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) – and 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 ASEA)

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)

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 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 Spécialités Pharmaceutiques Grand Public (Association of the European Self-Medication Industry)

AF – Application Form

AFAR – Association Française des Affaires Reglementaires (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:
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>AI</td>
<td>Artificial intelligence</td>
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<tr>
<td>AIFA</td>
<td>Agenzia Italiana del Farmaco (Italy's health authority)</td>
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<tr>
<td>AIM</td>
<td>Active ingredient manufacturer</td>
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<tr>
<td>AIMD</td>
<td>Active implantable medical device</td>
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<tr>
<td>AITS</td>
<td>Adverse Incident Tracking System (medical devices sector)</td>
</tr>
<tr>
<td>AKP</td>
<td>Alkaline phosphatase</td>
</tr>
<tr>
<td>ALARP</td>
<td>As low as reasonably practical</td>
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<tr>
<td>ALATF</td>
<td>As low as technically feasible (terminology superseded by “ALARP” – see above)</td>
</tr>
<tr>
<td>ALIMS</td>
<td>Medicines and Medical Devices Agency (Serbia)</td>
</tr>
<tr>
<td>ALL</td>
<td>Acute lymphocytic leukaemia</td>
</tr>
<tr>
<td>ALT</td>
<td>Alanine aminotransferase (ALT = SGPT)</td>
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<tr>
<td>AM</td>
<td>Agence du Medicament (France)</td>
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<tr>
<td>AMA</td>
<td>American Medical Association</td>
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<tr>
<td>AMEG</td>
<td>AntiMicrobial advice ad hoc Expert Group</td>
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<tr>
<td>AMI</td>
<td>Acute myocardial infarct</td>
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<tr>
<td>AML</td>
<td>Acute myeloid leukaemia</td>
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<tr>
<td>AMM</td>
<td>Autorisation de mise sur le marché (France) = Product licence</td>
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<tr>
<td>AMP</td>
<td>Authorised medicinal product – and also: Auxiliary medicinal product (formerly non-investigational medicinal product, NIMP)</td>
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<tr>
<td>AMR</td>
<td>Antimicrobial resistance</td>
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<tr>
<td>AMRH</td>
<td>African Medicines Regulatory Harmonisation</td>
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<tr>
<td>ANADA</td>
<td>Abbreviated New Animal Drug Application (US)</td>
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<tr>
<td>ANDA</td>
<td>Abbreviated new drug application</td>
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<tr>
<td>ANDS</td>
<td>Abbreviated new drug submission (Canada)</td>
</tr>
<tr>
<td>ANMV</td>
<td>Agence nationale du médicament vétérinaire (French vet medicines agency)</td>
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<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
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<tr>
<td>ANPR</td>
<td>Advanced notice of proposed rulemaking (US)</td>
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<tr>
<td>ANSES</td>
<td>Agence Francaise de Securite Sanitaire des Aliments Agence nationale due medicament veterinaire</td>
</tr>
<tr>
<td>ANSM</td>
<td>French regulatory agency (Agence nationale de sécurité du médicament et des produits de santé) [formerly Afssaps]</td>
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<tr>
<td>ANZTPA</td>
<td>Australia New Zealand Therapeutic Products Agency (scheduled to come into force in 2016 – replacing Australia's TGA and New Zealand's Medsafe)</td>
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<tr>
<td>AO</td>
<td>Auditing organisation</td>
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<tr>
<td>AOAC</td>
<td>Association of Official Analytical Chemists (US)</td>
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<tr>
<td>AOB</td>
<td>Any other business</td>
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<tr>
<td>AP</td>
<td>Accredited person – and also: Adaptive pathway</td>
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<tr>
<td>AP</td>
<td>Authorised representative</td>
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<tr>
<td>APEC</td>
<td>Asia-Pacific Economic Cooperation</td>
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<td>APHIS</td>
