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)
AADA – Abbreviated antibiotic drug application
AAP – Accelerated approval pathway (US) – but also:
AAP – Accelerated assessment procedure (EU)
AAPS – American Association of Pharmaceutical Scientists
AAR – Accelerated access review
AAS – Atomic absorption spectroscopy
AAV – Adeno-associated virus
ABHI – Association of British Healthcare Industries (medical devices sector)
ABPI – Association of the British Pharmaceutical Industry
A-CASI – Audio computer-assisted self-interviewing
ACO – Addendum to clinical overview
ACRP – Association of Clinical Research Professionals
ACSS – Australia, Canada, Singapore, Switzerland Consortium
ACT – Artemisinin-based combination therapy
ACTD – ASEAN common technical dossier (see ASEAN)
ACVM – Agricultural Compounds and Veterinary Medicines (New Zealand)
AdaM – Analysis data model
ADC – Additional data collection – but 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)
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
AEFI – Adverse event following immunisation
AEGIS – Adverse Experience Gathering Information System
AEM – 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 Spécialités Pharmaceutiques Grand Public (Association of the European Self-Medication Industry)
AF – Application Form
AFAR – Association Française des Affaires Réglamentaires (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 – Österreichische 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
AITIS – Adverse 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 (Serbia)
ALL – Acute lymphocytic leukaemia
AM – Agence du Medicament (France)
AMA – American Medical Association
AMEG – AntiMicrobial advice ad hoc Expert Group
AMI – Acute myocardial infarct
AML – Acute myeloid leukemia
AMM – Autorisation de mise sur le marché (France) = Product licence
AMP – Authorised medicinal product – **but also:**
AMP – Auxiliary medicinal product (**formerly non-investigational medicinal product, NIMP**)
AMR – Antimicrobial resistance
AMRH – African Medicines Regulatory Harmonisation
ANDA – 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 – **but also:**
AP – Adaptive pathway
APEC – Asia-Pacific Economic Cooperation
APHIS – Animal and Plant Health Inspection Service (US)
API – Active pharmaceutical ingredient
APIC – Active Pharmaceutical Ingredients Committee
APLB – Advertising and Promotional Labeling Branch (FDA’s CBER)
APMA – Australian Pharmaceutical Manufacturers Association
APVA – Additional pharmacovigilance activities
APVMA – Australian Pesticides and Veterinary Medicines Authority (Australia)
AQL – Acceptable quality level
AR – Adverse reaction – **but also:**
AR – Assessment Report (EU) – **and also:**
AR – Authorised representative
ARfd – Acute reference dose (veterinary)
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
ASPR – Anonymised single patient report (formerly ASPP – anonymised single patient printout)
ASR – Annual safety report
AST – Aspartate aminotransaminase (AST = SGOT)
ATA – Alternatives to antibiotics
ATC – Anatomical – therapeutic – chemical (WHO) – but 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”)
ATU – Authorisation for temporary use
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
BE – Bioequivalence
BEMA – Benchmarking of European Medicines Agencies
BFArM – Federal Institute for Drugs and Medical Devices (Bundesinstituts für Arzneimittel und Medizinprodukte)
(Berlin’s regulatory authority)
BGMA – British Generic Manufacturers Association
BIBRA – British Industrial Biological Research Association
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
BMI – Bundesministerium für Gesundheit = Federal Ministry of Health (Germany)
BMGF – Bundesministerium fuer Gesundheit und Frauen (Austria)
BMWP – Biosimilar Medicinal Products Working Party
BNF – British National Formulary
BoH – Board of Health
BOS – Break-out session
BP – Blood pressure – but also:
BP – British Pharmacopoeia
BPC – British Pharmacopoeia Commission – but also:
BPC – Bulk pharmaceutical chemicals
BPCA – Best Pharmaceuticals in Children Act (US)
BPG – Best Practice Guide
BPI – Bundesverband der Pharmazeutischen Industrie (German pharmaceutical industry trade association)
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 – but 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
CAS – Central alerting system (UK) – but also:
CAS – Chemical abstract systems
CAT – Committee for Advanced Therapies (EMA)
CATMP – Combined Advanced Therapy Medicinal Product
CAVDR1 – 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)
CBP – Corticoid binding protein
CC – Candidate country (EU)
CCDP – Complete clinical data package
CCDS – Company core data sheet
CCG – Clinical Commissioning Group (UK NHS)
CCG IAC – Clinical Commissioning Group Indicator Advisory Committee
CGTPs – Cell and gene therapy products
CCI – Commercially confidential information
CCSI – Company core safety information
CD – Caesarean derived – but also:
CD – Controlled drug
CDC – Centers for Disease Control and Prevention (US)
CDDD – Clinical dossier of drug development (Brazil)
CDEC – Canadian Drug Expert Committee (Canada)
CDER – Center for Drug Evaluation and Research (US FDA)
CDISC – Clinical Data Interchange Standards Consortium
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 Organization (India’s clinical trials licensing authority)
CDSM – Committee on Dental and Surgical Materials (UK)
CDx – Companion Diagnostics
CE Mark – Conformité European (approval for EU medical devices)
CEA – Cost-effectiveness analysis
CEC – Central ethics committee but also:
CEC – Commission of the European Communities
CED – Coverage with evidence development
CEE – Central and Eastern Europe
CEE – Central and Eastern European Countries
