GLOSSARY OF REGULATORY HEALTHCARE ACRONYMS & ABBREVIATIONS

Note: Medical disorders and prescription abbreviations can be searched at several dedicated websites, eg:
Prescription abbreviations: http://www.abbreviations.com/acronyms/PRESCRIPTION

3Rs – Replacement, refinement and reduction (in research using animals)
510(k) – Medical device premarket notification (US FDA)
AADA – Abbreviated antibiotic drug application
AAPS – American Association of Pharmaceutical Scientists
AAS – Atomic absorption spectroscopy
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
ACTD – ASEAN common technical dossier (see ASEAN)
ARfd – Acute reference dose (veterinary)
ACVM – Agricultural Compounds and Veterinary Medicines (New Zealand)
ADC – Additional data collection
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
AE – Adverse event
AEFI – Adverse event following immunisation
AEGIS – Adverse Experience Gathering Information System
AEM – Agencia Española del 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)
AFAR – Association Française des Affaires Réglementaires (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 Ernährungssicherheit GmbH (Austria’s medicines & devices agency)
AHSC – Academic Health Science Centre (UK)
AI – Adverse incident (medical devices sector)
AIFA – Agenzia Italiana del Farmaco (Italy’s health authority)
AIM – Active ingredient manufacturer
AIMD – Active implantable medical device
AITS – 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)
ALT – Alanine aminotransferase (ALT = SGPT)
AM – Agence du Medicament (France)
AMA – American Medical Association
AMI – Acute myocardial infarct
AML – Acute myeloid leukemia
AMM – Autorisation de mise sur le marché (France) = Product licence
AMP – Authorised medicinal product
AMR – Antimicrobial resistance
AMRH – African Medicines Regulatory Harmonisation
ANADA – Abbreviated New Animal Drug Application (US)
ANDA – Abbreviated new drug application
ANDS – Abbreviated new drug submission (Canada)
ANMV – Agence nationale du médicament vétérinaire (French vet medicines agency)
ANOV – Analysis of Variance
ANSES – Agence Francaise de Securite Sanitaire des Aliments 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)
AOAC – Association of Official Analytical Chemists (US)
APEC – Asia-Pacific Economic Cooperation
APMA – Australian Pharmaceutical Manufacturers Association
APVMA – Australian Pesticides and Veterinary Medicines Authority (Australia)
AQL – Acceptable quality level
AR – Adverse reaction – but also:
AR – Assessment Report (EU)
ASCII – American Standard Code for Information Interchange Quality Assurance
ASEAN – Association of Southeast Asian Nations
ASMF – Active Substance Master File
ASPR – Anonymised single patient report (formerly ASPP – anonymised single patient printout)
AST – Aspartate aminotransaminase (AST = SGOT)
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
ATF – Alcohol – Tobacco and Firearms (Bureau of) (US)
ATMPs – Advanced therapy medicinal products (aka "advanced therapies")
AUCx – Area under the concentration time curve between zero and infinity
AUCx – Area under the curve during a given time
AVEG – AIDS Vaccine Evaluation Group
AXREM – Association of X-ray Equipment Manufacturers
BA – Bioavailability
BACPAC – Bulk active chemical post approval changes (US)
BAI – Breath actuated inhaler
BAID – Batch identifier
BAN – British Approved Name
BAP – Biotechnology Action Programme
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
BFArM – Federal Institute for Drugs and Medical Devices (Bundesinstituts für Arzneimittel und Medizinprodukte) (Germany’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)
BMA – British Medical Association
BMD – Bone mineral density
BMG – Bundesministerium für Gesundheit = Federal Ministry of Health (Germany)
BMGF – Bundesministerium fuer Gesundheit und Frauen (Austria)
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)
BPI – Bundesverband der Pharmazeutischen Industrie (German pharmaceutical industry association)
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>BPWP</td>
<td>Blood Products Working Party (EMA)</td>
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<tr>
<td>Br</td>
<td>Barrier reared (in older reports – ‘Brown’)</td>
</tr>
<tr>
<td>BRAS</td>
<td>Belgian Regulatory Affairs Society</td>
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<tr>
<td>BRAT</td>
<td>Benefit–Risk Action Team</td>
</tr>
<tr>
<td>BRIC</td>
<td>Brazil, Russia, India &amp; China</td>
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<tr>
<td>BRICK</td>
<td>Brazil, Russia, India, China &amp; (South) Korea</td>
</tr>
<tr>
<td>BRICS</td>
<td>Brazil, Russia, India, China &amp; South Africa</td>
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<tr>
<td>BROMI</td>
<td>Better Regulation of Over the Counter Medicines Initiative</td>
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<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy</td>
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<tr>
<td>BTD</td>
<td>Breakthrough therapy designation (US)</td>
</tr>
<tr>
<td>BWP</td>
<td>Biotech Working Party (EMA)</td>