<td>Animal and Plant Health Inspection Service (US)</td>
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<td>API</td>
<td>Active pharmaceutical ingredient</td>
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<td>APIC</td>
<td>Active Pharmaceutical Ingredients Committee</td>
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<tr>
<td>APLB</td>
<td>Advertising and Promotional Labeling Branch (FDA’s CBER)</td>
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<tr>
<td>APMA</td>
<td>Australian Pharmaceutical Manufacturers Association</td>
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<tr>
<td>APVA</td>
<td>Additional pharmacovigilance activities</td>
</tr>
<tr>
<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority (Australia)</td>
</tr>
<tr>
<td>AQL</td>
<td>Acceptable quality level</td>
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<tr>
<td>AR</td>
<td>Adverse reaction – and also: Assessment Report (EU) – and also: Authorised representative</td>
</tr>
<tr>
<td>AREFD</td>
<td>Acute reference dose (veterinary)</td>
</tr>
<tr>
<td>ARMAs</td>
<td>Additional risk minimisation activities</td>
</tr>
<tr>
<td>ARMMs</td>
<td>Additional risk minimisation measures</td>
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<tr>
<td>AS</td>
<td>Active Substance</td>
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<tr>
<td>ASAP</td>
<td>Accelerated Stability Assessment Program</td>
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<tr>
<td>ASCII</td>
<td>American Standard Code for Information Interchange Quality Assurance</td>
</tr>
<tr>
<td>ASDI</td>
<td>Acceptable single-dose intake</td>
</tr>
<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>ASMF</td>
<td>Active Substance Master File</td>
</tr>
<tr>
<td>ASMF WG</td>
<td>Working Group on Active Substance Master File procedures</td>
</tr>
<tr>
<td>ASPR</td>
<td>Anonymised single patient report (formerly ASPP – anonymised single patient printout)</td>
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<tr>
<td>ASR</td>
<td>Annual safety report</td>
</tr>
<tr>
<td>AST</td>
<td>Aspartate aminotransaminase (AST = SGOT)</td>
</tr>
</tbody>
</table>
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”)
ATU – Authorisation for temporary use
AUC∞ – Area under the concentration time curve between zero and infinity
AUCt – 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) (Germany’s regulatory authority)
BGMA – British Generic Manufacturers Association
BINO – 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 – 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 – 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
CAS – Central alerting system (UK) – and also:
CAS – Chemical abstract systems
CAT – Committee for Advanced Therapies (EMA)
CATMP – Combined Advanced Therapy Medicinal Product
CAVDR – 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
CCR – Change control review board
CCSI – Company core safety information
CD – Caesarean derived – and also:
CD – Controlled drug
CDA – China Drug Administration
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
CDMA – Canadian Drug Manufacturers Association
CDR – Common Drug Review (Canada)
CDRH – Center for Devices and Radiological Health (US FDA)
CDS – Clinical decision support
CMR – Centre for Medicines Research
CMS – Concerned member state (EU)
CMT – Convergent medical technologies
COC/CoA – 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
COSH – 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)
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
CQA – Clinical quality assurance – and also:
CQA – Critical quality attribute
CR – Computed radiology – and also:
CR – Controlled release
CRF – Case report form
CRG – Clinical reference group (UK)
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
CT – Clinical trial – 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
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>CTFG</td>
<td>Clinical Trials Facilitation Group</td>
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<tr>
<td>CTIS</td>
<td>Clinical Trials Information System <em>(formerly the EU clinical trial portal and database, EudraCT)</em></td>
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<tr>
<td>CTMP</td>
<td>Cell therapy medicinal product</td>
</tr>
<tr>
<td>CTMS</td>
<td>Clinical trial management system</td>
</tr>
<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 – and also: Communication Tracking System <em>(formerly Eudratrack)</em></td>
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<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>
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<td>CUP</td>
<td>Compassionate use programme</td>
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<tr>
<td>CV</td>
