

A Glossary of Acronyms and Abbreviations in use in the PIM Project

The following list of items includes acronyms and abbreviations widely used by the PIM project.

QRD list of abbreviations also available on the website: , www.emea.eu.int/hmts/human/qrd/qrdpl/2723603en.pdf

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Term or Abbreviation	
A	
AAC	<i>Audit Advisory Committee</i>
ABPI	<i>Association of the British Pharmaceutical Industry.</i>
ACPC	<i>Advisory Committee on Procurement and Contracts</i>
ACRPI	<i>Association for Clinical Research in the Pharmaceutical Industry</i>
ADI	<i>Acceptable Daily Intake</i>
ADME	<i>Absorption, Distribution, Metabolism, Excretion.</i>
ADR	<i>Adverse Drug Reaction</i>
AE	<i>Adverse Event</i>
AED	<i>Anti Epileptic drug</i>
AESA / EFSA	<i>Association Européenne de Sécurité des Aliments / European Food Safety Authority</i>
AESGP	<i>Association Européenne des Spécialités Pharmaceutiques Grand Public</i>
AFSSA	<i>Agence Française de Sécurité Sanitaire des Aliments</i>
AFSSaPS	<i>Agence Française de Sécurité Sanitaire des Produits de Santé</i>
Agemed	<i>Agencia Española de Medicamentos y Productos Sanitarios</i>
AIDS	<i>Acquired ImmunoDeficiency Syndrome</i>
AIFA	<i>Agenzia Italiana del Farmaco</i>
ALAT	<i>L-alanine aminotransferase</i>
ALP	<i>Alkaline phosphatase</i>
Alternate text	<i>The ALTERNATE TEXT is a portion of text, with or without format that is provided by the AGENCY as a proposed alternative to a text proposed by the applicant.</i>
AMM	<i>Autorisation de mise sur le marché</i>
ANOVA	<i>Analysis of Variance</i>
API	<i>Active Pharmaceutical Ingredient</i>
Applicant	<i>Organisation that makes a Marketing Authorisation Application (MAA) The company or organisation that sends a SUBMISSION for review or approval to the AGENCY. This should be the same as the Marketing Authorisation Holder</i>
Application	<i>An APPLICATION is a request for AGENCY approval of a set of product information. Within PIM, APPLICATIONS are either Initial Marketing Authorisation Applications (MAA) or Post-Authorisation Procedures. An APPLICATION life-cycle is made up of a sequence of PI-VERSIONS exchanged between the APPLICANT and the AGENCY. Within a given PRODUCT, an APPLICATION is uniquely defined by an assigned APPLICATION NUMBER. If the product is an eCTD sequence, it will also have an assigned ectd sequence number which is recorded in the DES envelope</i>
Application Number	<i>The APPLICATION NUMBER is assigned to the APPLICATION by the receiving agency. For the Centralised Procedure, APPLICATIONS are primarily identified by the name and the active substance(s) of the product. However for administrative purposes, each application is also given a core-number composed of four sections: EMEA/H/C/..., where H stands for Human, C for centralised procedure and the three dots correspond to a sequential number for the product identification.</i>
AR	<i>Assessment Report: a report written by a regulatory agency about a regulatory submission</i>

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ASAT	<i>L-aspartate aminotransferase</i>
Accession Countries	<i>New countries that enter the European Commission (with a defined accession date) – This requires extra translations for Product Information</i>
ASCII	<i>American Standard Code for Information Interchange Quality - One of the standards defined for the storage of information within IT files</i>
ASMF	<i>Active Substance Master File</i>
ATC	<i>Anatomical, Therapeutic, Chemical code. - ATC is a classification system for drug substances that is maintained by the WHO Division of Drug Management and Policies (DMP). The 5-level classification system is as follows: Level 1 Fourteen main groups: Drugs classified by anatomical organ or system• Level 2 and Level 3 Therapeutic/pharmacological subgroup• Level 4 Therapeutic/pharmacological/chemical subgroup• Level 5 The individual substances</i>
AUC	<i>Area Under the Curve</i>
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B	
BA	<i>Bioavailability</i>
BAN	<i>British Approved Name</i>
Baseline	<i>The baseline is the last submission inline with a positive CHMP opinion or with a positive EC decision. There is one baseline per product. Each new baseline automatically supersedes the previous one or the set of PI that has been adopted at the last CHMP Opinion, except for Type IA and Notifications where it corresponds to the EC Decision. This Baseline contain Product Information that can be used as starting point for another application.</i>
BE	<i>Bioequivalence</i>
BEUC	<i>Bureau Européen des Unions de Consommateurs</i>
BfArM	<i>Bundesinstitut für Arzneimittel und Medizinprodukte</i>
BMG	<i>Bundesministerium für Gesundheit</i>
BMI	<i>Body Mass Index</i>
BMWP	<i>CHMP Working Party on Similar Biological Medicinal Products</i>
BPWG	<i>Blood Products Working Group</i>
Browser	<i>A program that allows the user to read hypertext, to view contents of Web pages, and to navigate from one page to another (e.g., Netscape Navigator, Mosaic, Microsoft Internet Explorer.)</i>
BSE	<i>Bovine Spongiform Encephalopathy</i>
Business Champion	<i>An individual or group taking responsibility for promotion and pioneering implementation of systems or procedures amongst colleagues and peers.</i>
BWG	<i>Biotechnology Working Group (See COMP)</i>
BWP	<i>Biotechnology Working Party (See CHMP)</i>
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C	
CA (Aka: Regulatory Authority)	<i>See Competent Authority</i>
CALS	<i>Continuous Acquisition and Life-Cycle Support.</i>
CAPs	<i>Centrally Authorised Products</i>
CAS	<i>Chemical Abstracts Services</i>
CAVDRI	<i>Collaboration Agreement between Veterinary Drug Registration Institutions</i>
CBER	<i>FDA Center for Biologics Evaluation and Research.</i>
CDC	<i>Centers for Disease Control and Prevention</i>
CDER	<i>FDA Center for Drug Evaluation and Research.</i>

