PART VII

EAC COMMON GLOSSARY OF TERMS USED IN MEDICINES REGISTRATION

ABBREVIATIONS AND ACRONYMS

BMGF	-	Bill and Melinda Gates Foundation
EAC	-	East African Community
EAC-MRH	-	East African Community Medicines Regulatory
EMA	-	European Medicines Agency
GMP	-	Good Manufacturing Practice
ICH	-	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
MA	-	Marketing Authorization
MAH	-	Marketing Authorization Holder
MER	-	Medicines Evaluation and Registration
NEPAD	-	New Partnership for African Development
NMRA	-	National Medicines Regulatory Authority
		Requirements for Registration of Pharmaceuticals for Human Use
TWG	-	Technical Working Group
US FDA	-	United States Food and Drug Administration
WHO	-	World Health Organization
SRA	-	Stringent Regulatory Authority

1. INTRODUCTION

Glossary of terms in medicines registration have been developed to minimize misunderstanding of words used in medicines registration as this process is at the nexus of many key stakeholders. There is also an increasing proliferation and duplication of terms and definitions, as the medicines registration field itself is still evolving and adapting itself to new and changing contexts.

The glossary provides information on the range of terms and definitions encountered in medicines registration. It does not present new or different definitions of terms, but draws together definitions from many existing sources. Changes to definitions have been minimal, and only made to unify the style of the Glossary, e.g. some spelling has been standardised, and the plural form of terms has been replaced by the singular form.

2. SELECTION OF TERMS

The terms were selected from existing glossaries appended to guidelines on application for registration of medicines from respective EAC Partner States. Also, the terms were selected from international guidelines such as USFDA, WHO, EMA, Health Canada and other international publications.
Furthermore, definitions were selected using the criteria of widespread acceptance, wide spread use and consultation from EAC National Medicines Regulatory Authorities.

3. SCOPE

This glossary of terms primarily addresses terms that are used in various EAC harmonized guidelines on registration of human medicinal products. The terms are defined in context of EAC Human Medicines Registration Harmonization Project as they are confined to the respective regulations and guidelines that are intended to be used in EAC Region.

4. GLOSSARY

In the context of EAC-Human Medicines Registration Harmonization the following words/phrases are defined as follows:

Active pharmaceutical ingredient (API)	An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. *(USFDA Glossary of terms, it can be found in line at Drugs@FDA Glossary of Terms).*
Acceptance criteria	The product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units). *(WHO guide to good manufacturing practice (GMP) requirements, at http://www.who.int/vaccines-documents/DocsPDF/www9651.pdf).*
Active Pharmaceutical Ingredient Master File-(APIMF)	See Drug Master File (DMF)
Active Substance	See Active pharmaceutical ingredient (API)
Adverse reaction (Adverse Drug Reaction, ADR)	An adverse drug reaction is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. *At:http://www.who.umc.org/DynPage.aspx?id=13111&mn=1513]*
Applicant	*See Marketing Authorization Holder*

Batch (or lot)	A defined quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Batch number (or lot number)	A distinctive combination of numbers and/or letters which specifically identifies a batch or lot and from which the production history can be determined. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Bio-equivalence	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 becomes available at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study. *(Glossary (terms and abbreviations)/EMA).*
Bulk product	Any product that has completed all processing stages up to, but not including, final packaging. *(WHO guide to good manufacturing practice (GMP) requirements, at http://www.who.int/vaccines-documents/DocsPDF/www9651.pdf).*
Calibration	A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Certificate of Pharmaceutical Product (CPP)	WHO-type certificate as defined in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce.