<td>Controlled vocabulary</td>
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<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>
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<tr>
<td>CVO</td>
<td>Chief Veterinary Officer</td>
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<tr>
<td>CVS</td>
<td>Cardiovascular system</td>
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<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>
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<tr>
<td>DAB</td>
<td>German Pharmacopoeia <em>(Deutsches Arznei Buch)</em></td>
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<tr>
<td>DAC</td>
<td>Data analysis centre</td>
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<tr>
<td>DAE</td>
<td>Detailed and critical summary</td>
</tr>
<tr>
<td>DACS</td>
<td>Detailed description of pharmacovigilance system</td>
</tr>
<tr>
<td>DAMOS</td>
<td>Drug application methodology with optical storage</td>
</tr>
<tr>
<td>DB</td>
<td>Device Bulletin <em>(MHRA)</em></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 <em>(Directorate General of Health Services in the Ministry of Health and Family Welfare)</em></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>
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<tr>
<td>DD</td>
<td>District Director (US)</td>
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<tr>
<td>DDC(P)</td>
<td>Drug-device combination <em>(product)</em></td>
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<tr>
<td>DDD</td>
<td>Defined daily dose</td>
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<tr>
<td>DDMAC</td>
<td>Division of Drug Marketing, Advertising and Communications <em>(CDER)</em></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>
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<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>
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<tr>
<td>DES</td>
<td>Design inputs document</td>
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<tr>
<td>DES</td>
<td>Drug exchange standard (EU) – and also: Drug eluting stent</td>
</tr>
<tr>
<td>DEI</td>
<td>Drug efficacy study implementation (US)</td>
</tr>
<tr>
<td>DG</td>
<td>Directorate-General <em>(at the European Commission)</em></td>
</tr>
<tr>
<td>DGEM</td>
<td>Disease-gene expression matching</td>
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<tr>
<td>DGV</td>
<td>Direcção Geral de Veterinaria <em>(Veterinary Medicines Agency)</em> (Portugal)</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health (UK) – and also: Digital healthcare</td>
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<td>DHPC</td>
<td>Direct healthcare professional communication <em>(formerly ‘Dear Doctor Letter’)</em></td>
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<tr>
<td>DIA</td>
<td>Drug Information Association (US)</td>
</tr>
<tr>
<td>DJIBD</td>
<td>Development international birth date</td>
</tr>
<tr>
<td>DID</td>
<td>Design inputs document</td>
</tr>
<tr>
<td>DII</td>
<td>Deutsches Institut für Medizinische Dokumentation und Information <em>(Germany)</em></td>
</tr>
<tr>
<td>DKMA</td>
<td>Lægemiddelstyrelsen/Danish Medicines Agency (Denmark)</td>
</tr>
<tr>
<td>DLP</td>
<td>Data lock point</td>
</tr>
</tbody>
</table>
DMF – Drug master file
DMPK – Drug metabolism and pharmacokinetics
DMRC – Defective Medicines Report Centre (MHRA)
DMS – Document management system
DMT – Disease modifying therapy
DOE – Design of experiments
DoR – Duration of Response
DP – Drug product
DPI – Dry powder inhaler
DPIA – Data protection impact assessment
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
DPR(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
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 – Established conditions (ICH Q12 Guideline) – and also:
EC – Ethics committee – and also:
EC – European Commission – and also:
EC – Exceptional circumstances
ECDC – European Centre for Disease Prevention and Control
ECG – Electrocardiogram
ECHAMP – European Coalition on Homoeopathic and Anthroposophic Medicinal Products
ECHHR – 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
EDT – Electronic data transfer
EDX – 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
EPSA – 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)
EMA – European Medicines Agency (formerly European Medicines Evaluation Agency – EMEA)
EMACOLEX – European Medicines Agencies Co-operation of Legal and Legislative Issues
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)
EMV – 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)
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
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
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:

EU – 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

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

EURD – European Union reference date

EUREC – European Network of Research Ethics Committees

EURL – EU reference laboratory

EUR-OP – EU Office for Publications

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

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
FDC – Fixed dose combination
FDC Act – Food – Drug and Cosmetic Act (US)
FDF – Finished dosage form
FIM – First-in-man
FIMEA – 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 Odontoaiatri (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

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 Cooperation 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)
GMiA – Generic Medicines Industry Association (Australia)
GMO – Genetically modified organism
GMP – Good manufacturing practice – and 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 – 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)
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
GTWP – Gene Therapy Working Party
GVD – Global value dossier
GvH – 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
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>HCT/P</td>
<td>Human cells, tissues, and cellular and tissue-based products</td>
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<tr>
<td>HDE</td>
<td>Humanitarian device exemption</td>
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<tr>
<td>HDI</td>
<td>Human development index</td>
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<tr>
<td>HE</td>
<td>Hospital exemption</td>
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<tr>
<td>HEOR</td>
<td>Health economics and outcomes research</td>
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<tr>
<td>HEW</td>
<td>Health, Education and Welfare (US)</td>
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<td>HFE</td>
<td>Human factors engineering</td>
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<tr>
<td>HGAC</td>
<td>Human Genetics Advisory Committee</td>
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<tr>
<td>HGSPRT</td>
<td>Hypoxanthine-guanine-phosphoribasyltransferase activity</td>
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<tr>
<td>HHMG</td>
<td>Human Harmonisation Maintenance Group</td>
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<tr>
<td>HHS</td>
<td>US Department of Health and Human Services</td>
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<tr>
<td>HIC</td>
<td>High income countries</td>
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<tr>
<td>HIMA</td>
<td>Health Industry Manufacturers Association (US)</td>
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<tr>
<td>HL7</td>
<td>Health Level Seven</td>
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<tr>
<td>HLG1</td>
<td>High level group term (in MedDRA)</td>
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<tr>
<td>HLT</td>
<td>High level term (in MedDRA)</td>
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<tr>
<td>HMA</td>
<td>Heads of Medicines Agencies (Human and Veterinary) (EU)</td>
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<tr>
<td>HMO</td>
<td>Health, Education and Welfare (US)</td>
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<tr>
<td>HMR</td>
<td>Human Medicines Regulations</td>
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<tr>
<td>HNSTD</td>
<td>Highest Non Severely Toxic Dose</td>
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<tr>
<td>HoA</td>
<td>Heads of Agencies</td>
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<tr>
<td>HPB</td>
<td>Health Protection Board (Canada)</td>
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<td>HPLC</td>
<td>High performance liquid chromatography</td>
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<tr>
<td>HPRA</td>
<td>Health Products Regulatory Authority (formerly Irish Medicines Board)</td>
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<tr>
<td>HR</td>
<td>Heart rate</td>
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<tr>
<td>HRA</td>
<td>Health Research Authority (UK)</td>
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<tr>
<td>HRB</td>
<td>Health Research Board</td>
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<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<tr>
<td>HRQoL</td>
<td>Health-related quality of life</td>
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<tr>
<td>HRT</td>
<td>Hormone replacement therapy</td>
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<tr>
<td>HSA</td>
<td>Human serum albumin</td>
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<tr>
<td>HSC</td>
<td>Haematopoietic stem cells</td>
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<tr>
<td>HSE</td>
<td>Health and Safety Executive (UK)</td>
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<tr>
<td>HST</td>
<td>Highly specialised technologies</td>
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<tr>
<td>HTA</td>
<td>Health technology assessment</td>
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<tr>
<td>HTS</td>
<td>High-throughput screening</td>
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<tr>
<td>HV</td>
<td>Healthy volunteer</td>
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<tr>
<td>III</td>
<td>Imaging and acute care (medical devices sector)</td>
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<tr>
<td>IAM</td>
<td>Identity and Access Management</td>
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<tr>
<td>IAPO</td>
<td>International Alliance of Patients’ Organisations</td>
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<tr>
<td>IB</td>
<td>Investigator’s brochure</td>
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<tr>
<td>IBD</td>
<td>International Birth Date</td>
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<tr>
<td>IBMS</td>
<td>Institute of Basic Medical Sciences (China)</td>
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<tr>
<td>IC</td>
<td>Informed consent</td>
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<tr>
<td>ICD</td>
<td>Informed consent document – and also:</td>
</tr>
<tr>
<td>ICD</td>
<td>International Classification of Diseases</td>
</tr>
<tr>
<td>ICDRA</td>
<td>International Conference of Drug Regulatory Authorities</td>
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<tr>
<td>ICER</td>
<td>Incremental cost-effectiveness ratio</td>
</tr>
<tr>
<td>ICF</td>
<td>Informed consent form</td>
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<tr>
<td>ICH</td>
<td>International Council for Harmonisation (formerly International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use)</td>
</tr>
<tr>
<td>ICI</td>
<td>Immune checkpoint inhibitor</td>
</tr>
<tr>
<td>ICMJE</td>
<td>International Committee of Medical Journal Editors</td>
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<tr>
<td>ICMRA</td>
<td>International Coalition of Medical Regulatory Authorities</td>
</tr>
<tr>
<td>ICP-MS</td>
<td>Inductively coupled plasma mass spectrometry</td>
</tr>
<tr>
<td>ICSR</td>
<td>Individual case safety report</td>
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<tr>
<td>ICT</td>
<td>Information and communications technology</td>
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<tr>
<td>ICTRIP</td>
<td>International Clinical Trials Registry Platform (WHO)</td>
</tr>
</tbody>
</table>
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
ISS – Integrated summary of safety
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)