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Cessation	<i>Applicant decision to stop the marketing of a product, or a portion of a product</i>
CdT	<i>Centre de Traduction</i>
CE	<i>Council of Europe</i>
CEECs	<i>Central and Eastern European countries</i>
CEITAF	<i>CHMP/EMEA Implementation Task Force</i>
Centralised Procedure	<i>A Community registration procedure created by Council Regulation (EEC) No. 2309/93 for the authorisation of medicinal products, for which there is a single application, a single evaluation and a single authorisation allowing direct access to the single market of the European Community. The single scientific evaluation is made by a review team that is lead by a Rapporteur and Co-rapporteur (both CHMP members) on behalf of all EU Member States and is undertaken in 210 days. The opinion of the CHMP is transmitted to the European Commission to be transformed in a further 90 days into a single marketing authorisation applicable to the whole European Union. This procedure is compulsory for medicinal products derived from biotechnology, and available at the request of companies for other innovative new products. Applications are submitted directly to the EMEA.</i>
CFCs	<i>ChloroFluoroCarbons</i>
CHF	<i>Congestive Heart Failure</i>
CHMP	<i>Committee for Medicinal Products for Human Use</i>
CIG	<i>Central Information Group</i>
CIOMS	<i>Council for International Organization of Medical Sciences</i>
CJD	<i>Creutzfeldt-Jakob Disease</i>
Cmax	<i>Concentration maximum</i>
CMC	<i>Chemistry Manufacturing and Controls.</i>
CMD(h)	<i>Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human</i>
CMS	<i>Concerned Member State</i>
Conflict in PI	<i>Combined collections contain Product Information texts that are stored in a set of submissions and those submissions</i>
Combined Collection	<i>Term used to identify a set of submissions that contain Product Information about the same product, and that should be combined in order to provide a unique representation of the Product Information.</i>
COMP	<i>Committee for Orphan Medicinal Products</i>
Comment	<i>The COMMENT is the concept that gathers a reason, a department (where is the author of the comment), a date / time, the commented text and an alternate text.</i>
Commented Submission	<i>A COMMENTED SUBMISSION is a specific set of information about a product that is transmitted by the AGENCY to the APPLICANT. It is a sub-type of FROZEN PI-VERSION within the LAT, meaning that a COMMENTED SUBMISSION cannot be edited. A COMMENTED SUBMISSION must refer to at least one SUBMISSION previously received by the AGENCY from the APPLICANT, but may possibly refer to several such SUBMISSIONS.</i>
Complete cumulative view	<i>A snapshot of the PIM submission created based upon all submissions across the lifecycle which presents all current and historical information in context. A piece of text provided by either a competent authority or an Applicant that provides an observation or request associated with the PIM submission</i>
Competent Authority	<i>An Authority in a European Member States responsible for the autorisation and supervision of medicinal products - See also Regulatory Authority, CA, NCA and MSCA</i>
Conversion	<i>The process by which a PIM submission is created at Day 120/Day 121 for draft product information which was initially submitted at Day 0 as Word-based documents. The conversion is a process that transforms a PIM submission from a DES version to another one</i>
COPD	<i>Chronic Obstructive Pulmonary Disease</i>