	(WHO Model Quality Assurance System for Procurement Agencies; it can be found at http://www.myaccessrh.org/documents/10157/37547/ ModelQualityAssurance.pdf).
Clinical trial (clinical study)	A clinical trial is any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, in order to discover or verify the effects of, and/or identify any adverse reaction to, investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf*)
Comparator	An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial. *(http://www.gcphelpdesk.com/index.php/glossary/10-c)*
Comparator product	A pharmaceutical product with which the multisource product is intended to be interchangeable in clinical practice (https(://www.who.int/medicines/areas/quality_safety/quality_assurance/guidanceontheselectionofcomparatorpharmproducts-etc_qas14-596_18072014.pdf)
Composition	Composition in relation to a medicinal product means the ingredients of which it consists, proportions, degree of strength, quality and purity in which those ingredients are contained. *Kenya and Guidelines on submission for Documentation for Registration of Human medicinal Product-TFDA).*

Conflict of interest	A conflict of interest is a situation in which a public official's decisions are influenced by the official's personal interests. *[At: http://wordnet.princeton.edu/]*
Contamination	The unintended, non-process related, introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a material during production, sampling, packaging or repackaging, storage or transport. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Continuous production	A process in which a material is continuously produced in a step or series of steps. In a continuous process the batches of raw materials and the process parameters can be statistically, but not absolutely, correlated to the material produced in a given window of time. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Controlled Medicines	Narcotic medicines and psychotropic substances regulated by provisions of national medicines laws. (WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf)
Cross contamination	Contamination of a material or product with another material or product, thus cross contamination is a particular form of contamination. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Data exclusivity	Data exclusivity is the protection of an originator pharmaceutical company’s data preventing other parties from using these data for a commercial purpose.

	(OECD – Pharmaceutical Pricing Policies in a Global Market, at: *http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html*).
Design Space	The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. *(ICHQ8- Glossary at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002872.pdf)*
Direct to consumer advertising	Direct-to-consumer advertising (DTC advertising) usually refers to the marketing of medicines aimed directly toward the public, rather than healthcare professionals. Forms of DTC advertising include TV, print, and radio. *(OECD – Pharmaceutical Pricing Policies in a Global Market, at: http://www.oecd.org/document/36/0,3343,en_2649_33929_41000996_1_1_1_37407,00.html).*
Distribution category	Distribution category indicates how a drug product is sold or dispensed. For example Prescription Only Medicines (POM), Over the Counter (OTC refer to national guideline).*(WHO glossary of terms)*
Dosage form	See pharmaceutical form
Drug Master File (DMF)	Is a master file that provides a full set of data on an active pharmaceutical ingredient (API). In other circumstances the term may also comprise data on an excipient. *(Guidelines to Submission of Applications for Registration of Drug, Pharmacy and Poisons Board-Kenya).*
Drug Product	A finished dosage form, for example, a tablet, capsule or solution that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients. Reference:

	Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients FDA Guidance (https://www.registrarcorp.com/fdadrugs/definitions/)
Drug Substance	See Active pharmaceutical ingredient (API)
Duplicate license	Marketing authorization issued to a product that is identical in terms of qualitative and quantitative composition, manufacturing process and sites as well as quality controls to an already registered medicinal product. The only difference would be the brand name and product labels.
Efficacy	The ability of a drug to produce the intended effect as determined by scientific methods, for example in pre-clinical research or clinical research studies. *(WHO Glossary of terms used in Pharmacovigilance, at http://who-umc.org/Graphics/24729.pdf).*
Essential medicines	Essential medicines satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. *(At: http://www.who.int/topics/essential_medicines/en/)*
Ethics Committee (EC)/ Institutional Review Board (IRB)	Ethics Committees (EC) ensure that biomedical research follows international guidelines, including the Declaration of Helsinki, the WHO and ICH Guidelines for Good Clinical Practice. The purpose of an EC in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants. *(Operational Guidelines for Ethics Committees That Review Biomedical Research Geneva 2000, can be found online at: http://apps.who.int/tdr/publications/training-guideline-publications/operational-guidelines-ethics-biomedical-research/pdf/ethics.pdf)*