J
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)

K
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

L
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
LoA – Letter of access (China)
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), 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
MAUDE – 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 – 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 (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
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
NAS – 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)
NICHHD – National Institute of Child Health and Human Development (US)
NIH – National Institutes of Health (US)
NIHR – National Institute for Health Research (UK)
NJMP – 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)
NMMPA – National Medical Products Administration (China) (国家药品监督管理局) (formerly CFDA)
NMR – Nuclear magnetic resonance
NMRA s – 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 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
NRG – (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)
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
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
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
PAl – 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
PCG – Product Coordination Group (EU)
PCID – Package identifier
pCODR – pan-Canadian Oncology Drug Review
PCOIR – 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)
PPEC – Patient Engagement Collaborative, and also:
PPEC – 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)
PDM (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
Ph Eur – 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
PhI – 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
PhVWG – 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)
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:
PIR – 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 leaflet (US)
PLA – Product license application (for biologics) (US)
PLLRI – Parallel import licence [product licence parallel import]
PLR – Physician Labeling Rule (US)
PLR – Product license renewal (US) – and also:
PLT – Platelet count
PMA – Premarket approval (application for medical devices) (US)
PMAR – 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
PNN – Pre-market notification
PMAO – Primary mode of action
PMF – Post Market Performance Follow-up
PMPSR – Patented Medicines Price Regulation Scheme
PMR – Postmarketing requirements (US)
PMS – Postmarket(ing) surveillance – and also:
PMS – Product data management service/product management services
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]
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) – 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)
PQP – Prequalification of Medicines Programme (WHO)
PQR – Product quality review
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
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-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
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
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 x-ray 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]
QRM – Quality risk management
QS – Quality system
QSE – Quality, safety and efficacy
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)
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 – 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 – 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 – and 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 – and also:
RSI – Request for supplementary information (EU)
RTF – Refusal-to-file (US)
RTI – Respiratory tract infection
RTQ – Response to questions
RTRT – Real time release testing
RTT – Right to Try
RU-MRP – Repeat use mutual recognition procedure
RUP – Repeat use procedure
RWD – Real world data
RWE – Real world evidence
Rx – Prescription

SSS
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 – and also:
SAP – Statistical analysis plan
SAR – Safety assessment report – and 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 – and 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) 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
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 – 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
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
– and also:
SRN – Stroke Research Network (part of NIHR, UK)
SSC – Scientific Steering Committee
SSFC – 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 – 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
SUSAR – Suspected unexpected serious adverse reaction
SWOT (analysis) – Strengths, weaknesses, opportunities, threats
SWP – Safety Working Party (CHMP)
Sx – Symptoms