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<tr>
<td>C&amp;P</td>
<td>Chemistry and Pharmacy</td>
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<tr>
<td>CA</td>
<td>Commercial appraisal – <strong>but also:</strong> Competent authority</td>
</tr>
<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission (veterinary sector)</td>
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<tr>
<td>CAD</td>
<td>Coronary artery disease</td>
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<tr>
<td>CADREAC</td>
<td>Collaboration agreement between drug regulatory authorities of European Union associated countries (also nCADREAC – new Collaboration Agreement)</td>
</tr>
<tr>
<td>CAMD</td>
<td>Competent Authorities for Medical Devices</td>
</tr>
<tr>
<td>CAMS</td>
<td>Chinese Academy of Medical Sciences</td>
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<td>CANDA</td>
<td>Computer assisted new drug application</td>
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<tr>
<td>CAO</td>
<td>Central Agricultural Office (Hungary)</td>
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<tr>
<td>CAP</td>
<td>Centrally authorised product</td>
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<tr>
<td>CAPA</td>
<td>Corrective action and preventive action</td>
</tr>
<tr>
<td>CAPLA</td>
<td>Computer Assisted Product Licence Application</td>
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<td>CAPRA</td>
<td>Canadian Association of Pharmaceutical Regulatory Affairs</td>
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<tr>
<td>CAS</td>
<td>Central alerting system (UK) – <strong>but also:</strong> Chemical abstract systems</td>
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<tr>
<td>CAT</td>
<td>Committee for Advanced Therapies (EMA)</td>
</tr>
<tr>
<td>CAVDRI</td>
<td>Collaboration agreement between veterinary drug registration institutions</td>
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<td>CAVOMP</td>
<td>Clinical added value orphan medicinal product</td>
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<tr>
<td>CBER</td>
<td>Center for Biologics Evaluation and Research (US FDA)</td>
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<tr>
<td>CBBG/MEB</td>
<td>Medicines Evaluation Board (the Netherlands)</td>
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<td>CBP</td>
<td>Corticoid binding protein</td>
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<td>CC</td>
<td>Candidate country (EU)</td>
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<tr>
<td>CCDS</td>
<td>Company core data sheet</td>
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<tr>
<td>CCG</td>
<td>Clinical Commissioning Group (UK NHS)</td>
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<tr>
<td>CCSI</td>
<td>Company core safety information</td>
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<tr>
<td>CD</td>
<td>Caesarean derived – <strong>but also:</strong> Controlled drug</td>
</tr>
<tr>
<td>CD</td>
<td>Caesarean derived</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention (US)</td>
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<tr>
<td>CDER</td>
<td>Center for Drug Evaluation and Research (US FDA)</td>
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<tr>
<td>CDMA</td>
<td>Canadian Drug Manufacturers Association</td>
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<td>CDRH</td>
<td>Center for Devices and Radiological Health (US FDA)</td>
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<tr>
<td>CDSCO</td>
<td>Central Drug Standard Organization (India’s clinical trials licensing authority)</td>
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<td>CDSM</td>
<td>Committee on Dental and Surgical Materials (UK)</td>
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<td>CDx</td>
<td>Companion Diagnostic</td>
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<tr>
<td>CE Mark</td>
<td>Conformité European (= approval for EU medical devices)</td>
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<tr>
<td>CEC</td>
<td>Commission of the European Communities</td>
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<tr>
<td>CEE</td>
<td>Central and Eastern Europe</td>
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<tr>
<td>CEEEC</td>
<td>Central and Eastern European Countries</td>
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<tr>
<td>CEFTA</td>
<td>Central Europe Free Trade Area</td>
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<tr>
<td>CEN</td>
<td>Comité Européan des Normes – European Committee for Standardization</td>
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<tr>
<td>CEP</td>
<td>Central enquiry point (MHRA) – <strong>but also:</strong> Certificate of Europea Pharmacopoeia (aka Certificate of Suitability)</td>
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<tr>
<td>CER</td>
<td>Comparative effectiveness research</td>
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<td>CESP</td>
<td>Common European submissions platform</td>
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<tr>
<td>CF</td>
<td>Cystic fibrosis</td>
