Glossary

This list contains a glossary of commonly used words, phrases and abbreviations which may be particularly useful to those new to the Agency. The list is compiled by the Library team, please contact Information Services to suggest amendments.

Term	Definition
A-D	
ABHI	Association of British Healthcare Industries.This is the trade association representing medical device technology manufacturers and distributors in the UK
ABPI	Association of the British Pharmaceutical Industry. This is the trade association representing the manufacturers of prescription only medicines in the UK
Abridged application	An application for a marketing authorisation in which the applicant is not required to provide full results of tests and trials because the product is essentially similar to one already licensed in the UK (or the constituents of the product have a well established medicinal use)
ADR	Adverse Drug Reaction. A harmful and unintended reaction that occurs at a dose normally used for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function
ADROIT	Obsolete term. Replaced by the Sentinel PV Case Folder
AEGIS	Obsolete term. Replaced by secure internet portal
AFSAPPS	The French Medicines Regulator
AGES	Austrian Agency for Health and Food Safety
AI	Adverse incident. This is an event that produces, or has the potential to produce, unwanted effects involving the safety of patients, users or other persons
AIMDD	Active Implantable Medical Devices Directive

AITS	Adverse Incident Tracking System. This is the the MHRA internal database for processing and monitoring medical adverse incident reports from health professionals and members of the public
AM	Agency Memorandum. An official notice about MHRA developments
API	ctive Pharmaceutical Ingredient
AR	Assessment Report
ARM	Application to reclassify a medicine. A consultative letter issued when an application is made for a change in legal status of a product
ASMF	Active Substance Manufacturer. A Marketing Authorisation Holder will often purchase the active from an external supplier and the MHRA will refer to their drug master file
ASPRs	Anonymised Single Patient Reports. [Formerly ASPPs: Anonymised Single Patient Print Outs]
ATC	Anatomical, Therapeutic, Chemical. This is a World Health Organisation classification of drug substances
AT	Assistive Technology. This is any device or technology that assists a disabled person. Formerly: P&CC
AXREM	Association of X-ray Equipment Manufacturers
BAN	British Approved Names. This is a list of officially recognised names of medicinal substances produced by the British Pharmacopoeia Commission.
BARQA	British Association of Research Quality Assurance
BCPNN	Bayesian Confidence Propagation Neural Network – used for drug safety signal detection
BCGA	British Compressed Gases Association
BAV	British Avenue, Blackpool (Centre for Assistive Technology).
BEMA	Benchmarking of European Medicines Agencies

BfArM	German Federal Institute for Drugs and Medical Devices
BGMA	British Generic Manufacturers Association –represents the interests of UK based manufacturers and suppliers of generic medicines and promotes development of generic medicine industry.
BHMA	British Herbal Medicines Association – represents the interests of herbal medicine in the United Kingdom and ensures its continued statutory recognition.
Biological medicinal products **Biological products** **Biopharmaceutical products**	A biological medicinal product contains an active biological substance. The following are considered as biological medicinal products: recombinant proteins, monoclonal antibodies, blood products and immunological products such as sera and vaccines, allergens and advanced technology products such as gene and cell therapy products.
Biologicals	Products which cannot be tested adequately by chemical means such as vaccines.
Biosimilar	The active substance of a biosimilar medicine is comparable to a biological reference medicine. Biosimilar and biological reference medicines are used at the same dose to treat the same disease. The name, appearance and packaging of a biosimilar medicine differs to that of a biological reference medicine.
Biotechnology	A biotechnology product is one manufactured by recombinant DNA technology, one where genetic manipulation of cells is required, or a monoclonal antibody. Applications for these products are required to be submitted through the European Centralised procedure.
BIR	British Institute of Radiology. The BIR is unique in the UK as a multidisciplinary radiological organisation which welcomes all radiological professionals into its membership. Equal medical/non-medical representation is maintained on its Council. Multidisciplinary collaboration and networking is fostered in particular through its scientific committees and scientific meetings.
BMA	British Medical Association
BNF	British National Formulary. This is a list of medicines used in the UK compiled by the British Medical Association and the Royal Pharmaceutical Society.

Borderline products	Products which are close to the boundary between medicines which need a licence, and products such as nutritional supplements, cosmetics etc. which do not. Classification depends either on the ingredient or the claim or both
BP	British Pharmacopoeia. This is the only comprehensive collection of standards for UK medicinal substances. It is an essential reference for all individuals and organisations involved in pharmaceutical research, development, manufacture and testing.
BPC	British Pharmacopoeia Commission. is responsible for preparing new editions of the British Pharmacopoeia and for selecting and devising British Approved Names (BANs).
BROMI	Better Regulation of Over the Counter Medicines Initiative.
BSE	Bovine Spongiform Encephalopathy
BSI	British Standards Institution
CA	Competent Authority. This is a body which has the authority to act on behalf of the government of an EU Member State to ensure that the requirements of the Directives are carried out in that MemberState
CAP	Centrally authorised product. In the European Union (EU), a company may submit a single application to the European Medicines Agency (EMA) for a marketing authorisation (licence) that is valid simultaneously in all EU Member States, plus Iceland, Liechtenstein and Norway. This is mandatory for certain types of medicines and optional for others
CAS	Current Awareness Service. This is a service provided by the Library services of the Information Centre designed to help you stay informed of relevant research, news and issues for your business area. The main parts of the service include selective dissemination of articles from scientific journals; the provision of electronic table of contents alerts for new issues of journals and the circulation of print journals
Case	The Sentinel application suite includes a case-based system, in which requests are progressed and tracked as individual cases. A case (or casefolder) is a single unit of work. Different types of cases represent different types of submissions in the lifecycle. Generally speaking there is an initial case which following approval can result in further submissions

