GLOSSARY OF REGULATORY HEALTHCARE ACRONYMS & ABBREVIATIONS
www.topra.org/glossary

Note: Medical prescription abbreviations can be found at www.abbreviations.com/acronyms/PRESCRIPTION

1-1-1 – One dossier, one European scientific assessment, one decision for marketing authorisation
3Rs – Replacement, refinement and reduction (in research using animals)
510(k) – Medical device premarket notification (US FDA)
AA – Accelerated assessment/approval
AAC – Accelerated Access Collaborative (UK) **– and also:**
AAC – Autorisation d'Accès Compassionnel (Authorisation for compassionate use), France
AADA – Abbreviated antibiotic drug application
AAP – Accelerated approval pathway (US) **– and also:**
AAP – Accelerated assessment procedure (EU) **– and also:**
AAP – Autorisation d'Accès Précoce (Authorisation for early access), France
AAPS – American Association of Pharmaceutical Scientists
AAR – Accelerated access review
AAS – Atomic absorption spectroscopy
AAV – Adeno-associated virus
ABHI – Association of British HealthTech Industries (medical devices sector)
ABPI – Association of the British Pharmaceutical Industry
A-CASI – Audio computer-assisted self-interviewing
ACCESS Consortium – Australia-Canada-Singapore-Switzerland-United Kingdom Consortium (formerly **ACSS**)
ACI – Autologous chondrocyte implantation
ACO – Addendum to clinical overview
ACRP – Association of Clinical Research Professionals
ACSS Consortium – Australia-Canada-Singapore-Switzerland Consortium (now **ACCESS,** see above)
ACT – Artemisinin-based combination therapy
ACTD – ASEAN common technical dossier (see **ASEAN**)
ACVM – Agricultural Compounds and Veterinary Medicines (New Zealand)
ADA – Anti-drug antibodies
ADaM – Analysis data model
ADC – Additional data collection – **and also:**
ADC – Antibody–drug conjugate
ADCC – Antibody-dependent cellular cytotoxicity
ADE – Adverse device event (AE judged to be related to the medical device)
ADEC – Australian Drug Evaluation Committee
ADI – Acceptable daily intake
ADME – Absorption, distribution, metabolism and excretion/elimination (also **AME –** absorption, metabolism, excretion/elimination)
ADMET – Absorption, distribution, metabolism, elimination, and toxicity
ADR – Adverse drug reaction
ADROIT – Adverse Drug Reactions On-Line Tracking System
ADVAC – Ad hoc group on veterinary vaccine availability (CVMP)
ADVENT – Ad Hoc Expert Group on Veterinary Novel Therapies
AE – Adverse event
AEC – Authorisation under exceptional circumstances
AEFI – Adverse event following immunisation
AEGIS – Adverse Experience Gathering Information System
AEM – Agencia Espanola Medicamento (Spain)
AEMPS – Agencia Española de Medicamentos y Productos Sanitarios (Spain)
AEPAR – Asociación Española de Profesionales de Actividades de Registro (Spanish Regulatory Affairs Association)
AERS – Adverse event reporting system (US FDA)
AESGP – Association Européenne des Spécialitiés Pharmaceutiques Grand Public (Association of the European Self-Medication Industry)
AESI – Adverse events of special interest
AET – Analytical evaluation thresholds
AF – Application Form

AFAR – Association Française des Affaires Reglémentaires (French Regulatory Affairs Association)
AFDO – Association of Food and Drug Officials (US)
AFMPS – Agence Fédérale des Médicaments et des Produits de Santé (Belgium)
Afssaps – former French regulatory agency (Agence Française de Sécurité Sanitaire des Produits de Santé) – replaced by **ANSM** in 2012 (see below)
AGES PharmMED – Osterreichische Agentur fur Gesundheit und Ernahrungssicherheit GmbH (Austria's medicines & devices agency)
AHSC – Academic Health Science Centre (UK)
AHWP – Asian Harmonisation Working Party
AI – Adverse incident (medical devices sector) **– and also:**
AI – Artificial intelligence
AIFA – Agenzia Italiana del Farmaco (Italy's health authority)
AIM – Active ingredient manufacturer
AIMD – Active implantable medical device
AIMDD – Active implantable medical device directive
AITS – Adverse/Automated Incident Tracking System (medical devices sector)
AKP – Alkaline phosphatase
ALARP – As low as reasonably practical
ALATF – As low as technically feasible (terminology superseded by "ALARP" – see above)
ALIMS – Medicines and Medical Devices Agency of Serbia
ALL – Acute lymphocytic leukaemia
ALT – Alanine aminotransferase (ALT = SGPT)
AM – Agence du Medicament (France)
AMA – American Medical Association
AMEG – Antimicrobial advice ad hoc Expert Group
AMI – Acute myocardial infarct
AML – Acute myeloid leukaemia
AMM – Autorisation de mise sur le marché (France) = Product licence
AMP – Authorised medicinal product – **and also:**
AMP – Auxiliary medicinal product *(formerly non-investigational medicinal product, NIMP)*
AMR – Antimicrobial resistance
AMRH – African Medicines Regulatory Harmonisation
ANADA – Abbreviated New Animal Drug Application (US)
ANDA – Abbreviated new drug application
ANDS – Abbreviated new drug submission (Canada)
ANMV – Agence nationale du médicament vétérinaire (French vet medicines agency)
ANOVA – Analysis of Variance
ANPR – Advanced notice of proposed rulemaking (US)
ANSES – Agence Francaise de Securite Sanitaire des Aliments Agence nationale due medicament veterinaire
ANSM – French regulatory agency **(**Agence nationale de sécurité du médicament et des produits de santé) [formerly **Afssaps**]
ANZTPA – Australia New Zealand Therapeutic Products Agency (scheduled to come into force in 2016 – replacing Australia's TGA and New Zealand's Medsafe)
AO – Auditing organisation
AOAC – Association of Official Analytical Chemists (US)
AOB – Any other business
AP – Accredited person – **and also:**
AP – Adaptive pathway
APEC – Asia-Pacific Economic Cooperation
APHIS – Animal and Plant Health Inspection Service (US)
API – Active pharmaceutical ingredient – **and also:**
API – Application programming interface
APIC – Active Pharmaceutical Ingredients Committee
APLB – Advertising and Promotional Labeling Branch (FDA's CBER)
APMA – Australian Pharmaceutical Manufacturers Association
APR – Annual product report
APVA – Additional pharmacovigilance activities
APVMA – Australian Pesticides and Veterinary Medicines Authority (Australia)
AQL – Acceptable quality level
AR – Adverse reaction – **and also:**
AR – Assessment Report (EU) – **and also:**
AR – Authorised representative

ARfD – Acute reference dose (veterinary)
ARM – Alliance for Regenerative Medicine
ARMAs – Additional risk minimisation activities
ARMMs – Additional risk minimisation measures
AS – Active Substance
ASAP – Accelerated Stability Assessment Program
ASCII – American Standard Code for Information Interchange Quality Assurance
ASDI– Acceptable single-dose intake
ASEAN – Association of Southeast Asian Nations
ASMF – Active Substance Master File
ASMF WG – Working Group on Active Substance Master File procedures
ASMR – Amélioration du Service Médical Rendu (ie, actual medical benefit), France
ASPR – Anonymised single patient report (formerly ASPP – anonymised single patient printout)
ASR – Annual safety report
ASRM –Act on the Safety of Regenerative Medicines (Japan)
AST – Antibiotic susceptibility testing – **and also:**
AST – Aspartate aminotransaminase (AST = SGOT)
ATA – Alternatives to antibiotics
ATC – Anatomical – therapeutic – chemical (WHO) – **and also:**
ATC – Animal Test Certificate (UK) – **and also:**
ATC Code – Anatomical Therapeutic Chemical Code
ATC Vet Code – Anatomical Therapeutic Chemical Veterinary Code
ATC(/DDD) – Anatomical Therapeutic Chemical classification system (with Defined Daily Doses)
ATD – Access to documents (EMA policy) **– and also:**
ATD – Anticipated therapeutic dose – **and also:**
ATD – Anti-tampering device
ATECT – Advanced T-cell Engineering for Cancer Therapy
ATF – Alcohol – Tobacco and Firearms (Bureau of) (US)
ATMPs – Advanced therapy medicinal products (aka "advanced therapies")
ATRG – Australian Register of Therapeutic Goods
ATU – Authorisation for temporary use
ATUc – ATU de cohort (Cohort ATU), France
ATUn – ATU nominative (Named-patient ATU), France
AUC_{∞} – Area under the concentration time curve between zero and infinity
AUCx – Area under the curve during a given time
AVEG – AIDS Vaccine Evaluation Group
AWP – Antimicrobials Working Party
AXREM – Association of X-ray Equipment Manufacturers
AYA – Adolescents and young adults

BBB
BA – Bioavailability
BA/BE – Bioavailability/bioequivalence
BACPAC – Bulk active chemical post approval changes (US)
BAI – Breath actuated inhaler
BAID – Batch identifier
BAN – British Approved Name
BAP – Biotechnology Action Programme/Biosimilars Action Plan
BARQA – British Association of Research Quality Assurance
BCS – Biopharmaceutics Classification System
bd/bid – twice a day *(Latin: bis in die)*
BDA – Bulgarian drug agency
BDSG – Big Data Steering Group
BDTF – Big Data Task Force
BE – Bioequivalence
BEMA – Benchmarking of European Medicines Agencies
BfArM – Federal Institute for Drugs and Medical Devices (Bundesinstituts für Arzneimittel und Medizinprodukte) (Germany's regulatory authority)
BGMA – British Generic Manufacturers Association
BIMO – Bioresearch Monitoring Program
BIND – Biological investigational new drug

BIO – Biotechnology Industry Organization (US)
BLA – Biologics license application (US)
BM – Bone marrow
BMA – British Medical Association
BMD – Bone mineral density
BMG – Bundesministerium für Gesundheit = Federal Ministry of Health (Germany)
BMGF – Bundesministerium fuer Gesundheit und Frauen (Austrian agency)
BMWP – Biosimilar Medicinal Products Working Party
BNF – British National Formulary
BoH – Board of Health
BOS – Break-out session
BP – Blood pressure – **and also:**
BP – British Pharmacopoeia
BPC – British Pharmacopoeia Commission – **and also:**
BPC – Bulk pharmaceutical chemicals
BPCA – Best Pharmaceuticals in Children Act (US)
BPG – Best Practice Guide
BPI – Brief pain inventory – **and also:**
BPI – Bundesverband der Pharmazeutischen Industrie (German pharmaceutical industry trade association)
BPOG – Biophorum Operations Group
BPR – Biocidal Products Regulation
BPWP – Blood Products Working Party (EMA)
Br – Barrier reared (in older reports – 'Brown')
BRAS – Belgian Regulatory Affairs Society
BRAT – Benefit–Risk Action Team
BRIC – Brazil, Russia, India & China
BRICK– Brazil, Russia, India, China & (South) Korea
BRICS – Brazil, Russia, India, China & South Africa
BROMI – Better Regulation of Over the Counter Medicines Initiative
BSE – Bovine Spongiform Encephalopathy
BTD – Breakthrough therapy designation (US)
BTDR – Breakthrough therapy designation request
BTF – Brexit Task Force
BWP – Biotech Working Party (EMA)