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<td>CFC</td>
<td>Chlorofluorocarbons</td>
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<tr>
<td>CFDA</td>
<td>China Food and Drug Administration (formerly State FDA – SFDA)</td>
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<tr>
<td>CFR</td>
<td>Code of Federal Regulations (US)</td>
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<tr>
<td>CFS</td>
<td>Certificate of Free Sale</td>
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<tr>
<td>CFSAN</td>
<td>Center for Food Safety and Applied Nutrition (US)</td>
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<tr>
<td>cGLP</td>
<td>Current good laboratory practice</td>
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</tbody>
</table>
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’]
CTFG – Clinical Trials Facilitation Group
CTMS – Clinical trial management system
CTN – Clinical trial notification (Australia)
CTOC – Comprehensive Table of Contents Headings and Hierarchy
CTS – Common technical specification – but also:
CTS – Communication Tracking System (formerly Eudratrack)
CTX – Clinical trial exemption (UK)
CV – Controlled vocabulary
CVM – Center for Veterinary Medicine (US)
CVMP – Committee for Medicinal Products for Veterinary Use (EMA)
CVO – Chief Veterinary Officer
CVS – Cardiovascular system
CVZ – Dutch Health Care Insurance Board
CZ – Climatic zone

DAB – German Pharmacopoeia (Deutsches Arznei Buch)
DACS – Detailed and critical summary
DAE – Discontinuation due to an adverse event
DAL – Defect action level (US)
DAMOS – Drug application methodology with optical storage
DB – Device Bulletin (MHRA)
DCGI – India’s regulatory authority (Directorate General of Health Services in the Ministry of Health and Family Welfare)
DCGI – Drugs Controller General of India
DCP – Decentralised procedure (EU)
DD – District Director (US)
DDD – Defined daily dose
DDMAC – Division of Drug Marketing, Advertising and Communications (CDER)
DDPS – Detailed description of pharmacovigilance system
DDX – Doctors and dentists exemption (UK)
DEA – Drug Enforcement Agency (US)
DEREK – Deductive estimate of risk from existing knowledge
DES – Data exchange standard (EU) – but also:
DES – Drug eluting stent
DEST – Drug efficacy study implementation (US)
DG – Directorate-General (at the European Commission)
DGV – Direccao Geral de Veterinaria (Veterinary Medicines Agency) (Portugal)
DH – Department of Health (UK)
DHHS – Department of Health and Human Services (US)
DHPC – Direct healthcare professional communication (formerly ‘Dear Doctor Letter’)
DIA – Drug Information Association (US)
DJB – Development international birth date
DIMDI – Deutsches Institut für Medizinische Dokumentation und Information (Germany)
DKMA – Laegemiddelstyrelsen/Danish Medicines Agency (Denmark)
DLP – Data lock point
DMF – Drug master file
DMPK – Drug metabolism and pharmacokinetics
DMRC – Defective Medicines Report Centre (MHRA)
DMS – Document management system
DOE – Design of experiments
DP – Drug product
DPI – Dry powder inhaler
DR – Deliberate release – but also:
DR – Digital radiology
DRA – Drug Regulatory Authority (non-EU)
DRF(S) – Dose range finding (study)
DS – Drug substance
DSC – Differential scanning calorimetry
DSRU – Drug Safety Research Unit (EMA)
DSUR – Development safety update report
DTaP – Diphtheria, tetanus and pertussis
DTC – Direct-to-consumer
DUS – Drug utilisation study
DVPHNFS – Department for Veterinary Public Health, Nutrition and Food Safety (Italy)
Dx – Diagnostic

EA – Environmental assessment
eAF – electronic Application Form
EAI – Estimated acute intake
EAMS – Early Access to Medicines Scheme (UK)
EBE – European Biopharmaceutical Enterprises
EC – Ethics committee – but also:
EC – European Commission
ECDC – European Centre for Disease Prevention and Control
ECG – Electrocardiogram
ECHAMP – European Coalition on Homoeopathic and Anthroposoph 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’
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 & HealthCare
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
EFA – European Federation of Allergy and Airways Diseases Patients' Associations
EFPAA – European Federation of Pharmaceutical Industries and Associations
EFQM – European Foundation for Quality Management
EFTA – European Free Trade Association
EGA – European Generic medicines Association
EHR – Electronic healthcare record
EINECS – European Inventory of Existing Chemical Substances
ELA – Establishment license application (US)
EMA – European Medicines Agency (formerly European Medicines Evaluation Agency – EMEA)
EMCDDA – European Monitoring Centre for Drugs and Drug Addiction
EMEA – see above – but also:
EMEA – Europe, Middle East & Africa
EMEAA – Europe, Middle East, Africa & Asia
EMRC – European Medical Research Councils (a unit of the ESF – see below)
EMVS – European Medicines Verification System
ENCePP – European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
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)
EOP1 – End of Phase 1 (US)
EOP2 – End of Phase 2 (US)
EOQ – European Organization for Quality