	for amendments or changes (referred to as variations in the Product Licence Case Folder).
Case attributes	The case attributes page within a casefolder that contains high level information about the case. For example, for a Product Licence case this is where information can be found about the submission type, type of procedure and worktype. Other information includes: Product Name, Active Substances, etc
CAPLA/CANDA	Computer Assisted Product Licence Application/ Computer Assisted New Drug Application. This is a means of submitting product licence applications by computer
CBER	(FDA) Centre for Biologics Evaluation & Research
CCDS	Core company data sheet is a company-internal global reference labelling document used to direct the content of local (affiliate) labelling. The CCDS may also be used as an attachment to a Periodic Safety Update Report (PSUR), in this context, all the safety information in a CCDS, or a specifically identified (e.g by bold print) subset of this safety information, serves as reference information for determining “listedness”
CD	A controlled drug
CDF	Competence Development Framework
Centralised application	This is part of the EU licensing system resulting in a single European MA and direct access to a single community market. The Rapporteur/ Co-rapporteur are responsible for the pre-authorisation assessment and the Rapporteur continues with post-authorisation evaluation and pharmacovigilance via the EMA. Refer to the EudraPharm database on the EMA’s website for comprehensive information on Centralised Products.
CDRH	The Centre for Devices and Radiological Health is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products. Radiation-emitting products regulated by the CDRH include medical ultrasound and x-ray machines.
CE(O)	Chief Executive (Officer).
CE MARK	European mark of approval for medical devices

CEN	Comité Européen de Normalisation (European Committee for Standardization).
CENELEC	Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardization).
Centralised procedure	This is part of the EU licensing system resulting in a single European MA and direct access to a single community market. The Rapporteur/ Co-rapporteur is responsible for the pre-authorisation assessment and the Rapporteur continues with post-authorisation evaluation and pharmacovigilance.
CEP	Central Enquiry Point. This is the first contact point for callers to the MHRA who do not know who they wish to speak to.
CFC	Chlorofluorocarbons. These are used as propellants in aerosols and are currently being phased out in inhalers
CHAI	Obsolete acronym. See: Care Quality Commission
CHI	Obsolete acronym. See: Care Quality Commission
CMD(h)	Coordination Group for Mutual Recognition and Decentralised procedures (human).
CHM	Commission on Human Medicines. Formed by the amalgamation of the Medicines Commission and the Committee on the Safety of Medicines.
CHMP	Committee for Medicinal Products for Human Use (CHMP) This is a European Committee based at the EMA
CIOMS	Council for International Organizations of Medical Sciences. A WHO authority.
CJD	Creutzfeldt-Jakob Disease
CLIN	Clinical Division
CMS	Concerned MemberState. This is a member state involved with the licensing process but not the state doing the assessment.
COMMS	Communications Division.

Concertation procedure	Obsolete term. See: Centralised procedure
Co-rapporteur	Works with rapporteur to provide expert evaluation for a centralised procedure. See also Rapporteur
CPD	Continuing Professional Development
CPRD	Clinical Practice Research Datalink
CPS	Chemistry Pharmacy and Standards Sub-Committee
CQC	Care Quality Commission
CR	Computed radiology
CRCSV	Clinical Research Computerised System Validation
CRO	A clinical services business involved in the clinical trial process on behalf of medicines or devices manufacturers
CSCI	Obsolete acronym. See: Care Quality Commission
CSD	Committee on the Safety of Devices. This is an external group responsible for giving advice on a wide range of device related initiatives
CSM	Obsolete acronym. See: CHM
CT	Computed tomography
CTA	Clinical trial authorisation
CTD	Clinical Trials Directive. Common Technical Document.
CVMP	Committee for Veterinary Medicinal Products
DAP	Drug analysis print. Prepared from the ADROIT (q.v.) database. Aggregated information about suspected adverse drug reactions collected through the Yellow Card scheme
DB	Device Bulletin