CEFTA – Central Europe Free Trade Area
CEN – Comité Européen des Normes – European Committee for Standardization
CEP – Central enquiry point (MHRA) but also:
CEP – Certificate of European Pharmacopoeia (aka Certificate of Suitability)
CER – Clinical evaluation report but also:
CER – Comparative effectiveness research
CESS – 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)
CFSA – Certificate of Free Sale
CFSAN – Center for Food Safety and Applied Nutrition (US)
cGDP – 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
CHMB – Creatine kinase Muscle Brain
CHMP – Committee for Medicinal Products for Human Use (EMA)
CHMP – Committee for Medicinal Products for Human Use (previously: CPMP)
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, Uzbekistan, Turkmenistan, Ukraine
CK – Creatine kinase
Cl – Total body clearance
Class Ia – 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
Cmax or Cmax – 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)
CMDR – Canadian Medical Device Regulation
CMDv – Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (EMA)
CMN – Comité de Molecules Nuevas” (New Molecules Committee) (Mexico)
CMP – Certificate of Medicinal Product but also:
CMP – Common product model
CMR – Carcinogenic, mutagenic or reprotoxic [toxic to reproduction] but also:
CMR – Centre for Medicines Research
CMS – Concerned member state (EU)
CMT – Convergent medical technologies
COA/CofA – Certificate of analysis
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) – but 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 – but 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) – but also:
  CPS – Clinical performance study
CPS – Clinical performance study plan
CPU – Clinical pharmacology unit
CPWP – Cell-based Products Working Party (EMA)
CQA – Clinical quality assurance – but also:
  CQA – Critical quality attribute
CR – Computed radiology – but also:
  CR – Controlled release
CRF – Case report form
CRG – Clinical reference group (UK)
CRO – Clinical Research Organisation
CNP – Canadian reference product (WHO) – but also:
  CPR – Collaborative registration procedure
CRS – The Caribbean Regulatory System – but also:
  CRS – Cytokine release syndrome
CS – Clinically significant – but also:
  CS – Common specifications
CSA – Controlled Substances Act
CSI – Core safety information
CSM – Centralised statistical monitoring – but 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
CT – Clinical trial – but also:
  CT – Computed tomography
CTA – Clinical trial application – but also:
  CTA – Clinical trial assay – and also:
  CTA – Clinical trial authorisation
CTAG – Clinical Trials Action Group (Australia) – but also:
  CTAG – Clinical Trials Coordination and Advisory Group
CTC – Clinical trial certificate (Hong Kong, Singapore)
CTD – Clinical Trials Directive – but also:
  CTD – Common technical document* [*Although ‘dossier’ has become commonplace – the correct term is ‘document’]
CTEG – Clinical Trials Expert Group
CTFG – Clinical Trials Facilitation Group
CTIS – Clinical Trials Information System (formerly the EU clinical trial portal and database, EudraCT)
CTMP – Cell therapy medicinal product
CTMS – Clinical trial management system
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>CTN</td>
<td>Clinical trial notification (Australia)</td>
</tr>
<tr>
<td>CTOC</td>
<td>Comprehensive Table of Contents Headings and Hierarchy</td>
</tr>
<tr>
<td>CTR</td>
<td>Clinical Trial Regulation</td>
</tr>
<tr>
<td>CTS</td>
<td>Common technical specification – but also: Communication Tracking System <em>(formerly Eudratrack)</em></td>
</tr>
<tr>
<td>CTTI</td>
<td>Clinical Trials Transformation Initiative</td>
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<tr>
<td>CTU</td>
<td>Clinical trials unit</td>
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<tr>
<td>CTX</td>
<td>Clinical trial exemption (UK)</td>
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<tr>
<td>CUA</td>
<td>Cost utility analysis</td>
</tr>
<tr>
<td>CUP</td>
<td>Compassionate use programme</td>
</tr>
<tr>
<td>CV</td>
<td>Controlled vocabulary</td>
</tr>
<tr>
<td>CVM</td>
<td>Center for Veterinary Medicine (US)</td>
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<tr>
<td>CVMP</td>
<td>Committee for Medicinal Products for Veterinary Use (EMA)</td>
</tr>
<tr>
<td>CVO</td>
<td>Chief Veterinary Officer</td>
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<tr>
<td>CVS</td>
<td>Cardiovascular system</td>
</tr>
<tr>
<td>CVZ</td>
<td>Dutch Health Care Insurance Board</td>
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<tr>
<td>CWoW</td>
<td>Combined Ways of Working</td>
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<tr>
<td>CZ</td>
<td>Climatic zone</td>
</tr>
<tr>
<td>DDD</td>
<td>German Pharmacopoeia (Deutsches Arznei Buch)</td>
</tr>
<tr>
<td>DAC</td>
<td>Data analysis centre</td>
</tr>
<tr>
<td>DACS</td>
<td>Detailed and critical summary</td>
</tr>
<tr>
<td>DAES</td>
<td>Discontinuation due to an adverse event</td>
</tr>
<tr>
<td>DAL</td>
<td>Defect action level (US)</td>
</tr>
<tr>
<td>DAMOS</td>
<td>Drug application methodology with optical storage</td>
</tr>
<tr>
<td>DB</td>
<td>Device Bulletin (MHRA)</td>
</tr>
<tr>
<td>DCGI</td>
<td>Drugs Controller General of India</td>
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<tr>
<td>DCGI</td>
<td>India’s regulatory authority (Directorate General of Health Services in the Ministry of Health and Family Welfare)</td>
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<tr>
<td>DCP</td>
<td>Decentralised procedure (EU)</td>
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<tr>
<td>DCTs</td>
<td>Decentralised clinical trials</td>
</tr>
<tr>
<td>DD</td>
<td>District Director (US)</td>