CCC
C&P – Chemistry and Pharmacy
CA – Commercial appraisal – **and also:**
CA – Competent authority
CAC – Codex Alimentarius Commission (veterinary sector)
CAD – Coronary artery disease
CADREAC – Collaboration agreement between drug regulatory authorities of European Union associated countries (also **nCADREAC** – new Collaboration Agreement)
CADTH – Canadian Agency for Drugs and Technologies in Health (formerly CCOHTA)
CAMD – Competent Authorities for Medical Devices
CAMS – Chinese Academy of Medical Sciences
CANDA – Computer assisted new drug application
CAO – Central Agricultural Office (Hungary)
CAP – Centrally authorised product
CAPA – Corrective action and preventive action
CAPA plan – Corrective and preventive action plan
CAPLA – Computer Assisted Product Licence Application
CAPRA – Canadian Association of Pharmaceutical Regulatory Affairs
CAR – Chimeric antigen receptor
CARPHA – The Caribbean Public Health Agency
CART-T – Chimeric antigen receptor T-cells
CAS – Central alerting system (UK) – **and also:**
CAS – Chemical abstract systems
CAT – Chamber for Advanced Cell Therapy (Brazil) – **and also:**
CAT – Committee for Advanced Therapies (EMA)
CATMP – Combined Advanced Therapy Medicinal Product
CAVDRI – Collaboration agreement between veterinary drug registration institutions

CAVOMP – Clinical added value orphan medicinal product
CBER – Center for Biologics Evaluation and Research (US FDA)
CBG/MEB – Medicines Evaluation Board (the Netherlands)
CBHC – Cross-border healthcare
CBP – Corticoid binding protein
CC – Candidate country (EU) – **and also:**
CC – Compliance check
CCDP – Complete clinical data package
CCDS – Company core data sheet
CCG – Clinical Commissioning Group (UK NHS)
CCG IAC – Clinical Commissioning Group Indicator Advisory Committee
CCG OIS – Clinical Commissioning Group Outcomes Indicator Set
CGTPs – Cell and gene therapy products
CCI – Commercially confidential information
CCMO – Central Committee on Research Involving Human Subjects (the Netherlands)
CCRB – Change control review board
CCS – Container closure system
CCSI – Company core safety information
CD – Caesarean derived – **and also:**
CD – Controlled drug
CDA – China Drug Administration (now **NMPA**, see below)
CDC – Centers for Disease Control and Prevention (US)
CDDD – Clinical dossier of drug development (Brazil)
CDE – Center for Drug Evaluation (China)
CDEC – Canadian Drug Expert Committee (Canada)
CDER – Center for Drug Evaluation and Research (US FDA)
CDISC – Clinical Data Interchange Standards Consortium
CDM – Common data model
CDMA – Canadian Drug Manufacturers Association
CDR – Common Drug Review (Canada)
CDRH – Center for Devices and Radiological Health (US FDA)
CDS – Clinical decision support
CDSCO – Central Drug Standard Control Organization (India's clinical trials licensing authority)
CDSM – Committee on Dental and Surgical Materials (UK)
CDx – Companion Diagnostics
CE – Capillary electrophoresis
CE Mark – Conformité European (approval for EU medical devices)
CEA – Cost-effectiveness analysis
CEC – Central ethics committee **– and also:**
CEC – Commission of the European Communities
CED – Coverage with evidence development
CEE – Central and Eastern Europe
CEEC – Central and Eastern European Countries
CEFTA – Central Europe Free Trade Area
CEN – Comité Européan des Normes – European Committee for Standardization
CEP – Central enquiry point (MHRA) – **and also:**
CEP – Certificate of European Pharmacopoeia (aka Certificate of Suitability)
CEPS – Comité Economique des Produits de Santé (Pricing committee), France
CER – Clinical evaluation report – **and also:**
CER – Comparative effectiveness research – **and also:**
CER – Critical expert report
CESP – Common European submission portal
CF – Cystic fibrosis
CFC – Chlorofluorocarbons
CFDA – China Food and Drug Administration (formerly State FDA – **SFDA**)
CFR – Code of Federal Regulations (US)
CFS – Certificate of Free Sale
CFSAN – Center for Food Safety and Applied Nutrition (US)
cGLP – Current good laboratory practice
cGMP – Current good manufacturing practice
CGP – Clinical Guidance Panel (Canada)

CH – Clinical hold
CHAI – Commission for Healthcare Audit and Inspection (UK)
CHC – Consumer healthcare
CHIM – Controlled human infection model
CHM – Commission on Human Medicines
CHMB - Creatine kinase Muscle Brain
CHMP – Committee for Medicinal Products for Human Use (EMA)
CHO – Chinese hamster ovary cells
CHPA – Consumer Healthcare Products Association
CI – Confidence Interval, **and also:**
CI – Contraindication
CIA – Corporate Integrity Agreement (US)
CIOMS – Council for International Organizations of Medical Sciences (WHO)
CIRS – Centre for Innovation in Regulatory Science
CIS (countries) – Commonwealth of Independent States (members are former Soviet Republic countries, currently including Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Usbekistan, Turkmenistan, Ukraine
CK – Creatine kinase
Cl – Total body clearance
Class Im – Class I with measuring function (medical devices)
CLIA – Clinical Laboratory Improvement Amendments (US*)*
CLL – Chronic lymphocytic leukaemia
CLO – Clinical overview
CLP – Classification, labelling and packaging (medical devices)
CLS – Clinical summary
C_m or C_{max} – Maximum plasma concentration at steady state
CMA – Conditional marketing authorisation (US)
CMC – Chemistry, manufacturing, and controls
CMDCAS – Canadian Medical Devices Conformity Assessment System
CMDh – Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (EMA)
CMDOs – Contract manufacturing/development organisations
CMDR – Canadian Medical Device Regulation
CMDv – Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (EMA)
CMI – Consumer medicines information (Australia – equivalent to a PIL in other regions)
CMN – Comité de Moléculas Nuevas" (New Molecules Committee) (Mexico)
CMP – Certificate of Medicinal Product **– and also:**
CMP – Common product model
CMR – Carcinogenic, mutagenic or reprotoxic [toxic to reproduction] **– and also:**
CMR – Centre for Medicines Research
CMS – Concerned member state (EU)
CMT – Convergent medical technologies
COA/CofA – Certificate of analysis **– and also:**
COA – Clinical Outcome Assessment
CoAg – Cooperative Agreement
COE – Council of Europe
COMET – Core Outcome Measures in Effectiveness Trials
COMP – Committee for Orphan Medicinal Products (EMA)
COREPER – Committee of Permanent Representatives to the Community
COSHH – Control of Substances Hazardous to Health
COSTART – Coding Symbols for a Thesaurus of Adverse Reaction Terms
CoU – Context of Use
CP – Centralised procedure (EU) – **and also:**
CP – Comparability protocol (US)
CPAC – Central Pharmaceutical Affairs Council (Japan)
CPC – Combination Products Coalition
CPD – Continuing professional development
CPI – Critical Path Initiative (US)
CPMP – Committee for Proprietary Medicinal Products (EMA)
CPP – Certificate of pharmaceutical product – **and also:**
CPP – Critical process parameter
CPQ – Costs per quality-adjusted life year

CPR – Cosmetic Products Regulation
CPRD – Clinical Practice Research Datalink (MHRA)
CPS – Chemistry – Pharmacy and Standards Subcommittee of the CSM (UK) – **and also:**
CPS – Clinical performance study
CPSP – Clinical performance study plan
CPU – Clinical pharmacology unit
CPWP – Cell-based Products Working Party (EMA)
CQA – Clinical quality assurance – **and also:**
CQA – Critical quality attribute
CR – Computed radiology – **and also:**
CR – Controlled releasse
CRA – Concerned regulatory agency
CRF – Case report form
CRG – Clinical reference group (UK)
CRM – Comments resolution meeting
CRO – Clinical Research Organisation
CRP – Canadian reference product (WHO) – **and also:**
CRP – Collaborative registration procedure
CRS – The Caribbean Regulatory System **– and also:**
CRS – Cytokine release syndrome
CS – Clinically significant – **and also:**
CS – Common specifications
CSA – Controlled Substances Act **CSI –** Core safety information
CSM – Centralised statistical monitoring **– and also:**
CSM – Committee on Safety of Medicines (UK)
CSO – Consumer Safety Officer (US)
CSP – Core safety profile
CSR – Clinical study report (EU)
CSV – Comma-separated values – **and also:**
CSV – Computer system development and validation
CT – Clinical trial – **and also:**
CT – Commission de Transparence (Transparency Commission), France – **and also:**
CT – Computed tomography
CTA – Clinical trial application – **and also:**
CTA – Clinical trial assay – **and also:**
CTA – Clinical trial authorisation
CTAG – Clinical Trials Action Group (Australia) – **and also:**
CTAG – Clinical Trials Coordination and Advisory Group
CTC – Clinical trial certificate (Hong Kong, Singapore)
CTD – Clinical Trials Directive – **and also:**
CTD – Common technical document* [*Although 'dossier' has become commonplace – the correct term is 'document']
CTEG – Clinical Trials Expert Group
CTFG – Clinical Trials Facilitation and Coordination Group
CTIS – Clinical Trial Information System *(formerly the EU clinical trial portal and database, EudraCT)*
CTMP – Cell therapy medicinal product
CTMS – Clinical trial management system
CTN – Clinical trial notification (Australia)
CTOC – Comprehensive Table of Contents Headings and Hierarchy
CTR – Clinical Trial Regulation
CTS – Common technical specification – **and also:**
CTS – Communication Tracking System *(formerly Eudratrack)*
CTTI – Clinical Trials Transformation Initiative
CTU – Clinical trials unit
CTX – Clinical trial exemption (UK)
CUA – Cost utility analysis
CUP – Compassionate use programme
CV – Controlled vocabulary
CVM – Center for Veterinary Medicine (US)
CVMP – Committee for Medicinal Products for Veterinary Use (EMA)
CVO – Chief Veterinary Officer

CVS – Cardiovascular system
CVZ – Dutch Health Care Insurance Board
CWoW – Combined Ways of Working
CZ – Climatic zone

