Cortellis CMC Intelligence | CMC Content Glossary

ABBREVIATION	DEFINITION	COUNTRY	DESCRIPTION
ABN	Australian Business Number	Australia	
ACTD	ASEAN Common Technical Dossier	Malaysia, Thailand, Philippines, Vietnam, Indonesia, Cambodia, Myanmar	This ASEAN Common Technical Dossier (ACTD) is a guideline of the agreed upon common format for the preparation of a well-structured Common Technical Dossier (CTD) applications that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use.
ADR	Additional Document Request	Taiwan	
AEUNDS	Abbreviated Extraordinary Use New Drug Submission	Canada	
AGES	The Agency for Health and Nutritional Security GmbH	Austria	
AI	Additional indication	Switzerland	
ALIMS	Agencija za lekove i medicinska sredstva	Serbia	Medicines and Medical Devices Agency of Serbia
AMA	African Medicines Agency	Kenya	
AMG	Arzneimittelgesetz	Germany, Austria	Drug Law
AND	Annual Drug Notification	Canada	A Notification sent to Health Canada annually, before October, by a drug sponsor/manufacturer, confirming that all information previously supplied with regard to that drug is correct, in order to comply with section C.01.014.5 of the Food and Drug Regulations. The Annual Drug Notification Form (ADNF) is available to assist manufacturers in complying with the said regulations.
ANDA	Abbreviated New Drug Application	USA	An Abbreviated New Drug Application (ANDA) is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.
ANM	Autoridad Nacional de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios	Peru	
ANPP	National Agency of Pharmaceutical Products	Algeria	
ANVISA	Agência Nacional de Vigilncia Sanitária	Brazil	The Brazilian Health Regulatory Agency (ANVISA) is an autarchy linked to the Ministry of Health, part of the Brazilian National Health System (SUS) as the coordinator of the Brazilian Health Regulatory System (SNVS), present throughout the national territory.
APAC	Asia-Pacific	Bangladesh, Cambodia, China, India, Indonesia, Malaysia, Myanmar, Nepal, Pakistan, Philippines, Thailand, Vietnam	Asia-Pacific or Asia Pacific (abbreviated as APAC, Asia-Pac, AsPac, APJ, JAPA or JAPAC) is the part of the world in or near the Western Pacific Ocean. The region varies in area depending on which context, but it typically includes much of East Asia, South Asia, Southeast Asia, and Oceania.
API	Active Pharmaceutical Ingredient	All Countries	
ARV	Antiretroviral	IDA, PFSCM	
ASEAN	Association of Southeast Asian Nations	Malaysia, Thailand, Philippines, Vietnam, Indonesia, Cambodia, Myanmar	The Association of Southeast Asian Nations is a regional intergovernmental organization comprising ten Southeast Asian countries that promotes intergovernmental cooperation and facilitates economic, political, security, military, educational, and sociocultural integration amongst its members and other Asian states.
ATC	Anatomical Therapeutic Chemical Classification System	Common	
AUE	Authorization for the exceptional use of medicinal products	Portugal	
AVAREF	African Vaccines Regulatory Forum	Kenya	

AWB	Air Waybill	Iraq	
AWEG	German Medicinal Products Import Act	Austria	
BA	Bioavailability	All Countries	BA for a given formulation provides an estimate of the relative fraction of the orally administered dose that is absorbed into the systemic circulation.
BAES	Federal Office for Food Security	Austria	
BASG	Bundesamt für Sicherheit im Gesundheitswesen	Austria	Federal Office for Security in Health Care
BDA	Bulgarian Drug Agency	Bulgaria	
BE	Bioequivalence	All Countries	Bioequivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study [US-21 CFR 320.1(e)].
BFAC	Business Facilitation Advisory Committee	Hong Kong	
BFARM	Bundesinstitut für Arzneimittel und Medizinprodukte	Germany	Federal Institute for Drugs and Medical Devices
BLA	Biologic License Application	USA	
BMI	Business Monitor International	Iraq	
BP	British Pharmacopoeia	PFSCM	
BSE	Bioequivalence Study Evaluation	Taiwan	
CADTH	Canadian Agency for Drugs and Technologies in Health	Canada	The Canadian Agency for Drugs and Technologies in Health, or CADTH, is a Canadian national organization that provides research and analysis to healthcare decision-makers.
CAM	Comissão de Avaliação de Medicamentos	Portugal	
CAPA	Corrective Actions Preventive Actions	Lebanon	
CARICOM	Caribbean Community and Common Market	Guyana, Haiti	The Caribbean Community (CARICOM) is a grouping of twenty countries: fifteen Member States and five Associate Members based on four main pillars: economic integration; foreign policy coordination; human and social development; and security.
CARPHA	Carribean Public Health Agency	Guyana, Haiti	
CBER	Center for Biologics Evaluation and Research	USA	The Center for Biologics Evaluation and Research is one of six main centers for the U.S. Food and Drug Administration, which is a part of the U.S. Department of Health and Human Services.
CCMO	Centrale Commissie Mensgebonden Onderzoek	Netherlands	
CDC	Center for Drug Certification	China	
CDE	Center for Drug Evaluation	China	
CDER	Center for Drug Evaluation and Research	USA	The Center for Drug Evaluation and Research is a division of the U.S. Food and Drug Administration that monitors most drugs as defined in the Food, Drug, and Cosmetic Act. Some biological products are also legally considered drugs, but they are covered by the Center for Biologics Evaluation and Research.
CDISC	Clinical the Data Interchange Standards Consortium	China	
CDR	Center for Drug Reevaluation	China	
CEC	Central Ethics Committee	Hungary	
CEC	Clinical Site's Ethics Committee	Portugal	
CECOMA	Central de Compras de Medicamentos e meios medicos de Angola	Angola	Central Procurement Agency for Medicines and Medical Supplies
CEI	Centro Etico de Investigación	Mexico	A research ethics committee (CEI) is responsible for the ethical evaluation of the research protocols on human beings. For elaborating institutional guidelines for health research, and for the following up on its recommendations.
CEI	Comité d'éthique institutionnel - Institutional Ethics Committee	DR Congo	
CEIC	National Ethics Committee for Clinical Research	Portugal	