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<tr>
<td>DDC(P)</td>
<td>Drug-device combination (product)</td>
</tr>
<tr>
<td>DDD</td>
<td>Defined daily dose</td>
</tr>
<tr>
<td>DDMAC</td>
<td>Division of Drug Marketing, Advertising and Communications (CDER)</td>
</tr>
<tr>
<td>DDPS</td>
<td>Detailed description of pharmacovigilance system</td>
</tr>
<tr>
<td>DDX</td>
<td>Doctors’ and dentists’ exemption (UK)</td>
</tr>
<tr>
<td>DE</td>
<td>Designated examination</td>
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<tr>
<td>DEA</td>
<td>Drug Enforcement Agency (US)</td>
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<tr>
<td>DEREK</td>
<td>Deductive estimate of risk from existing knowledge</td>
</tr>
<tr>
<td>DES</td>
<td>Data exchange standard (EU) – but also: Drug eluting stent</td>
</tr>
<tr>
<td>DESI</td>
<td>Drug efficacy study implementation (US)</td>
</tr>
<tr>
<td>DG</td>
<td>Directorate-General (at the European Commission)</td>
</tr>
<tr>
<td>DGEM</td>
<td>Disease-gene expression matching</td>
</tr>
<tr>
<td>DGV</td>
<td>Direccao Geral de Veterinaria (Veterinary Medicines Agency) (Portugal)</td>
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<tr>
<td>DH</td>
<td>Department of Health (UK)</td>
</tr>
<tr>
<td>DHHS</td>
<td>Department of Health and Human Services (US)</td>
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<tr>
<td>DHPC</td>
<td>Direct healthcare professional communication (formerly 'Dear Doctor Letter')</td>
</tr>
<tr>
<td>DIA</td>
<td>Drug Information Association (US)</td>
</tr>
<tr>
<td>DIBD</td>
<td>Development international birth date</td>
</tr>
<tr>
<td>DID</td>
<td>Design inputs document</td>
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<tr>
<td>DIMDI</td>
<td>Deutsches Institut für Medizinische Dokumentation und Information (Germany)</td>
</tr>
<tr>
<td>DKMA</td>
<td>Lægemiddelstyrelsen/Danish Medicines Agency (Denmark)</td>
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<tr>
<td>DLP</td>
<td>Data lock point</td>
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<tr>
<td>DMF</td>
<td>Drug master file</td>
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<tr>
<td>DMPK</td>
<td>Drug metabolism and pharmacokinetics</td>
</tr>
<tr>
<td>DMRC</td>
<td>Defective Medicines Report Centre (MHRA)</td>
</tr>
<tr>
<td>DMS</td>
<td>Document management system</td>
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<tr>
<td>DMT</td>
<td>Disease modifying therapy</td>
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</tbody>
</table>
**DOE** – Design of experiments
**DoR** – Duration of Response
**DP** – Drug product
**DPI** – Dry powder inhaler
**DPR** – Dual Pack import Registration
**DR** – Deliberate release – **but also:**
**DR** – Digital radiology
**DRA** – Drug Regulatory Authority
**DRF(S)** – Dose range finding (study)
**DRMP** – Developmental risk management plan
**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
**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**
**EA** – Environmental assessment
**EAC** – East African Community
**eAF** – electronic Application Form
**EAI** – Estimated acute intake
**EAMS** – Early Access to Medicines Scheme (UK)
**EBE** – European Biopharmaceutical Enterprises
**Ebm** – Evidence-based medicine
**EC** – Ethics committee – **but also:**
**EC** – European Commission – **and also:**
**EC** – Exceptional circumstances
**ECDC** – European Centre for Disease Prevention and Control
**ECG** – Electrocardiogram
**ECHAMP** – European Coalition on Homeopathic 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
**EDQM** – European Directorate for the Quality of Medicines
**EDT** – Electronic data transfer
**EDX** – Effective dose at X%
**EEA** – European Economic Area (comprising the EU countries, plus Iceland, Liechtenstein and Norway)
**ECC** – European Economic Community
**EEG** – Electroencephalogram
**eERA** – extended Environmental Risk Assessment
**EEU** – Eurasian Economic Union
**EFA** – European Federation of Allergy and Airways Diseases Patients' Associations
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations (<a href="http://www.efpia.eu">http://www.efpia.eu</a>)</td>
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<tr>
<td>EFPIA</td>
<td>European Federation of Pharmaceutical Industries and Associations</td>
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<td>EFQM</td>
<td>European Foundation for Quality Management</td>
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<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>EFTA</td>
<td>European Free Trade Association</td>
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<td>EGA</td>
<td>European Generic medicines Association – <em>Name changed 10 March 2016 to “Medicines for Europe”</em></td>
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<tr>
<td>EGGVP</td>
<td>European Group for Generic Veterinary Products</td>
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<td>EGP</td>
<td>Economic Guidance Panel (Canada)</td>
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<tr>
<td>EHR</td>
<td>Electronic healthcare record</td>
</tr>
<tr>
<td>EIA</td>
<td>Environmental Impact Assessment</td>
</tr>
<tr>
<td>EINECS</td>
<td>European Inventory of Existing Chemical Substances</td>
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<tr>
<td>ELA</td>
<td>Establishment license application (US)</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency (formerly European Medicines Evaluation Agency – EMEA)</td>
</tr>
<tr>
<td>EMACOLEX</td>
<td>European Medicines Agencies Co-operation of Legal and Legislative Issues</td>
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<tr>
<td>EMCDDA</td>
<td>European Monitoring Centre for Drugs and Drug Addiction</td>