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Co-Rapporteur	<i>In the Centralised Procedure, a member of the CxMP appointed to co-ordinate the evaluation of an application, taking into account any proposal from the applicant for choice of rapporteur.</i>
Core Number	<i>The core number is the application number for the initial marketing authorisation for that product. For human products under centralised procedure, it consists of 4 parts: EMEA, H (for Human), C (for Centralised) and a number.</i>
Core Team	<i>The steering and management committee for the PIM project.</i>
COSTART	<i>Coding Symbols for Thesaurus of Adverse Reaction Terms</i>
COTS	<i>Commercial Off-The-Shelves software :a COTS software is a product which purchased and used as it is. COTS products are designed to be easily installed and to interoperate with existing system components</i>
COX-2	<i>Cyclooxygenase-2</i>
CPME	<i>Comité Permanent des Médecins Européens</i>
CPMP	<i>Committee for Proprietary Medicinal Products (now CHMP)</i>
CRF	<i>Chronic Renal Failure</i>
CRF	<i>Case Report Form</i>
CRO	<i>Contract Research Organization</i>
CT	<i>PIM Specifications project Core team - see also PIM CT</i>
CTD	<i>Common Technical Document (International Conference on Harmonization topic M4)</i>
Cumulative view	<i>A snapshot of the PIM submission created based upon the currently approved information created from multiple separate filings</i>
Cumulative approach	<i>The CUMULATIVE APPROACH is the strategic design used in eCTD and PIM to transfer only information that has changed since the previous submission. In other PIM documentation the term "delta" has been used to refer to these transmitted sets of changed data to delineate them from complete sets of product information.</i>
Current Submission	<i>The most recent filing of product information that is undergoing review</i>
Current Working version	<i>A CURRENT WORKING VERSION of a product is the only PI-VERSION of a PRODUCT that may be edited. For any given PRODUCT, there is zero or one CURRENT WORKING VERSION. When the LAT user has finished editing, a CURRENT WORKING version is turned into a FROZEN PI-VERSION of type SNAPSHOT if it is meant to be kept outside of the official PIM exchange cycle between the APPLICANT and the AGENCY or a SUBMISSION in it is meant to be part of that cycle.</i>
CVMP	<i>Committee for Medicinal Products for Veterinary Use .</i>
CxMP	<i>Generic abbreviation used to represent more than one of the medicinal committees (CHMP, COMP, HMPC and CVMP)</i>
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D	
Data Exchange Standard	<i>See DES</i>
DDD	<i>Defined Daily Dose</i>
DDL	<i>Dear Doctor Letter</i>
DES	<i>PIM Data Exchange Standard - see also PIM DES</i>
DG	<i>Directorate General</i>
DG ENTR	<i>European Commission : Directorate General Enterprise</i>
DIA	<i>Drug Information Association.</i>
Directory	<i>The operating system method of organizing and providing access to individual files. Also called a folder. See Also Folder</i>
DLT	<i>Dose Limiting Toxicity</i>
DMARD	<i>Disease Modifying Anti-Rheumatic Drug</i>
DMF	<i>Drug Master File</i>
Document	<i>The minimum amount of information to be exchanged. Ideally, this is a single physical file.</i>
DPI	<i>Dry Powder Inhaler</i>

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DRA	<i>Drug Regulatory Authority</i>
DSA	<i>Bureau Européen d'Information pour le Développement de la Santé Animale, European Information Office for the Development of Animal Health</i>
DTC	<i>Direct to Consumer</i>
DCP	<i>Decentralised procedure</i>
DTD	<i>Document Type Definition. A hierarchical organisation or representation of the information contents of a document utilised by SGML or XML.</i>
DTP	<i>Diphtheria Tetanus Pertussis</i>
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E	
EbXML	<i>Electronic Business XML. A modular suite of specifications for standardizing XML globally in order to facilitate trade between organisations regardless of size. The specification gives business a standard method to exchange XML-based business messages, conduct trading relationships, communicate data in common terms and define and register business process. Detail on ebXML can be found at http://www.ebxml.org.</i>
EC	<i>European Commission</i>
ECCLS	<i>European Committee on Clinical Laboratory Standards</i>
ECJ	<i>European Court of Justice.</i>
eCTD (or e-CTD)	<i>Electronic Common Technical Document : The eCTD is defined as an interface for industry to Agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission. The focus of the eCTD is to provide the ability to transfer the registration application electronically from industry to a regulatory authority.</i>
eCTD EU M1	<i>eCTD EU Module 1 : module of the eCTD containing the PI</i>
EDI	<i>Electronic Data Interchange</i>
EDMF	<i>European Drug Master File (open/closed part)</i>
EDMS	<i>Electronic Document Management System</i>
EDQM	<i>European Department for the Quality of Medicines</i>
EEA	<i>European Economic Area.</i>
EEC	<i>European Economic Community.</i>
EFPIA	<i>European Federation of Pharmaceutical Industry Associations.</i>
EGA	<i>European Generic Medicines Association</i>
EGGVP	<i>European Group for Generic Veterinary Products</i>
EMEA	<i>European Medicines Agency</i> <i>The EMEA created by Council Regulation (EEC) No. 2309/93 of 22 July 1993 is based in Canary Wharf, London. The Agency is responsible for coordinating the existing scientific resources put at its disposal by the competent authorities of the Member States for the evaluation and supervision of medicinal products. (was European Agency for the Evaluation of Medicinal Products until May 04)</i>
EOF	<i>National Pharmaceutical Organization, Ministry of Health</i>
EORTC	<i>European Organization for Research and Treatment of Cancer.</i>
EP	<i>European Parliament</i>
EPAR	<i>European Public Assessment Report</i>
EPO	<i>Erythropoietin</i>
EPO	<i>European Patent Office</i>
ERA	<i>Environmental Risk Assessment</i>
ESCOP	<i>European Scientific Cooperative on Phytotherapy</i>
ESRA	<i>European Society of Regulatory Affairs.</i>
ESTRI	<i>Electronic Standard for the Transfer of Regulatory Information</i>