CENS	Comité National d'Éthique de la Santé- National Health Ethics Committee	DR Congo	
CEPA	Canadian Environmental Protection Act	Canada	
CESG	Common Electronic Submissions Gateway	Canada	The Common Electronic Submissions Gateway (CESG) is a method of securely providing regulatory transactions for review in the electronic Common Technical Document (eCTD) format. Health Canada is collaborating with United States uses CESG for submission of applications.
CESP	Common European Submission Portal	All EU nations, European Union	
CFA	Central African Franc	Central African Countries	The Central African CFA franc is the currency of six independent states in Central Africa: Cameroon, Central African Republic, Chad, Republic of the Congo, Equatorial Guinea and Gabon.
CFDA	China Food and Drug Administration	China	
CFDI	Center for Food and Drug Inspection	China	
CFR	Code of Federal Regulations	USA	The Code of Federal Regulations (CFR) is the codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation.
CHAI	Clinton Health Access Initiative	IDA, UNFPA	
CHM	Commision on Human Medicines	United Kingdom	
CIEI	Comité Ética en Investigación	Peru	The Investigational Ethic Committee is a committee of the National Health Institute with the aim to protect Rights, Life, Health, Intimity, Dignity and Welfare of persons participating in clinical trials, referring to the ethical principles defined by the national normative and agreement subscribed by Peru on ethics and investigation.
CIF	Cost Insurance and Freight price	Iraq	
CIMI	Centro de Informação do Medicamento e dos Produtos de Saúde	Portugal	
CIOMS	Council for International Organisations of Medical Sciences	South Africa	
CIS	The Commonwealth of Independent States	Armenia, Georgia, Kyrgyzstan, Tajikistan	The Commonwealth of Independent States (CIS) formed when the former Soviet Union totally dissolved in 1991. At its conception it consisted of ten former Soviet Republics: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan
CLINO	Ordinance on Clinical Trials in Human Research (Ordinance on Clinical Trials)	Switzerland	
CMDH	Co-ordination Group for Mutual Recognition and Decentralised procedures - Human	Netherlands	
CMED	Câmara de Regulação do Mercado de Medicamentos	Brazil	
CMH	Commission for Medicinal Products for Human Use	Belgium	
CMNS	Changed Medicine Notifications	New Zealand	
CNBI	Comité Nacional de Bioetica de la Investigaccion	Panama	National body managed by the MoH with an independent organization and autonomous in its functions
CNDA	China Nation Drug Administration	China	
COA	Certificate of Analysis	All Countries	
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios	Mexico	
COIFA	Coordenação de Registro de Insumos Farmacêuticos Ativos	Brazil	API registration department of the Brazilian Health Regulatory Agency (ANVISA)
COMIECO	Consejo de Ministros de Integración Económica	Honduras	
CONITEC	Comissão Nacional de Incorporação de Tecnologias	Brazil	National Committee for Technology Incorporation