</tr>
<tr>
<td>EMEA</td>
<td>Europe, Middle East &amp; Africa</td>
</tr>
<tr>
<td>EMEAA</td>
<td>Europe, Middle East, Africa &amp; Asia</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic medical records</td>
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<tr>
<td>EMRC</td>
<td>European Medical Research Councils (a unit of the ESF – see below)</td>
</tr>
<tr>
<td>EMVO</td>
<td>European Medicines Verification Organisation</td>
</tr>
<tr>
<td>EMVS</td>
<td>European Medicines Verification System</td>
</tr>
<tr>
<td>ENCePP</td>
<td>European Network of Centres for Pharmacoepidemiology and Pharmacovigilance</td>
</tr>
<tr>
<td>eNDA</td>
<td>Electronic New Drug Application</td>
</tr>
<tr>
<td>ENP</td>
<td>European Neighborhood Policy</td>
</tr>
<tr>
<td>Enpr-EMA</td>
<td>European Network of Paediatric Research at the European Medicines Agency</td>
</tr>
<tr>
<td>ENS</td>
<td>Early notification system</td>
</tr>
<tr>
<td>EOF</td>
<td>Ethnikos Organismos Farmakon – aka National Organization for Medicines (Greece’s regulatory agency)</td>
</tr>
<tr>
<td>EoP</td>
<td>End of Procedure</td>
</tr>
<tr>
<td>EOP1</td>
<td>End of Phase 1 (US)</td>
</tr>
<tr>
<td>EOP2</td>
<td>End of Phase 2 (US)</td>
</tr>
<tr>
<td>EQQ</td>
<td>European Organization for Quality</td>
</tr>
<tr>
<td>EP</td>
<td>European Parliament – <em>but also:</em></td>
</tr>
<tr>
<td>EP/Ph Eur</td>
<td>European Pharmacopoeia (aka Pharm Eur)</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency (US) and (Ireland)</td>
</tr>
<tr>
<td>EPAA</td>
<td>European Partnership for Alternative approaches to Animal testing</td>
</tr>
<tr>
<td>EPAD</td>
<td>European Prevention of Alzheimer’s Dementia</td>
</tr>
<tr>
<td>EAPDES</td>
<td>European Parliament Document Exchange Server</td>
</tr>
<tr>
<td>EPAR</td>
<td>European public assessment report</td>
</tr>
<tr>
<td>EPC</td>
<td>European Pharmacopoeia Commission</td>
</tr>
<tr>
<td>EPHA</td>
<td>European Public Health Alliance</td>
</tr>
<tr>
<td>ePI</td>
<td>Electronic product information</td>
</tr>
<tr>
<td>EPI</td>
<td>Essential Program for Immunisation</td>
</tr>
<tr>
<td>EPID</td>
<td>Extended (also Expanded) Public Information Document</td>
</tr>
<tr>
<td>EPITT</td>
<td>European Pharmacovigilance Issues Tracking Tool</td>
</tr>
<tr>
<td>EPL</td>
<td>Effective patent life</td>
</tr>
<tr>
<td>EPO</td>
<td>European Patent Office</td>
</tr>
<tr>
<td>EPOSI</td>
<td>European Platform for Patients’ Organisation – Science &amp; Industry</td>
</tr>
<tr>
<td>EPPV</td>
<td>Early post-marketing phase vigilance (eg, in Japan)</td>
</tr>
<tr>
<td>EPRG</td>
<td>European Pharmacovigilance Research Group</td>
</tr>
<tr>
<td>EPRUMA</td>
<td>European Platform for the Responsible Use of Medicines in Agriculture</td>
</tr>
<tr>
<td>EPS</td>
<td>Eco-Pharmaco-Stewardship</td>
</tr>
<tr>
<td>ePSUR</td>
<td>électronique periodic safety update report</td>
</tr>
<tr>
<td>EQM</td>
<td>Equivalence margin</td>
</tr>
<tr>
<td>ERs</td>
<td>Essential requirements (devices)</td>
</tr>
<tr>
<td>ERA</td>
<td>Environmental risk assessment – <em>but also:</em></td>
</tr>
<tr>
<td>ERA</td>
<td>European regulatory affairs</td>
</tr>
<tr>
<td>ERB</td>
<td>Ethical review board</td>
</tr>
<tr>
<td>eRMR</td>
<td>electronic Reaction Monitoring Report</td>
</tr>
<tr>
<td>EMS</td>
<td>European risk management strategy</td>
</tr>
<tr>
<td>ERMS-FG</td>
<td>European Risk Management Strategy Facilitation Group (HMA)</td>
</tr>
<tr>
<td>ERP</td>
<td>European Reference Medicinal Product</td>
</tr>
</tbody>
</table>
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
ETOMEPE – 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
EU-IN – EU Innovation Network
EUCERD – EU Committee of Experts on Rare Diseases
EUCOMED – European Confederation of Medical Device Associations
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
EURL – EU reference laboratory
EURL – EU Office for Publications
EUTCT – European Union Telematics Controlled Terms
EUTMB – EU Telematics Management Board
EV – EudraVigilance – European Union Drug Regulating Authorities Pharmacovigilance
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
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)
FAAR – 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
FDC – Fixed dose combination
FDC Act – Food – Drug and Cosmetic Act (US)
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
FNOM-CeO – 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
FY – Fiscal year

GGG
GAIN Act – Generating Antibiotic Incentives Now Act (US)
GATT – General Agreement on Tariffs and Trade
GCC (region) – Gulf Cooperation Council (region)
GCC-DR – Gulf Central Committee for Drug Registration
GCD – Global clinical development
GCG – Global Coopération Group (ICH)
GCP – Good clinical practice
GCPv – Good Clinical Practice (Veterinary)
GDP – Good distribution practice
GDPR – General Data Protection Regulation
GDUFA – Generic Drug User Fee Amendments (FDA)
GEG – Geriatrics Expert Group
GEP – Good epidemiological practice
GGP – Good guidance practice
GHTF – Global Harmonisation Task Force
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 – but also:
GNA – Grounds for non-acceptance
GPAG – Granularity and Periodicity Advisory Group
GPhP – Good Pharmacopoeial Practices
GPIA – Generic Pharmaceutical Industry Association (US)
GPMSP – Good postmarketing surveillance practice (Japan)
GPP – Good paediatric practice – but also:
GPP – Good pharmacoepidemiology practice
GPP2 – Good publication practice
GPSP – Good Post-marketing Study Practice
G PV P – 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 – but also:
GRP – Good review practice (US)
GSL – General sales list
GSP – Good statistics practice