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EU	<i>European Union : The Union of 25 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Irish Republic, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.</i>
EUCAST	<i>European Committee on Antimicrobial Susceptibility Testing</i>
EUDRA	<i>European Drug Regulatory Authorities</i>
EudraCT	<i>Database of information on clinical trials taking place in the Community</i>
Eudralink	<i>Application for secure message transfer and communications between EMEA, EU Member State Drug Regulatory Authorities and Industry.</i>
Eudranet	<i>European Drug Regulatory Network</i>
EuroPharm, EPh	<i>European Pharmaceutical Products database</i>
EURS	<i>European Union Review System (eCTD)</i>
EV	<i>EudraVigilance</i>
EVM	<i>European Vaccines Manufacturers</i>
EWP	<i>Efficacy Working Party</i>
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F	
FAQ	<i>Frequently Asked Questions</i>
FDA	<i>Food and Drug Administration</i>
FEDESA	<i>Fédération Européenne de la Santé Animale , European Federation of Animal Health</i>
FOI	<i>Freedom of Information</i>
Folder	<i>The operating system method of organizing and providing access to individual files. Also called a directory.</i>
Format	<i>Format is the set of graphical features allowed by QRD templates within sections like bold, italics, underline, lists, tables, figures</i>
Frozen PI-Version	<i>Frozen PI-Version is a PI-Version that cannot be edited by the applicant. A Frozen PI-Version is either a Submission, a Commented Submission or a Snapshot. A Frozen PI-Version must be valid against the PIM DES rules</i>
FT	<i>PIM Project Full Team - see also PIM FT. This group comprises representatives from the EMEA, Member States, and Industry representatives of companies who have co-financed the PIM initiative.</i>
FUM	<i>Follow-up Measure</i>
FVE	<i>Federation of Veterinarians of Europe</i>
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G	
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H	
HMA	<i>Heads of Medicines Agencies (with three groups:HMA-Joint, HMA-Human and HMA-Vet)</i>
HMPC	<i>Committee for Herbal Medicinal Products</i>
HoA	<i>Was Heads of Agencies to Oct04 - use HMA-Human</i>
HTML	<i>HyperText Markup Language. Commonly used to format Web pages.</i>
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I	
IC	<i>Informed Consent</i>
ICD, ICD-10	<i>International Classifications of Diseases, 10th edition</i>
ICDRA	<i>International Conference of Drug Regulatory Authorities</i>

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ICH	<i>International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</i> A program of conferences in which representatives from regulatory authorities and trade associations in the European Union, the United States, and Japan meet to develop common standards and approaches to various aspects of pharmaceutical regulation, classified by topics under either Quality (Q), Safety (S, non-clinical), Efficacy (E) or Multidisciplinary (M).
ICSR	<i>Individual Case Safety Reports</i>
ID	<i>Identifier</i>
IDA	<i>Interchange of Data between Administrations</i>
IFAH	<i>International Federation for Animal Health</i>
IFPMA	<i>International Federation of Pharmaceutical Manufacturers Association.</i>
IMB	<i>Irish Medicines Board (Bord Leigheasra na hÉireann)</i>
IMP	<i>Investigational medicinal product</i>
IND	<i>Investigational New Drug</i>
INFARMED	<i>Instituto Nacional da Farmácia e do Medicamento, Medicaments and Pharmacies National Institute</i>
Infrastructure	<i>The basic support services for computing; the hardware, operating system, and network on which applications and data are stored and on which the database management systems run.</i>
INN	<i>International Non-proprietary Name.</i>
Integrated PI Texts	<i>When running parallel applications, it might be interesting / needed to integrate texts of a more advanced application (e.g. post-opinion) into a starting application, so that the newest application can benefit the review already done. This principle to integrate PI texts is also denoted as a reference to an application.</i>
Internet	<i>The worldwide network of computers for accessing, sending, sharing, and transferring information between sites at different locations. It is uncontrolled and unadministered, and when you connect to the Internet, you actually become a part of it.</i>
ISE	<i>Integrated Summary of Efficacy (CTD)</i>
ISO	<i>International Standards Organisation, founded in 1946, it is the principal international standards-setting organisation.</i>
ISO639	<i>ISO language codes (either in 2 or 3-letters).</i> http://www.w3.org/WAI/ER/IG/ert/iso639.htm
ISS	<i>Integrated Summary of Safety (CTD)</i>
ITF	<i>Innovation Task Force</i>
ITT	<i>Invitation to Tender</i>
IUPAC	<i>International Union of Pure and Applied Chemistry</i>
IWP	<i>Immunological Veterinary Medicinal Products</i>
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J	
Java	<i>High-level programming language developed by Sun Microsystems</i>
JPEG	<i>Joint Photographic Experts Group format.</i>
JIGes	<i>Joint Telematics Implementation Group for electronic submissions. This group comprises representatives from EU</i>
JSP	<i>Java Server Page</i>
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L	
LAN	<i>Local Area Network</i>
LAT	<i>PIM Light Authoring Tool</i>
LD50	<i>Lethal Dose 50</i>
LFTs	<i>Liver Function Tests</i>
LLT	<i>Lower Level Term (MedDRA)</i>
LOCF	<i>Last Observation Carried Forward</i>
LoQ	<i>List of Questions (authored by the CxMP and addressed to the Applicant at Day 120)</i>