COO	Country Of Origin	Jordan	
COPP	Certificate of Pharmaceutical Product	All Countries	
COS/CEP	Certificate of Suitability	Iraq	
CPC	Chinese Pharmacopoeia Commission	China	
CPID	Certified Product Information Document	Canada	CPID is the part of module 1 CMC document summarizing quality part of the DS and DP in short.
CPP	Certificate of Pharmaceutical Products	All Countries	
CPPP	Central Public Procurement Portal	India	The Central Public Procurement Portal of Government of India facilitates all the Central Government Organizations to publish their Tender Enquiries, Corrigendum and Award of Contract details. The primary objective of this portal is to provide a single point access to the information on procurements made across various central government organizations.
CPSU	Contracting and Procurement Services Unit	UNICEF	
CPTU	Central Procurement Technical Unit	Bangladesh Procurement Agency	
CQA	Critical Quality Attributes	All Countries	
CRC	Contracts Review Committee	UNICEF	Internal independent body
CRF	Case Report Form	Jordan	
CRP	Canadian Reference Product	Canada	
CRPPHU	Committee for Registration of Pharmaceutical Products for Human Use	Sudan	
CRS	Caribbean Regulatory System	Haiti, Guyana	The Caribbean Regulatory System (CRS) is an initiative of the Caribbean Community and Common Market (CARICOM) and is managed as a regulatory unit within CARICOM's regional public health body, the Caribbean Public Health Agency (CARPHA).
CT	Clinical Trial	All Countries	
CTC	Clinical Trial Certificate	Hong Kong	
CTD-Q	Common Technical Document - Quality	All Countries	
CTN	Clinical Trial Notification scheme	Australia	
CTP	Clinical Trial Permission	China	
CTX	Clinical Trial Exemption scheme	Australia	
DAB	Deutsches Arzneibuch	Germany	German Pharmacopoeia
DAM	Medicines Evaluation Department	Portugal	
DAV	Drug Administration of Vietnam	Vietnam	
DB	Data Box	Czech Republic	
DCGI	Drug Controller General of India	India	Central Drugs Standard Control Organization is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India.
DDA	Department of Drug Administration	Nepal	
DDCM	Dossiês de Desenvolvimento Clínico de Medicamentos	Brazil	Dossier of Clinical Development for a Medicine
DDCM	Dossier of Clinical Development for a Medicine	Brazil	
DEL	Drug Establishment License	Canada	
DFCA	Drug and Food Control Authority	South Sudan	
DFDA	Dossier of Clinical Development for a Medicine		
DGDA	Directorate General of Drug Administration	Bangladesh	
DGFP	Directorate General of Family Planning	Bangladesh Procurement Agency	
DGPML	Direction Generale de la Pharmacie du Medicament et des Laboratoires	Burkina Faso	

DGVMN	Dirección General de Vigilancia del Marco Normativo	Honduras	
DH	Department of Health	Hong Kong	
DHPC	Direct Healthcare Professional Communication	Hungary	
DICA	Directorate of Investment and Company Administration	Myanmar	The Directorate of Investment and Company Administration, a government agency under the Ministry of National Planning and Economic Development, is Myanmar's company register. DICA was formed on 13 October 1993, and serves as the primary interface between businesses and the government.
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas	Peru	
DIN	Drug Identification Number	Canada	The Drug Identification Number (DIN) is the 8 digit number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD) and approved for sale in Canada.
DKMA	Danish Medicines Agency	Denmark	
DMF	Drug Master File	All Countries	
DML	Drug Manufacturing License	Pakistan	
DMP	Direction du Médicament et de la Pharmacie	Gabon	
DNDI	Drugs for Neglected Diesseases Initiative	IDA	
DNF	Drug Notification Form	Canada	
DNFD	Dirección Nacional De Farmacia y Drogas	Panama	
DNME	Direcçao National de Medicamentos e Equipamentos (National Directorate of Drugs and Equipment)	Angola	
DNPL	Direction Nationale de la Pharmacie et des Laboratoires	Guinea	
DO	Drug Office	Hong Kong	
DOH	Department of Health	South Africa	
DPER	Directorate of Product Evaluation and Registration	Kenya	
DPLET	Directorate Pharmacies, Laboratories and Technical Equipment	Togo	
DPM	Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle	Haiti	
DPM	Direction de la Pharmacie et du Medicament	DR Congo, Senegal	
DPMED	Direction des Pharmacies, du Medicament et des Explorations Diagnostiques	Benin	
DPML	Direction de la Pharmacie, du Medicament et des Laboratoires	Chad, Côte d'Ivoire	
DPU	Directorate Pharmacy Unit	Cambodia	
DRAP	Drug Regulatory Authority of Pakistan	Pakistan	
DRCPFA	Direccion General De Regulación, Vigilancia y Control de la Salud	Guatemala	Department for Regulation and Control of Pharmaceutical and Related Products with the function to ensure that all the health establishments in Guatemala shall respect regulations.
DRL	Department of Registration and Licensing	South Sudan	
DSTS	Drug Submission Tracking System	Canada	
DTA	Directorate technical affairs	Iraq	
EAC	East African Community	Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda	