EP – European Parliament – but also:
EP/Ph Eur – European Pharmacopoeia (aka Pharm Eur)
EPA – Environmental Protection Agency (US)
EPAA – European Partnership for Alternative approaches to Animal testing
EPADES – European Parliament Document Exchange Server
EPAR – European public assessment report
EPH – European Pharmacopoeia Commission
EPAH – European Public Health Alliance
EPID – Essential Program for Immunisation
EPID – Extended (also Expanded) Public Information Document
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>FIM-A</td>
<td>Federal Institute for Medicines (Austria)</td>
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<tr>
<td>FIMEA</td>
<td>Finnish Medicines Agency (Finland)</td>
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<tr>
<td>FIP</td>
<td>International Pharmaceutical Federation</td>
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<tr>
<td>FMD</td>
<td>Falsified Medicines Directive (EU)</td>
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<tr>
<td>FMEA</td>
<td>Failure mode and effects analysis</td>
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<tr>
<td>FMECA</td>
<td>Failure Modes Effects and Criticality Assessment</td>
</tr>
<tr>
<td>FNOM-CoO</td>
<td>Federazione Nazionale degli Ordini dei Medici-Chirurghi e degli Odontoiatri (IT) = Italian organisation of doctors and dentists</td>
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<tr>
<td>FOFI</td>
<td>Federazione Ordini Farmacisti Italiani (IT) = Italian Organisation of Pharmacists</td>
</tr>
<tr>
<td>FOM</td>
<td>Freedom of Information Act (US)</td>
</tr>
<tr>
<td>FONS</td>
<td>Finding of no significant impact</td>
</tr>
<tr>
<td>FPPIF</td>
<td>Finnish Pharmaceutical Industry Association</td>
</tr>
<tr>
<td>FPP</td>
<td>Finished pharmaceutical product</td>
</tr>
<tr>
<td>FPRC</td>
<td>Final product release control</td>
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<tr>
<td>FPRR</td>
<td>Final product release responsibility</td>
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<tr>
<td>FR</td>
<td>Federal Register (US)</td>
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<tr>
<td>FrP</td>
<td>French Pharmacopoeia (Pharmacopée Française, aka PF)</td>
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<tr>
<td>FSCA</td>
<td>Field safety corrective action (veterinary sector)</td>
</tr>
<tr>
<td>FSIS</td>
<td>Food Safety and Inspection Service (US)</td>
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<tr>
<td>FSN</td>
<td>Field safety notice (medical devices)</td>
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<td>FTC</td>
<td>Federal Trade Commission (US)</td>
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<tr>
<td>FTE</td>
<td>Full Time Equivalent (employee)</td>
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<tr>
<td>FTIM</td>
<td>First-time-in-human</td>
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<tr>
<td>FTIR</td>
<td>Fourier Transform infra-red</td>
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<tr>
<td>FU</td>
<td>Farmacopea Ufficiale – the Italian Pharmacopoeia</td>
</tr>
<tr>
<td>FUM</td>
<td>Follow-up measures</td>
</tr>
<tr>
<td>FVAR</td>
<td>Final Variation Assessment Report</td>
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<tr>
<td>FY</td>
<td>Fiscal year</td>
</tr>
<tr>
<td>GAIN</td>
<td>Generating Antibiotic Incentives Now Act (US)</td>
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<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
</tr>
<tr>
<td>GCC</td>
<td>Gulf Cooperation Council (region)</td>
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<tr>
<td>GCC-DR</td>
<td>Gulf Central Committee for Drug Registration</td>
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<tr>
<td>GCG</td>
<td>Global Cooperation Group (ICH)</td>
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<tr>
<td>GCP</td>
<td>Good clinical practice</td>
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<tr>
<td>GCPv</td>
<td>Good Clinical Practice (Veterinary)</td>
</tr>
<tr>
<td>GDP</td>
<td>Good distribution practice</td>
</tr>
<tr>
<td>GGP</td>
<td>Good guidance practice</td>
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<tr>
<td>GHTF</td>
<td>Global Harmonisation Task Force</td>
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<tr>
<td>GLC</td>
<td>Gas liquid chromatograph</td>
</tr>
<tr>
<td>GLP</td>
<td>Good laboratory practice</td>
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<tr>
<td>GLPMA</td>
<td>Good Laboratory Practice Monitoring Authority (UK)</td>
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<tr>
<td>GMA</td>
<td>Global marketing authorisation</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council (UK)</td>
</tr>
<tr>
<td>GMDN</td>
<td>Global medical device nomenclature (medical devices sector)</td>
</tr>
<tr>
<td>GMIA</td>
<td>Generic Medicines Industry Association (Australia)</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
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<tr>
<td>GMP</td>
<td>Good manufacturing practice – <strong>but also:</strong></td>