DCP	DeCentralised Procedure. This is applicable in cases where an authorisation does not yet exist in any of the EU Member States.
DDL	Dear Doctor Letter. This is an important communication tool that can aid education and risk management for healthcare professionals
DDPS	Detailed Description of Pharmacovigilance System
DDX	Doctors and Dentist Exemptions. These are letters of approval issued by the Clinical Trials Section to doctors and dentists who want to do drug research.
DG	Directorate General (of the European Commission)
DH	Department of Health
DHPC	Direct healthcare professional communication. Sometimes translated as 'Dear Healthcare Professional communication'
DIA	Drug Information Association
DIRC	Departmental Industrial Relations Council
DLP	Data Lock Point. This is defined as the cut-off date for data to be included in a PSUR. It may be set according to the European birth date (EBD) or IBD of the medicinal product
DMF	Drug Master File. This describes the active substance manufacturing process. [See: ASM]
DMRC	Defective Medicines Report Centre. This is a Unit in IESD that assesses suspected quality defect reports and co-ordinates product recalls.
DOB	Distribution of Business. The DH business activity directory.
DR	Digital radiology
DSRU	Drug safety research Unit. This is an independent unit in Southampton that collects information on significant events in patients who have been prescribed selected new medicines.
DSU	Drug Safety Update

DTS	Device Technology & Safety. Obsolete term. Devices Division until 2010.
E-H	
EAG	Expert Advisory Group
EAMS	Early access to medicines scheme
EB	Executive Board
EBGM	Emperical Bayes Geometric Mean. Used for drug safety signalling. An estimate of the relative reporting rate taking into account statistical variability due to small counts, small expected values, and multiple comparisons. Typically, an EBGM of ≥2.5 is taken as the cut off point for identifying potential signals
EC	See: EU
eCTD	electronic Common Technical Document
ECPHIN	European Community Pharmaceutical Information Network
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area. Member States of the EC together with Iceland, Leichtenstein and Norway.
EEC	See: EU
EFTA	European Free Trade Association
EFPIA	European Federation of Pharmaceutical Industries Associations. European equivalent of the ABPI.
EFQM	European Foundation for Quality Management. This was created in 1989 to promote quality management within European businesses.
EMACOLEX	A group of European lawyers from health departments and regulatory agencies.
EMA	European Medicines Agency. The European Medicines Agency is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed

	by pharmaceutical companies for use in the European Union.
EMEA	European Medicines Evaluation Agency. Obsolete term. See: EMA
EORTC	European Organisation for Research & Treatment of Cancer
EP	See: Ph. Eur.
EPAR	European Public Assessment Report for medicines
EPID	Extended (also Expanded) Public Information Document. This provides information about their products, provided by the pharmaceutical industry to the public.
EQA	European Quality Award. An award given to business organisations by the EFQM for practicing quality management in their area of business.
ERA	(Devices Policy) European & Regulatory Affairs. Part of Policy Division.
ETSI	European Telecommunications Standards Institute
EU	European Union. Currently comprised of 27 member states.
EUDRA	European Union Drug Regulatory Authorities
EudraCT	The Clinical Trial application and database, which is hosted by the EMA.
EudraGMP	The Community database containing information on all pharmaceutical manufacturers. It also includes details of those manufacturers' Manufacturing and Importation Authorisations and GMP Certificates. EudraGMP is typically accessed by Inspectorates. Write access to EudraGMP requires user authentication.
EUDRALEX	Web server for the on-line dissemination of Community guidelines, Notice to Applicants and pharmaceutical legislation.
EUDRALINK	As EudraNet II can only be accessed and used by the National Competent Authorities, the EudraLink secure communication service has been developed allowing secure information exchange with pharmaceutical industry, research institutes and pharmaceutical experts via the Public Internet.
EUDRAMAIL	A dedicated secure e-mail system based on functional mailboxes, which

	allow working groups to exchange messages relevant to their specific group.
EUDRANET	A European human and veterinary pharmaceuticals telecommunication network allowing scientific experts, those working on pharmaceutical business processes and policy makers to have a secure and well structured electronic environment to 'meet', exchange information and work together on a pan-European scale.
EUDRANET II	EudraNet II is a managed virtual private IP network (IP VPN) based on encrypted tunnels over the public Internet. It uses the IPSec protocol and 3DES encryption. EudraNet II is a star shaped network with the EMA being the central site. A second star network has been implemented to allow access to the CTS database, which is hosted at DIMDI in Cologne, Germany.
EUDRAPHARM	The central European database providing core data on all centrally authorised medicinal products, including MRLs for veterinary medicinal products and nationally authorised products from Member States ready to supply data as part of a pilot exercise.
EUDRAPORTAL	The central entry point for all the Eudra applications. The portal will evolve to become a communications platform for the Eudra community.
EUDRATRACK	A tracking and communication system for Mutual Recognition and decentralised applications for member states.
EudraVigilance	A data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).
EURD list	List of European Reference Dates and frequency of submisison of Periodic Safety Reports. The new legislation introduces the principle of EU single assessment of periodic safety update reports (PSURs) where a substance is authorised in more than one Member State and establishes the list of European Union Reference Dates (EURD).
EVMPD	EudraVigilance Medicinal Product Dictionary
FARAW	Fairness & Respect at Work. This is the formal DH/MHRA grievance policy.

