific Advice
SAE	Serious Adverse Event
SAG	(EMA) Scientific Advisory Group
SAP	Statistical Analysis Plan
SAWP	(EMA CHMP) Scientific Advice Working Party (see SAWP)
SAWP-V	(EMA CVMP) Scientific Advice Working Party (see SAWP-V)
SB	Significant Benefit
SBP	Similar Biotherapeutic Product (WHO term for biosimilar)
sc	subcutaneous
SCAR	Serious Cutaneous Adverse Reaction
SDO	Standards Development Organisations
SEND	Standard for Exchange of Nonclinical Data
SFDA	State Food and Drug Authority (China) (see International agreements)
SI	Substance Intermediate
SLR	Systematic Literature Review (see Medical literature monitoring)
SM	Signal Management (see Signal Management)
SM	Source/Starting Material
SmAR	Summary Assessment Report
SMART	Specific Measurable Achievable Relevant Time-based
SMART WG	Signal Management Review Technical Working Group (see SMART WG)
SMEs	Small and Medium-sized Enterprises (see Support to SMEs)
SME	Subject Matter Expert
SmPAR	Summary Pharmacovigilance Assessment Report
SmPC	Summary of Product Characteristics for human medicines (see How to prepare and review a SmPC)
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 EU-M4all)
SoHo	Substance of Human origin
SOP	Standard Operating Procedure
SPC	Supplementary Protection Certificate
SPC	Summary of Product Characteristics for veterinary medicines
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 SPOC WP) - MD-SPOC WP = (EMA) Medical Device Shortages Single Point of Contact Working Party - iSPOC = Industry SPOC
SPOR	Substance, Product, Organisation and Referential (see SPOR master data)
SPQS	Structured Product Quality Submission
SRA	(WHO) Stringent Regulatory Authority (see WHO-Listed Authorities)
SRLM	(EMA CxMP) Strategic Review & Learning Meeting
SRP	Subsequent Recognition Procedure
SSA	(EMA) Signal and Safety Analytics
SSR	Summary Safety Reports
STAMP	(EC Group on) Safe and Timely Access to Medicines for Patients (see STAMP)
SUSAR	Suspected Unexpected Serious Adverse Reactions
Swissmedic	Swiss Agency for Therapeutic Products (see International agreements)
SWP-V	(EMA CVMP) Safety Working Party (see SWP-V)
TCM	Traditional Chinese Medicine
tDG	(EMA) temporary Drafting Group (see Working parties and domains)
TDD	Total Daily Dose
TGA	Therapeutic Goods Administration (Australia) (see International agreements)
THMP	Traditional Herbal Medicinal Product (see EU herbal monographs)
TMF	Trial Master File
ToC	Table of Conclusions
ToC	Table of Contents
ToD	Table of Decisions
TTP	Time To Progression
TU	Traditional Use (see EU herbal monographs)
TUR	Traditional Use Registration (see EU herbal monographs)
UDI	Unique Device Identifier (see Medical Devices)
UI	Unique Identifier (see Falsified medicines: overview)
UMN	Unmet Medical Need
UPD	Union Product Database (see UPD)
UPhV	Union Pharmacovigilance Database (see EudraVigilance Veterinary)
USR	Urgent Safety Restriction
VarWP	(EMA) Working Party on Variation Regulation (see Variations for human medicines)
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (see VICH)

VeDDRA	Veterinary Dictionary for Drug Regulatory Activities
VMP	(ECDC/EMA) Vaccine Monitoring Platform (see Vaccine Monitoring Platform)
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 VWP)
WEU	Well-established use
WG	Working Group
WHO	World Health Organization (see WHO)
WHO-UMC	WHO-Uppsala Monitoring Centre (see WHO-UMC)
WLA	WHO-Listed Authority (see WHO-Listed Authorities)
WOAH	World Organisation for Animal Health
WP	Working party (see Working parties and domains)
WS	Worksharing

Country codes of EU/EEA Countries[2]

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
Bulgaria (V)	BG	Bulgarian Food Safety Authority	BFSA
Croatia	HR	Agency for medicinal products and medical devices of Croatia	HALMED
Croatia (V)	HR	Ministry of Agriculture - Veterinary and food safety directorate	MPS
Cyprus	CY	Ministry of Health -Pharmaceutical Services	MOH
Cyprus (V)	CY	Veterinary Services, Ministry of Agriculture, Natural Resources and Environment	MOA
Czechia	CZ	State Institute for Drug Control	SUKL
Czechia (V)	CZ	Institute for State Control of Veterinary Biologicals and Medicines	USKVBL
Denmark	DK	Danish Medicines Agency	DKMA
Estonia	EE	State Agency of Medicines	SAM
Finland	FI	Finnish Medicines Agency	FIMEA

[2] Sources: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Country_codes ; https://commission.europa.eu/strategy-and-policy/policies/eu-enlargement_en ; Tutorial:Country codes and protocol order - Statistics Explained ; Online Browsing Platform (OBP)

France	FR	National Agency for the Safety of Medicines and Health Products	ANSM
France (V)	FR	French Agency for Food, Environmental and Occupational Health & Safety	ANSES
Germany (H+V)	DE	Federal Institute for Drugs and Medical Devices	BfArM
Germany (H+V)	DE	Paul Ehrlich Institute	PEI
Greece	GR (ISO) EL[2]	National Organization for Medicines	EOF
Hungary	HU	National Centre for Public Health and Pharmacy	NNK
Hungary (V)	HU	Directorate of Veterinary Medicinal Products	NEBIH
Iceland	IS	Icelandic Medicines Agency	IMA
Ireland	IE	Health Products Regulatory Authority	HPRA
Italy	IT	Italian Medicines Agency	AIFA
Italy (V)	IT	Ministry of Health	
Latvia	LV	State Agency of Medicines	ZVA
Latvia (V)	LV	Food and Veterinary Service	PVD
Liechtenstein	LI	Office of Health/ Department of Pharmaceuticals	LLV
Lithuania	LT	State Medicines Control Agency	VVKT
Lithuania (V)	LT	State Food and Veterinary Service	VMVT
Lithuania (V)	LT	National Food and Veterinary Risk Assessment Institute	NMVRVI
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 Medicinal Products Agency	DMP
Poland	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	URPL
Portugal	PT	National Authority of Medicines and Health Products	INFARMED
Portugal (V)	PT	National Authority for Animal Health	DGAV
Romania	RO	National Agency for Medicines and Medical Devices of Romania	ANM
Romania (V)	RO	Institute for Control of Biological Products and Veterinary Medicines	ICBMV
Slovakia	SK	State Institute for Drug Control	SUKL

Slovakia (V)	SK	Institute for State Control of Veterinary Biologicals and Medicaments	USKVBL
Slovenia	SI	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	JAZMP
Spain	ES	Spanish Agency of Medicines and Medical Devices	AEMPS
Sweden	SE	Swedish Medical Products Agency	MPA

Country Codes of EU candidate countries[2]

Country	Country Code
Bosnia and Herzegovina	BA
Montenegro	ME
Moldova	MD
North Macedonia	MK
Georgia	GE
Albania	AL
Serbia	RS
Turkey	TR
Ukraine	UA

Country Codes of Other European Countries[2]

Country	ISO Country Code
Andorra	AD
Armenia	AM
Azerbaijan	AZ
Belarus	BY
Holy See (Vatican City State)	VA
Kosovo	XK
Monaco	MC
Russia	RU
San Marino	SM
Switzerland	CH
Vatican City State	See *Holy See*

Other Country Codes[2]

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