DDD
DAB – German Pharmacopoeia (Deutsches Arznei Buch)
DAC – Data analysis centre
DACS – Detailed and critical summary
DAE – Discontinuation due to an adverse event
DAL – Defect action level (US)
DAMOS – Drug application methodology with optical storage
DB – Device Bulletin (MHRA)
DCGI – Drugs Controller General of India – **and also:**
DCGI – India's regulatory authority (Directorate General of Health Services in the Ministry of Health and Family Welfare)
DCP – Decentralised procedure (EU)
DCTs – Decentralised clinical trials
DD – District Director (US)
DDC(P) – Drug-device combination (product)
DDD – Defined daily dose
DDMAC – Division of Drug Marketing, Advertising and Communications (CDER)
DDPS – Detailed description of pharmacovigilance system
DDX – Doctors' and dentists' exemption (UK)
DE – Designated examination
DEA – Drug Enforcement Agency (US)
DEREK – Deductive estimate of risk from existing knowledge
DES – Data exchange standard (EU) – **and also:**
DES – Drug eluting stent
DESI – Drug efficacy study implementation (US)
DG – Directorate-General (at the European Commission)
DGEM – Disease-gene expression matching
DGV – Direccao Geral de Veterinaria (Veterinary Medicines Agency) (Portugal)
DH – Department of Health (UK) – **and also:**
DH – Digital healthcare
DHHS – Department of Health and Human Services (US)
DHPC – Direct healthcare professional communication (formerly 'Dear Doctor Letter')
DIA – Drug Information Association (US)
DIBD – Development international birth date
DICE – Division of Industry and Consumer Education (US FDA)
DID – Design inputs document
DIMDI – Deutsches Institut für Medizinische Dokumentation und Information (Germany)
DKMA – Lægemiddelstyrelsen/Danish Medicines Agency (Denmark)
DL – Deep learning
DLP – Data lock point
DMF – Drug master file
DMPK – Drug metabolism and pharmacokinetics
DMRC – Defective Medicines Report Centre (MHRA)
DMS – Document management system
DMT – Disease modifying therapy
DNEL – Derived no-effect level
DOA – Date of application
DOE – Design of experiments
DoR – Duration of Response
DP – Drug product
DPI – Dry powder inhaler
DPIA – Data protection impact assessment
DMPK – Drug metabolism and pharmacokinetics
DPO – Data Protection Officer
DPR – Data Protection Representative – **and also:**
DPR – Dual Pack import Registration

DR – Deliberate release – **and also:**
DR – Digital radiology
DRA – Drug Regulatory Authority
DRF(S) – Dose range finding (study)
DRMP – Developmental risk management plan
DRR – Drug Registration Regulation (China) **– and also:**
DRR – Durable response rate
DS – Drug substance
DSC – Differential scanning calorimetry
DSMC – Data safety monitoring committee
DSRU – Drug Safety Research Unit (EMA)
DSUR – Development safety update report
DT – Decision tree
DTaP – Diphtheria, tetanus and pertussis
DTC – Direct-to-consumer
DTD – Document type definition
DUNS – Data universal numbering system
DUS – Drug utilisation study
DVPHNFS – Department for Veterinary Public Health, Nutrition and Food Safety (Italy)
DWH – Data warehouse
Dx – Diagnostic

EEE
E&Ls – Extractables and leachables
EA – Environmental assessment (US)
EAC – East African Community
EAEU – Eurasian Economic Union
eAF – electronic Application Form
EAI – Estimated acute intake
EAMS – Early Access to Medicines Scheme (UK)
EAP – Early Access Programme
EBE – European Biopharmaceutical Enterprises
EbM – Evidence-based medicine
EC – Established conditions (ICH Q12 Guideline) – **and also:**
EC – Ethics committee – **and also:**
EC – European Commission **– and also:**
EC – Exceptional circumstances
eCPP – Electronic certificate of pharmaceutical product
ECDC – European Centre for Disease Prevention and Control
ECG – Electrocardiogram
ECHAMP – European Coalition on Homoeopathic and Anthroposophic Medicinal Products
ECHR – European Court of Human Rights
ECJ – European Court of Justice
ECPHIN – European Community Pharmaceutical Information Network
ECRAB – European Committee on Regulatory Aspects of Biotechnology (EBCG)
eCRF – electronic case report form
eCTD – electronic common technical document [not dossier*] *Although 'dossier' has become commonplace – the correct term is 'document'
ED – Early dialogue
EDA – Egyptian Drug Authority
EDC – electronic data capture
EDMF – European drug master file
eDMS – electronic document management system
EPDB – European Data Protection Board
EDQM – European Directorate for the Quality of Medicines EDQM – European Directorate for the Quality of Medicines |
EDT – Electronic data transfer
ED_X – Effective dose at X%
EEA – European Economic Area (comprising the EU countries, plus Iceland, Liechtenstein and Norway)
EEC – European Economic Community
EEG – Electroencephalogram

eERA – extended Environmental Risk Assessment
EEU – Eurasian Economic Union
EFA – European Federation of Allergy and Airways Diseases Patients' Associations
EFPIA – European Federation of Pharmaceutical Industries and Associations (http://www.efpia.eu)
EFPIA – European Federation of Pharmaceutical Industries and Associations
EFQM – European Foundation for Quality Management
EFSA – European Food Safety Authority
EFTA – European Free Trade Association
EGA – European Generic medicines Association **– Name changed 10 March 2016 to "Medicines for Europe"**
EGGVP – European Group for Generic Veterinary Products
EGP – Economic Guidance Panel (Canada)
EHR – Electronic health record
EIA – Environmental Impact Assessment
EINECS – European Inventory of Existing Chemical Substances
ELA – Establishment license application (US)
ELSIE – Extractables and Leachables Safety Information Exchange
EMA – European Medicines Agency (formerly European Medicines Evaluation Agency – **EMEA**)
EMACOLEX – European Medicines Agencies Co-operation of Legal and Legislative Issues
EMANS – European Medicines Agencies Network Strategy
EMCDDA – European Monitoring Centre for Drugs and Drug Addiction
EMEA – Europe, Middle East & Africa
EMEA – see above – **and also:**
EMEAA – Europe, Middle East, Africa & Asia
EMR – Electronic medical records
EMRC – European Medical Research Councils (a unit of the **ESF** – see below)
EMVO – European Medicines Verification Organisation
EMVS – European Medicines Verification System
ENCePP – European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
eNDA – Electronic New Drug Application
ENDS – Electronic nicotine delivery system
ENP – European Neighborhood Policy
Enpr-EMA – European Network of Paediatric Research at the European Medicines Agency
ENS – Early notification system
EOF – Ethnikos Organismos Farmakon – aka National Organization for Medicines (Greece's regulatory agency)
EoP – End of Procedure
EOP1 – End of Phase 1 (US)
EOP2 – End of Phase 2 (US)
EOQ – European Organization for Quality
EP – European Parliament – **and also:**
EP/Ph Eur – European Pharmacopoeia (aka Pharm Eur)
EPA – Environmental Protection Agency (US) and (Ireland) – **and also:**
EPA – Environmental Protection Authority (New Zealand) – **and also:**
EPA – Expert patient advocate
EPAA – European Partnership for Alternative approaches to Animal testing
EPAD – European Prevention of Alzheimer's Dementia
EPADES – European Parliament Document Exchange Server
EPAR – European public assessment report
EPC – European Pharmacopoeia Commission
EPCU – Early Phase Clinical Units
EPHA – European Public Health Alliance
ePI – Electronic product information
EPI – Essential Program for Immunisation
EPID – Extended (also Expanded) Public Information Document
EPITT – European Pharmacovigilance Issues Tracking Tool
EPL – Effective patent life
EPO – European Patent Office
EPOC – European Oligonucleotides Consortium
EPPOSI – European Platform for Patients' Organisation – Science & Industry
EPPV – Early post-marketing phase vigilance (eg, in Japan)
EPRG – European Pharmacovigilance Research Group
EPRUMA – European Platform for the Responsible Use of Medicines in Agriculture

EPS – Eco-Pharmaco-Stewardship
ePSUR – electronic periodic safety update report
EQM – Equivalence margin
ERs – Essential requirements (devices)
ERA – Environmental risk assessment – **and also:**
ERA – European regulatory affairs
ERB – Ethical review board
eRMR – electronic Reaction Monitoring Report
ERMS – European risk management strategy
ERMS-FG – European Risk Management Strategy Facilitation Group (HMA)
ERP – European Reference Medicinal Product
ESF – European Science Foundation
ESG – Electronic submissions gateway (FDA)
ESM – European stakeholder model
ESPAR – Executive Summary Pharmacovigilance Assessment Report (EU)
ESR – Erythrocyte Sedimentation Rate
ESRA – European Society of Regulatory Affairs
ESTRI – Electronic Standards for the Transfer of Regulatory Information
ESVAC – European Surveillance of Veterinary Antimicrobial Consumption
ETASU – Elements to ensure safe use (US)
eTMF – electronic Trial Master File
ETOMEP – European Technical Office for Medical Products (within EMA)
EU – European Union
EU5 – Group of countries comprising Germany, France, Italy, Spain and the UK
EUA – Emergency use authorisation
EU-ADR – Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge (formerly known as ALERT) (EU)
EUBAN – European Borderline Assessment Network
EUIG – EU Implementation Guide
EU-IN – EU Innovation Network
EUCERD – EU Committee of Experts on Rare Diseases
EUCOMED – European Confederation of Medical Device Associations
ECTR – EU Clinical Trials Register
EUDAMED – European Databank on Medical Devices
EUDRA – European Union Drug Regulatory Authorities
EudraCT – European Union Drug Regulatory Authorities Clinical Trials database
EudraNet – European Union Drug Regulatory Authorities Network
EudraSmPC – Summary of Product Characteristics
EUnetHTA – European Network for Health Technology Assessment
EU-NTC – EU Network Training Centre
EUPATI – European Patients' Academy on Therapeutic Innovation
EUPD – EU Portal and Database
EuPFI – European Paediatric Formulation Initiative
EURD – European Union reference date
EUREC – European Network of Research Ethics Committees
EURL – EU reference laboratory
EUR-OP – EU Office for Publications
EU-SRS – EU Substance Registration System (aka EU SRS)
EUTCT – European Union Telematics Controlled Terms
EUTMB – EU Telematics Management Board
EV – EudraVigilance – European Union Drug Regulating Authorities Pharmacovigilance
EVALI – e-cigarette or vaping product use-associated lung injury
EVCTM – EudraVigilance clinical trial module
EV-EWG – EudraVigilance Expert Working Group
EVIDENT – Evidence Database on New Technologies
EVM – European Vaccine Manufacturers
EVMPD – EudraVigilance medicinal products dictionary
EVPM – EudraVigilance post-authorisation module
EVPRM – EudraVigilance product report message
EVV/EVVet3 – (EudraVigilance) Union pharmacovigilance database
EWG – Expert Working Group

EWP – Efficacy Working Party (EMA)