Fast tracking	The urgent processing of a licence application by the MHRA.
FDA	Food and Drug Administration. The MHRA/FSA equivalent in the United States.
FIN	Finance Division. Now part of Operations & Finance.
FOI	Freedom Of Information. The FOI Act allows easier access to official information.
FSA	Food Standards Agency
FVAR	Final Variation Assessment Report. Report produced after assessment of company responses at the end of a variation procedure
GCP	Good Clinical Practice. Guidelines for the conduct of clinical trials of medicines. The GCP Inspectorate is part of the Inspection, Enforcement and Standards Division.
GDP	Good Distribution Practice. That part of quality assurance which ensures that products are consistently stored, transported and handled under suitable conditions.
Generic medicine	A copy of a medicine no longer protected by patent, labelled with an approved name or brand name (“branded generics”). It contains the same active ingredient as an originator’s existing, licensed medicine although it may be of a different strength and/or presentation.
GHTF	Global Harmonisation Task Force. This was conceived in 1992 to achieve greater uniformity between medical device regulatory systems.
GLP	Good Laboratory Practice. This is a recognised standard for laboratories which conduct safety tests in which laboratory studies are planned, performed, monitored, recorded, reported and archived.
GLPMA	Good Laboratory Practice Monitoring Authority. This is a team within the Inspection, Enforcement and Standards Division.
GMDN	Global Medical Device Nomenclature. This provides provides generic descriptors for the identification of medical devices and other healthcare related products.
GMO	Genetically Modified Organism

GMP	Good Manufacturing Practice. This is a recognised standard for pharmaceutical processing and manufacture ensuring medicinal products are consistently produced and controlled.
GMPLA	Good Manufacturing Practice Licensing Authority
GP	General Practitioner
GPvD	Good Pharmacovigilance Practice. The MHRA Pharmacovigilance Inspectorate is part of the Inspections, Enforcement and Standards Division of the MHRA. It assesses pharmaceutical companies' compliance with UK and EU legislation relating to the monitoring of the safety of medicines given to patients.
GSI	Government Secure Intranet
GSL	General Sales List. This is a category of medicines which may be sold without the supervision of a pharmacist, equivalent to over-the-counter sales.
GxP	General abbreviation for Good Practice standards.
Herbal highs	Products that mimic, or claim to mimic, the effects of controlled drugs.
HFMA	Health Food Manufacturers' Association
HMA	Heads of Medicines Agencies
HMPC	European Committee on Herbal Medicinal Products
HMSO	Her Majesty's Stationery Office, now part of the National Archives. See also: TSO.
HPA	Health Protection Agency. This was established in its current form in 2005 and incorporates the NRPB. To be abolished shortly.
HR	Human Resources Division
HSA	Singapore Health Sciences Authority
HSE	Health & Safety Executive

I-L	
IA	Impact Analysis.
IAG	Inspection Action Group
I&AC	Imaging and Acute Care. A unit within Devices.
ICH	International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use. This is specifically for technical requirements for registration of pharmaceuticals for human use. This is a group consisting of the US, Japan and the EU regulatory authorities and experts from the pharmaceutical industry
ICR	The International Conference on Harmonisation of Technical Requirements for Human Use
ICR	Institute of Clinical Research
ICSR	Individual Case Safety Report. This includes technical information on MHRA specific additional requirements to incorporate when submitting electronic reports, between marketing authorisation (MAHs)holders and the MHRA
IE&S	Inspections, Enforcement and Standards Division
IiP	Investors in People
IM	Intramuscular. An intramuscular (IM) medication is injected directly into the muscle.
IMD	Information Management Division
IMP	Investigational medicinal products. These are unlicensed medicines undergoing clinical trial.
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
ImPACT	Imaging Performance Assessment of CT scanners. This is one of twelve CEP device evaluation centres in the UK, based at Tooting, London.
IMS	Information Management Strategy

INFARMED	The Portuguese National Authority of Medicines & Health products
INN	International Nonproprietary Name. This is the official non-proprietary or generic name given to a pharmaceutical substance. (See also rINN).
IP	International and Parliamentary function. This is a team situated within Policy Division.
IPEM	Institute of Physics and Engineering in Medicine
IPU	Information Processing Unit. This is part of the Information Management Division (IMD) responsible for receiving and entering pharmaceutical company submissions onto Sentinel.
IRAS	Integrated Research Application System. This is a single system for applying for the permissions and approvals for health and social care/community research in the UK. It streamlines the process for seeking relevant approvals as you are not required to enter the details for a single projrct in separate application forms.
IRC	Industrial Relations Council. This is the MHRA management/unions consultative committee.
IRG	Independent Review Group on silicone gel breast implants.
IR(ME)R	IR(ME)R Ionising Radiation (Medical Exposure) Regulations
IRR	Ionising Radiation Regulations
IUPAC	International Union of Pure & Applied Chemistry
IWG	Inspectors Working Group
IVDMDD	In Vitro Diagnostic Medical Device Directive
ISAC	Independent Scientific Advisory Committee for MHRA database research.
ISBN	International Standard Book Number. This is used by the publishing industry to identify a specific item.
ISO 9000	A series of international standards for quality systems.
IUCD	IntraUterine Contraceptive Device

