Glossary

A

Abridged Review / Abridged Regulatory Pathways
Regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or widely based on the application of reliance

Act
Medicines and Related Products Act, 2014

Active (Pharmaceutical) Ingredient (API)
A substance or mixture of substances used in a finished pharmaceutical product (medicine), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions

Active Substance
Synonym for Active Pharmaceutical Ingredient

Adverse Event (AE) / Adverse Experience
Any unfavourable and unintended sign including an abnormal laboratory finding, symptom, or disease temporally associated with the use of a medicine, whether or not considered related to this medicine

Adverse Events Following Immunisation (AEFI)
Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease

Adverse Reaction (AR) / Adverse Drug Reaction (ADR)
A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man

Advertisement
Any form of notice or announcement whether publication, or by display of any notice or by means of a catalogue, price list, letter, whether circular or addressed to a particular person or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or online media or any other means of communication to promote the prescription, supply, sale or consumption of medicines or related products. It also includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicines or related products.

Agency
Medicines Control Agency

Authorisation Certificate / Authorisation Letter
An authorisation certificate or letter issued by the Agency

Authorised Officer
A person authorised in writing by the Agency or the Minister to perform under the Act or Regulations

B

Batch
A defined quantity of a medicine or related product manufactured in a single manufacturing cycle and which has homogeneous properties

Batch Number
A unique number or combination of numbers or codes allocated to a batch by the manufacturer that identifies a batch and from which the production and distribution history can be determined

Benefit-Risk Balance
An assessment of the positive therapeutic effects of the medicine or related product in a relationship to its risks

Beyond Use Date (BUD)
The date after which a compounded preparation or repackaged medicine should not be used and which is assigned by the pharmacy for a preparation that the pharmacy has compounded or by a re-packager that the re-packager has assigned to a repackaged medicine

Bioequivalence
The absence of a difference within the predefined acceptance criteria in the bioavailability of the active pharmaceutical ingredient or its metabolite at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study

Biological / Biologics / Biological Medicine / Biological Product / Biopharmaceutical
A diverse category of medicines that generally are large, complex molecules including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins of human, animal, plant or microorganism origin; these medicines may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterise than small molecule medicines

Biosimilar Product
A biological that is highly similar to and has no clinically meaningful difference from an approved biological or reference product

Bonded Warehouse
A system of public storage or warehouse established or authorised by the Customs and Excise Act 2010

Brand Name / Trade Name / Proprietary Name
The invented name given by the pharmaceutical company or manufacturer which is unique to the particular medicine or related product by which the product is generally identified and registered

Bulk product
Any product which has completed all processing stages up to, but not including, final packaging

C

Clinical Trial
Any investigation in human subjects or animals intended to discover or verify the clinical, pharmacological and other pharmacodynamics effects of an investigational product, or to identify any adverse reactions to an investigational product, or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and efficacy, as defined by the International Council for Harmonisation

Clinical Trial Protocol
A document that describes the objective, design, methodology, statistical considerations, and organisation of a clinical trial

Clinical Trial Protocol Amendment
A written description of a change or formal clarification of a clinical trial protocol

Compassionate Use
Access to unregistered medicines in special or emergency situations for a patient having a severe or life-threatening illness and existing therapy has failed, or the disease is a rare one for which specialist medicines do not have a marketing authorisation; the medicine is still experimental, or at any rate unproven

Compounding
A practice in which a registered Pharmacist or Pharmacy Support Personnel combines, mixes, or alters ingredients of a medicine to create a medicine tailored to the needs of an individual patient

Container / Package
The material employed in the packaging of a medicine; containers include primary and secondary containers and transportation containers

Container Closure System / Packaging System
The sum of packaging components that together contain and protect the dosage form which includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the medicine

Contamination
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a medicine or related product during handling, sampling, packaging or repackaging, storage or transportation

Controlled Medicine / Controlled Drug
Any medicine or other substance as listed in the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

Coordinating Investigator
An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre clinical trial

Cosmetic
A substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eye or teeth and deodorants and perfumes

Counterfeit Medicine / Counterfeit Product
A deliberately and fraudulently mislabelled product with respect to source and/or identity
Note: A detailed description is provided in Section 38 of the Act