GSPrs – General Safety and Performance Requirements
GTI – Genotoxic impurity
GTMP – Gene therapy medicinal product
GTP – Gene therapy product
GTWP – Gene Therapy Working Party
GVD – Global value dossier
GvHD – Graft versus Host Disease
GVP – Good pharmacovigilance practice
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
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)
IM – Intramuscular – but 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
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)
INN – International nonproprietary name
IO – Immune-oncology
IP – Intellectual property – but 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
IPO – Intellectual Property Office
IPR – Intellectual property rights
IPRF – International Pharmaceutical Regulators Forum
iPSP – initial Paediatric Study Plan
IPU – Irish Pharmaceutical Union
IQM – Integrated quality management
IR – Infra-red – but also:
IR (tablets) – 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 – but also:
IRT – Interdisciplinary Review Team (US)
IS – Information science/systems – but also:
IS – Internal standard
ISCT – In silico clinical trial
ISE – Integrated summary of efficacy
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; but also:  
IV – Intravenous  
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  
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  
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  
KOL – Key opinion leader  
KOM – Kick-off meeting  

LLL  
LABST – Laboratory animal batch safety testing  
LAT – Light authoring tool (EU)  
LCM – Lifecycle management  
LD50 – 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 markets (veterinary)  
LMA – Limited marketing authorisation  
LMICs – Low and middle income countries  
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  
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), but also:
MAD – Mutual acceptance of data (OECD Council Decision)
MAFF – Ministry of Agriculture, Forestry and Fisheries (Japan)
MAH – Marketing authorisation holder
MAID – Manufacturer, 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
MAUD – Manufacturer and User Facility Device Experience (US)
MAWP – Multi-Annual Work Plan (HMA)
MaxSPRT – Maximised sequential probability ratio test
MB – Management Board
MCC – Medicines Control Council (South Africa)
MCDA – Multi-criteria decision analysis
MCH – Mean cell haemoglobin concentration
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 – but 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 – but also:
MDR – Medical device reporting – and also:
MDR – Multi-drug resistant
MDSAP – Medical Device Single Audit Program (US, Canada)
MDV – Medical device vigilance
MEB – Medicines Evaluation Board (the Netherlands) – also known as Dutch College
MedDevs – Guidelines 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
MENA – Middle East and North Africa
MERS – Multi-agency electronic regulatory system
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)
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 – but also:
ML – Manufacturer’s licence (UK)
MLD – Minimal lethal dose
MLM – Medical literature monitoring
MMA – Malta Medicines Authority – but also:
MMA – Mobile medical app
MNAT – Multinational Assessment Team
MO – Major Objection
MoA – Mechanism of action – but also:
MOA – Ministry of Agriculture
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoCA</td>
<td>Mechanism of Coordinated Access</td>
</tr>
<tr>
<td>MOD 1</td>
<td>Module One (laboratory facility) (US)</td>
</tr>
<tr>
<td>MOD 2</td>
<td>Module Two (laboratory facility) (US)</td>
</tr>
<tr>
<td>MORE</td>
<td>Manufacture's Online Reporting Environment (MHRA) (medical devices sector)</td>
</tr>
<tr>
<td>mOS</td>
<td>median Overall Survival</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MPA</td>
<td>Medical Products Agency – Sweden</td>
</tr>
<tr>
<td>MPD</td>
<td>Medicinal Products Directive</td>
</tr>
<tr>
<td>MPID</td>
<td>Medicinal product identifier</td>
</tr>
<tr>
<td>MQAS</td>
<td>Model Quality Assurance System</td>
</tr>
<tr>
<td>MQSA</td>
<td>Mammography Quality Standards Act of 1992 (US)</td>
</tr>
<tr>
<td>MR</td>
<td>Mutual Recognition</td>
</tr>
<tr>
<td>MRAs</td>
<td>Medicines regulatory authorities – but also:</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>MRD</td>
<td>Multiple rising dose</td>
</tr>
<tr>
<td>MRFG</td>
<td>Mutual Recognition Facilitation Group (EMA)</td>
</tr>
<tr>
<td>MRH</td>
<td>Medicines regulatory harmonisation</td>
</tr>
<tr>
<td>MRI (scan)</td>
<td>Magnetic resonance imaging (scan) – but also:</td>
</tr>
<tr>
<td>MRI</td>
<td>Mutual recognition information</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum residue limit</td>
</tr>
<tr>
<td>MRP</td>
<td>Mutual recognition procedure (EU)</td>
</tr>
<tr>
<td>MRSD</td>
<td>Maximum recommended safe dose</td>
</tr>
<tr>
<td>MRU</td>
<td>Medicines Regulatory Unit (Health Division Malta)</td>
</tr>
<tr>
<td>MS</td>
<td>Mass spectrometry – but also:</td>
</tr>
<tr>
<td>MS</td>
<td>Member state/s (EU)</td>
</tr>
<tr>
<td>MSWG</td>
<td>Modelling and Simulation Working Group</td>
</tr>
<tr>
<td>MTD</td>
<td>Maximum tolerated dose</td>
</tr>
<tr>
<td>MTS</td>
<td>Medicines testing scheme (MHRA)</td>
</tr>
<tr>
<td>MUMS</td>
<td>Minor use and minor species (veterinary)</td>
</tr>
<tr>
<td>N</td>
<td>Next</td>
</tr>
<tr>
<td>N-11</td>
<td>Next 11 (group of countries comprising Bangladesh, Egypt, Indonesia, Iran, Korea, Mexico, Nigeria, Pakistan, Philippines, Turkey and Vietnam)</td>
</tr>
<tr>
<td>NAD</td>
<td>No abnormality detected</td>
</tr>
<tr>
<td>NADA</td>
<td>New animal drug application (US)</td>
</tr>
<tr>
<td>NAFCDAC</td>
<td>National Agency for Food and Drug Administration and Control (Nigeria)</td>