IUD	IntraUterine Device. See: IUCD
IVDs	In Vitro Diagnostic Medical Devices. For example, test kits used to examine specimens derived from the body.
IV	Intravenous ["within a vein"].
JPAC	Joint Professional Advisory Committee
JSS	Job Specific Selection. The system used within DH/MHRA to fill internal vacancies.
LGC	Laboratory at Teddington. [Formerly the Laboratory of the Government Chemist, now an independent chemical analysis laboratory].
LibCat	The DH library catalogue containing holdings of the MHRA and the Department of Health, accessible from a PC in the InfoSpace (4.T).
M-P	
MAC	Microbiology Advisory Committee
MA	Marketing Authorisation. This is the European licensing system for medicines that replaced the Product Licence (PL) system.
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MAIL	Medicines Act Information Letter. Journal replaced by the Medicines Regulatory News section of the MHRA website in 2007.
MAL	Medicines Act Leaflet. This is an information booklet covering particular aspects of the Medicines Act. Replaced in 1998 by the MHRA Guidance Note series.
MC	Medicines Commission. See: CHMP
MCA	Medicines Control Agency. Merged with the Medicines Devices Agency in 2003 to become the MHRA.
MDA	Medical Devices Agency. Merged with the Medicines Control Agency in 2003 to become the MHRA.

MDA	Medical Device Alert. Issued since 2003 and replaced Hazard Notices, Safety Notices, Advice Notes and Device Alerts.
MDD	Medical Devices Directive
MDD	Medical Devices Directorate. Obsolete acronym. Pre-1994 forerunner to Medical Devices Agency.
MDLO	Medical Device Liaison Officer. This person's primary role is to encourage the effective reporting of adverse incidents.
MDR	Medical Device Reporting or Medical Device Regulations (SI 2002/618 and 2003/1697).
MEDDRA	Medical Dictionary for Drug Regulatory Affairs (See also MedDRA).
MedDRA	Medical Dictionary for Regulatory Activities. This is the internationally accepted medical terminology for use in drug regulation. Developed under the auspices of the ICH and based on MEDDRA which was in turn based on the MHRA's medical dictionary.
Mediated online literature searching	Service provided by the Library services of the Information Centre. Authoritative databases such as Embase, Biosis and SciSearch are searched to provide literature reviews containing information not available via Google.
Medicines Division	A division in DH; previous name for MCA (now MHRA).
MEDS	Management of Electronic Document Strategy. This is a Lotus Notes based DH/Device Records Management System (RMS).
Member states	This term means a member state of the European Union (EU). See Wkipedia entry here: Member State of the European Union.
MGPS	Multi-item Gamma Poisson Shrinker. Used for drug safety signal detection.
MHRA	Medicines and Healthcare Products Regulatory Agency
MIA	Manufacturers/Importers Authorisation
MISG	Ministerial Industry Strategy Group

ML	Manufacturer's Licence. This is required by manufacturers of medicinal products in the UK.
MLX	MLX Consultative letters sent out by the MHRA to interested organisations, companies and individuals when considering proposals to amend the Orders and Regulations made under the Medicines Act.
MORE	Manufacturer's On-line Reporting Environment. This is a web based system for device manufacturers to submit reports to the MHRA.
MRA	Mutual Recognition Agreement. MRAs are agreements between the EU and third countries to recognise each others' Good Manufacturing Practices.
MRC	Medical Research Council
MRFG	Mutual Recognition Facilitation Group. Now obsolete. See: CMD(h.)
MRI	Magnetic resonance imaging
MRP	Mutual Recognition Procedure. Regulatory process whereby member states recognise an authorisation already granted in another member state.
MS	Member State
MT	Obsolete acronym. MarketTowers. MHRA headquarters in Vauxhall, London until 2010.
MTL	Medicines Testing Laboratory. This was formerly the Laboratory of the Government Chemist and is based at Teddington.
MTS	The MHRA's Medicines Testing Scheme. This exists for sampling and testing medicines, both planned market surveillance and "one-off."
Multi-state procedure	Obsolete term. See: Mutual Recognition.
Mutual recognition	Part of the EC licensing system. Aimed at facilitating access to a single market using the principle of Mutual Recognition. Identical dossiers are submitted to the Reference Member State (RSM) and the Concerned Member States (CSM). The second or subsequent MemberState should mutually recognise, within 90 days, the MA in the RMS.

NAO	National Audit Office
NAP	Nationally Authorised Product
NAS	New Active Substance. This is a new chemical or biological substance.
NB	Notified Body. This is a certification organisation which the Competent Authority of a MemberState has designated to carry out in an independent manner one or more of the Conformity Assessment Procedures described in the annexes of the Directives.
NBOG	Notified Body Operations Group. This is a a Europe wide group ensuring Notified Bodies operate to common standards.
NBTC	National Blood Transfusion Committee
NCA	National Competent Authority
NCAS	National Clinical Assessment Service. This service monitors the performance of doctors and dentists (Formerly the National Clinical Assessment Authority).
NCE	New Chemical Entity.
NCRN	National Cancer Research Network
ND	Norsk Data. This is the original computer system on which the Product Licence Database was stored.
NHS	National Health Service.
NIBSC	National Institute for Biological Standards and Control. This body provides independent testing of biological medicines.
NICE	National Institute for Health and Care Excellence, a non-departmental public body responsible for providing national guidance and advice to improve health and social care.
NIHR	National Institute for Health Research
NOP	Non-Orthodox Practitioner. For example, homeopaths.
NOS	Not Otherwise Specified