FFF
FACC – Food Additives and Contaminants Committee (UK)
FAGG – Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (Belgium)
FAIR (data) – Findable, accessible, interoperable and reusable (data)
FAMHP – Federal Agency for Medicines and Healthcare Products (Belgium)
FAR – Final assessment report
Farmindustria – Association of Italian Pharmaceutical Manufacturers (Italy)
FCC – Food and Chemical Codex
FDA – Food and Drug Administration (the US regulatory authority)
FDAAA – FDA Amendments Act
FDAMA – FDA Modernization Act
FDASIA – Food and Drug Administration Safety and Innovation Act
FD&C Act – Food, Drug and Cosmetic Act (US) [aka **FDCA** & **FFDCA**]
FDC – Fixed dose combination
FDF – Finished dosage form
FHIR – Fast healthcare interoperability resources (framework)
FIH – First-in-human [aka **FIM** – first-in-man; and **FTIM** – first-time-in-human]
FIM – First-in-man
FIM-A – Federal Institute for Medicines (Austria)
FIMEA – Finnish Medicines Agency (Finland)
FIP – International Pharmaceutical Federation
FMD – Falsified Medicines Directive (EU)
FMEA – Failure mode and effect analysis
FMECA – Failure modes effects and criticality assessment
FNOMCeO – Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri (IT) = Italian organisation of doctors and dentists
FOB – Follow-on biologic
FOFI – Federazione Ordini Farmacisti Italiani (IT) – Italian Organisation of Pharmacists
FOI Act – Freedom of Information Act (US)
FOM – Francophone overseas markets
FONSI – Finding of no significant impact
FOP – Follow-on protein
FPA – Food producing animal
FPFV – First patient first visit
FPIF – Finnish Pharmaceutical Industry Association
FPP – Finished pharmaceutical product
FPRC – Final product release control
FPRR – Final product release responsibility
FQA – Full quality assurance
FR – Federal Register (US)
FRPs – Facilitated regulatory pathways
FrP – French Pharmacopoeia (Pharmacopée Française, aka **PF**)
FSCA – Field safety corrective action (medical devices sector)
FSIS – Food Safety and Inspection Service (US)
FSN – Field safety notice (medical devices)
FTA – Fault tree analysis
FTC – Federal Trade Commission (US)
FTD – Fast track designation (US)
FTE – Full time equivalent (employee)
FTIM – First-time-in-human
FTIR – Fourier transform infra-red
FU – Farmacopea Ufficiale – the Italian Pharmacopoeia
FUM – Follow-up measures
FVAR – Final variation assessment report
FW – Food and water (consumptions)
FY – Fiscal year

GGG
GAIN Act – Generating Antibiotic Incentives Now Act (US)
GATT – General Agreement on Tariffs and Trade

GbCF – Global competency framework
GC – Gas chromatography
GCC (region) – Gulf Cooperation Council (region)
GCC-DR – Gulf Central Committee for Drug Registration
GCD – Global clinical development
GCG – Global Cooperation Group (ICH)
GCP – Good clinical practice
GCPv – Good clinical practice. veterinary
GCTs – Gene and cell therapies
GDMP – Good manufacturing and distribution practices
GDP – Good distribution practice
GDPR – General Data Protection Regulation
GDUFA – Generic Drug User Fee Amendments (FDA)
GEG – Geriatrics Expert Group
GEP – Good engineering practice – **and also:**
GEP – Good epidemiological practice
GGP – Good guidance practice
GHTF – Global Harmonisation Task Force (now IMDRF)
GIVIMP – Good *in vitro* method practices
GLC – Gas liquid chromatography
GLP – Good laboratory practice
GLPMA – Good Laboratory Practice Monitoring Authority (UK)
GMA – Global marketing authorisation
GMC – General Medical Council (UK)
GMDN – Global medical device nomenclature (medical devices sector)
GMiA – Generic Medicines industry Association (Australia)
GMO – Genetically modified organism
GMP – Good management practice
GMP – Good manufacturing practice – **and also:**
GNA – Grounds for non-acceptance
GPAG – Granularity and Periodicity Advisory Group
GPhP – Good Pharmacopoeial Practices (WHO)
GPIA – Generic Pharmaceutical Industry Association (US)
GPMSP – Good postmarketing surveillance practice (Japan)
GPP – Good paediatric practice – **and also:**
GPP – Good pharmacoepidemiology practice
GPP2 – Good publication practice
GPSP – Good post-marketing study practice
GpvP – Good pharmacovigilance practice
GQCLP – Good quality control laboratory practice
GQP – Good quality practice
GRAS – Generally recognised as safe (US)
GRB – Global Regulatory Board
GRP – Good regulatory practice – **and also:**
GRP – Good review practice (US)
GSEA – Gene set enrichment analysis
GSL – General sales list
GSP – Good statistics practice – **and also:**
GSP – Good storage practice
GSPRs – General safety and performance requirements
GTI – Genotoxic impurity
GTMP – Gene therapy medicinal product
GTP – Gene therapy product – **and also:**
GTP – Good tissue practices (USA)
GTWP – Gene Therapy Working Party
GUI – Graphical user interface
GVD – Global value dossier
GvHD – Graft versus host disease
GVP – Good pharmacovigilance practice (aka good vigilance practice)
GVPP – Good veterinary pharmacovigilance practice
GWAS – Genome-wide association study

GxP – general term for "good practice" quality guidelines and regulations, where "*x*" is the symbol for the variable descriptor

HHH
HA – Health authority
HACCP – Hazard analysis critical control point (inspection technique) (US)
HAI – Health Action International
HAS – Haute Autorité de santé (French health authority)
Hb – Haemoglobin
HBD – Harmonised birth date
HCD – Historical control data
HCP – Healthcare professional
HCPWP – Healthcare Professionals Working Party (EMA)
HCR – Holder of certificate of registration (South Africa)
HCRW – Health and Care Research (Wales)
HCT – Haematocrit
HCT/P – Human cells, tissues, and cellular and tissue-based products
HDE – Humanitarian device exemption
HDI – Human development index
HE – Hospital exemption
HEOR – Health economics and outcomes research
HEW – Health, Education and Welfare (US)
HFE – Human factors engineering
HGAC – Human Genetics Advisory Committee
HGPRT – Hypoxanthine-guanine-phosphoribasyltransferase activity
HHMG – Human Harmonisation Maintenance Group
HHS – US Department of Health and Human Services
HIC – High income countries
HIMA – Health Industry Manufacturers Association (US)
HL7 – Health Level Seven
HLGT – High level group term (in MedDRA)
HLT – High level term (in MedDRA)
HMA – Heads of Medicines Agencies (Human and Veterinary) (EU)
HMO – Health Maintenance Organisation (US)
HMPC – Committee on Herbal Medicinal Products (EMA)
HMR – Human Medicines Regulations
HNSTD – Highest Non Severely Toxic Dose
HoA – Heads of Agencies
HPB – Health Protection Board (Canada)
HPLC – High performance liquid chromatography
HPRA – Health Products Regulatory Authority (formerly Irish Medicines Board)
HR – Heart rate
HRA – Health Research Authority (UK)
HRB – Health Research Board
HREC – Human Research Ethics Committee
HRQoL – Health-related quality of life
HRT – Hormone replacement therapy
HSA – Human serum albumin
HSC – Haematopoietic stem cells
HSE – Health and Safety Executive (UK)
HST – Highly specialised technology
HTA – Health technology assessment
HTS – High-throughput screening
HV – Healthy volunteer

III
I&AC – Imaging and acute care (medical devices sector)
IAM – Identity and Access Management – **and also:**
IAM – Individual account management (EMA)
IAPO – International Alliance of Patients' Organisations
IB – Investigator's brochure
IBC – International biosafety committee (USA)

IBD – International Birth Date
IBMS – Institute of Basic Medical Sciences (China)
IC – Informed consent
ICD – Informed consent document c
ICD – International Classification of Diseases
ICDRA – International Conference of Drug Regulatory Authorities
ICER – Incremental cost-effectiveness ratio
ICF – Informed consent form
ICH – International Council for Harmonisation (formerly International *Conference on Harmonisation of* Technical Requirements for Registration of Pharmaceuticals for Human Use
ICI – Immune checkpoint inhibitor
ICMJE – International Committee of Medical Journal Editors
ICMRA – International Coalition of Medical Regulatory Authorities
ICP – Immune correlate of protection
ICP-MS – Inductively coupled plasma mass spectrometry
ICSR – Individual case safety report
ICT – Information and communications technology
ICTRP – International Clinical Trials Registry Platform (WHO)
IC_X – Inhibition concentration at X%
IDE – Investigational Drug Exemption
IDMP – Identification of medicinal products – **and also:**
IDMP – Infectious diseases management program (US)
IDR – Idiosyncratic drug reaction
IDRAC – International Drug Registration Assisted by Computer
IEC – Independent ethics committee
IFAH – International Federation for Animal Health
IFP – International Pharmaceutical Federation
IFPMA – International Federation of Pharmaceutical Manufacturers and Associations
IFU – Instructions for use
IG – Implementation guide
IGDG – Informal Generic drug Discussion Group
IGDRP – International Generic Drug Regulators Pilot
IGPA – International Generic Pharmaceutical Alliance
IGZ – the Netherlands Healthcare Inspectorate
IIG – Inactive ingredient guide (US FDA)
IIS – Investigator initiated study
IM – Intramuscular **– and also:**
IM – Issue management
IM(ER)R – Ionising radiation (medical exposure) regulations
IMA – Lyfjastofnun/Icelandic Medicines Agency (Iceland)
IMB – Irish Medicines Board [name changed in July 2014 to **HPRA –** Health Products Regulatory Authority]
IMCA – Lyfjastofnun/Icelandic Medicines Control Agency (Iceland)
IMD – Implantable medical device
IMDA – Irish Medical Device Association
IMDRF – International Medical Device Regulators Forum (formerly GHTF)
IME – Important medical event
IMI – Innovative Medicines Initiative
IMM – Irreversible morbidity or mortality
IMP – Investigational medicinal product
ImPACT – Imaging performance assessment of CT scanner
IMPD – Investigational medicinal product dossier
IMRDF – International Medical Device Regulatory Forum
IMS – Information management strategy
INADA – Investigational new animal drug application
IND – Investigational new drug (US)
INDA – Investigational new drug application (US)
INDC – Investigational New Drug Committee
INFARMED – Instituto Nacional da Farmacia e do Medicamento (Portugal's regulatory agency)
INHAND – International Harmonization of Nomenclature and Diagnostic Criteria
INN – International nonproprietary name
IO – Immune-oncology