</tr>
<tr>
<td>NAFTA</td>
<td>North American Free Trade Association (US)</td>
</tr>
<tr>
<td>NAI</td>
<td>No action indicated</td>
</tr>
<tr>
<td>NAO</td>
<td>National Audit Office (UK)</td>
</tr>
<tr>
<td>NAP</td>
<td>Nationally authorised product</td>
</tr>
<tr>
<td>NAS</td>
<td>New active substance</td>
</tr>
<tr>
<td>NB</td>
<td>Notified body (EU)</td>
</tr>
<tr>
<td>NBE</td>
<td>New biological entity</td>
</tr>
<tr>
<td>NBIC</td>
<td>Nanotechnology, biotechnology, information science and cognitive science</td>
</tr>
<tr>
<td>NBO</td>
<td>Notified body opinion</td>
</tr>
<tr>
<td>NBOG</td>
<td>Notified Body Operations Group (EU)</td>
</tr>
<tr>
<td>NC3Rs</td>
<td>National Centre for the Replacement, Refinement and Reduction of Animals in Research (UK)</td>
</tr>
<tr>
<td>NCA</td>
<td>National competent authority</td>
</tr>
<tr>
<td>NCAS</td>
<td>New chemical active substance</td>
</tr>
<tr>
<td>NCD</td>
<td>Non-communicable diseases</td>
</tr>
<tr>
<td>NCE</td>
<td>New chemical entity</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute (US) – but also:</td>
</tr>
<tr>
<td>NCI</td>
<td>National Coordinating Investigator</td>
</tr>
<tr>
<td>NCO</td>
<td>Non clinical overview</td>
</tr>
<tr>
<td>NCS</td>
<td>Non clinical summary</td>
</tr>
<tr>
<td>NCTR</td>
<td>National Center for Toxicological Research (US)</td>
</tr>
<tr>
<td>NDA</td>
<td>New drug application (US)</td>
</tr>
<tr>
<td>NDAC</td>
<td>New Drug Advisory Committee (India)</td>
</tr>
<tr>
<td>NDMA</td>
<td>Non-Prescription Drug Manufacturers Association (US)</td>
</tr>
</tbody>
</table>
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) – but also:
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)
NMRR – Nuclear magnetic resonance
NMRA – National Medicines Regulatory Authorities
NMVRVI – Nacionalinis Maistro Ir Veterinarijos Rizikos Vertinimo Institutas (National Food and Veterinary Risk Assessment Institute) (Lithuania)
NOAEL – No observable adverse effect level
NOAH – National Office of Animal Health (UK)
NOAL – No observed adverse effect level
NOC – Notice of Compliance (Canada)
NOC/c – Notice of Compliance with Conditions (Canada)
Nocte – Night
NOEL – No observable effect level
NoMA – Norwegian Medicines Agency
NPCB – National Pharmaceutical Control Bureau (Malaysia)
NPP – Named patient product
NPRM – Notice of Proposed Rulemaking
NPT – Near-patient test
NRA – National regulatory authority
NRR – (invented) Name Review Group
NSA – National Security Agency (US)
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)
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)
OC – Office of Combination Products (US FDA)
od – once a day [Latin: omne in die] – but 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
OJ/OJEC – Official Journal of the European Communities
OLE (study) – Open label extension (study)
OMAR – Orphan Maintenance Assessment Report
OMCL – Official Medicines Control Laboratories (part of EDQM)
OMP – Orphan medicinal product
OMS – Organisations data management service
OPD – 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
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 – but also: PA – Protocol assistance
PAB – Pharmaceutical Affairs Bureau (Japan)
PAC-ATS – 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 – but 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)
PC – Packaged commodities (India)
PCA – Perception, cognition, action
PCG – Product Coordination Group (EU)
PCID – Package identifier
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
PDUFA – Prescription Drug User Fee Act (US)
PDX – Patient-derived xenograft
PE – Pharmacoeconomics
PEAG – Pharmacovigilance Expert Advisory Group (MHRA)
PCC – Patient Engagement Collaborative, and also:
PCC – 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
PGD – Patient group directions (written instructions)
PGENI – Pharmacogenetics for Every Nation Initiative
PGI – Potentially genotoxic impurity
PgWP – Pharmacogenomics Working Party
PGx – Pharmacogenomics
PhEur – European Pharmacopoeia
PHA – Preliminary hazard analysis
PHARE – Poland and Hungary; aid of the Restructure of the Economy; Now the Phare programme is one of the three pre-accession instruments financed by the European Communities to assist the applicant countries of central Europe in their preparations for joining the EU
PHARMO – Institute for Drug Outcomes Research (the Netherlands)
PHC – Personalised healthcare
PhIP – Pharmacological intelligence
PhPID – Pharmaceutical product identifiers (EU)
PhRMA – Pharmaceutical Research and Manufacturers of America
PHS – Public Health Service (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 – but 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)
PIE – Pharmaceuticals in the environment
PIIGS – Portugal, Ireland, Italy, Greece and Spain
PIL – Patient information leaflet
PIM – Product information management (EMA) – but also:
PIM – Promising innovative medicine
PIN – Patient identification number
PIP – Paediatric investigation plan – but 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 – but also:
PL – Product license (US)
PLA – Product licence application (for biologics) (US)
PLPI – Parallel import licence [product licence parallel import]
PLR – Physician Labeling Rule (US)
PLR – Product license renewal (US) – but also:
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)
PMFI – Pressurised metered dose inhaler
PMDL – Pharmaceutical and Medical Device Law (Japan)
PMN – Pre-market notification
PMR – Postmarketing requirements (US)
PMF – Plant master file (US and Canada)
PMI – Pharmacological, metabolic and immunological
PMOA – Primary mode of action
PMPF – Post Market Performance Follow-up
PMPRB – Patented Medicines Prices Review Board (Canada)