NPSA	National Patient Safety Agency. This is a special health authority created to monitor medication errors and other patient safety incidents occurring in the NHS.
NRES	National Research Ethics Service
NRPB	National Radiological Protection Board. [See Health Protection Agency].
NUI	Non-Urgent request for information
OCTGT	(FDA) Office of Cellular, Tissue & Gene Therapies
OH	Occupational Health.
OECD	Organisation for Economic Cooperation and Development.
OG	Open Government.
OGD	Other Government Department.
OIS	The Department of Health's IT system.
OMCL	Official Medicines Control Laboratory
Orange guide	Alternative title for the "Rules and Guidance for Pharmaceutical Manufacturers and Distributors" because of its orange cover.
Orphan drug	A drug for a rare disease. The indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence .
OTC products	Over the Counter products. For example, aspirin tablets bought in a chemist shop. Encompasses both Pharmacy (P) and GSL status in the UK. Not necessarily kept behind a counter.
P (Medicine)	Pharmacy medicines. This is a category of medicine which does not require a prescription but which has to be sold under the supervision of a pharmacist. "P" appears on the label.
P&CC/ WMS	See: AT
PACS	Picture Archiving and Communications Systems.
PACSnet	Picture Archiving and Communications Systems National Evaluation

	Team. Provides independent technical evaluation of PACS. Based in the Modern Physics Department of St George'sHospital in London
PAES	Post Authorisation Efficacy Study. These are studies looking at the efficacy or effectiveness of a drug, usually conducted as part of a product's risk management plan (RMP). They are epidemiological studies or, on some occasions, clinical trials carried out in accordance with the terms of the marketing authorisation.
PAGB	Proprietary Association of Great Britain. This association represents represents manufacturers mainly producing OTC/P medicines.
Parallel import	A pharmaceutical product therapeutically equivalent to an existing licensed UK product and licensed in the UK in accordance with the rules of the parallel import scheme.
PAR	Public Assessment Report. In accordance with Directive 2004/27/EC, the MHRA makes a scientific assessment report called a Public Assessment Report available for new licenses granted after 30 October 2005, albeit with commercially or personally confidential information removed.
PASA	Purchasing and Supply Agency. This is an executive agency of the Department of Health that promotes value for money when purchasing goods and services.
PASS	Post Authorisation Study. These are studies looking at the safety of a drug, usually conducted as part of a product's risk management plan (RMP). They are epidemiological studies or, on some occasions, clinical trials carried out in accordance with the terms of the marketing authorisation.
PAT	Process Analytical Technology
PCT	Primary Care Trust.
PCS	Public and Commercial Services Union.
PDA	Performance Development Agreement.
PDA	Parenteral Drug Association
PDCO	Paediatric Committee. EMA committee to assess the content of paediatric investigation plans and give other advice relating to medicines for children

	and EU Paediatric Regulation.
PDP	Personal Development Plan.
PEAG	Pharmacovigilance Expert Advisory Group
PEG	Paediatric Expert Group. Now defunct advisory committee to EMA on Paediatric matters prior to implementation of Paediatric Regulation.
PEM	Prescription Event Monitoring. Scheme run by DSRU that provides proactive post-marketing surveillance on a national scale.
Person appointed	Independent assessor(s) appointed by the Licensing Authority to hear an appeal against a proposed licensing action.
PET	Positron emission tomography
PET/CT	Positron emission tomography (PET) and computerized tomography (CT).
PFL	A prefix applied to all MHRA policy files.
PGD	Patient Group Directions. PGD's are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.
Pharmacopoeia	A compendium of standards for pharmaceutical or chemical substances.
Pharmacovigilance	A technical term used for identifying and responding to risk/benefit issues emerging for authorised medicines as used in clinical practice, and including the effective dissemination of such information to optimise the safe and effective use of medicines.
Ph. Eur.	A commonly used abbreviation for the European Pharmacopoeia.
PHSS	Pharmaceutical & Healthcare Sciences Society
PhVWP	Pharmacovigilance Working Party. A working party of the CHMP.
PIC	Pharmaceutical Inspection Convention. An international organisation which mutually recognises inspection reports on manufacturers (excludes EC members).
PICS	Pharmaceutical Inspection Co-operation Scheme. The scheme's goal is to