IP – Indian Pharmacopoeia – **and also:**
IP – Intellectual property – **and also:**
IP – Interested Parties – **and also:**
IP – Intraperitoneal
IPAC – International Pharmaceutical Aerosol Consortium
IPC – International Pharmaceuticals Council
IPCs – In-process controls
IPD – Individual Patient Data
IPEC – International Pharmaceutical Excipients Council
IPI – International Pricing Index
iPiE – Intelligence-led assessment of Pharmaceuticals in the Environment
IPM – Indian pharmaceutical market
IPO – Intellectual Property Office
IPR – Intellectual property rights
IPRF – International Pharmaceutical Regulators Forum
iPSP – initial Paediatric Study Plan
IPU – Irish Pharmaceutical Union
IQ – International Consortium for Innovation and Quality in Pharmaceutical Development
IQM – Integrated quality management
IR – Infra-red – **and also:**
IR (medication) – Immediate release
IRAS – Integrated Research Application System
IRB – Institutional review board (aka Independent Ethics Committee (**IEC**) or Ethical Review Board (**ERB**))
IRC – Institutes Review Committee
IRD – International registration document
IRDiRC – International Rare Diseases Research Consortium
IRN – Incident Review Network
IRP – Independent review panel
IRR – Ionising radiation regulation
IRT – Interactive response technology – **and also:**
IRT – Interdisciplinary Review Team (US)
IS – Information science/systems – **and also:**
IS – Internal standard
ISA – Integrated scientific advice
ISCT – In silico clinical trial
ISE – Integrated summary of efficacy
ISI – Integrated summary of immunogenicity
ISO – International Standards Organisation
ISRB – Integrated summary of risk benefit
ISS – Integrated summary of safety
IT – Information technology
ITF – Innovation Task Force (EMA)
ITT – Intent-to-treat
IU – International unit
IUPAC – International Union of Pure and Applied Chemistry
IV – Intravenous
IVD – *in vitro* (medical) device; **and also:**
IVD – *in vitro* diagnostics
IVDR – In Vitro Diagnostic Regulation
IVIVC – *in vitro in vivo* correlation
IVMP – Immunological veterinary medicinal product
IVRS – Interactive voice response system
IWG – Implementation working group
IWP – Immunologicals Working Party (EMA)

JJJ
JAN – Japanese Approved Name
JAS – Juvenile animal study
JAZMP – Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Slovenia's regulatory agency)
JFDA – Jordan Food & Drug Administration
JIACRA – Joint Interagency Antimicrobial Consumption and Resistance Analysis

J-NDA/JNDA – Japanese New Drug Application
JP – Japanese Pharmacopoeia
JPMA – Japan Pharmaceutical Manufacturers Association
J-RMP – Japanese risk management plan (template)

KKK
KAS – Known active substance
KFDA – Korean Food and Drug Administration
KIT – Key intelligence topic
KM – Knowledge management
KNN – K-nearest neighbour
KOL – Key opinion leader
KOM – Kick-off meeting

LLL
LAAB – Long-acting antibody
LABST – Laboratory animal batch safety testing
LAT – Light authoring tool (EU)
LCM – Lifecycle management
LD – Low dose
LD_{50} – Lethal dose required to kill 50% of the study population
LDH – Lactate dehydrogenase
LEC – Local ethics committee
LED – Least Effect Dose
LEEM – Les Entreprises du Médicament (French Pharmaceutical Industry Association)
LFT – Liver function test
LiCT – Low-intervention clinical trial
LIF – Läkemedelsindustriföreningen (Swedish Pharmaceutical Industry Association)
LLL – Lifelong learning
LM – Limited market(s) (veterinary)
LMA – Limited marketing authorisation
LMICs – Low and middle income countries
LMO – Living modified organism
LoA – Letter of access (China)
LOAEL – Lowest observed adverse-effect level
LOD – Loss on drying
LOI – Letter of intent (US)
LoNR – Letter of non-repudiation agreement (FDA)
LoOI – List of Outstanding Issues
LoQ – List of Questions
LPLV – Last patient last visit
LR – Logistic regression
LSIF – Life Sciences Innovation Forum
LT (stability) – Long term
LTT – Lines to take [document usually not for publication] (EMA)
LVP – Large volume parenterals

MMM
M&S – Modelling and simulation
MA – Marketing authorisation
MAA – Marketing authorisation application (EU)
MABEL – Minimal anticipated biological effect level
MAD – Multiple ascending dose (study), **and also:**
MAD – Mutual acceptance of data (OECD Council Decision)
MAFF – Ministry of Agriculture, Forestry and Fisheries (Japan)
MAH – Marketing authorisation holder
MAID – Manufacturers, authorised representatives, importers and distributors
MALAM – Medical Lobby for Appropriate Marketing
Mane – Morning
MANSEV – Marketing Authorisation by Network Submission and Evaluation
MAPPs – Medicines adaptive pathways to patients

MAS – Module assessment summary
MAUDE – Manufacturer and User Facility Device Experience (US)
MAWP – Multi-Annual Work Plan (HMA)
MaxSPRT – Maximised sequential probability ratio test
MB – Management Board
MCB – Master cell bank
MCC – Medicines Control Council (South Africa)
MCDA – Multi-criteria decision analysis
MCH – Mean cell haemoglobin concentration
MCID – Minimally clinical important difference
MCPC – Major contribution to patient care
MCV – Mean cell volume
MD – Medical device
MDA – Medical device alert
MDCG – Medical Device Coordination Group
MDD – Medical Device Directive – **and also:**
MDD – Medical Devices Directorate
MDDS – Medical device data systems
MDEG – Medical Devices Expert Group
MDEG-BC – Medical Devices Expert Group on Borderline and Classification
MDI – Metered dose inhaler
MDLO – Medical Device Liaison Officer
MDR – Medical Device Regulation – **and also:**
MDR – Medical device reporting – **and also:**
MDR – Multi-drug resistant
MDSAP – Medical Device Single Audit Program
MDSW – Medical device software
MDV – Medical device vigilance
ME – Market exclusivity
MEB – Medicines Evaluation Board (the Netherlands) – also known as Dutch College
MedDevs – Guidances outlining the requirements of the Medical Device Directive
MedDRA – Medical Dictionary for Regulatory Activities
MEDEV – Medicine Evaluation Committee (EU)
MEDSAFE – New Zealand Medicines and Medical Devices Safety Authority
MEGS – Medical and Educational Goods and Services
MENA – Middle East and North Africa
MERS – Multi-agency electronic regulatory system
MF – Medicated feed – **and also:**
MF – Modifying factor
MFDS – Ministry of Food and Drug Safety (Korea)
MgSzH – Mezogazdasagi Szakigazgatasi Hivatal Dictorate of Veterinary Medicinal Products (Hungary)
MHRA – Medicines and Healthcare products Regulatory Agency
MHW – Ministry of Health and Welfare (Japan)
MI – Mutagenic impurity
MIA – Manufacturing and Importation Authorisation
MIA(IMP) – Manufacturer's Authorisations for IMPs
MIDD – Model-informed drug development (US)
MIMS – Monthly Index of Medical Specialities (UK)
MINE – Medicines Information Network for Europe
MIR – Manufacturer incident report
MISG – Ministerial industry strategy group
ML – Machine learning **– and also:**
ML – Manufacturer's licence
MLD – Minimal lethal dose
MLM – Medical literature monitoring
MMA – Malta Medicines Authority – **and also:**
MMA – Mobile medical app
MNAT – Multinational Assessment Team
MO – Major Objection
MoA – Mechanism of action – **and also:**
MOA – Ministry of Agriculture
MoCA – Mechanism of Coordinated Access

MOD 1 – Module One (laboratory facility) (US)
MOD 2 – Module Two (laboratory facility) (US)
MOHAP – Ministry of Health and Prevention (UAE)
MORE – Manufacture's Online Reporting Environment (MHRA) (medical devices sector)
mOS – median Overall Survival
MOU – Memorandum of Understanding
MPA – Medical Products Agency, Sweden (now **SEMPA**)
MPD – Medicinal Products Directive
MPID – Medicinal product identifier
MPQ – McGill pain questionnaire
MQAS – Model Quality Assurance System
MQSA – Mammography Quality Standards Act of 1992 (US)
MR – Mutual Recognition
MRA – Mutual recognition agreement – **and also:**
MRAs – Medicines regulatory authorities
MRC – Medical Research Council
MRCT – Multi-regional clinical trial
MRD – Multiple rising dose
MRFG – Mutual Recognition Facilitation Group (EMA)
MRH – Medicines regulatory harmonisation
MRI (scan) – Magnetic resonance imaging (scan) – **and also:**
MRI – Mutual recognition information
MRL – Maximum residue limit
MRP – Mutual recognition procedure (EU)
MRSD – Maximum recommended safe dose
MRTP – Modified risk tobacco product
MRU – Medicines Regulatory Unit (Health Division Malta)
MS – Mass spectrometry – **and also:**
MS – Member state/s (EU)
MSWG – Modelling and Simulation Working Group
MTD – Maximum tolerated dose
MTS – Medicines testing scheme (MHRA)
MUMS – Minor use and minor species (veterinary)
MUS – Multiple-use system
MVP – Minimum viable product
MWD – Manufacturing and wholesale distribution database

NNN
N&ET – New and emerging technologies (see also: NET WG)
N-11 – Next 11 (group of countries comprising Bangladesh, Egypt, Indonesia, Iran, Korea, Mexico, Nigeria, Pakistan, Philippines, Turkey and Vietnam)
NAD – No abnormality detected
NADA – New animal drug application (US)
NAFDAC – National Agency for Food and Drug Administration and Control (Nigeria)
NAFTA – North American Free Trade Association (US)
NAI – No action indicated
NAO – National Audit Office (UK)
NAP – Nationally authorised product
NAS – New active substance
NB – Notified body (EU)
NBE – New biological entity
NBIC – Nanotechnology, biotechnology, information science and cognitive science
NBO – Notified body opinion
NBOG – Notified Body Operations Group (EU)
NC3Rs – National Centre for the Replacement, Refinement and Reduction of Animals in Research (UK)
NCA – National competent authority
NCAS – New chemical active substance
NCD – Non-communicable diseases
NCE – New chemical entity
NCI – National Cancer Institute (US) – **and also:**
NCI – National Coordinating Investigator
NCO – Non clinical overview