Layout	<i>The standards for visual representation of information on-screen and/or paper - synonymous with format (see Format)</i>
LoOI	<i>List of Outstanding Issues (authored by the CxMP and addressed to the Applicant)</i>
LoI	<i>List of Issues (authored by the CxMP and addressed to the Applicant)</i>
Leaf	<i>The eCTD DTD XML element that describes the content to be provided. The leaf consists of a file and themeta-data associated with that file. Such files are placed in a directory structure that is similar to branchesof a tree.</i>
Label	<i>A display of written, printed, or graphic matter upon the immediate container of any article.</i>
Labelling	<i>In the US, labelling includes all written, printed or graphic matter (e.g. package insert, patients instructions, carton, label) accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. In the EU, labelling refers only to the immediate packaging (e.g. carton and label).</i>
Lifecycle	<i>The ability to incorporate different submissions of regulatory information during the life cycle of a medicinal product into a single accessible system.</i>
Linguistic Merge	<i>The linguistic merge is a business process that compiles translations in different languages of the same English texts, into a single PIM file.</i>
LCM	<i>Life Cycle Management - See Lifecycle</i>
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M	
MA	<i>Marketing Authorisation Application : Across all European markets, plus Australia, New Zealand, South Africa, and Israel (exceptions amongst major markets include USA, Canada, China and Japan), the Marketing Authorisation Application (MAA) is a common document used as the basis for a marketing application (an application for approval to market the product based on a full review of all quality, safety, and efficacy data, including clinical study reports). In the USA, the New Drug Application (NDA) is the MAA equivalent. In Canada, the New Drug Submission (NDS) is the MAA equivalent.</i>
MAA	<i>Marketing Autorisation : Approval to market a medicinal product in a EU Member State.</i>
MAH	<i>Marketing Authorization Holder</i>
Marker	<i>The marker is one or more characters that identify a procedure type.</i>
MB	<i>Management Board</i>
MCA	<i>was Medicines Control Agency, see MHRA</i>
MDI	<i>Metered Dose Inhaler</i>
MD5	<i>Message-Digest algorithm. The level of security to be sufficient for implementing very high security hybrid digital-signature schemes based on MD5 and a public-key cryptosystem.</i>
MedDRA	<i>Medical Dictionary for Regulatory Activities</i>
Merge	<i>Resolution of conflicts in PI can be achieved by merging applications. In this case, the submission needs to be exchanged; this submission carries the application numbers of the applications to merge. Merge is the process by which part of the Product Information coming from one submission is combined with the Product Information of another submission. The intention of the "merge process" is to create a new set of documents that contain all the relevant information of both submissions. In certain cases this "merge process" can be automated and in other cases human intervention is needed to combine the Product Information of the two submissions.</i>
Merged Applications	<i>See Merge</i>
MIC	<i>Minimum Inhibitory Concentration</i>
MHRA	<i>Medicines and Health care products Regulatory Agency (UK)</i>

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Migration	<i>The process by which a baseline in PIM is established for an authorised product for which product information has previously been managed as Word-based documents. The migration is also the technical process that transforms product information from paper (RTF or Ms Word) to PIM (XML).</i>
MPA	<i>Medical Products Agency (Sweden)</i>
MR	<i>Mutual Recognition Procedure - See also MRP</i>
MRA	<i>Mutual Recognition Agreement</i>
MRFG	<i>Mutual Recognition Facilitation Group</i>
MRL	<i>Maximum Residue Limit</i>
MRP	<i>Mutual Recognition Procedure : A community registration procedure described by Council Directive 75/319/EEC (as amended) for the authorisation of medicinal products. Mutual Recognition Procedure: One of the routes for seeking regulatory approval in the European Union. A submission is first made to a EU Member State authority that assesses, grants a national approval and prepares an assessment report. This report is circulated by the initial authority to the other (concerned) Member States who are expected to recognize this decision and grant their own national authorisation within a period of 90 days following the initial approval. The 90-day period is used to resolve any issues between Member States. If serious objections are raised then the application is referred to CHMP for arbitration leading to a binding decision. Note: Concerned Member State: A Member State that is concerned (i.e. included in the mutual recognition phrase) with an application for Mutual Recognition, and expected to recognize the initial approval of the Reference Member State.</i>
MS	<i>Member State</i>
MSCA	<i>Member State Competent Authority (see also CA)</i>
MSSO	<i>Maintenance Support Services Organization (MedDRA)</i>
MTD	<i>Maximum Tolerated Dose</i>
MUMS	<i>Minor Uses and Minor Species</i>
Mutual Recognition Procedure	<i>See MRP</i>
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N	
National Competent Authority	<i>See NCA and CA</i>
NCCLS	<i>National Committee on Clinical Laboratory Standards</i>
NCA	<i>National Competent Authority (see also CA)</i>
NCE	<i>New Chemical Entity.</i>
NCIC CTC	<i>National Cancer Institute of Canada Common Toxicity Criteria</i>
NfG	<i>Note for Guidance</i>
NME	<i>New Molecular Entity</i>
NNRTI	<i>Non Nucleoside analogue Reverse Transcriptase Inhibitor</i>
NOEL	<i>No-observed effect level</i>
NRG	<i>Invented Name Review Group</i>
NRTI	<i>Nucleoside analogue Reverse Transcriptase Inhibitor</i>
NSAID	<i>Non Steroidal Anti-Inflammatory Drug</i>
NTA	<i>Notice to Applicants</i>
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O	
OCABR	<i>Official Control Authority Batch Release</i>
OE	<i>Oral Explanation</i>
OECD	<i>Organization of Economic Co-operation and Development.</i>
OFI	<i>Opportunity for Improvement</i>
OHIM	<i>Office for Harmonisation in the Internal Market</i>
OIE	<i>Office International des Epizooties</i>