D

Dispensing
The process of preparing and giving a medicine to a named person or animal on the basis of a prescription by a healthcare professional

Distribution
The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medicines or related products, with the exception of the dispensing or providing them directly to a patient

Dosage Form
The pharmaceutical form in which the active ingredients, excipients and physical formulation of a medicine is presented e.g. tablet, capsule, solution for injection, cream, etc

Drug
Another term for medicine or medicinal product, the finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients

Drug Substance
Synonym for Active Pharmaceutical Ingredient

E

Effectiveness
The performance of a medicine under 'real-world' conditions

Efficacy
The measurement of a medicine's desired effect under ideal conditions

Ethics Committee / Institutional Review Board
A multidisciplinary body responsible for reviewing biomedical research for safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants

Excipient
Anything other than the Active Pharmaceutical Ingredient in the dosage form

Expiry Date
The date stated on the label of a medicine or related product up to which the product is expected to remain within specifications, if stored correctly; it is established for each batch by adding the shelf life to the date of manufacture and is determined by using stability studies

F

Falsified Medicine
Any medicine with a false representation of its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients, its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder, or its history, including the records and documents relating to the distribution channels used

Finished (Pharmaceutical) Product
A medicine that is presented in its finished dosage form and has undergone all stages of production, including packaging in its final container and labelling

First Expiry First Out (FEFO) / First In - First Out (FIFO)
A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date

Fixed Dose Combination (FDC)
A combination of two or more active pharmaceutical ingredients in a fixed ratio of doses

G

Generic Medicine / Generic Drug / Multisource Medicine
A legitimately-produced medicine which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine and performs the same way

Generic Name
Synonym for International Non-proprietary Name

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

Good Distribution Practice (GDP)
A standard that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain

Good Manufacturing Practices
A standard concerning the production, processing, packing, release, and holding of a medicine which ensure that medicines are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorisation

Good Storage Practice (GSP)
A standard that ensures that the quality of medicines and related products is maintained by means of adequate control throughout the storage thereof

H

Haemovigilance
The set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients including their follow-up including the monitoring, reporting, investigation, and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence

Health Facility
A publicly, privately-owned or non-governmental health institution that provides healthcare services to individuals

Herbal Medicine
Any medicine, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations

Herbal Preparations
Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation; these include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates

Herbal Substances
All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh; certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances

Homeopathic Medicine
Any medicine prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the pharmacopoeias currently used officially; a homeopathic medicine may contain a number of principles

I

Immediate Packaging
Synonym for Primary Container or Primary Packaging

Informed Consent
A process by which an adult subject competent to make the decision voluntarily confirms his or her willingness to participate in a particular research study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate

Innovative Medicine / Innovator pharmaceutical product
A medicine which was first authorised for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality according to requirements at the time of the authorisation

Inspection
The act by a regulatory authority of conducting an official examination of documents, facilities, records, products and any other resources

International Non-proprietary Name (INN) / Generic Name
An official, unique name given to a pharmaceutical ingredient recommended by WHO and that is globally recognised and public property

Investigational Medicinal Product
A medicine or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use

Investigational Product
Any product used in a clinical trial including medicine, herbal medicine, nutritional supplement, homeopathic medicine, food and food/dietary or nutritional supplement, medical device, diagnostic, cosmetic and any other related product

Investigator / Sub-investigator
A member of the clinical trial team designated and supervised by the principal investigator at a trial site to perform critical trial-related procedures or make important trial-related decisions and includes associates, residents, and research fellows

Investigator's Brochure (IB)
A compilation of the clinical and nonclinical data on the investigational product which is relevant to the study of the investigational product in human participants

L

Label
Information on the immediate (primary) or outer (secondary) packaging of a medicine which includes a legend, tag, brand, word or mark, pictorial or any other descriptive matter written printed, stencilled, marked embossed or impressed on or attached to a medicine

Labelling
The process of identifying a medicine

Legal Guardian
A person who is the guardian of a child by virtue of the provision the Children's Act 2005 or a person lawfully appointed to be guardian of the child by Deed or Will or by an order of a court of competent jurisdiction or by operation of law