EAC MRH	East African Community Medicines Regulatory Harmonization	Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda	The East African Community Medicines Regulatory (EAC - MRH) Programme was launched in 2012 becoming the first Regional Economic Community (REC) in Africa to initiate harmonization procedures for medicines regulation under the African Medicines Registration Harmonization Initiative (AMRHI). The Programme aimed at establishing harmonized and functioning medicines registration and regulation systems within the East African Community (EAC) in accordance to the national and internationally recognized standards and best practices. Implementation of the Programme is done by the National Medicines Regulatory Authorities (NMRAs) in all EAC Partner States namely: The Department of Pharmacy, Medicines and Laboratories (DPML) of Burundi, The National Drug Authority (NDA) of Uganda, Pharmacy and Poisons Board (PPB) of Kenya, Pharmacy Task Force (PTF) of Rwanda, Drug and Food Control Authority (DFCA) of South Sudan as well as The Tanzania Food and Drugs Authority (TFDA) and The Zanzibar Food and Drugs Agency (ZFDA) of the United Republic of Tanzania.
EAI	Evaluation of Additional Information	New Zealand	
EBHMC	Executive Board of the Health Ministers' Council for GCC States	Saudi Arabia, Kuwait, Qatar, Bahrain, Oman, United Arab Emirates, Yemen	
ECOWAS	Economic Community of West African States	Niger	
EDL	Essential Drugs List	China Procurement Agency	
EED	National Ethics Committee	Greece	
EJDWS	electronic Jordan Drug Workflow System	Jordan	
ELF	Electronic Listing Facility	Australia	
EMD	Earnest Money Deposit	All Countries	
EOF	The National Organization for Medicines, Greece	Greece	
ERP	Expert Review Panel	PFSCM	
ETT-KFEB	Medical Research Council Ethics Committee for Clinical Pharmacology	Hungary	
EUCUA	Emergency Use & Compassionate Use Authorization	Kenya	
EUND	Extraordinary Use New Drug	Canada	Health Canada, the federal regulatory authority that evaluates the quality, safety, and efficacy of human drugs available in Canada, recognizes that there are circumstances in which sponsors cannot reasonably provide substantial evidence demonstrating the safety and efficacy of a therapeutic product as there are logistical or ethical challenges in conducting the appropriate human clinical trials. The Extraordinary Use New Drugs (EUND) pathway was developed to allow a mechanism for authorization of these drugs based on non-clinical and limited clinical information.
EUNDS	Extraordinary Use New Drug Submission	Canada	
FAMHP	Federal Agency for Medicines and Health Products	Belgium	
FDA	Food and Drug Administration	USA, Thailand	Health regulatory entity in the United States
FDA	Food and Drugs Authority	Ghana	
FDR	Food and Drug Regulations	Canada	The legislation that oversees and sets out requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of foods, and prescription and non-prescription drugs in Canada. Requirements for drug clinical trials are also set out in the regulations. Health Canada develops and enforces regulations under Government of Canada legislation. The Department consults with the Canadian public, industry and other interested parties in the development of laws that protect health and safety. They also prepare guidelines and policies in order to help interpret and clarify the legislation surrounding drugs and health products. The purpose of the legislation is to protect the health and safety of Canadians with respect to the sales of food and drug products.
FFI	Foreign Factory Information	Taiwan	
FGBU	National Center of Pharmaceutical Products Expertise	Russia	

FMHACA	Food and Medicine Health and Control Agency	Ethiopia Procurement Agency	
FOEN	Federal Office for the Environment	Switzerland	
FOPH	Federal Office of Public Health	Switzerland	
FPMC	Foreign Pharmaceutical Manufacturing Company	Afghanistan	
FPP	Finished Pharmaceutical Product	All Countries	
FPRC	Final Product Release Control	South Africa	
FPRC	Finished Product Release Control	Bangladesh	
FPRC	Final Product Release Control	South Africa, Bangladesh	
FPRR	Finished Product Release Responsibility	Bangladesh	
FSC	Free Sale Certificate	All Countries	
FSMP	Foods for special medical purposes	Czech Republic	
FT	Fast-track	All Countries	
FTP	Fast-track authorization procedure	Switzerland	
FTR	Fast track registration	Iraq	
FUM	Follow-up measure	Croatia	
GCC	Gulf Central Committee	Iraq	
GCC	Gulf Cooperation Council	UAE	
GCC-DR	Gulf Central Committee for Drug Registration	Saudi Arabia, Kuwait, Qatar, Bahrain, Oman, United Arab Emirates, Yemen	
GDPA	General Directorate of Pharmaceutical Affairs	Afghanistan	
GDUFA	Generic Drug User Fee Amendments	USA	The Generic Drug User Fee Act is a law designed to speed access to safe and effective generic drugs to the public, and reduce costs to industry.
GFATM	Global Fund to Fight Aids, Tuberculosis and Malaria	IDA, PFSCM	
GLP	Good Laboratory Practices	All Countries	
GMO	Genetically Modified Organism	Jordan	
GMP	Good Manufacturing Practice	All Countries	
GRM	Global Regulatory Management	All Countries	
GRTPNZ	Guideline for the Regulation of Therapeutic Products in New Zealand	New Zealand	
GTAC	Gene Technology Advisory Committee	New Zealand	
HALMED	Agency for Medicinal Products and Medical Devices	Croatia	
HC	Helsinki Committee	Israel	
HDEC	Health and Disability Ethics Committees	New Zealand	
HKAPI	Hong Kong Association of the Pharmaceutical Industry	Hong Kong	
HKSAR	Hong Kong Special Administrative Region	Hong Kong	
HMA	The Heads of Medicines Agencies	Netherlands	
HMRTC	Human Medicines Registration Technical Committee	Tanzania	
HP	Voluntary Harmonisation Procedure	Hungary	
HRC	Health Research Council	New Zealand	
HUPI	Hungarian Product Information	Hungary	

ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	Common	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration.
ICSMCF	State Institute of Drug Control and Pharmaceutical Research	Romania	
IDA	International Dispensary Association	IDA	An independent social enterprise providing medicines and medical goods to healthcare organizations worldwide at the best price possible.
IGAD	Intergovernmental Authority on Development	Kenya, Somalia	The Intergovernmental Authority on Development is an eight-country trade bloc in Africa. It includes governments from the Horn of Africa, Nile Valley and the African Great Lakes. Its headquarters are in Djibouti City.
IGJ	Health and Youth Care Inspectorate	Netherlands	
IMP	Investigational Medicinal Product	All Countries	Investigational Drug Product
IND	Investigational New Drug	USA	
INF	Iraqi National formulary	Iraq	
INHRR	National Institute of Hygiene "Rafael Rangel"	Venezuela	
INSP	Institut National de Santé Publique	Guinea	
INVIMA	National Institute of Drugs and Food Vigilance	Colombia	
IP	isoelectric point	All Countries	
IPI	Inactive Pharmaceutical Ingredient	South Africa	
IR	Infrared Spectroscopy	All Countries	
IRB	Institutional Review board	USA	Also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical. Such boards are formally designated to approve (or reject), monitor, and review biomedical and behavioral research involving humans.
ISCP	Institute for Standardization and Control of Pharmaceuticals	Israel	
IT	Index Therapeuticus	Switzerland	
JFDA	Jordan Food and Drug Administration	Jordan	
KAS	Medicinal products with known active substances	Switzerland	
LBBDBT	Law on Blood, Blood Donation and Blood Transfusion	Bulgaria	
LBCTR	Lebanon Clinical Trials Registry	Lebanon	
LEC	Local Ethics Committee	UAE	
LIC.	License	All Countries	
LMHRA	Liberia Medicines and Health Products Regulatory Authority	Liberia	
LMP	Law on Medicinal Products	Bulgaria	
LMPHM	Law on Medicinal Products in Humane Medicine	Bulgaria	
LNCPP	National Laboratory for Quality Control of Pharmaceutical Products	Algeria	
LNSP	Laboratoire National de la Sante Publique	Côte d'Ivoire	
LRDRC	Law and Regulationa Datbase of the Republic of China	Taiwan	
LVFS	Medical Products Agency's provisions	Sweden	
MAA	Marketing Authorisation Application	All Countries	
MAF	Ministry of Agriculture & Forestry	New Zealand	

MAPP	Manual of Policies and Procedures	USA	
MCA	Medicines Control Agency	Gambia	
MCAZ	Medicines Control Authority of Zimbabwe	Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ) is responsible for regulating medicines and other pharmaceutical products in Zimbabwe.
MEB	Medicines Evaluation Board	Netherlands	
MEDDRA	Medical Dictionary for Drug Regulatory Authorities	All Countries	
MEDSAFE	New Zealand Medicines and Medical Devices Safety Authority	New Zealand	
MEK	Ethics Committee for Multicentric Clinical Trials	Czech Republic	
MENA	Middle East and North Africa	Afghanistan, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Cote d'Ivoire, DR Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Eswatini, Tanzania, Togo, Uganda, Yemen, Zambia, Zanzibar, Zimbabwe	MENA is an English-language acronym referring to the Middle East and North Africa region. An alternative for the same group of countries is WANA. The term covers an extensive region stretching from Morocco to Iran, including all Mashriq and Maghreb countries
METC	Medisch Ethische To etsings commissie	Netherlands	Medical Ethics Review Committees
MFDA	Myanmar Food and Drug Administration	Myanmar	The Department of Food and Drug Administration is Burma's food safety regulatory body, which oversees the safety and quality of food, drugs, medical devices and cosmetics. FDA was established in 1995
MFDS	Regulatory Authority South Korea	South Korea	
MHRA	Medicines and Healthcare Products Regulatory Agency	United Kingdom	
ML	Manufacturing License	Jordan	
MOA	Method of Analysis	PFSCM	
MOC	Ministry of Commerce	Cambodia	
MOH	Ministry of Health	All Countries	
MOHAP	Ministry of Health and Prevention	UAE	
MOHCW	Minister of Health and Child Welfare	Zimbabwe	
MOHFW	Ministry of Health & Family Welfare	Bangladesh Procurement Agency	
MOPH	The Ministry of Public Health Lebanon	Lebanon	
MPA	Swedish Medical Products Agency	Sweden	
MPLO	Medicinal Products Licensing Ordinance	Switzerland	
MPPS	Ministry of Popular Power for Health	Venezuela	
MPT	MinPromTorg	Russia	Ministry of Industry and Trade of the Russian Federation