OJ	<i>Official Journal of the European Communities</i>
OMCLs	<i>Official Medicines Control Laboratories</i>
ORGAM	<i>Ad hoc group on Organisational Matters of the CHMP</i>
OTC	<i>Over-the-counter</i>
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P	
pdf (or PDF)	<i>Portable Document Format : a proprietary (Adobe Systems) de facto standard for the electronic transfer of documents.</i>
PDVE	<i>PIM Data Validation Engine. IT is a tool that validates the business rules of a PIM file</i>
PECA	<i>Protocol to the Europe Agreement on Conformity Assessment and Acceptance of industrial products</i>
PgWP	<i>Pharmacogenetics Working Party</i>
PE	<i>PolyEthylene</i>
PER Scheme	<i>Scheme for the Mutual Recognition of Evaluation Reports on Pharmaceutical Products</i>
PEG	<i>Paediatric Expert Group</i>
PERF	<i>Pan European Regulatory Forum</i>
PET	<i>Positron Emission Tomography</i>
PGEU	<i>Pharmaceutical Group of the European Union</i>
pH	<i>Measure of acidity.</i>
PHARE	<i>Poland and Hungary; Aid of the Restructure of the Economy</i>
PhV	<i>Pharmacovigilance</i>
PhVWP	<i>Pharmacovigilance Working Party</i>
PI	<i>Product Information. A summary of the essential scientific information needed for the safe and effective use of the drug that should be made available for pharmacists and for patients. The Product Information is composed of the following documents :</i> <ul style="list-style-type: none"> - Annex I : Summary of Product Characteristics (SPC), - Annex II : Manufacturer information - Annex IIIa : the Labelling - Annex IIIb : the Package Leaflet (PL)
PI Instance	<i>A single submission containing product information</i>
PI Version	<i>A PI-Version is a specific set of information within a PIM Application cycle. During the approval process many versions of the Application are exchanged between the Applicant and the Agency. The initial PI-Version will be a complete Submission of product information from Applicant to Agency. All other Submissions and commented submissions will contain only changed information (deltas). Within a given product, each PI-Version is uniquely defined by the DES envelope field <pim-sequence>. A PI-Version is either a frozen PI-Version or the current working version.</i>
PIs	<i>Protease Inhibitors</i>
PIA	<i>Pharmaceutical Industries Association.</i>
PIC	<i>Pharmaceutical Inspection Convention</i>
PIC/S	<i>Pharmaceutical Inspection Co-operation Scheme</i>
PIL	<i>Patient Information Leaflet - synonymous with PL</i>
PIM	<i>Product Information Management : Joint EFPIA-EMEA project for the electronic management of Product Information</i>
PIM CT	<i>PIM Project Core team - see also CT</i>
PIM DES	<i>PIM Data Exchange Standard Team - see also DES</i>

PIM Directory Structure	<i>A PIM DIRECTORY STRUCTURE is a set of files organized in a pre-defined directory structure containing each file needed to represent a frozen PI-Version. These files include the PIM Instance accompanied by an optional MD5 checksum, the util files containing the DTD and stylesheets and additional documents and images referenced by the PIM instance. The PIM Directory Structure is governed by the DES rules. A PIM Directory Structure is compressed in a package.</i>
PIM Instance	<i>A PIM Instance refers to the XML document called "pim.xml" that is found within a container.</i>
PIM FT	<i>PIM Project Full Team - see also FT</i>
PIM LAT	<i>PIM Light Authoring Tool - see also LAT</i>
PIM RS	<i>PIM Review System</i>
PIPIT	<i>Product Information Process Improvement Team</i>
PIQ	<i>Product Information Quality</i>
Pivot Language	<i>In the Mutual Recognition and Decentralised Procedures, the first stage of the review consists of a scientific assessment of the product in a language common to the RMS and CMSs, usually in English. In some cases (e.g. when RMS is Germany and CMS Austria), the language used for the scientific assessment and product information submitted might be another EU official language (e.g. German). To support that flexibility, and not to limit this stage to a review in English, the term "Pivot Language" is used.</i>
PKI	<i>Public Key Infrastructure</i>
PL	<i>Patient Leaflet/Package Leaflet.</i>
PM	<i>Project Manager</i>
PMF	<i>Plasma Master File</i>
PMS	<i>Post-Marketing Surveillance</i>
PNG	<i>Portable Network Graphics</i>
PoC	<i>Proof of Concept.</i>
PQP	<i>Project Quality Plan</i>
PRO	<i>Patient-reported outcome</i>
Product	<i>Term used to reference the pharmaceutical product for which the product information is being submitted to the AGENCY. A PRODUCT within PIM is uniquely defined by the DES envelope fields containing this information: <applicant>+<invented name> or <applicant>+<number>.</i>
Product Information	<i>See PI</i>
PRS	<i>See PIM RS</i>
PSUR	<i>Periodic Safety Update Report</i>
PT	<i>Preferred Term (MedDRA)</i>
PTL	<i>Project Team Leader</i>
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Q	
QA	<i>Quality Assurance</i>
QC	<i>Quality Control</i>
QMS	<i>Quality Management System</i>
QoL	<i>Quality of Life</i>
QOS	<i>Quality Overall Summary (CTD)</i>
QP	<i>Qualified Person</i>
QRD	<i>Quality Review of Documents</i>
QRD Template	<i>The MicroSoft Word guidance documents used as the basis of PI documents.</i>
QRD WG	<i>Quality Review of Documents Working Group</i>
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R	
R&D	<i>Research and Development.</i>