PMS – Postmarket(ing) surveillance – but also:
PMS – Product data management service/product management services
PMS study – Post-marketing safety study
PNC – Pre-notification consultation (Canada)
PNEC – Predicted no-effect concentration
po – by mouth/orally [Latin: per os]
POC – Proof of concept
POCA – Phonetic and Orthographic Computer Analysis
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 PK
PPA – Parallel production authorisation
PPD – Protected personal data
PPI – Patient and Public Involvement (UK) – but 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)
PQP – Prequalification of Medicines Programme (WHO)
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
PRIME – Priority medicines scheme
PR-PURSE – 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-relevant 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
PSRP – 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
PuAR – Public assessment report
PUL module – Performance of the Upper Limb module
PUMA – Paediatric-use marketing authorisation
PV – Pharmacovigilance
PVAR – Preliminary Variation Assessment Report
PXRD – Powder xray diffraction

QQQ
(Q)SAR – Quantitative structure activity relationships
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)
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]
QS – Quality system
QSE – Quality, safety and efficacy
QSI – Quality System Inspection Technique (US FDA)
QTTP – 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 – but 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)
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
REA – Relative effectiveness assessment
REACH – Registration, evaluation, authorisation and restriction of chemicals
REC – Research Ethics Committee
RefMP(s) – Reference Medicinal Product(s), see also RMP(s)
REMS – Risk evaluation and mitigation strategy (US)
RFD – Reference dose (veterinary)
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 – Regulatory information management
RING – Regulatory Intelligence Network Group (EU)
rINN – Recommended international non-proprietary name
RiskMAP – Risk minimisation action plan
RLD – Reference listed drug (US)
RMM – Risk minimisation materials – but also:
RMP – Reference medicinal product – but also:
RMP – Risk management plan
RMR – Reaction monitoring report – but also:
RMR – Risk management report
RMS – Reference member state (Europe) – but 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 – but also:
ROI – Return on investment
RONAFA – Reduction of need for antimicrobials in food-producing animals
RoW – Rest of (the) World
RP – Responsible person
RPA – Robotic process automation
RPI – Research Product Identifier (formerly called ‘Unique Product Identifier, UPI)
RPS – Regulated product submission
RPSGB – Royal Pharmaceutical Society of Great Britain
RQA – Research quality assurance
RR – Relative risk – but also:
RR – Respiratory rate – and also:
RR – Risk ratio
RRI – Regional regulatory initiatives
RRR – Relative risk reduction
RSA – Risk share agreement
RSI – Reference safety information – but also:
RSI – Request for supplementary information (EU)
RTF – Refusal-to-file (US)
RTI – Respiratory tract infection
RTQ – Response to questions
RTT – Right to Try
RU-MRP – Repeat use mutual recognition procedure
RUP – Repeat use procedure
RWD – Real world data
RWE – Real word evidence
Rx – Prescription

S+T – Sampling and testing
SA – Scientific advice
SAARC – South Asia 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 – but also:
SAP – Statistical analysis plan
SAR – Safety assessment report – but also:
SAR – Serious adverse reaction
SAT – Special Action Team (EFPIA)
SAWP – Scientific Advice Working Party
SBA/SBOA – Summary basis of approval (US)
SBP – Similar biotherapeutic product (WHO)
sc – subcutaneous (aka sq)
SCB – Scientific Coordination Board
SCCS – Self-controlled case series design
SCF – Scientific Committee for Food (UK)
SCOTT – Ethics and Standing Committee on Therapeutic Trials (Australia)
SCT – Stem cell transplant
sCTMP – somatic Cell Therapy Medicinal Product
SD – Standard deviation
SLDC – Software development lifecycle
SDR – Statistic of disproportionate reporting
SDRG – Study data reviewer's guide
SDTM – Study Data Tabulation Model (US)
SE – Standard error – but also:
SE – Substantially equivalent/substantial equivalence
SEAR – Safety, Efficacy and Adverse Reactions (sub-committee of CSM)
SEB – Subsequent entry biologic
SEED Consortium – Shaping European Early Dialogues Consortium
SEND – Standard for exchange of nonclinical data
SFDA – Formerly China’s State Food and Drug Administration (now CFDA) but 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 – but 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
SMS – Substance data management service
SNDA – supplemental new drug application (US)
SNDS – Supplemental new drug submission (Canada)
SNIF – Summary Notification Information Format
SO – Scientific opinion
SOC – Standard of care – but 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) – but also:
SPC – Supplementary protection certificate (EU)
SPECT – Single photon emission computed tomography
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
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
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 files
STR – Stirred tank bioreactors
STRPC – Scientific, Technical and Regulatory Policy Committee (EFPIA)
SUD – Single use device – but 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
SUSAR – Suspected unexpected serious adverse reaction
SWOT (analysis) – Strengths, weaknesses, opportunities, threats
SWP – Safety Working Party (CHMP)
Sx – Symptoms

**T**

\( t_{1/2} \) – Terminal half-life of elimination
TA – Targeted assessment – but also:
TA – Therapeutic area