MRL	Maximum Residue Limit	Serbia	
MS	Mass Spectroscopy	All Countries	
MSCT	Multisite Clinical trial	Taiwan	
MSD	Medical Stores Depots	All Countries	
MSHP	Ministere de la Snate et de l'Hygiene Publique	Gabon	
MSP	MIKHAILYUK SOROKOLAT & PARTNERS	Ukraine	Patent and Trademark Attorneys
MSP	Ministere de la Sante e de la Prevention	Senegal	
MSP	Ministére de la Santé Publique	Cameroon	
MSPAS	Ministerio de salud publica y asistencia social	Guatemala	Ministry of Health and Welfare
NAFDAC	National Agency for Food & Drug Administration & Control	Nigeria	The National Agency of Drug and Food Control of Republic of Indonesia or NADFC (Indonesian: Badan Pengawas Obat dan Makanan) or Badan POM is a government agency of Indonesia, BPOM is responsible for protecting public health through the control and supervision of prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, dietary supplements, food safety and cosmetics. Task and purposes of this agency is similar to USFDA.
NAMMDR	National Agency for Medicines and Medical Devices of Romania	Romania	
NAS	Medicinal products with new active substances	Switzerland	
NCDCR	National Center for Drug Control and Research	Iraq	
NDA	New Drug application	All Countries	
NDRA	National Drug Regulatory Authority	PFSCM	
NDRC	National Development and Reform Commission	China Procurement Agency	
NDS	New Drug Submission	Canada	
NHEP	National Health Emergency Plan	New Zealand	
NHFPC	National Health and Family Planning Commission	China	
NHFPC	National Health and Family Planning Commission	China	
NHS	National Health Service	United Kingdom	
NICE HTA	National Institute for Health and Care Excellence - Human Tissue Authority	United Kingdom	
NIFDC	National Institute for Food and Drug Control	China	
NMA	National Medicine Agency	Greece	
NMA	New Medicine Applications	New Zealand	
NMC	New Molecules Committee	Mexico	Commission that evaluate dossier on New molecules submitted in Mexico. The decision of NMC influence COFEPRIS evaluation of the registration dossier
NMPA	National Medicine Product Administration	China	
NMPB	National Medicines and Poisons Board	Sudan	
NMR	Nuclear Magnetic Resonance	All Countries	
NOC	Notice of Compliance	Canada	Notification issued by Health Canada indicating that a manufacturer has complied with the requirements of the Food and Drug Regulations at the end of the review of an NDS, ANDS, S/NDS or S/ANDS.
NOC	No Objection Certificate	All Countries	
NOD	Notice of Deficiency	Canada	If deficiencies and/or significant omissions that preclude continuing the review are identified during the review of a submission, a NOD will be issued.
NOL	No Objection Letter	Canada	For sponsors who wish to import a drug into Canada for the purpose of a clinical trial, a No Objection Letter should be provided at the time of importation to facilitate shipment and to demonstrate compliance with section C.05.006 or section C.05.008 of the Regulations.

NON	Notice of Noncompliance	Canada	
NPRA	National Pharmaceutical Regulatory Agency	Malaysia	The National Pharmaceutical Regulatory Agency (NPRA) in Malaysia ensures the quality and safety of pharmaceutical products. The NPRA site contains information about the agency, lists of guidelines and updates, and a product search feature.
NRA	National Regulatory Authority	All Countries	
NRDL	National Reimbursement Drug List	China Procurement Agency	
NSN	Not-Satisfactory Notice	Canada	A notice issued by the Director of the responsible reviewing Bureau/Centre if deficiencies are identified during the review of a Clinical Trial Application, Clinical Trial Application-Amendment or Notifiable Change. The deficiencies will be specified and review of the submission will stop on the date of the Not Satisfactory Notice.
NSSF	National Social Security Fund	Lebanon	
NT	Normal-track	All Countries	
OGITT	Oficina General de Investigación y Transferencia Tecnológica	Peru	General Office of Research and Technological Transfer - an advisory body responsible for the development of health research and technology and its transfer to the health sector/community; OGITT acts as an internal and external coordination body in matters of its competence.
OGYÉI	National Institute of Pharmacy and Nutrition	Hungary	
OMCL	Official Medicines Control Laboratory Division	Croatia	
OPL	Order of Pharmacists	Lebanon	
ORMP	Office for Registration of Medicinal Products, Medical Devices and Biocides	Poland	
OTC	Over the counter	USA	Drugs are defined as drugs that are safe and effective for use by the general public without seeking treatment by a health professional.
PAA	Pharmaceutical Affairs Act	Taiwan	
PAM	Post-Authorisation Measures	Croatia	
PAN	Permanent Account Number		
PANDRH	Pan American Network on Drug Regulatory Harmonization		
PBS	The Pharmaceutical Benefits Scheme	Australia	The Pharmaceutical Benefits Scheme (PBS) is a program of the Australian Government that provides subsidized prescription drugs to residents of Australia, as well as certain foreign visitors covered by a Reciprocal Health Care Agreement.
PBSL	Pharmacy Board of Sierra Leone	Sierra Leone	
PC	Poisons Committee	Hong Kong	
PDUFA	Prescription Drug User Fee Act	USA	The Prescription Drug User Fee Act was a law passed by the United States Congress in 1992 which allowed the Food and Drug Administration to collect fees from drug manufacturers to fund the new drug approval process.
PEI	Paul-Ehrlich-Institut	Germany	
PFDA	Provincial FDA	China	
PFSCM	Partnership for Supply Chain Management	PFSCM	PFSCM strengthens public health supply chains, ensuring lifesaving commodities are accessible and available to communities in hard-to-reach places.
PH. HELV.	Pharmacopoeia Helvetica	Switzerland	
PHARMAC	Pharmaceutical Management Agency	New Zealand	
PHEIC	Public Health Emergency of International Concern	Kenya	
PIC/S	Pharmaceutical Inspection Co-operation Scheme	All Countries	
PKA	dissociation constant	All Countries	
PMF	Plant Master File	Taiwan	
PMPB	Pharmacy, Medicines and Poisons Board	Malawi	
POR	Presidence of the Republique	Côte d'Ivoire	