NCS – Non clinical summary
NCTR – National Center for Toxicological Research (US)
NDA – New drug application (US)
NDAC – New Drug Advisory Committee (India)
NDMA – Non-Prescription Drug Manufacturers Association (US)
NDS – New drug submission (Canada)
NED – Non effect dose
NeeS – Non eCTD electronic submission
NEFARMA – Netherlands Pharmaceutical Industries Association
NET WG – New & Emerging Technologies Working Group
NF – National Formulary
NfG – Note for Guidance (EU)
NGS – Next generation sequencing
NHL – non-Hodgkin's lymphoma
NHP – Non-human primate
NHS – National Health Service
NHV – Normal healthy volunteer
NIAID – National Institute of Allergy and Infectious Diseases
NIBSC – National Institute for Biological Standards Control (UK)
NICE – National Institute for Health and Care Excellence (formerly 'Clinical' Excellence)
NICHD – National Institute of Child Health and Human Development (US)
NIH – National Institutes of Health (US)
NIHR – National Institute for Health Research (UK)
NIMP – Non-investigational medicinal product *(but see **AMP –** Auxiliary medicinal product)*
NIR – near infrared (spectroscopy) **– and also:**
NIR – Non-interventional research
NIS – Non-interventional study
NK cells – Natural killer cells
NLEA – Nutrition Labelling and Education Act of 1990 (US)
NLN – Nordic Council on Medicines
NMA – National Medicines Agency (Romania)
NMCA – Norwegian Medicines Control Agency (aka **SLK**)
NME – New molecular entity
NMFS – National Marine Fisheries Service (US)
NMPA – National Medical Products Administration (China) (国家药品监督管理局) (formerly CFDA)
NMR – Nuclear magnetic resonance
NMRAs – National Medicines Regulatory Authorities
NMVO – National Medicines Verification Organisation
NMVRVI – Nacionalinis Maistro Ir Veterinarijos Rizikos Vertinimo Institutas (National Food and Veterinary Risk Assessment Institute) (Lithuania)
NOAEL – No observed adverse effect level
NOAH – National Office of Animal Health (UK)
NOEL – No observed effect level
NOC – Notice of Compliance (Canada)
NOC/c – Notice of Compliance with Conditions (Canada)
Nocte – Night
NOEL – No observable/obsmferved effect level
NoMA – Norwegian Medicines Agency
NPCB – National Pharmaceutical Control Bureau (Malaysia)
NPP – Named patient product/programme
NPRM – Notice of Proposed Rulemaking
NPT – Near-patient test
NRA – National regulatory authority
NRG – (invented) Name Review Group
NRS – Numerical rating scale
NSA – National Security Agency (US)
NSAI – National Standards Authority of Ireland
NSAID – Nonsteroidal anti-inflammatory drug
NSB – National Standards Body **– and also:**
NSB – Non-similar biologic
NSCLC – Non-small cell lung cancer

NSF – No biologically significant finding (may be used in older reports)
NSN – New substances notification (Canada)
NSR – Non-significant risk
NSVA – National Sanitary Veterinary Agency (Romania)
NtA – Notice to applicants (EC)
NTD – Neglected tropical disease
NTE – No toxic effect level
NTI – Narrow therapeutic index
NUI – Non-urgent information (aka "Infofax") (EU)
NVR – New Veterinary Regulation (being replaced by **VMP-Reg**)
NWIP – New work item proposal (EU)

OOO
O/E – Observed versus expected [analysis]
oab – On anhydrous basis
oasfb – On anhydrous solvent free basis
OBL – Own brand labelling
OBP – On-boarding partner
OC – Office of the Commissioner (US)
OCA – Office of Consumer Affairs (US)
OCABR – Official control authority batch release
OCI – Office of Criminal Investigation (US)
OCP – Office of Combination Products (US FDA)
od – once a day *[Latin: omne in die]* – **and also:**
OD – Orphan drug
ODA – Orphan Drugs Act (US)
ODC – Optimal diagnostic concentration (used on allergy products)
ODD – Orphan drug designation
OE – Oral explanation
OECD – Organisation for Economic Co-operation and Development
OEI – Official establishment inventory (US)
OEM – Original equipment manufacturer
OES – Original equipment supplier
OGTR – Office of the Gene Technology Regulator (Australia)
OGYI/NIP – National Institute of Pharmacy (Hungary)
OH – Oral Hearing
OHDSI – Observational Health Data Science and Informatics
OIA – Official action indicated
OIE – World Organisation for Animal Health
OINDP – Orally inhaled and nasal drug product
OJ/OJEC – Official Journal of the European Communities
OLE (study) – Open label extension (study)
OM – Organ measurements
OMAR – Orphan Maintenance Assessment Report
OMCL – Official Medicines Control Laboratories (part of **EDQM**)
OMP – Orphan medicinal product
OMS – Organisations data management service
OOPD – Office of Orphan Products Development (US FDA)
OOS – Out of specification
OPA – Office of Public Affairs (US)
OPD – Original pack dispensing
OPDP – Office of Prescription Drug Promotion (FDA's CDER)
OPE – Office of Planning and Evaluation (US)
ORA – Office of Regulatory Affairs (US FDA)
ORGAM – Organisational Matters
ORR – Overall response rate
OS – Overall survival
OTAT – Office of Tissues and Advanced Therapies (US CBER)
OTC – Over-the-counter

PPP
P – Pharmacy only (ie, medicinal product dispensed by a pharmacist)

P to GSL – Pharmacy to General Sales List
P&L – Packaging and labelling
P&R – Pricing and reimbursement
PA – Product authorisation – **and also:**
PA – Protocol assistance
PAB – Pharmaceutical Affairs Bureau (Japan)
PAC-ATLS – Post Approval Change – Analytical Testing Laboratory Site (US)
PACMP – Post-approval change management protocol
PAD – Pharmacologically active dose
PaedPAR – Paediatric Public Assessment Report
PAES – Post authorisation efficacy study
PAGB – Proprietary Association of Great Britain
PAI – Pre-approval inspection
PAL – Pharmaceutical Affairs Law (Japan)
PAM – Patient activation measure (UK)
PAM(s) – Post Authorisation Measure(s)
PAO – Period after opening (cosmetic products)
PAR – Preliminary assessment report
PAR – Public Assessment report
PARENT – Patient Registries Initiative (EU)
PAS – Patient Affairs Staff, **and also:**
PAS – Public Affairs Specialist (US)
PASS – Post authorisation safety study
PAT – Priority Action Team (EFPIA)
PAT – Process analytical technology – **and also:**
PBAC – Pharmaceutical Benefits Advisory Committee (Australia)
PBI – Protein-bound iodine
PBPK – Physiologically based pharmacokinetic modelling
PBRER – Periodic benefit–risk evaluation report
PBS – Pharmaceutical Benefit Scheme (Australia)
PBT – Persistent, bioaccumulative and toxic (biocidal products)
PC – Packaged commodities (India)
PCA – Perception, cognition, action – **and also:**
PCA – Principal component analysis
PCG – Product Coordination Group (EU)
PCID – Package indentifier
pCODR – pan-Canadian Oncology Drug Review
PCORI – Patient-Centered Outcomes Research Institute
PCPA – Pan-Canadian Pricing Alliance
PCT – Primary care trust (UK)
PCWP – Patients' and Consumers' Working Party
PD – Parallel distribution, **and also:**
PD – Pharmacodynamics
PdAR – Paediatric Assessment Report
PDCO – Paediatric Committee (EMA)
PDE – Permitted daily exposure
PDG – Pharmacopoeial discussion group
PDMA – Prescription Drug Marketing Act (US)
PDP – Product development protocols (for medical devices) (US)
PDPs – Product development partnerships
PDR – Physician's desk reference
PDS – Public disclosure synopsis/system
PDT – Prescription digital therapeutics
PDUFA – Prescription Drug User Fee Act (US)
PDURS – Prescription Drug Use Related Software
PDX – Patient-derived xenograft
PE – Pharmacoeconomics
PEAG – Pharmacovigilance Expert Advisory Group (MHRA)
PEC – Patient Engagement Collaborative – **and also:**
PEC – Patient expert centre – **and also:**
PEC – Predicted environmental concentration
PECA – Protocol to the Europe Agreement on Conformity Assessment and Acceptance of industrial products

PED – Patient experience data
PEFR – Peak expiratory flow rate
PEFRAS – Pan European Federation of Regulatory Affairs
PEI – Paul-Ehrlich-Institut (Federal Institute for Vaccines and Biomedicines (one of the two German regulatory agencies)
PEM (study) – Prescription-event monitoring (study)
PER – Pharmaceutical evaluation report
PeRC – Paediatric Review Committee (US)
PERF – Pan European Regulatory Forum
PET/CT – Positron emission tomography and computerised tomography
pfa (or b) – pure free acid (or base)
PFDD – Patient-focused drug development
PFI – Pediatric Formulation Initiative (US)
PFMD – Patient Focused Medicine Development
PFS – Progression-free survival
PFSB – Pharmaceutical and Food Safety Bureau (Japan)
PGD – Patient group directions (written instructions)
PGENI – Pharmacogenetics for Every Nation Initiative
PGI – Potentially genotoxic impurity
PgWP – Pharmacogenomics Working Party
PGx – Pharmacogenomics
Ph Eur – European Pharmacopoeia
PHA – Preliminary hazard analysis
PHAR-QA – Quality assurance in European pharmacy education
PHARE – Poland and Hungary; aid of the Restructure of the Economy
PHARMO – Institute for Drug Outcomes Research (the Netherlands)
PHC – Personalised healthcare
PhI – Pharmacological intelligence
PhPID – Pharmaceutical product identifiers (EU)
PhRMA – Pharmaceutical Research and Manufacturers of America
PHS (Act) – Public Health Services (Act) (US)
PhV – Pharmacovigilance **(**aka **PV)**
PhV WSP WP – Pharmacovigilance Procedures Work Sharing Working Party
PhVIWG – Pharmacovigilance Inspectors Working Group
PhVWP – Pharmacovigilance Working Party (EMA)
PhVWP-V - Pharmacovigilance Working Party – Veterinary
PI – Package insert – **and also:**
PI – Parallel import – **and also:**
PI – Prescribing information – **and also:**
PI – Principal investigator – **and also:**
PI – Production information – **and also:**
PI – Protease inhibitor
PIA – Pharmaceutical Industries Association
PIC – Pharmaceutical Inspection Convention (EU)
PIC/S – Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PICO – Population, intervention, comparator, outcome(s)
PICS – Pharmaceutical inspection cooperation scheme (EU)
PID – Pain intensity differences
PIE – Pharmaceuticals in the environment
PIIGS – Portugal, Ireland, Italy, Greece and Spain
PIL – Patient information leaflet
PIL-ICF – Patient information leaflet-informed consent form
PIM – Product information management (EMA) – **and also:**
PIM – Promising innovative medicine
PIN – Patient identification number
PIP – Paediatric investigation plan – **and also:**
PIP – Poly Implant Prothèse (breast implant)
PIQ – Product Information Quality Review Group
PK – Pharmacokinetics
pKa – acid dissociation constant
PKWP – Pharmacokinetic Working Party
PL – Package leaflet – **and also:**