M

Manufacture / Manufacturing
Any total or partial operation of producing, preparing, formulating, treating, processing, filling, decanting, packaging, labelling and release of medicines and the related controls

Manufacturer
Any person or entity engaged in manufacturing activities including implementation of oversight and controls over the manufacture of medicines to ensure quality

Marketing Authorisation
A legal document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product in one or more countries after evaluation for safety, efficacy and quality

Marketing Authorisation Holder (MAH)
The company or other legal entity that has the authorisation to market a medicine or related product and who is responsible for its quality, efficacy and safety and for compliance with conditions of registration

Market Package
The container closure system, labelling and associated components (e.g., dosing cups, droppers, spoons), and the external packaging (e.g., cartons)

Medical Device
any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, material or other similar or related article including the software necessary for its proper application, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- providing information by means of in vitro examination of specimens derived from the human body

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Medicine / Medicinal Product
Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings or animals

Misbranded
Labelling which is false, misleading or inaccurate or fails to provide information as required

Multisource Medicine / Multisource Product
Synonym for generic medicine

N

National Authorities
The Customs and Excise, Drug Law Enforcement Agency of The Gambia, Police and State Intelligence Service;

New Medicine
A pharmaceutical product type, for example tablet, capsule, solution, cream, etc., which has not previously been issued with a marketing authorisation, and which contains an active pharmaceutical ingredient generally, but not necessarily in association with excipients

New Molecular Entity (NME) / New Chemical Entity
The designated therapeutic moiety, which has not previously been issued with a marketing authorisation as an ingredient of any medicine; it may be a complex, simple ester, or salt of a previously approved active ingredient

Non-clinical Study
A biomedical study not performed on human beings

Non-interventional Observational Study
A study in the context of which findings resulting from persons' treatment with medicines or related products are analysed using epidemiological methods; the treatment including the diagnosis shall not follow a predetermined study protocol but shall result exclusively from current medical practice

Nutritional Supplement
Products that contain one or more ingredients such as vitamins, minerals, herbs, amino acids or other nutrients and that are intended in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, or restoring, correcting or modifying organic functions

O

Outer Packaging
Synonym for Secondary Container or Secondary Packaging

Over-the-counter (OTC) Medicine
Medicines that can be bought or supplied without a prescription or without the supervision of a Pharmacist

P

Package
A box, packet or any other article in which one or more primary containers of medicines is or are to be enclosed in one or more other boxes, packets or articles

Packaging System
Synonym to container closure system

Primary Container / Primary Packaging / Immediate Container
A packaging component that is or may be in direct contact with the dosage form

Package Leaflet / Package Insert
A leaflet in every pack of medicine containing information on the medicine for the user

Parallel Import
Importing a medicine without authorisation of the marketing authorisation holder from another country where it is legitimately located

Participant
Synonym to subject or trial subject

Patient Information Leaflet (PIL) / Patient Package Insert (PPI)
Synonym for Package Leaflet / Package Insert

Person
Natural or juristic person

Pharmaceutical Company
A commercial business licensed to research, develop, market and/or distribute medicines

Pharmaceutical Form:
Synonym to Dosage Form

Pharmaceutical Product
Any product intended for human or veterinary use presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects of a medicine-related problem

Pharmacy Only Medicine (POM)
A restricted medicine classified as such other than prescription only or over the counter medicines which may be sold or supplied by or under the supervision of a registered pharmacist

Pharmacy Support Personnel
Pharmacy Technicians, Dispensing or Pharmacy Assistants or Nurse Dispenser

Precursor Chemicals
All substances used in the manufacture of narcotic drugs or Psychotropic substances as provided for under the International Drug Control Conventions

Premise
Land, building, structure, basement, and vessel, and in relation to a building, includes a part of a building and the cartilage, forecourt, yard or place of storage used in connection with the building or part of the building, and in relation to a vessel, includes a ship, boat, an aircraft, a carriage or receptacle of any kind whether open or closed

Prescription (Rx)
A written instruction by an authorised prescriber to dispense or supply a medicine or related product for the purpose of the medical or dental treatment of an individual person or animal

Prescription Only Medicine (POM)
A restricted medicine classified as such which shall only be sold or supplied in accordance with a valid prescription given by a medical practitioner, dentist, veterinary practitioner or any person authorised by the Agency