PP	Pharmaceutical Product	Hong Kong	
PPA	Public Procurement & Property Administration Agency	Ethiopia Procurement Agency	
PPB	Pharmacy and Poisons Board	Hong Kong	
PPB	Pharmacy and Poisons Board	Kenya	The Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.
PPB	Pharmacy and Poisons Board	Hong Kong	
PPO	Pharmacy and Poisons Ordinance	Hong Kong	
PPR	Pharmacy and Poisons Regulations	Hong Kong	
PRAC	Pharmacovigilance Risk Assessment Committee	Bulgaria	
PRS	Pharmaceutical Registration System	Hong Kong	
PRV	Swedish Patent and Registration Office	Sweden	
PSF	Product Specific File	South Africa	
PSI	Pre-Shipment Inspection	UNICEF	
PSUR	Periodic Safety Updated Report	All Countries	Periodic Safety Update Reports (PSURs) A Periodic Safety Update Report is a pharmacovigilance document intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points post-authorization.
QAU	Quality Assurance Unit	UNICEF	
QC	Quality Control	All Countries	
QRM	Quality Risk Management	All Countries	
RC	Registration Committee	Hong Kong	
RCMOHP	Regulatory Committee at the Ministry of Health and Prevention	UAE	
RCR	Report of Complete Review	Taiwan	
RDB	Rwanda Development Board	Rwanda	
REB	Research Ethics Board	Canada	A body that is not affiliated with the sponsor, mandated to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being. The body needs at least five members, that are in majority Canadian citizens or permanent residents under the Immigration Act, and composed of both men and women. Additional criteria apply.
REC	Research Ethics Committees	South Africa	Ensure the protection of, and respect the rights, safety and well being of participants involved in a trial and to provide public assurance of that protection by reviewing, approving and providing comment on clinical trial protocols, the suitability of investigator(s), facilities, methods and procedures used to obtain informed consent
REMS	Risk Management Plan	All Countries	
REP	Regulatory Enrolment Process	Canada	
RFIS	Requests for Further Information	New Zealand	
RFPS	Request fro Proposal	PFSCM	Is a document that solicits proposal, often made through a bidding process, by an agency or company interested in procurement of a commodity, service, or valuable asset, to potential suppliers to submit business proposals.
RLD	Reference Listed Drug	All Countries	
RNEC	Registo Nacional de Estudos Clínicos	Portugal	
RSS	Repuplic of South Sudan	South Sudan	
RZN	Roszdravnadzor	Russia	Ministry of Health and the Federal Service for Surveillance in Healthcare
SACS	Autonomous Service of Sanitary Comptroller	Venezuela	
SADC	South African Development Community	African countries- Malawi,	
SADC	Southern African Development Community	Zimbabwe	