PL – Product license (US)
PLA – Product license application (for biologics) (US)
PLCM – Product lifecycle management
PLEG – Post launch evidence generation
PLLR – Pregnancy and Lactation Labeling Rule (US)
PLPI – Parallel import licence [product licence parallel import]
PLR – Physician Labeling Rule (US) **– and also:**
PLR – Product license renewal (US)
PLS – Plain language summary
PLT – Platelet count
PMA – Pre-market approval (application for medical devices) (US)
PMC – Postmarketing commitments (US)
PMCF – Post-market clinical follow-up (studies)
PMDA – Japan's regulatory agency – the Pharmaceutical and Medical Devices Agency (within the Ministry of Health, Labor and Welfare – **MHLW**)
PMDI – Pressurised metered dose inhaler
PMDL – Pharmaceutical and Medical Device Law (Japan)
PMF – Plant master file (US and Canada)
PMI – Pharmacological, metabolic and immunological
PMN – Pre-market notification
PMOA – Primary mode of action
PMPF – Post Market Performance Follow-up
PMPRB – Patented Medicines Prices Review Board (Canada)
PMR – Postmarketing requirements (US)
PMS – Postmarket(ing) surveillance – **and also:**
PMS – Product data management service/product management services – **and also:**
PMS – Product Management System
PMS study – Post-marketing safety study
PMTA – Premarket tobacco application
PNC – Pre-notification consultation (Canada)
PNEC – Predicted no-effect concentration
po – by mouth/orally *[Latin: per os]* – **and also:**
PO – Product owner
POC – Proof of concept
POCA – Phonetic and Orthographic Computer Analysis
PoD – Point of departure
PODP – Parenteral and ophthalmic drug products
POM – Prescription-only medicine
POM to P – Prescription-only medicine to pharmacy
PONV – Post-operative nausea and vomiting
POP db – Planned and Ongoing Projects database (an EUnetHTA database)
PopPK – Population pharmacokinetics
PP – Patient preference
PPA – Parallel production authorisation
PPD – Protected personal data
PPI – Patient and Public Involvement (UK) – **and also:**
PPI – Patient package insert (US)
PPP – Pregnancy Prevention Programme
PPP – Public-private partnership
PPRS – Pharmaceutical Price Regulation Scheme
PPSR – Proposed Paediatric Study Request (US)
PQ/CMC – Pharmaceutical quality/chemistry, manufacturing and controls
PQP – Prequalification of Medicines Programme (WHO)
PQR – Product quality review
PQRI – Pharmaceutical Quality Research Institute
PQS – Pharmaceutical quality system
PR – Pulse rate
PRAC – Pharmacovigilance Risk Assessment Committee (EMA)
PRAG – PSUR Repository Advisory Group
PrAR – Preliminary Assessment Report
PRD-PRV – Pediatric rare disease priority review voucher (US)

PREA – Paediatric Research Equity Act (US)
PREG – Pandemic Response Expert Group
PRI – Pain rating index
PRIME – Priority medicines scheme
P-RMS – PSUR reference member state (also see **PSUR)**
prn – as needed *(Latin: pro re nata)*
PRO – Patient reported outcome
PRO-AE – Patient-reported outcomes in adverse event reporting
PROM – Patient-reported outcome measure
PROSPER – Patient-reported outcomes safety event reporting
PROTECT – Pharmacoepidemiological Research on Outcomes of Therapeutics
PRR – Proportional reporting ratio
PRRC – Person responsible for regulatory compliance
PRS – PIM review system (EU) – also see **PIM**
PRSPH – Potential serious risk to public health
PSA – Parallel scientific advice
PSBGL(s) – Product-specific bioequivalence guideline(s)
PSD – Particle size distribution
PSM – Pre-submission meeting
PSMF – Pharmacovigilance system master file
PSP – Paediatric study plan **– and also:**
PSP – Patient Support Programme
PSR – Periodic summary report **– and also:**
PSR – Product safety reference
PSRPH – Potential Serious Risk to Public Health
PSS – Personal social services
PSUR – Periodic safety update report
PSUSA – PSUR single assessment
PT – Preferred term **– and also:**
PT time – Prothrombin time
PtC – Points to consider.
PTD – Protection of technical documentation
PTE – Patent term extension
PTMF – Platform technology master file
PuAR – Public assessment report
PUL module – Performance of the Upper Limb module
PUMA – Paediatric-use marketing authorisation
PUT – Protocole d'Utilisation Thérapeutique (Therapeutic use protocol), France
PV – Pharmacovigilance
PVAR – Preliminary Variation Assessment Report
PVMF –Pharmacovigilance master file
PXRD – Powder xray diffraction

QQQ
(Q)SAR – Quantitative structure activity relationship
QA – Quality assurance
QALY – Quality-adjusted life year
QbD – Quality by design
QC – Quality control
qd – once a day *[Latin: quaque die]*
qds/qid – four times a day *[Latin: quater die sumendum/quater in die]*
QIDP – Qualified infectious disease product (US)
Q-IMPD – Quality-investigational medicinal product dossier
QMS – Quality management system
QOF – Quality and Outcomes Framework (NICE, UK)
QOL – Quality of life
QoS – Quality overall summary
QP – Qualified person
QPPV – Qualified person for pharmacovigilance
QR(C) – Quick response (code) (EU)
QRD – Quality review of documents [template]
QRM – Quality risk management

QS – Quality system
QSE – Quality, safety and efficacy
QSR – Quality Systems Regulation
QSIT - Quality System Inspection Technique (US FDA)
QTPP – Quality target product profile
QUAMED – Quality Medicines for All
QWP – Quality Working Party (EMA)

RRR
R&D – Research & development
R4BP – Register for Biocidal Products
RA – Rapid alert – **and also:**
RA – Regulatory affairs
RA/NUI System – Rapid Alert/Non-Urgent Information System
RADAR – Risk assessment of drugs analysis and response
RAMA – Remote access for marketing authorisations (MHRA)
RAPS – Regulatory Affairs Professionals Society (US)
RAS – Rapid alert system
RAT – Regenerative advanced therapy
RBC – Red blood cell count
RBI – Risk-based inspection
RBM – Risk-based monitoring
RCB – Registered certification body (Japan)
RCEP – Regional Comprehensive Economic Partnership (trading bloc)
RCFID – Registration Certificate for Import of Drug
RCH – Remove clinical hold
RCP – Royal College of Physicians (UK)
RCT – Randomised controlled trial
RCTP – Regenerative and cellular therapy product
RDE – Remote data entry
RDI – Research, development and innovation
RDP – Regulatory data protection
RDS – Repeat dose study
RDT – Rising-dose tolerance
RE – Relative effectiveness
REA – Relative effectiveness assessment
REACH – Registration, evaluation, authorisation and restriction of chemicals
REC – Research Ethics Committee
REdI – Regulatory Education for Industry (US FDA)
RefMP(s) – Reference Medicinal Product(s), see also RMP(s)
REMS – Risk evaluation and mitigation strategy (US)
RFD – Request for designation (US)
RfD – Reference dose
RfD/C – Chronic reference dose/concentration
RFDD – Regional Food and Drug Director (US)
RFI – Request for information
RfMs – Requests for modifications
RH – Relative humidity
RHSC – Regulatory Harmonisation Steering Committee
RI – Regulatory intelligence
RIM(S) – Regulatory information management (system)
RING – Regulatory Intelligence Network Group (EU)
rINN – Recommended international non-proprietary name
RiskMAP – Risk minimisation action plan
RLD – Reference listed drug (US)
RMAT – Regenerative medicine advanced therapy (US)
RMM – Risk minimisation materials **– and also:**
RMM – Risk minimisation measure
RMP – Reference medicinal product – **and also:**
RMP – Risk management plan
RMR – Reaction monitoring report **– and also:**

RMR – Risk management report
RMS – Reference member state (Europe) – **and also:**
RMS – Referentials data management service
rMS – Reporting member state (Europe)
ROG – Regulatory Optimisation Group
RoHS – Restriction of hazardous substances (Directive)
ROI – Residues on ignition – **and also:**
ROI – Return on investment
RONAFA – Reduction of need for antimicrobials in food-producing animals
RoW – Rest of (the) World
RP – Reflection paper – **and also:**
RP – Responsible person
RPA – Robotic process automation
RPI – Research Product Identifier (formerly called 'Unique Product Identifier, UPI) – **and also:**
RPI – c)
RPS – Regulated product submission
RPSGB – Royal Pharmaceutical Society of Great Britain
RQA – Research quality assurance
RR – Relative risk – **and also:**
RR – Respiratory rate – **and also:**
RR – Risk ratio
RRA – Reference regulatory agency
RRI – Regional regulatory initiatives
RRR – Relative risk reduction
RSA – Risk share agreement
RSI – Reference safety information – **and also:**
RSI – Request for supplementary information (EU)
RSM – Regulatory starting material(s)
RSS – Regulatory Science Strategy (EMA)
RTF – Refusal-to-file (US)
RTI – Respiratory tract infection
RTQ – Response to questions
RTR – Refusal to receive (US)
RTRT – Real time release testing
RTT – Right to try
RTU – Recommandation Temporaire d'Utilisation (Temporary recommendation for use)
RU–MRP – Repeat use mutual recognition procedure
RUP – Repeat use procedure
RWD – Real world data
RWE – Real word evidence
Rx – Prescription

SSS
S+T – Sampling and testing
SA – Scientific advice – **and also:**
SA – Statistical analysis
SAARC – South Asian Association for Regional Cooperation
SaaS – Software as a service
SABS – Safety alert broadcast system
SAD – Single ascending dose (study)
SADR – Serious adverse drug reaction
SAE – Serious adverse event
SAG – Scientific Advisory Group
SAL – Sterility assurance level
SaMD – Software as a Medical Device
SAMM – Safety assessment of marketed medicines (US)
SANDS – Supplemental abbreviated new drug submission (Canada)
SAP – Scientific advice procedure – **and also:**
SAP – Statistical analysis plan
SAR – Safety assessment report – **and also:**
SAR – Serious adverse reaction – **and also:**
SAR – Structure-activity relationship