	improve cooperation between regulatory authorities and the pharmaceutical industry in the field of Good Manufacturing Practice.
PIEAG	Patient Information Expert Advisory Group.
PIL	Patient Information Quality. Part of VRMM Division dealing with labelling and leaflets for medicines. [Formerly: Patient Information Unit].
PIP	Paediatric Investigation Plan. Contains proposals of studies to support the use of a drug in all individuals from birth to age 18 years.
PIQ	Patient Information Quality. Part of VRMM Division dealing with labelling and leaflets for medicines. [Formerly: Patient Information Unit].
PIU	See: PIQ
PL	Product Licence. See: Marketing authorisation.
PLAT	Product Licensing Assessment Teams.
PL(PI)	Product Licence (Parallel Import) See also Parallel Import
PLR	Product Licence of Right. This is a licence granted to medicines already on the Market when the 1968 Medicines Act came into force. See also Committee on Review of Medicines
Plus	Product Licence User System. This managed the medicines licensing process and has been replaced by SENTINEL..
PMEAG	Paediatric Medcines Expert Advisory Group.
PMDA	Japanese Pharmaceuticals and Devices Agency
PMS	Post-Marketing Surveillance. This is adverse reaction monitoring for medicines already in the UK market.
PO	Private Office. Encompasses ministers and top civil servants. [These initials also refer to correspondence from MPs and Ministers].
POM	Prescription only medicines i.e. medicines available only on prescription from a doctor.
POM TO P	The means by which a Prescription Only Medicine can become a

	Pharmacy Medicine [i.e. available only from a pharmacist]. It is also known as “de-pomming.”
PPI	Patient Pack Initiative.
PPE	Patient and Public Engagement.
PQ	Parliamentary Question i.e. a question asked by an MP in the House of Commons or from a member of the House of Lords. This may be an oral question or one put down for a written answer.
PQG	Pharmaceutical Quality Group
Prospect	The union for MHRA professionals, negotiates on your behalf at the MHRA, Department of Health and Civil Service levels on pay and conditions, and takes up personal cases.
PRAC	Pharmacovigilance and Risk Assessment Committee. This committee is responsible for all aspects of the risk management of medicines in the EU. The PRAC will provide recommendations to the CHMP or the CMDh (depending on the type of procedure and authorisation route of the medicinal products involved), the EMA and European Commission.
PR	Peer Reviewer.
PRP	Performance Related Pay.
PRR	Proportional Reporting Ratio. Used for drug safety signal detection. A statistical tool used in signal detection, which compares the proportion of reports for a specific adverse reaction reported for an individual drug with the proportion for that reaction in all other drugs (the background proportion). Typically, a PRR of ≥2 is taken as the cut off point for identifying potential signals – ie when the reaction of interest accounts for at least twice the proportion of the total reports than the ‘background’ proportion.
PRRs	Proportioned Reporting Ratios.
PSD	Pharmacovigilance Service Desk.
PSG	Professional Skills for Government.
PSMF	Pharmacovigilance Systems Master File. The new legislation from 2 July

	2012 for products authorised via the Centralised procedure and from 21 July 2012 for Mutual Recognition/Decentralised and National procedures – requires the introduction of a Pharmacovigilance System Summary in the marketing authorisation (MA), and removes the requirement for new applications to contain a Detailed Description of the Pharmacovigilance System, DDPS.
PSURs	Periodic Safety Update reports. Once a medical product is registered in the EU, Periodic Safety Update Reports (PSUR) must be submitted. These provide an update of the worldwide safety experience of a medicinal product to Competent Authorities at defined time points post-authorisation.
PT	Preferred Term. Part of MedDRA terminology. Medical/clinical term is recognised and agreed internationally (e.g. pancytopenia).
PUMA	Paediatric-Use Marketing Authorisation. These are granted by the European Medicines Agency (EMA) for medical products that are intended exclusively for paediatric use, that is, for use in patients younger than 18 years. Like ordinary EMA marketing authorisations, a PUMA approval is valid in all countries of the European Economic Area (the European Union as well as Iceland, Liechtenstein and Norway). The PUMA process was established to make it more profitable for pharmaceutical companies to market drugs for children. For this purpose, PUMA approved drugs are patent protected for a longer period of time, and are partially exempt from fees.
PUWER	Provision and Use of Work Equipment Regulations.
PV	Pharmacovigilance.
PVAR	Preliminary Variation Assessment Report. Report produced after initial assessment of variation application.
QP	Qualified Person
QPPV	Qualified Person Responsible for Pharmacovigilance
QRD	Quality Review of Documents Group. This is the EMA group which looks at labelling and PIL for centrally authorised medicines.
QRM	Quantitative Risk Management

Q-T	
QA	Quality Assurance. This is the sum total of the organised arrangement made with the object of ensuring that medicinal products or services are of the quality required for their intended purpose.
QC	Quality Control. This involves checking a service or process to make sure it is of the correct quality.
QOS	Quality Overall Summary. This is a summary of the quality data included in support of a marketing authorisation application for a medicinal product.
QP	Qualified Person. A QP must certify every batch of a medicine before release to the EU market. Article 51 of Directive 2001/83/EC defines the duties of the Qualified Person and more information can be found in the Orange Guide.
QPPV	Qualified Person responsible for Pharmacovigilance.
RamaXL	This is a subscription service that gives subscribers easy access to non-confidential information on all medicinal products authorised in the UK together with the ability to track their own applications as they progress through the assessment process. [Formerly: RAMA].
Rapp	Rapporteur.
Rapporteur	A member of the Committee for Proprietary Medicinal Products who provides expert evaluation.
RCGP	RoyalCollege of General Practitioners.
RCR	RoyalCollege of Radiologists.
RFI	Request for Further Information.
RFM	Request for Modification.
rINN	Recommended International Non-proprietary Name.
RIVM	Netherlands National Institute for Public Health and the Environment
RMP	Risk Management Plan.