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<tr>
<td>GMP</td>
<td>Good management practice</td>
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<tr>
<td>GNA</td>
<td>Grounds for non-acceptance</td>
</tr>
<tr>
<td>GPIA</td>
<td>Generic Pharmaceutical Industry Association (US)</td>
</tr>
<tr>
<td>GPMSP</td>
<td>Good postmarketing surveillance practice (Japan)</td>
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<tr>
<td>GPP</td>
<td>Good paediatric practice – <strong>but also:</strong></td>
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<tr>
<td>GPP</td>
<td>Good pharmacoepidemiology practice</td>
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<tr>
<td>GPP2</td>
<td>Good publication practice</td>
</tr>
<tr>
<td>GpvP</td>
<td>Good pharmacovigilance practice</td>
</tr>
<tr>
<td>GRAS</td>
<td>Generally Recognised as Safe (US)</td>
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<tr>
<td>GRB</td>
<td>Global Regulatory Board</td>
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<td>GRP</td>
<td>Good regulatory practice – <strong>but also:</strong></td>
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<tr>
<td>GSP</td>
<td>Good review practice (US)</td>
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<tr>
<td>GSL</td>
<td>General sales list</td>
</tr>
<tr>
<td>GSP</td>
<td>Good statistics practice</td>
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<td>GTI</td>
<td>Genotoxic impurity</td>
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</tbody>
</table>
GTWP – Gene Therapy Working Party
GVP – Good pharmacovigilance practice
Gxp – general term for “good practice” quality guidelines and regulations, where “x” is the symbol for the variable descriptor

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
HCP – Healthcare professional
HCWP – Healthcare Professionals Working Party (EMA)
HCR – Holder of certificate of registration (South Africa)
HCT – Haematocrit
HDE – Humanitarian device exemption
HDI – Human development index
HEOR – Health economics and outcomes research
HEW – Health, Education and Welfare (US)
HAGC – Human Genetics Advisory Committee
HGPRT – Hypoxanthine-guanine-phosphoribasyltransferase activity
HHS – US Department of Health and Human Services
HIMA – Health Industry Manufacturers Association (US)
HLT – High level term (in MedDRA)
HMA – Heads of Medicines Agencies (Human and Veterinary) (EU)
HMO – Health Maintenance Organisation (US)
HMPC – Committee on Herbal Medicinal Products (EMA)
HoA – Heads of Agencies
HPB – Health Protection Board (Canada)
HPLC – High performance liquid chromatography
HPRA – Health Products Regulatory Authority (formerly Irish Medicines Board)
HR – Heart rate
HRA – Health Research Authority (UK)
HREC – Human Research Ethics Committee
HRT – Hormone replacement therapy
HSA – Human serum albumin
HTA – Health technology assessment
HTS – High-throughput screening

I&AC – Imaging and acute care (medical devices sector)
IAPO – International Alliance of Patients’ Organisations
IB – Investigator’s brochure
IBD – International Birth Date
IBMS – Institute of Basic Medical Sciences (China)
IC – Informed consent
ICD – Informed consent document – but also:
ICD – International Classification of Diseases
ICDRA – International Conference of Drug Regulatory Authorities
ICH – International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICMJE – International Committee of Medical Journal Editors
ICMRA – International Coalition of Medical Regulatory Authorities
ICP-MS – Inductively coupled plasma mass spectrometry
ICSR – Individual case safety report
ICTRP – International Clinical Trials Registry Platform (WHO)
ICx – Inhibition concentration at X%
IDE – Investigational Device Exemption
IDMP – Identification of medicinal products – but also:
IDMP – Infectious diseases management program (US)
IDR – Idiosyncratic drug reaction
IDRAC – International Drug Registration Assisted by Computer
IEC – Independent ethics committee
IFAH – International Federation for Animal Health
IFPMA – International Federation of Pharmaceutical Manufacturers and Associations
IGPA – International Generic Pharmaceutical Alliance
IGZ – the Netherlands Healthcare Inspectorate
III – Inactive ingredient guide (US FDA)
IRAS – Integrated Research Application System
IRP – Independent review panel
IRR – Ionising radiation regulation
IM – Intramuscular – but also: Issue management
IMA – Lyfjastofnun/Icelandic Medicines Agency (Iceland)
IMB – Irish Medicines Board [name changing from 1 July 2014 to HPRA – Health Products Regulatory Authority]
IMCA – Lyfjastofnun/Icelandic Medicines Control Agency (Iceland)
IMDA – Irish Medical Device Association
IMDRF – International Medical Device Regulators Forum
IME – Important medical event
IM(ER)R – Ionising radiation (medical exposure) regulations
IMI – Innovative Medicines Initiative
IMM – Irreversible morbidity or mortality
ImPACT – Imaging performance assessment of CT scanner
IMP – Investigational medicinal product
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
IP – Intellectual property – but also: Intraperitoneal
IPAC – International Pharmaceutical Aerosol Consortium