A Glossary of Acronyms and Abbreviations in use at the EMEA

Rapporteur	<i>In the Centralised Procedure, a member of the CxMP appointed to co-ordinate the evaluation of an application, taking into account any proposal from the applicant for choice of rapporteur.</i>
RAS	<i>Rapid Alert System</i>
RBC	<i>Red Blood cell Count</i>
RDBMS	<i>Relational Data Base Management System</i>
RDE	<i>Remote Data Entry</i>
rDNA	<i>Recombinant DesoxyriboNucleic Acid</i>
Reconciliation	<i>The reconciliation is the term used to identify the additional step which may be needed to provide a unique representation of Product Information based on applications approved in parallel.</i>
Reference	<i>The reference is the term used to identify that texts of a submission utilise texts that have been approved in the context of another application.</i>
Regulator	<i>Refer to Competent Authority.</i>
Regulatory Authority (Aka : Competent Authority)	<i>National body that administers the full spectrum of drug regulatory activities, including at least all of the following functions: - Marketing authorization of new products and variation of existing products - Quality control laboratory testing - Adverse drug reaction monitoring - Provision of drug information and promotion of rational drug use - GMP inspections and licensing of manufacturers, wholesalers and distribution channels - Enforcement operations - Monitoring of drug utilisation. See also CA, NCA and MsCA</i>
Renewal	<i>A report submitted to a European or International regulatory authority on a regular basis (every 5 years for the EU Mutual Recognition (MR) and Centralised Procedures,) for every active marketing authorization. The nearest US equivalent is the Annual Report.</i>
RFC	<i>Request for comments</i>
RFC1321	<i>http://www.faqs.org/rfcs/rfc1321.html</i>
RMS	<i>Reference Member State</i>
RoW	<i>Rest of the world.</i>
RSI	<i>Request for Supplementary Information</i>
RTF	<i>Rich Text Format</i>
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S	
S&E	<i>Safety & Efficacy</i>
S+T	<i>Sample and Testing</i>
SA	<i>Scientific Advice</i>
SAE	<i>Serious Adverse Event</i>
SAG	<i>Scientific Advisory Group</i>
SAGAM	<i>Scientific Advisory Group on AntiMicrobials</i>
SAWG	<i>Scientific Advice Working Group</i>
SAWP	<i>Scientific Advice Working Party</i>
SGML	<i>Standard Generalized Mark-up Language</i>
Series of Submissions	<i>Two or more filings made by the applicant to a competent authority associated with a single product</i>
SIAMED	<i>Sistema de Información Automatizada sobre MEDicamentos</i>
SMF	<i>Site Master File</i>