Excipient	Is any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient (Guideline on excipients in the dossier for application for marketing authorization of a medicinal product, it can be found on line at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003380.pdf).
Extension application	A new application that is a modification/addition to an already registered medicinal product. The modification/addition shall be such that it does not fulfil criteria for minor or major variations but is similar enough to the original (already registered) product in terms of quality, safety and efficacy. A new marketing authorization will be issued for extension applications.
Finished Pharmaceutical Product (FPP)	A finished dosage form of a pharmaceutical product which has undergone all stages of manufacture, including packaging in its final container and labelling (*WHO Glossary)*
Formulary	A formulary is a manual containing clinically oriented summaries of pharmacological information about selected medicines. *(How to develop a national formulary based on the WHO model formulary, a practical guide Geneva 2004, can be found online at: http://apps.who.int/medicinedocs/en/d/Js6171e/2.3.html)*
General Sales Medicines (GSM)	Medicines which may be sold either by way of retail or wholesale in an open shop such as supermarkets.
Generic product	Is a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

	(PHIS Glossary 2009, can be found on line at: http://phis.goeg.at/index.aspx?alias=phisglossary)
Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. *(PHIS Glossary 2009, can be found on line at: http://phis.goeg.at/index.aspx?alias=phisglossary)*
Good Manufacturing Practice (GMP)	Part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. *(WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf)*
Impurity	Any component present in the active pharmaceutical ingredient other than the substance defined as the active pharmaceutical ingredient *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer,* *At **http://apic.cefic.org/pub/1gmp-api9604.pdf**).*
Innovator medicinal product	Generally the medicinal product that was first authorized for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality. (WHO glossary of terms) *(Adapted from WHO glossary of terms)*
In-process control	Checks performed during production in order to monitor and, if necessary, to adjust the process, including repeating a process step, to ensure that the product conforms to its specification. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*

Intermediate	Partly processed material which must undergo further production steps before it becomes an Active Ingredient. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
International Conference on harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	The International Conference on Harmonization of Technical Requirements for Registration of 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 product registration. *[At: http://www.ich.org/cache/compo/276-254-1.html]*
Reference product	Pharmaceutical product with which the new product is intended to be interchangeable in clinical practice. The reference product will normally be the innovator product for which efficacy, safety and quality have been established. Where the innovator product is not available, the product which is the market leader may be used as a reference product, provided that it has been authorized for marketing and its efficacy, safety and quality have been established and documented. (http://apps.who.int/medicinedocs/en/d/Js5516e/19.2.html#Js5516e.19.2)
International Non-proprietary Name (INN)	INN is a unique name that is globally recognized and is public property. *[WHO Guidance on INN at: http://www.who.int/medicines/services/inn/innguidance/en/index.html]*
Label	Is a descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a packaging of any medicinal product. *(Adapted from USFDA Glossary of terms, can be found in line at Drugs@FDA Glossary of Terms).*

Law	Laws define the roles, rights and obligations of all parties involved in the subject matter in general terms. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf)*
Legal category	See Distribution category
Legislation	Legislation corresponds to the first stage of the legislative process, in which laws are passed by the legislative body of government with regard to a subject matter such as the control of pharmaceuticals. *(WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf)*
License Holder	A license holder is an individual or a corporate entity possessing a marketing authorization for a medicinal product. (WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf) (*Also see Market authorization Holder).*
Licensing system	National legal provisions on who should manufacture, import or supply medicinal products, what qualifications people in the supplying agency should have, and who should dispense and sell pharmaceutical products. *(WHO glossary of terms)*
Local Technical Representative	A person or company with sufficient pharmaceutical expertise that is incorporated within *the specific country* and who will be responsible for facilitating communication with the Applicant and when the product is registered shall assume all legal responsibilities.