*TTT*

\[ t_{\frac{1}{2}} \] 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

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

TFEU – Treaty on the Functioning of the European Union

TFM – Tentative final monograph (US)

TGA – Therapeutic Goods Administration (Australia’s regulatory agency) – and also:

TGA – Thermogravimetric analysis

THMP – Traditional herbal medicinal product

THMDPD – 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)

TPP – Target product profile

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 – Transmissible spongiform encephalopathy

TTC – Threshold of toxicological concern

TUBITAK – Scientific and Technological Research Council of Turkey

UUU
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</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>
</tr>
<tr>
<td>UDI</td>
<td>Unique device identification</td>
</tr>
<tr>
<td>UUI</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>UOU</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>USKVL</td>
<td>Ústav pro Statní Kontrolu Veterinárních Biopreparátů a Leciv (Institute for State Control of Veterinary Biologicals and Medicines) (Czech Republic) – and also: Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (Department of State Control of Veterinary Biologicals and Medicaments) (Slovenia)</td>
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<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>
</tr>
<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>
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<tr>
<td>UTI</td>
<td>Urinary tract infection</td>
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<tr>
<td>UUP</td>
<td>Urgent union procedure (European Commission)</td>
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**VVV**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<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>
</tr>
<tr>
<td>VAR</td>
<td>Variation assessment report</td>
</tr>
<tr>
<td>VarWP</td>
<td>Working Party on Variation Regulation, also: Variation Working Party</td>
</tr>
<tr>
<td>VBA</td>
<td>Value-based assessment</td>
</tr>
<tr>
<td>VBP</td>
<td>Value-based pricing</td>
</tr>
<tr>
<td>VCS</td>
<td>Viral challenge study</td>
</tr>
<tr>
<td>VDD</td>
<td>Veterinary Drugs Directorate (Canada)</td>
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<tr>
<td>VeDDRA</td>
<td>Veterinary Dictionary for Drug Related Affairs</td>
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<tr>
<td>VF</td>
<td>Ventricular failure</td>
</tr>
<tr>
<td>VHP</td>
<td>Voluntary harmonisation procedure</td>
</tr>
<tr>
<td>VICH</td>
<td>International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products</td>
</tr>
<tr>
<td>VIPP</td>
<td>Verified internet pharmaceutical practice site (US)</td>
</tr>
<tr>
<td>VMD</td>
<td>Veterinary Medicines Directorate</td>
</tr>
<tr>
<td>VMP</td>
<td>Veterinary medicinal product</td>
</tr>
<tr>
<td>VMRFG</td>
<td>Veterinary Mutual Recognition Facilitation Group</td>
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<tr>
<td>VNeeS</td>
<td>Veterinary non-eCTD electronic submission</td>
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<tr>
<td>VPC</td>
<td>Veterinary Products Committee (UK)</td>
</tr>
<tr>
<td>VPN</td>
<td>Virtual private network</td>
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<tr>
<td>vPvB</td>
<td>Very persistent and very bioaccumulative (biocidal products)</td>
</tr>
<tr>
<td>VSI</td>
<td>Validation Supplementary Information</td>
</tr>
<tr>
<td>VTE</td>
<td>Venous thromboembolism</td>
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<tr>
<td>VWP</td>
<td>Vaccines Working Party</td>
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**WWW**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>WBC</td>
<td>White blood cell</td>
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<tr>
<td>WC</td>
<td>Written confirmation (issued by competent authority)</td>
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<tr>
<td>WCPB</td>
<td>Women of childbearing potential</td>
</tr>
<tr>
<td>WDA</td>
<td>Wholesale dealer’s licence</td>
</tr>
<tr>
<td>WEBAE</td>
<td>Web adverse event(s)</td>
</tr>
<tr>
<td>WEB–RADR (project)</td>
<td>Recognising Adverse Drug Reactions</td>
</tr>
<tr>
<td>WEU</td>
<td>Well-established use</td>
</tr>
</tbody>
</table>
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 2020]