IPC – International Pharmaceuticals Council
IPEC – International Pharmaceutical Excipients Council
IPR – Intellectual property rights
IPRF – International Pharmaceutical Regulators Forum
IPU – Irish Pharmaceutical Union
IQM – Integrated quality management
IR – Infra-red – but also: Immediate release
IRB – Institutional review board (aka Independent Ethics Committee (IEC) or Ethical Review Board (ERB))
IRC – Institutes Review Committee
IRD – International registration document
IRN – Incident Review Network
IRT – Interdisciplinary Review Team (US)
IS – Information science/systems – but also: Internal standard
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: 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)
JAN – Japanese Approved Name
JAZMP – Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Slovenia’s regulatory agency)
JFDA – Jordan Food & Drug Administration
JNDA – Japanese New Drug Application
JP – Japanese Pharmacopoeia
JPMA – Japan Pharmaceutical Manufacturers Association
J-RMP – Japanese risk management plan (template)
KAS – Known active substance
KFDA – Korean Food and Drug Administration
KIT – Key intelligence topic
KM – Knowledge management
KOL – Key opinion leader
LAT – Light authoring tool (EU)
LCM – Lifecycle management
LD₅₀ – Lethal dose required to kill 50% of the study population
LDH – Lactate dehydrogenase
LED – Least Effect Dose
LEEM – Les Entreprises du Médicament (French Pharmaceutical Industry Association)
LFT – Liver function test
LIF – Läkemedelsindustriföreningen (Swedish Pharmaceutical Industry Association)
LLL – Lifelong learning
LMIC – Low and middle income countries
LOD – Loss on drying
LOI – Letter of intent (US)
LoOI – List of Outstanding Issues
LoQ – List of Questions
LT (stability) – Long term
LTT – Lines to take [document usually not for publication] (EMA)
LVP – Large volume parenterals
M&S – Modelling and simulation
MA – Marketing authorisation
MAA – Marketing authorisation application (EU)
MABEL – Minimal anticipated biological effect level
MAD – Multiple ascending dose (study)
MAFF – Ministry of Agriculture, Forestry and Fisheries (Japan)
MAH – Marketing authorisation holder
MALAM – Medical Lobby for Appropriate Marketing
Mane – Morning
MANSEV – Marketing Authorisation by Network Submission and Evaluation
MAUDE – Manufacturer and User Facility Device Experience (US)
MaxSPRT – Maximised sequential probability ratio test
MCC – Medicines Control Council (South Africa)
MCH – Mean cell haemoglobin concentration
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
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
MDSAP – Medical Devices Single-Audit Programme (Canada)
MDV – Medical device vigilance
MEB – Medicines Evaluation Board (the Netherlands) – also known as Dutch College
MedDev – 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
### Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>MENA</td>
<td>Middle East and North Africa</td>
</tr>
<tr>
<td>MERS</td>
<td>Multi-agency electronic regulatory system</td>
</tr>
<tr>
<td>MgSzH</td>
<td>Mezogazdasagi Szakigazgatasi Hivatal Dictorate of Veterinary Medicinal Products (Hungary)</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency (UK's regulatory authority)</td>
</tr>
<tr>
<td>MHW</td>
<td>Ministry of Health and Welfare (Japan)</td>
</tr>
<tr>
<td>MINE</td>
<td>Medicines Information Network for Europe</td>
</tr>
<tr>
<td>ML</td>
<td>Manufacturer's licence (UK)</td>
</tr>
<tr>
<td>MLD</td>
<td>Minimal lethal dose</td>
</tr>
<tr>
<td>MoA</td>
<td>Mechanism of action – <strong>but also:</strong></td>
</tr>
<tr>
<td>MOA</td>
<td>Ministry of Agriculture</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 On-line Reporting Environment (MHRA) (medical devices sector)</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MPA</td>
<td>Medical Products Agency – Sweden</td>
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<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>MRA</td>
<td>Mutual recognition agreement</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>MRI (scan)</td>
<td>Magnetic resonance imaging (scan) – <strong>but also:</strong></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>MRU</td>
<td>Medicines Regulatory Unit (Health Division Malta)</td>
</tr>
<tr>
<td>MS</td>
<td>Mass spectrometry – <strong>but also:</strong></td>
</tr>
<tr>
<td>MS (EM)</td>
<td>Member state/s (EU)</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 in minor species (veterinary)</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>NAFDA</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>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>NCE</td>
<td>New chemical entity</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute (US)</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>
<tr>
<td>NDS</td>
<td>New drug submission (Canada)</td>
</tr>
<tr>
<td>NED</td>
<td>Non effect dose</td>
</tr>
<tr>
<td>NeeS</td>
<td>Non eCTD electronic submission</td>
</tr>
<tr>
<td>NEFARMA</td>
<td>Netherlands Pharmaceutical Industries Association</td>
</tr>
<tr>
<td>NET WG</td>
<td>New &amp; Emerging Technologies Working Group</td>