SAT – Special Action Team (EFPIA)
SAWP – Scientific Advice Working Party
SBA/SBOA – Summary basis of approval (US)
SBIA – Small Business and Industry Assistance (US FDA)
SBP – Similar biotherapeutic product (WHO)
sc – subcutaneou (aka **sq**)
SCB – Scientific Coordination Board
SCCS – Self-controlled case series design
SCF – Scientific Committee for Food (UK) – **and also:**
SCF – Super critical fluid
SCOTT – Ethics and Standing Committee on Therapeutic Trials (Australia)
SCT – Safety concern threshold – **and also:**
SCT – Stem cell transplant
SCTP – Somatic cell therapy product
sCTMP – somatic Cell Therapy Medicinal Product
SD – Standard deviation
SD – Standard dose – **and also:**
SLDC – Software development lifecycle
SDR – Statistic of disproportionate reporting
SDRG – Study data reviewer's guide
SDTM – Study Data Tabulation Model (US)
SE – Standard error – **and also:**
SE – Substantially equivalent/substantial equivalence
SEAR – Safety, Efficacy and Adverse Reactions (sub-committee of CSM)
SEB – Subsequent entry biologic
SEC – Size exclusion chromatography
SEED Consortium – Shaping European Early Dialogues Consortium
SEMPA – Medical Products Agency, Sweden (formerly MPA)
SEND – Standard for exchange of nonclinical data
SENDIG – Standard for exchange of nonclinical data implementation guides
SFDA – Formerly China's State Food and Drug Administration (now CFDA) **and also:**
SFDA – Safety Features Delegated Act **– and also:**
SFDA – Saudi Food & Drug Authority
SFFC medicines – Spurious/falsely-labelled/falsified/counterfeit medicines (US)
SGML – Standard general mark-up language
SGOT – Serum glutamic oxalo-acetic acid transaminase (SGOT = AST)
SGPT – Serum glutamic pyruvic transaminase (SGPT = ALT)
SHBG – Sex-hormone-binding globulin
SI – Statutory instrument
SKU – stock-keeping unit
SLA – Service level agreement
SLK/NMCA – Statens legemiddelverk/Norwegian Medicines Control Agency
SmAR – Summary Assessment Report
SMC – Scottish Medicines Consortium
SMDA – Safe Medical Devices Act (US)
SME – Significant medical event – **and also:**
SMEs – Small and medium-sized enterprises
SMF – Site master file
SMO – Site management organisation
SmPAR – Summary Pharmacovigilance Assessment Report (EU)
SmPC – Summary of product characteristics (aka **SPC** in veterinary sector)
SMQ – Standardised MedDRA query
SMR – Service Médical Rendu (ie, medical benefit rendered), France
SMS – Substance data management service/Substance management system
SNDA – supplemental new drug application (US)
SNDS – Supplemental new drug submission (Canada)
SNIF – Summary Notification Information Format
SNSA – Simultaneous national scientific advice
SO – Scientific opinion
SOC – Standard of care – **and also:**
SOC – System organ class
SOCMA – Society of Chemical Manufacturers and Affiliates

SOCRA – Society of Clinical Research Associates (US-based)
SOP – standard operating procedure
SOUP – Software of unknown pedigree
SPA – Special protocol assessment
SPC – Summary of product characteristics (typically for veterinary sector) – **and also:**
SPC – Supplementary protection certificate (EU)
SPECT – Single photon emission computed tomography
SPID – Sum of pain intensity differences
SPIN – Special interest network
SPL – Structured product labelling (US)
SPOR data – Substance, product, organisation and referential data
SPS – Summary of Pharmacovigilance Systems
sq – subcutaneous (aka **sc**)
SQP – Suitably qualified person
SR – Significant risk
SRAs – Stringent regulatory authorities
SRM – Specified risk materials
c – and also:
SRN – Stroke Research Network (part of NIHR, UK)
SSC – Scientific Steering Committee
SSCP – Summary of safety and clinical performance
SSFFC – Substandard, spurious, falsely labelled, falsified and counterfeit (medical products)
SSRI – Selective serotonin reuptake inhibitor
SSU – Study start up
STA – Scientific-technical advice
STAMP – Safe and timely access to medicines for patients
stat – immediately *[Latin: statim]*
STD – Severely toxic dose
STED – Summary technical documentation [for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices Safety and Performance of Medical Devices]
StEM – Stakeholder engagement meeting (MHRA)
STF – Study tagging file
STP – Specific Treatment Programme/Specific Therapeutic Programme
STR – Stirred tank bioreactors
STRPC – Scientific, Technical and Regulatory Policy Committee (EFPIA)
SUD – Single use device – **and also:**
SUD – Sudden unexpected death
SUE – Serious undesirable effect
SUKL – State Institute for Drug Control (Czech Republic and Slovakia)
SUPAC – Scale-up and post-approval changes
SUPAC-IR – Scale up and post approval changes – immediate release
SUPAC-MR – Scale up and post approval changes – modified release
SUS – Single-use system
SUSAR – Suspected unexpected serious adverse reaction
SVM – Support vector machine
SVR – Scientific validity report
SWOT (analysis) – Strengths, weaknesses, opportunities, threats
SWP – Safety Working Party (CHMP)
Sx – Symptoms

TTT
$t_{½}$ _Terminal half-life of elimination
TA – Targeted assessment – **and also:**
TA – Therapeutic area
TABST – Target animal batch safety testing
TAG – Technical Advisory Group (UK's NICE) – **and also:**
TAG – Therapeutic Advisory Group
TAS (studies) – Target animal safety (studies**)**
TATFAR – TransAtlantic Task Force on Antimicrobial Resistance
TBC – The Biomarker Consortium
TBG – Thyroid binding globulin

TC – Transparency Commission (France)
TCA – Tricyclic antidepressant
TCM – Traditional Chinese medicine
TCP – Target candidate profile
TCT – Toxicity, Clinical Trials and Therapeutic Efficacy Subcommittee of the CSM (UK)
TD – Technical documentation
TDD – Transdermal drug delivery
TDI – Tolerable daily intake
TD-PRV – Tropical disease priority review voucher (US)
TDR – Totally drug-resistant
tds/tid – three times a day *[Latin: ter die sumendum/ter in die]* **– and also:**
TDS – Transdermal systems
TE – Therapeutic equivalence
TEAE – Treatment emergent adverse event
TEP – Tissue engineered product
TESS – Tamper evident security seal
TFEU – Treaty on the Functioning of the European Union
TFL – tables, figures and listings
TFM – Tentative final monograph (US)
TGA – Therapeutic Goods Administration (Australia's regulatory agency) – **and also:**
TGA – Thermogravimetric analysis
THMP – Traditional herbal medicinal product
THMPD – Traditional Herbal Medicinal Products Directive
THMRS – Traditional Herbal Medicines Registration Scheme
THR – Traditional herbal registration
TIGes – Telematic Implementation Group–electronic submissions
TIND – Treatment IND (see **IND**)
TK – Thymidine kinase **– and also:**
TK – Toxicokinetics
TLC – Thin layer chromatography
TLV – Threshold limit value
TMF –Trial Master File
TOC – Table of contents
TOD – Table of decisions
TOM – Target operating model
TOPRA – The Organisation for Professionals in Regulatory Affairs
TOPS – The Over-volunteering Prevention System (database)
TOTPAR – Total pain relief
TPP – Target product profile
TRC – Technical rejection criteria
TRF – Tamper-resistant formulation
TRIPS – Trade Related Aspects of Intellectual Property Rights
TRK – Tropomyosin receptor kinase
TRL – Total residue level (veterinary)
TSA – Therapeutic Substances Act
TSE – Transmittable spongiform encephalopathy
TTC – Threshold of toxicological concern
TUBITAK – Scientific and Technological Research Council of Turkey

UUU
UAT – User acceptance testing
UCN – Unique carton number
UDI – Unique device identification
UF – Uncertainty factor
UI – Unique Identifier (according to the FMD)
UII – Unique Ingredient Identifier
UKCA – UK conformity assessment [for UK medical devices previously subject to CE marking]
ULTRA – Unlocking Lifesaving Treatments for Rare-Diseases Act (US)
UMBRA – Unified Methodologies for Benefit–Risk Assessment
UMP – Beijing Union Medical and Pharmaceutical General Corp (the innovative arm of the Chinese Academy of Medical Sciences)
UOUP – User Interface of Unknown Provenance

UPD – Union Product Database
UPS-NF – United States Pharmacopeia and National Formulary
USAN – United States Approved Name
USC – United States Code
USDA – United States Department of Agriculture
USKVBL – Ustav pro Statni Kontrolu Veterinarnich Biopreparatu a Leciv (Institute for State Control of Veterinary Biologicals and Medicines) (Czech Republic) – **and also:**
USKVBL – Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (Department of State Control of Veterinary Biologicals and Medicaments) (Slovenia)
USP – United States Pharmacopoeia
USP-DI – United States Pharmacopeia-Drug Information
USPI – United States Product Insert
USP-NF – United States Pharmacopeia-National Formulary
USR – Urgent safety restriction
USRA – User safety risk assessment
UTI – Urinary tract infection
UUP – Urgent union procedure (European Commission)

VVV
VAERS – Vaccine adverse event reporting system (US)
VAESCO – Vaccine adverse event surveillance & communication
VAF – Virus antibody free
VAI – Voluntary action indicated
VAMF – Vaccine antigen master file
VAR – Variation assessment report
VarWP – Working Party on Variation Regulation, also: Variation Working Party
VAS – Visual analogue scale
VBA – Value-based assessment
VBP – Value-based pricing
VCS – Viral challenge study
VDD – Veterinary Drugs Directorate (Canada)
VDH – Veterinary Data Hub
VeDDRA – Veterinary Dictionary for Drug Related Affairs
VF – Ventricular failure
VHP – Voluntary harmonisation procedure
VICH – International Cooperation on Harmonization of Technical Requirements for Registration of **Veterinary** Products
VIPP – Verified internet pharmaceutical practice site (US)
VMD – Veterinary Medicines Directorate
VMP – Veterinary medicinal product
VMP-Reg – Veterinary Medicines Regulation (previously **NVR**)
VMRFG – Veterinary Mutual Recognition Facilitation Group
VNeeS – Veterinary non-eCTD electronic submission
VNRA – Variation(s) not requiring assessment
VPC – Veterinary Products Committee (UK)
VPH – Virtual physiological human
VPN – Virtual private network
vPvB – Very persistent and very bioaccumulative (biocidal products)
VRA – Variation(s) requiring assessment
VRS –Verbal rating scale
VSI – Validation Supplementary Information
VTE – Venous thromboembolism
VWP – Vaccines Working Party

WWW
WBC – White blood cell
WC – Written confirmation (issued by competent authority)
WCB – Working cell bank
WCPB – Women of childbearing potential
WDA – Wholesale dealer's licence
WEBAE – Web adverse event(s)
WEB-RADR (project) – Recognising Adverse Drug Reactions

WEU – Well-established use
WG – Working Group
WGEO – Working Group of Enforcement Officers (HMA)
WHO – World Health Organization
WL – Warning letter – **and also:**
WL – Wholesale dealer's licence
WOCBP – Women of child-bearing potential
WoE – Weight of evidence
WP – Working Party
WRAC – Worldwide Regulatory Affairs Committee
WS – Work sharing
WTO – World Trade Organisation

XXX
XEVIMPD – Extended EudraVigilance Investigational Medicinal Product Dictionary
XEVMPD – Extended EudraVigilance medicinal products dictionary
XEVPRM – Extended EudraVigilance product report message
XML – Extensible Markup Language
XRF – X-ray fluorescence

ZZZ
ZAPI – Zoonosis Anticipation and Preparedness Initiative
ZVA – Zalu Valsts Agentura (State Agency for Medicines) (Latvia)

[Last updated July 2021]