Manufacture (manufacturing)	Manufacturing includes all operations of receipt of materials, production, packaging, repackaging, labelling, relabeling, quality control, release, storage and distribution of active pharmaceutical ingredients and/or medicinal product. *[PHIS Glossary 2009, can be found on line at: http://phis.goeg.at/index.aspx?alias=phisglossary]*
Manufacturer	A manufacturer is a natural or legal person with responsibility for manufacturing of a medicinal product or active pharmaceutical ingredient. *(PHIS Glossary 2009, can be found on line at: http://phis.goeg.at/index.aspx?alias=phisglossary)*
Market Authorization Holder	Is a person who holds authorization to place a medicinal product in the EAC Partner Sates and is responsible for that product.
Marketing Authorization (MA)	Means approval to market a medicinal product in an EAC Partner States. (*Glossary of terms and abbreviations/EMA, it can be found at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099907.pdf).*
Medical device	Means an article which is intended to be used for human beings or animals for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, or control of conception and does not achieve its purpose by pharmacological, immunological or metabolic means. *(Upholding standards and public trust in pharmacy, at **http://www.pharmacyregulation.org/sites/default/files/Glossary%20of%20terms%20used%20in%20GPhC%20standards%20Feb%202012.pdf**)*
Medicinal Product	Any substance or combination of substances which may be administered to human beings or animals with

	a view to making a medical diagnosis or to restoring, prevention, correcting or modifying physiological functions in human beings or animals.
Medicinal Substance	See Active pharmaceutical ingredient (API)
Medicines Regulatory Authority	A national body that has the legal mandate to set objectives and administer the full spectrum of medicines regulatory activities. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:* ***http://infocollections.org/medregpack/interface/files/glossary.pdf****).*
National essential medicines list	The list of essential medicines that has been defined, adopted, and published at country level. (*WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf)*
Originator medicinal product/originator brand	An originator brand is generally the product that was first authorized worldwide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization. *(HAI/WHO Measuring medicine prices, availability, affordability and price components (2nd Edition) and at:* ***http://www.haiweb.org/medicineprices/manual/documents.html****)*
Over-The-Counter medicines (OTC)	Are medicines which are safe and effective for use by the general public without a doctor's prescription. (WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities Regulatory Support Series No. 014 at:

	http://infocollections.org/medregpack/interface/files/glossary.pdf)
Packaging materials	Any material used to protect an Active Pharmaceutical Ingredient or finished pharmaceutical product during storage and transport but excluding labels.*(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Patient Information Leaflet (PIL)	Packages insert which contains information for patient's understanding of how to safely use a medicinal product. *(USFDA Glossary of terms, can be found in line at Drugs@FDA Glossary of Terms).*
Pharmaceutical alternatives	Medicinal products are considered pharmaceutical alternatives if they contain the same therapeutic moiety, but are different salt, esters, or complexes of that moiety, or are different dosage forms or strengths. (USFDA Orange book, it can be found on line at *http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4137B1_07_Nomenclature.pdf*)
Pharmaceutical equivalents	Medicinal products are considered to be pharmaceutical equivalents if they contain the same active ingredient(s) same dosage form and route of administration and they are identical in strength or concentration. *(USFDA Glossary of terms, can be found in line at Drugs@FDA Glossary of Terms)*
Pharmaceutical form	The pharmaceutical form is the pharmaceutical-technological form in which an active substance is made available. Pharmaceutical may be administered in solid form (e.g. tablets, powers), in semi-liquid form (e.g. ointments, pastes), in liquid form (e,g, drops, injectables, infusions) or in gaseous form (inhalation). *(WHO glossary of terms).*
Pharmaceutical Product	A pharmaceutical product is any substance for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