RMS	Reference Member State.
RMS	Records Management System.
ROR	Reporting Odds Ratio.
RPPS	Regulatory Pharmacovigilance Prioritisation System.
RPSGB	Royal Pharmaceutical Society of Great Britain
Renewals	The five year renewal process for an existing Marketing Authorisation.
RP	Responsible Person. Article 79(b) of Directive 2001/83/EC requires the holder of a wholesale dealer's licence to have a "Responsible Person" who safeguards product users against potential hazards arising from poor distribution practices.
RPSGB	Royal Pharmaceutical Society of Great Britain.
RSC	Royal Society of Chemistry.
RSM	Royal Society of Medicine
Rx	Abbreviation for a medical prescription.
SABRE	Serious Adverse Blood Reactions & Events
SABS	Safety Alert Broadcast System.
SAE	Serious Adverse Effect
SAG	Scientific Advisory Group
SAMM	Safety Assessment of Marketed Medicines. SAMM guidelines apply to the conduct of all company sponsored studies designed to evaluate drug safety.
SAWP	Scientific advice working party
SCOP	See: PEAG.
SCS	Senior Civil Service.
SEAC	Spongiform Encephalopathy Advisory Committee.

Section 4 Committees	These are committees established under the Medicines Act: - to promote advice on the safety, quality or efficacy of medicines; - to promote the collection and investigation of information concerning adverse drug reactions.
Section 44 Letters	Letters issued under the 1968 Medicines Act to seek additional information. S 21(1) or S 28(3) LETTERS. This is the method by which provisional conclusions of the Committee on Safety of Medicines are conveyed to a company.
S 21(3) Letters	When an appeal under section 21(1) or S 28(3) of the Medicines Act is unsuccessful the Committee's advice is sent to the company. This offers the company further appeal rights to the Medicines Commission.
SI	Statutory Instrument.
SLA	Service level agreement. This is an agreement providing a measurable level of service between a service provider and a service receiver.
SMF	Site Master File.
SmPC	See: SPC.
SMQ	Standardised MedDRA query
SOC	System Organ Class. Part of MedDRA terminology. Highest hierarchical level in the MedDRA clinical terminology used in Sentinel (e.g. hepatobiliary disorders).
SOCA	Serious Organised Crime Agency
SOL	Department of Health Solicitor's Branch.
SOP	Standard Operating Procedure.
SPC	- Summary of Product Characteristics - Special Precautions and Contra-indications - Supplementary Protection Certificate.
SPECT	Single photon emission computed tomography.
SSRIs	Selective Serotonin Reuptake Inhibitors.

Structured data	Structured data is all data that is contained in the bottom pane of a Sentinel casefolder. All documents in the top pane of a casefolder are stored in Documentum, whereas all of the data in the bottom pane is stored within a structured data custom database.
SUSAR	Suspected Unexpected Serious Adverse Reaction.
T-Z	
TAG	Technical Advisory Group. The group that considers and prioritises referrals to NICE.
TCM	Traditional Chinese Medicine.
TGA	Therapeutic Goods Administration – the Australian medicines regulatory authority
THMPD	Traditional Herbal Medicinal Products Directive.
THMRS	Traditional Herbal Medicines Registration Scheme. Products must: - meet specific standards of safety and quality - be accompanied by agreed indications based on traditional usage - provide patient information to allow the safe use of the product.
TIL	Technical Information Leaflets.
TO	“Treat Official” This is a description used for all letters sent to the Secretary of State or Ministers to be answered by officials.
TOPRA	The organisation for regulatory affairs officials.
TOTO	Top of the Office.
TSE	Transmissible Spongiform Encephalopathy.
TSO	The Stationery Office.
UKBA	United Kingdom Border Agnecy
UKPAR	United Kingdom Public Assessment Report for Medicines.
UKRC	United Kingdom Radiological conference is the annual Congress for:

	- British Institute of Radiology - Royal College of Radiologists - Society and College of Radiographers - Institute of Physics and Engineering in Medicine.
USAN	United States Adopted Names. This is a list of drug names officially recognised in the US.
USP	United States Pharmacopoeia.
vAIC	Virtual Adverse Incident Centre.
Variations	An amendment to an existing product licence by a licence holder or the licensing authority.
VMD	Veterinary Medicines Directorate. An Executive Agency responsible for issues concerning the use and manufacture of veterinary medicines in the UK..
VRMM	Vigilance and Risk Management of Medicines
VTE	Venous thromboembolism.
WHO	World Health Organisation.
WIPO	World Intellectual Property Organisation
WL	Wholesale Dealer’s Licence.
YTD	Year to Date