TABST – Target animal batch safety testing
TAG – Technical Advisory Group (UK’s NICE) – but 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
TCA – Tricyclic antidepressant
TCM – Traditional Chinese medicine
TCP – Target candidate profile
TCT – Toxicity, Clinical Trials and Therapeutic Efficacy Subcommittee of the CSM (UK)
TDD – Transdermal drug delivery
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]
TE – Therapeutic equivalence
TEP – Tissue engineered product
TESS – Tamper evident security seal
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
</tr>
<tr>
<td>TFM</td>
<td>Tentative final monograph (US)</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration (Australia's regulatory agency) – but also:</td>
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<tr>
<td>TGA</td>
<td>Thermogravimetric analysis</td>
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<tr>
<td>THMP</td>
<td>Traditional herbal medicinal product</td>
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<tr>
<td>THMPD</td>
<td>Traditional Herbal Medicinal Products Directive</td>
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<tr>
<td>THMRS</td>
<td>Traditional Herbal Medicines Registration Scheme</td>
</tr>
<tr>
<td>THR</td>
<td>Traditional herbal registration</td>
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<tr>
<td>TIGes</td>
<td>Telematic Implementation Group–electronic submissions</td>
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<tr>
<td>TIND</td>
<td>Treatment IND (see IND)</td>
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<tr>
<td>TK</td>
<td>Thymidine kinase – but also:</td>
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<tr>
<td>TK</td>
<td>Toxicokinetics</td>
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<tr>
<td>TLC</td>
<td>Thin layer chromatography</td>
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<tr>
<td>TLV</td>
<td>Threshold limit value</td>
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<tr>
<td>TMF</td>
<td>Trial Master File</td>
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<tr>
<td>TOC</td>
<td>Table of contents</td>
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<tr>
<td>TOD</td>
<td>Table of decisions</td>
</tr>
<tr>
<td>TOM</td>
<td>Target operating model</td>
</tr>
<tr>
<td>TOPRA</td>
<td>The Organisation for Professionals in Regulatory Affairs</td>
</tr>
<tr>
<td>TOPS</td>
<td>The Over-volunteering Prevention System (database)</td>
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<tr>
<td>TPP</td>
<td>Target product profile</td>
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<tr>
<td>TRF</td>
<td>Tamper-resistant formulation</td>
</tr>
<tr>
<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>TRK</td>
<td>Tropomyosin receptor kinase</td>
</tr>
<tr>
<td>TRL</td>
<td>Total residue level (veterinary)</td>
</tr>
<tr>
<td>TSA</td>
<td>Therapeutic Substances Act</td>
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<tr>
<td>TSE</td>
<td>Transmittable spongiform encephalopathy</td>
</tr>
<tr>
<td>TTC</td>
<td>Threshold of toxicological concern</td>
</tr>
<tr>
<td>TUBITAK</td>
<td>Scientific and Technological Research Council of Turkey</td>
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</tbody>
</table>

**UUU**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>UAT</td>
<td>User acceptance testing</td>
</tr>
<tr>
<td>UCN</td>
<td>Unique carton number</td>
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<tr>
<td>UDI</td>
<td>Unique device identification</td>
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<tr>
<td>UI</td>
<td>Unique Identifier (according to the FMD)</td>
</tr>
<tr>
<td>ULTRA</td>
<td>Unlocking Lifesaving Treatments for Rare-Diseases Act (US)</td>
</tr>
<tr>
<td>UMBRA</td>
<td>Unified Methodologies for Benefit–Risk Assessment</td>
</tr>
<tr>
<td>UMP</td>
<td>Beijing Union Medical and Pharmaceutical General Corp (the innovative arm of the Chinese Academy of Medical Sciences)</td>
</tr>
<tr>
<td>UOP</td>
<td>User Interface of Unknown Provenance</td>
</tr>
<tr>
<td>UPS-NF</td>
<td>United States Pharmacopeia and National Formulary</td>
</tr>
<tr>
<td>USAN</td>
<td>United States Approved Name</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
</tr>
<tr>
<td>USKVBL</td>
<td>Ústav pro Statní Kontrolu Veterinárních Biopreparátu a Leciv (Institute for State Control of Veterinary Biologicals and Medicines) (Czech Republic) – but also:</td>
</tr>
<tr>
<td>USKVBL</td>
<td>Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (Department of State Control of Veterinary Biologicals and Medicaments) (Slovenia)</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
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<tr>
<td>USP-DI</td>
<td>United States Pharmacopeia-Drug Information</td>
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<tr>
<td>USPI</td>
<td>United States Product Insert</td>
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<tr>
<td>USP-NF</td>
<td>United States Pharmacopeia-National Formulary</td>
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<tr>
<td>USR</td>
<td>Urgent safety restriction</td>
</tr>
<tr>
<td>UTI</td>
<td>Urinary tract infection</td>
</tr>
<tr>
<td>UUP</td>
<td>Urgent union procedure (European Commission)</td>
</tr>
</tbody>
</table>

**VVV**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAERS</td>
<td>Vaccine adverse event reporting system (US)</td>
</tr>
<tr>
<td>VAESCO</td>
<td>Vaccine adverse event surveillance &amp; communication</td>
</tr>
<tr>
<td>VAF</td>
<td>Virus antibody free</td>
</tr>
<tr>
<td>VAI</td>
<td>Voluntary action indicated</td>
</tr>
<tr>
<td>VAMF</td>
<td>Vaccine antigen master file</td>
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