	[WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf]
Pharmacy	Pharmacies are premises which in accordance to the local legal provisions and definitions may operate as a facility in the provision of pharmacy services in the community or health facility setting. *(In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)*
Post-marketing surveillance	Post-marketing surveillance is testing medicine samples to assess the quality of medicines that have already been licensed for public use. *(In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: **http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/**)*
Post-marketing surveillance study	Studies performed after the pharmaceutical product has been marketed. *(In WHO Operational package for assessing, monitoring and evaluating country pharmaceutical situations at: http://www.who.int/medicines/publications/WHO_TCM_2007.2/en/)*
Pre-marketing	The stage before a drug is available for prescription or sale to the public.*(WHO Glossary of terms used in Pharmacovigilance, At **http://who-umc.org/Graphics/24729.pdf***
Prescription-Only Medicines	Prescription-only medicines are medicines supplied only in licensed pharmacies on the presentation of

	signed prescriptions issued by a licensed and registered medical practitioner, licensed and/or registered dentist (for dental treatment only), and/or licensed and/or registered veterinarian (for animal treatment only), and the supply and dispensing of these medicines must be carried out by a pharmacist or under the supervision of a pharmacist. *(WHO glossary of terms)*
Procedures	Description of the operations to be carried out, the precautions to be taken, and measures to be applied directly or indirectly related to the manufacture of an Active Ingredient and Finished Pharmaceutical product. *(European Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Process aids	Materials used as aids in the manufacture of an Active Ingredient and Finished Pharmaceutical Product which themselves do not participate in a chemical or biological reaction. *(Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Product Information	Product information refers to the summary of product characteristics (SmPC), labelling and patient information leaflet. (*Glossary of terms and abbreviations/EMA it can be found at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099907.pdf).*
Promotion	Promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs. [C:\Documents and Settings\CVialle\Desktop\Country profile - Instructions and glossary 14 Sept 2010\WHO. A model quality assurance system for procurement agencies.pdf Criteria for Medicinal Drug Promotion can be found online at:

	http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf]
Proprietary name	Name given for marketing purposes to any ready-prepared medicine placed on the market. *(PHIS Glossary 2009, it can be found at http://phis.goeg.at/downloads/glossary/PHIS%20Glossary_UpdatedApril2011.pdf).*
Quality Information Summary (QIS)	The QIS is a condensed version of the Quality Overall Summary – Product Dossier (QOS-PD) and represents the final, agreed upon key information from the PD review (inter alia identification of the manufacturer(s), API/FPP specifications, stability conclusions and relevant commitments)
Qualification	The action of proving that any equipment is properly installed, works correctly, and consistently produces the expected results. Qualification is part of, but not limited to, the validation process. *(Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Quality assurance	It is the sum total of the organized arrangements made with the object of ensuring that Active Ingredients and Finished Pharmaceutical products are of the quality required for their intended use. *(Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Quality attribute	Any product characteristic which may reflect quality, or may affect safety or efficacy of the product during its expected shelf life. (*Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*

Quality Control	Quality control is the part of Good Manufacturing Practices (GMP) concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use or products released for sale or supply, until their quality has been judged to be satisfactory. (*WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf).*
Quarantine	The status of materials isolated physically or by other effective means whilst awaiting a decision on their subsequent use. *(Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Rational use of medicines	Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. *(Promoting rational use of medicines: Core components Geneva 2002, can be found online at: http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf)*
Raw materials	Any material of defined quality used in the manufacture of an Active Ingredient, but excluding packaging materials or labels. *(European Federation of Pharmaceutical Industries and Associations; April 1996, Good manufacturing practices for Active ingredient manufacturers).*
Recovery	Any treatment of materials by a process intended to make them suitable for further use.

	(*Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Registration	*See Marketing Authorization*
Regulations	The second stage of the legislative process (the first stage being legislation). Regulations are specifically designed to provide the legal machinery to achieve the administrative and technical goals of legislation. *(WHO A model quality assurance system for procurement agencies Geneva 2007, can be found online at: http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf)*
Regulatory Inspection	A regulatory inspection is an officially conducted examination (i.e. review of quality assurance processes, personnel involved, any delegation of authority and audit) by relevant authorities at sites where pharmaceutical activities take place (i.e. manufacturing, wholesale, testing, distribution, clinical trials) to verify adherence to Good Practices. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at:* ***http://infocollections.org/medregpack/interface/files/glossary.pdf****)*
Reprocessing	The treatment of a batch or sub-batch of materials of unacceptable quality by repeating the same process steps from a defined stage of production so that its quality may be made acceptable. (*Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Reworking	The treatment of a batch or sub-batch of materials of unacceptable quality by using a process other than that used to produce the original material so that its quality may be made acceptable.