Snapshot	<i>Frozen PI-Version of a Current Working Version. Snapshots are saved, non-editable versions of a Product. Snapshots may be stored in a persistent fashion, or loaded and edited in a separate LAT instance. Snapshots are assigned their own sequence number outside of the "official" sequence numbers that serve as reference during the exchanges between the Applicant and the Agency. Snapshots must be valid against the PIM DES rules. Snapshots are internal files created within a company and not transmitted to an Agency. Snapshots may be saved and received in a similar fashion to PI-Versions to allow transfer of information between LAT instances.</i>
SOs	<i>Specific Obligations</i>
SOP	<i>Standard Operating Procedure</i>
SPC	<i>Summary of Product Characteristics Supplementary Protection Certificate</i> Means of extending the term of patent exclusivity for a new medicinal product for a fixed period from the date of first marketing authorization in a European Member State. The certificate takes effect at the end of the term of the basic patent. The extent of additional protection granted will depend on how long it took from lodging the patent to granting the first European MA, but will not exceed 5 years. SPC was created by Council Regulation (EEC) No. 1768/92 of 18 June 1992, and became effective on 2 January 1993.
Split Approved PI	<i>When Product Information is reviewed for merged applications, there might be a need to approve application separately. To do so, a split of PI documents (containing the same Product Information) may be needed.</i>
SSRIs	<i>Selective Serotonin Re-uptake Inhibitors</i>
Standard	<i>A technical specification that addresses a business requirement, has been implemented in viable commercial products, and, to the extent practical, complies with recognized standards organisations such as ISO.</i>
Standing Committee	<i>(EU) The Standing Committee is sometimes referred to as the Regulatory Committee. It embraces the following two Committees: 1. Committee for the Adaptation to Technical Progress of the Directive on the Elimination of Technical Barriers to Trade in the Sector of Coloring Matters which may be added to Medicinal Products set up under Council Directive 78/25/EEC, Article 5. It meets rarely. 2. Committee for the Adaptation to Technical Progress of the Directive on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector set up under Council Directive 75/318/EEC, Article 2. The name of this Committee was changed to Standing Committee (Council Directive 93/39/EEC). This Committee plays a major role in the decision-making process in the Centralized Procedure and in the Mutual Recognition (MR) Procedure if arbitration is involved. The two Committees are part of the Commission, with full representation from Member States.</i>
Stylesheet	<i>A stylesheet is a file that defines the layout of a document. When you create a stylesheet, you specify such parameters as the headers, the margins, and fonts. Stylesheets are useful because you can use the same stylesheet for many documents. For example, you could define one stylesheet for SPC, another for package leaflets, and a third for labellings. Stylesheets are also called templates.</i>
Submission	<i>Specific set of information about a product (a specific set of formulations, strengths and presentations) that is transmitted to the Agency for review or approval. It is a sub-type of Frozen PI-Version (see below) and therefore cannot be subsequently edited or modified. An Application follows a path of an initial Submission followed by a cycle of reviews and responses until approval. These responses are distinct Frozen PI-Versions sent by the Applicant to the Agency, and are separate Submissions. Except for the first Submission of a product (MAA Day 0), a submission is always based on a previous submission for the same product.</i>
SUSAR	<i>Suspected Unexpected Serious Adverse Reactions</i>
Suspension	<i>Temporary decision to cancel the marketing authorisation of a product or a portion of a product</i>
SVG	<i>Scalable Vector Graphic format</i>
SWP	<i>Safety Working Party</i>

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T	
TAG	<i>Therapeutic Advisory Group</i>
TB	<i>Tuberculosis</i>
Template	<i>The lowest level product information text within the PIM standard . Template refers to the <template> tag in the template zone of an PIM submission</i>
TIG	<i>Telematics Implementation Group</i>
TIGes	<i>Telematics Implementation Group for electronic submissions - this group comprises representatives from EU National Competent Authorities and the EMEA. Its mandate is the development and implementation of standards for the submission of electronic information in support of an application for a marketing authorisation.</i>
TLV	<i>Threshold Limit Value.</i>
TMC	<i>Telematics Management Committee</i>
TOC	<i>Table of Contents</i>
ToD	<i>Table of Decisions</i>
TSC	<i>Telematics Steering Committee</i>
TSE	<i>Transmissible Spongiform Encephalopathies</i>
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UML	<i>Unified Modelling Language</i>
USR	<i>Urgent Safety Restriction</i>
UT	<i>Unit test</i>
UAT	<i>User Acceptance test</i>
util	<i>Utility folder</i>
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Valid Submission	<i>A PIM submission that has been shown to be compliant with PIM standard as checked by a validation routine</i>
VAMF	<i>Vaccine Antigen Master File</i>
Variation	<i>In the context of regulatory submissions, a procedure used by the EMEA and national European agencies as one step in the Mutual Recognition (MR) and Centralized Procedures where the agency may refuse to accept marketing applications that are administratively deficient. This process is somewhat analogous to receiving an RTF (refusal to file) notice for an NDA, although reviews are primarily administrative. In the context of drug or computer system development, validation determines that a process does/produces what it is intended to do.</i>
Variation, Type I	<i>Modification to a Marketing Authorisation Application. A minor variation defined in Article 2 of Commission Regulations (EC) No. 541/95 of 10 March 1995 and No. 542/95 of 10 March 1995 and listed in Annex I of these Regulations. Analogous to Changes Being Effected supplemental NDA in the US.</i>
Variation, Type II	<i>A major variation to a marketing authorization application which cannot be deemed to be a type I variation and which is not a change leading to a new application as stated in Annex 2 of the Commission Regulations (EC) No. 541/95 and (EC) No. 542/95. Somewhat analogous to a pre-approvable supplemental NDA in the US.</i>
VedDRA	<i>Veterinary Dictionary for Drug Regulatory Activities</i>
VEG	<i>Vaccines Expert Group</i>
vICH	<i>International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products</i>
VMRFG	<i>Veterinary Mutual Recognition Facilitation Group</i>
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Well-formed Submission	<i>A PIM submission that has been produced to be compliant with PIM standard but has not been checked by a validation routine</i>
Withdrawal	<i>Definitive decision to cancel the marketing authorisation of a product or a portion of a product. This term covers two situations a) withdrawal of marketing authorisation; i.e. a MA was granted and is withdrawn for a reason or another (e.g. safety issue). b) withdrawal of a marketing authorisation application; this is the more frequent case where the applicant withdraws his request of a new marketing authorisation usually because the CHMP is going negative</i>
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XML	<i>eXtended Mark-up Language. - Specification developed by the W3C. XML is a pared-down version of SGML, designed especially for Web documents. It allows designers to create their own customised tags, enabling the definition, transmission, validation, and interpretation of data between applications and between organisations.</i>
XML instance	<i>XML file valid according to the PIM DES.</i>
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