Presentation
Any medicine or related product presented for supply including matters relating to the name of the product, the labelling and packaging of the product and any advertising or other informational material associated with the product

Primary Container / Primary Packaging
The container or other form of packaging that is or may be in direct contact with the dosage form

Principal investigator
An investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site

Production
All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product

Professional Information
The information about a medicine intended for the provision to professionals (e.g. Summary of Product Characteristics)

Proprietary Medicine
A medicinal compound whose formula and often mode of manufacture are owned by an individual or a corporation under a trademark or patent

Proprietary Name
Synonym to Brand Name / Trade Name

Public Sector
Health sector funded from the Consolidated Fund or directly out of moneys provided by National Assembly

Q

Qualified Person
A professional who has the expert knowledge and who is responsible for the compliance with technical and regulatory requirements related to the quality of finished products and the approval of the release of the finished products

Quality
The degree to which a set of inherent properties of a product, system, or process fulfils requirements as prescribed

Quality System
An appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality

Quarantine
The status of a medicine or related product isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing

R

Recall
The removal of specific batch/batches of a medicine or related product from the market for reasons relating to deficiencies in the quality, safety or efficacy

Recognition
The acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement

Recognised **Regulatory Authority**

Reference Medicine
A medicine which has been granted a marketing authorisation on the basis of a complete dossier with the submission of quality, pre-clinical and clinical data

Reference Regulatory Authority / Recognised Regulatory Authority (RA)
A capable national or regional authority the Agency can rely upon with confidence

Related Product
An article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in a human being or animal

Reliance
The act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

Repackaging
The act of taking a medicine from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the medicine

Retail
Professional services that include the supply or sale of medicines or related products to a patient or final consumer for personal non-business use from premises by the holder of a retail licence

Route of Administration
The way in which a medicine is taken or given, e.g. orally (by mouth), intravenously (into a vein), subcutaneously (under the skin), etc

S

Sampling
Operations designed to obtain a representative portion of a medicine or related product, based on an appropriate statistical procedure, for a defined purpose, e.g. quality testing, acceptance of consignments or batch release

Secondary Container / Secondary Packaging
A packaging component that is not and will not be in direct contact with the dosage form

Serious Adverse Event / Serious Adverse Reaction
Any untoward medical occurrence that at any dose
- results in death, or
- is life-threatening, or
- requires inpatient hospitalisation or prolongation of existing hospitalisation, or
- results in persistent or significant disability or incapacity, or
- results in a congenital anomaly (birth defect); or
- is a medically important event or reaction

Shelf-life:
The period of time during which a medicine, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of

batches of the product; the shelf-life is used to establish the expiry date of each batch

Site Master File
A document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings;

Specification
Lists of detailed requirements with which the products or materials used or obtained during manufacture have to conform; they serve as a basis for quality evaluation

Sponsor
An individual, company, institution or organisation that takes responsibility for the initiation, management and financing of a clinical trial

Standard Operating Procedure (SOP)
A set of step-by-step instructions compiled to carry out complex routine operations with the aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with requirements and regulations

Storage
The storing of medicines and related products from manufacturing up to their point of use

Strength
The content of the active substances in a medicine expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form

Summary of Product Characteristics (SmPC)
A document describing the properties and the officially approved conditions of use of a medicine; summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively

Supplier
A person or entity engaged in the activity of providing products and/or services

Subject / Trial Subject
An individual who participates in a clinical trial either as a recipient of the investigational product or as a control

T

Trade Name
Synonym to Brand Name / Proprietary Name

U

Unauthorised Person
A person engaged in any pharmaceutical activity without the required licence or permit

Unauthorised Premise
Any premise used for pharmaceutical activity without the required licence or permit

V

Variation
Any change to the terms of a marketing authorisation of a medicine which may involve administrative and/or more substantial changes and are subject to approval by the medicines regulatory authority

W

Wholesale Distribution
All activities consisting of procuring, holding, supplying or exporting medicines and related products, apart from supplying medicines and related products to the public

Wholesaler / Wholesale Pharmacy
A person or entity who holds, stores, distributes or purchases medicines and related products from a manufacturer or supplier for sell