	(*Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*
Route of administration	Is a way of administering a medicinal product to a site in a patient. *(USFDA Glossary of terms, can be found on line at Drugs@FDA Glossary of Terms).*
Sample	A sample is a portion of a material collected according to a defined sampling procedure. *WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf]*
Sampling	Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments, batch release. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf)*
Side effect	Any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug. *(WHO Glossary of terms used in Pharmacovigilance, at http://who-umc.org/Graphics/24729.pdf)*
Specifications	A document describing in detail the requirements such as physical, chemical, biological and microbiological test requirements with which the products or materials used or obtained during manufacture have to conform. *(A WHO guide to good manufacturing practice (GMP) requirements; it can be found at http://www.who.int/vaccinesdocuments/DocsPDF/www9651.pdf).*

Specifications	Test Procedures and Acceptance Criteria for active pharmaceutical ingredients and medicinal products. *(ICHQ8- Glossary at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002872.pdf)*
Standard operating procedure	An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature. *(WHO guide to good manufacturing practice (GMP) requirements, at http://www.who.int/vaccines-documents/DocsPDF/www9651.pdf).*
Stringent Regulatory Authority	A regulatory authority that is: a) A member of ICH prior to 23rd October 2015, namely the USFDA, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency, or b) An ICH observer prior to 23rd October 2015, namely the European Free Trade Association, as represented by Swissmedic and Health Canada, or c) A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23rd October 2015, namely Australia, Iceland, Liechtenstein and Norway.
Summary of Product Characteristics (SmPC)	Product information as approved by the Regulatory Authority. The SmPC serves as the basis for production of information for health personnel as well as for consumer information on labels and leaflets of medicinal products and for control of advertising. *(WHO Medicines Regulatory Package. A Collection of Tools for Medicines Regulatory Authorities - Regulatory Support Series No. 014 at: http://infocollections.org/medregpack/interface/files/glossary.pdf)*
Tentative Approval	If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative

	approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product. *(USFDA Glossary of terms, it can be found on line at Drugs@FDA Glossary of Terms).*
Theoretical yield	The quantity that would be produced at any appropriate phase of manufacture, processing, or packaging of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or an error in actual production. *(WHO guide to good manufacturing practice (GMP) requirements, at http://www.who.int/vaccines-documents/DocsPDF/www9651.pdf).*
Therapeutic Equivalence (TE)	Medicinal products are considered to be therapeutically equivalent only if they are pharmaceutical equivalents or pharmaceutical alternatives and their effect are essentially the same. This can be and have been scientifically demonstrated be bioequivalent. *(Adapted from WHO glossary of terms)*
Unique identifier	Is a unique code that is added to the medicinal product label (primary and/or secondary pack) in order to specifically identify and capture particulars of the product for market surveillance purposes. It may be in form of a code, barcode or security number that is unique for a specific product. The product registration number issued by the NMRA may be considered as a unique identifier.
Validation	Action of proving and documenting that any procedure, process, equipment, activity or system will, with a high degree of assurance, lead to the expected results. (*Federation of Pharmaceutical Industries and Association; GMP for API manufacturer, at http://apic.cefic.org/pub/1gmp-api9604.pdf).*

Variation	Variation is a change to a Marketing Authorization that is considered to fundamentally alter the terms of the MA for a medicinal product. (*Glossary of terms and abbreviations/EMA it can be found at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099907.pdf).*
Wholesale	All activities consisting of procuring, holding, supplying or exporting bulk medicinal products, apart from supplying medicinal products to the public. ***(****PHIS Glossary 2009, can be found on line at:* ***http://phis.goeg.at/index.aspx?alias=phisglossary****)* .