</tr>
<tr>
<td>NF</td>
<td>National Formulary</td>
</tr>
<tr>
<td>NFG</td>
<td>Note for Guidance (EU)</td>
</tr>
</tbody>
</table>
OTC – Over-the-counter

P&R – Pricing and reimbursement
P – Pharmacy only (ie, medicinal product dispensed by a pharmacist)
P to GSL – Pharmacy to General Sales List
PA – Product authorisation
PAB – Pharmaceutical Affairs Bureau (Japan)
PAC-ATLS – Post Approval Change – Analytical Testing Laboratory Site (US)
PACMP – Post-approval change management protocol
PAES – Post authorisation efficacy study
PAGB – Proprietary Association of Great Britain
PAI – Pre-approval inspection
PARENT – Patient Registries Initiative (EU)
PAS – Public Affairs Specialist (US)
PASS – Post authorisation safety study
PAT – Process analytical technology – but also:
PAT – Priority Action Team (EFPIA)
PACMP – Post-approval change management protocol
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)
PCG – Product Coordination Group (EU)
PCID – Package identifier
PCT – Primary care trust (UK)
PCWP – Patients’ and Consumers’ Working Party
PD – Pharmacodynamics
PCO – 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)
PDR – Physician’s desk reference
PDUFA – Prescription Drug User Fee Act (US)
PE – Pharmacoconomics
PEAG – Pharmacovigilance Expert Advisory Group (MHRA)
PECA – Protocol to the Europe Agreement on Conformity Assessment and Acceptance of industrial products
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))
P BUSy – Process analytical technology
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)
PFI – Pediatric Formulation Initiative (US)
PGD – Patient group directions (written instructions)
PGENI – Pharmacogenetics for Every Nation Initiative
PGI – Potentially genotoxic impurity
PGx – Pharmacogenomics
PgWP – Pharmacogenomics Working Party
Ph Eur – European Pharmacopoeia
PhARE – Institute for Drug Outcomes Research (the Netherlands)
PhRMA – Pharmaceutical Research and Manufacturers of America
PhI – Pharmacological intelligence
PhPID – Pharmaceutical product identifiers (EU)
PHS – Public Health Service (US)
PhV – pharmacovigilance (aka PV)
PV – Pharmacovigilance
PVAR – Preliminary Variation Assessment Report
PXRD – Powder x-ray diffraction

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/quoter in die]
QIDP – Qualified infectious disease product (US)
QMS – Quality management system
QOL – Quality of life
QoS – Quality overall summary
QP – Qualified person
QPPV – Qualified person for pharmacovigilance
QR (code) – Quick response (code) (EU)
QRD – Quality review of documents [template]
(Q)SAR – Quantitative structure activity relationships
QSE – Quality, safety and efficacy
QSDIT – Quality Systems Inspection Technique (US FDA)
QTPP – Quality target product profile
QUAMED – Quality Medicines for All
QWP – Quality Working Party (EMA)

R&D – Research & development
RA – Rapid alert – but also:
RA – Regulatory affairs
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
RBC – Red blood cell count
RBI – Risk-based inspection
RBM – Risk-based monitoring
RCFID – Registration Certificate for Import of Drug
RCH – Remove clinical hold
RCP – Royal College of Physicians (UK)
RCT – Randomised controlled trial
RDE – Remote data entry
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
REMS – Risk evaluation and mitigation strategy (US)
RFD – Reference dose (veterinary)
RFDD – Regional Food and Drug Director (US)
RH – Relative humidity
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 measure
RMP – Risk management plan – but also:
RMP – Reference medicinal product
RMR – Reaction monitoring report
RMS – Reference member state (Europe)
RoHS – Restriction of hazardous substances (Directive)
ROI – Residues on ignition – but also:
ROI – Return on investment
RoW – Rest of (the) World
RP – Responsible person
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
RRR – Relative risk reduction
RSI – Reference safety information – but also:
RSI – Request for supplementary information (EU)
RTF – Refusal-to-file (US)
RTI – Respiratory tract infection
RTRT – Real time release testing
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
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
SAMM – Safety assessment of marketed medicines (US)
SAP – Scientific advice procedure – but also:
SAP – Statistical analysis plan
SAR – Serious adverse reaction
SAT – Special Action Team (EFPIA)
SAWP – Scientific Advice Working Party
SBA/SBOA – Summary basis of approval (study)
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)
SD rats – Sprague-Dawley rats – but also:
SD – Standard deviation
SDR – Statistic of disproportionate reporting
SE – Standard error – but also:
SE – Substantially equivalent/substantial equivalence
SEAR – Safety, Efficacy and Adverse Reactions (sub-committee of CSM)
SEED Consortium – Shaping European Early Dialogues Consortium
SFDA – Formerly China’s State Food and Drug Administration (now CFDA) but 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
SMK/NMCA – Statens legemiddelverk/Norwegian Medicines Control Agency
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
SNDA – supplemental new drug application (US)