SAHPRA	South African Health Products Regulatory Authority	South Africa	Regulatory Agency under the Ministry of Health
SANCTR	South African Clinical Trial Register	South Africa	Register managed by the Department of Health
SANDS	Supplement to an Abbreviated New Drug Submission	Canada	
SAR	Subject of a valid authorization or registration	Portugal	
SCOTT	Standing Committee on Therapeutic Trials	New Zealand	
SD	Supply Division	UNICEF	
SDFCA	Secretariat Drug and Food Control Authority	South Sudan	
SDN	Screening Deficiency Notice	Canada	
SECB	Swiss Expert Committee for Biosafety	Switzerland	
SEU	Supplier Evaluation Unit	UNICEF	
SFDA	Saudi Food and Drug Authority	UAE	
SIAPS	Systems for Improved Access to Pharmaceuticals and Services	Angola	
SIR	Safety Incident Reports	Lebanon	
SMACS	Starting Materials Certification Scheme	All Countries	
SME	Subject Matter Expert	All Countries	
SMPC	Summary of Product Characteristics	All Countries	
SMRA	State Market Regulatory Administration	China	In March 2018, China established the State Market Regulatory Administration (SMRA), which will take on the responsibilities of the China Food and Drug Administration (CFDA) and several other government entities. The SMRA's State Drug Administration will replace the CFDA.
SMUH	Electronic System for the Management of Medicinal Products of Human Use	Portugal	
SNDS	Supplement to a New Drug Submission	Canada	
SPS	Strengthening Pharmaceutical Systems	Afghanistan	The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to the most efficacious, safe and cost-effective medicines and appropriate use of medicines.
SRA	Stringent Regulatory Authority	All Countries	
SUKL	State Institute for Drug Control	Czech Republic	
SUSAR	Suspected Unexpected Serious Adverse Reaction	Israel	
SUSARS	Suspected Unexpected Serious Adverse Reactions	Lebanon	
SVMMD	Station for Verification and Maintenance of Medical Devices	Romania	
SWISSPAR	Swiss Public Assessment Report	Switzerland	
TB	Tuberculosis	All Countries	
TEC	Tender Evaluation Committee	IDA	
TFDA	Tanzania Food & Drug Authority	Tanzania	Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGE) responsible for regulating safety, quality and effectiveness of food, medicines, cosmetics, medical devices and diagnostics.
TFDA	Thai Food & Drug Administration	Thailand	The main role of Thai FDA is to protect consumers' health through ensuring safety, quality and efficacy of consumable products within its remit. These include: foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country.

TFDA	Taiwan Food and Drug Administration	Taiwan	
TGA	Therapeutic Goods Administration	Australia	The Therapeutic Goods Administration is the regulatory body for therapeutic goods in Australia. It is a Division of the Australian Department of Health
TGA	Thermo-gravimetric Analyses	All Countries	
TGO	Therapeutic Goods Order	Australia	
TOMD	Technical Office for Medical Devices	Romania	
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)	Switzerland	
TPD	Therapeutic Products Directorate	Canada	Therapeutic Products Directorate is Canada's regulator of prescription drugs and medical devices for human use. Before giving permission to sell a product, the directorate must see scientific evidence of the product's safety, effectiveness, and quality, as required by the Food and Drugs Act and Regulations.
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (SR 812.212.23)	Switzerland	
TPLRO	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the Licensing Requirements for Therapeutic Products (SR 812.212.22)	Switzerland	
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)	Switzerland	
UEMOA	Unión Económica y Monetaria de África Occidental	Senegal	
UN	United Nations	UNFPA	
UNDP	United Nations Procurement Division	UNFPA	
UNFPA	United Nations Population Found	UNFPA	UNFPA is the United Nations sexual and reproductive health agency.
UNGM	United Nations Global Marketplace	UNFPA	
URPL	Urząd Rejestracji Produktów Leczniczych	Poland	
USADE	Unanticipated Serious Adverse Device Effect	Israel	
USAID'S SCMS	US Agency for International Development Supply Chain Management System	IDA, USA	
USP	United States Pharmacopoeia	PFSCM	
VHP	Voluntary Harmonisation Procedure	Austria	
VMP	Veterinary medicinal products	Switzerland	
VP	Validation Protocol	South Africa	
VR	Validation Report	South Africa	
VWS	Ministerie van Volksgezondheid, Welzijn en Sport	Netherlands	Ministry of Health, Welfare and Sport
WAEMU	West African Economic and Monetary Union	Niger	
WAHO	West African Health Organization	Nigeria	
WHO MQAS	Model Quality Assurance System for Procurement Agencies	WHO, IDA	
WHO'S STGS	WHO's Standard Treatment Guidelines	WHO, IDA, PFSCM, UNICEF	

WHO-PQ	WHO Prequalification Program	UNFPA, PFSCM	
WMA	World Medical Association	Iraq	
WMO	The Wet op medischwetenschappelijk onderzoek met mensen	Netherlands	Medical Research Involving Human Subjects (WMO Act)
XRPD	X-ray Powder Diffraction	All Countries	
ZAMRA	Zambia Medicines Regulatory Authority	Zambia	The Zambia Medicines Regulatory Authority formally the Pharmaceutical Regulatory Authority is the Statutory National Medicines Regulatory Body for Zambia established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control the manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances.
ZFDA	Zanzibar Food and Drugs Board	Zanzibar	Zanzibar Food and Drug Agency ZFDA is a regulatory body responsible for controlling the quality, safety and effectiveness of food, drugs, herbal drugs and medical devices for the purpose of protecting public health. Established under section 3(1) of the Zanzibar Food, Drug and Cosmetic Act No.2 of 2006,