SNDS – Supplemental new drug submission (US)
SOC – System organ class
SOCMA – Society of Chemical Manufacturers and Affiliates
SOCRA – Society of Clinical Research Associates (US-based)
SOP – standard operating procedure
SPA – Special protocol assessment
SPECT – Single photon emission computed tomography
SPC – Summary of product characteristics (typically for veterinary sector) – but also:
SPC – supplementary protection certificate (EU)
SPIN – Special interest network
SPL – Structured product labeling (US)
sq – subcutaneous (aka sc)
SR – Significant risk
SRM – Specified risk materials
SRN – Stroke Research Network (part of NIHR, UK)
SSC – Scientific Steering Committee
SSRI – Selective serotonin reuptake inhibitor
stat – immediately [Latin: statim]
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)
STRPC – Scientific, Technical and Regulatory Policy Committee (EFPIA)
SUD – Single use device – but also:SUD – Sudden unexpected death
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
SWOTs – Strengths, weaknesses, opportunities, threats
SWP – Safety Working Party (CHMP)
Sx – Symptoms

\( t_{1/2} \) – Terminal half-life of elimination

TAG – Technical Advisory Group (UK’s NICE) – but also:
TAG – Therapeutic Advisory Group
TAS (studies) – Target animal safety (studies)
TBC – The Biomarker Consortium
TBG – Thyroid binding globulin
TCA – Tricyclic antidepressant
TCM – Traditional Chinese medicine
TCT – Toxicity, Clinical Trials and Therapeutic Efficacy Subcommittee of the CSM (UK)
TDD – Transdermal drug delivery
TD-PRV – Tropical disease priority review voucher (US)
\( tds/tid \) – three times a day [Latin: ter die sumendum/ter in die]
TE – Therapeutic equivalence
TFEU – Treaty on the Functioning of the European Union
TGA – Therapeutic Goods Administration (Australia’s regulatory agency) – but also:
TGA – Thermogravimetric analysis
THMP – Traditional herbal medicinal product
THMPD – Traditional Herbal Medicinal Products Directive
THMRS – Traditional Herbal Medicines Registration Scheme
THR – Traditional herbal registration
TIGes – Telematic Implementation Group–electronic submissions
TIND – Treatment IND (see IND)
TK – Thymidine kinase – but also:
TK – Toxicokinetics
TLC – Thin layer chromatography
TLV – Threshold limit value
TMF – Trial Master File
TOC – Table of contents
TOD – Table of decisions
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
TRL – Total residue level (veterinary)
TSA – Therapeutic Substances Act
TSE – Transmittable spongiform encephalopathy
TTC – Threshold of toxicological concern
UDI – Unique device identification
ULTRA – Unlocking Lifesaving Treatments for Rare-Diseases Act (US)
UMBRA – Unified Methodologies for Benefit–risk Assessment
UMP – Beijing Union Medical and Pharmaceutical General Corp (the innovative arm of the Chinese Academy of Medical Sciences)
UPS-NF – United States Pharmacopeia and National Formulary
USAN – United States Approved Name
USC – United States Code
USDA – United States Department of Agriculture
USKVB – Ústav pro Statní Kontrolu Veterinárních Biopreparátu a Leciv (Institute for State Control of Veterinary Biologicals and Medicines) (Czech Republic) – also: Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (Department of State Control of Veterinary Biologicals and Medicaments) (Slovenia)
USP – United States Pharmacopeia
USPT – United States Product Insert
USP-DI – United States Pharmacopeia-Drug Information
USP-NF – United States Pharmacopeia-National Formulary
USR – Urgent safety restriction
UTI – Urinary tract infection
UUP – Urgent union procedure (European Commission)
VAERS – Vaccine adverse event reporting system (US)
VAESCO – Vaccine adverse event surveillance & communication
VAF – Virus antibody free
VAI – Voluntary action indicated
VAMF – Vaccine antigen master file
VAR – Variation assessment report
VBA – Value-based assessment
VBP – Value-based pricing
VDD – Veterinary Drugs Directorate (Canada)
VF – Ventricular failure
VHP – Voluntary harmonisation procedure
VICH – International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products
VIPP – Verified internet pharmaceutical practice site (US)
VMD – Veterinary Medicines Directorate
VMP – Veterinary medicinal product
VMRF – Veterinary Mutual Recognition Facilitation Group
VNeeS – Veterinary non-eCTD electronic submission
VPC – Veterinary Products Committee (UK)
VTE – Venous thromboembolism
VWP – Vaccines Working Party
WBC – White blood cell
WC – Written confirmation (issued by competent authority)
WCPB – Women of childbearing potential
WEBAE – Web adverse event(s)
WGEO – Working Group of Enforcement Officers (HMA)
WHO – World Health Organization
WL – Warning letter – but also:
WL – Wholesale dealer’s licence
WRAC – Worldwide Regulatory Affairs Committee
WTO – World Trade Organisation
XEVIMPD – Extended EudraVigilance Investigational Medicinal Product Dictionary
XEVMPD – Extended EudraVigilance medicinal products dictionary
XEVPRM – Extended EudraVigilance product report message
XRF – X-ray fluorescence
ZVA – Zalu Valsts Agentura (State Agency for Medicines) (Latvia)

[Last updated 5 August 2014]