TWG-MAG

DEFINITION OF TERMS

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The definitions given below are applicable to the jointly developed guidelines of the Joint technical working group for guidelines in marketing authorization (TWG-MAG). The terms used in this document may have different meanings in other contexts. The term “medicinal products” in the context of these guidelines include finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, *in-vitro* diagnostics, blood products and animal products, if not indicated otherwise.

Abridged Review / Abridged Regulatory Pathway / Review

Regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely, widely or partially based on the application of reliance.

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.
Synonym: Active Substance

Active substance

See Active (Pharmaceutical) Ingredient

Agency

See National Medicines Regulatory Authority

Agent

Pathogen/item specified in the declaration of emergency causing a serious or life-threatening disease or condition.

Applicant (for MA)

A person or entity who has applied for regulatory approval of a product or a change thereof. All applicants are to own the product. Representatives of product owners may not hold themselves as applicants unless they own the product.

In some jurisdictions this term is used in a wider sense (see “marketing authorization holder)”.

Approval

See Marketing Authorization

Batch

A defined quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits.
Synonym: Lot

Batch 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.
Synonym: Lot number

Bioequivalence

Bioequivalence is the absence of a significant difference in the rate and extent to which the active pharmaceutical ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

Biological (product)

A medicine whose active substance is made by a living organism.

Biosimilar Product

A medicine that is similar to a biological product that has already been authorized.

Brand Name

The invented name given by the manufacturer or applicant for marketing authorization which is unique to the particular medicinal product or related product by which the product is generally identified and registered.
Synonym: Trade Name / Proprietary Name

Cancellation

Action taken by the NMRA for the invalidation of a marketing authorization that was lawful at the time of its granting and for which the reason for invalidation occurred subsequently (e.g. due to additional [post-marketing] information about the medicinal product).

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.

Clinical Trial

A clinical trial is any systematic study on a medicinal product 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, an investigational product, and/or to study the absorption, distribution, metabolism and excretion of the product with the object of ascertaining its efficacy and safety.

Clinical Trial Protocol

A document that describes the objective, design, methodology, statistical considerations, and organization of a clinical trial/study.

Comparator product

A medicinal product with which the generic product is intended to be interchangeable in clinical practice.

Compassionate Use

Access to unauthorized medicinal products in special or emergency situations for a patient with a severe or life-threatening illness and for which no authorized product exists, existing therapy has failed, or the disease is a rare one for which specialist medicinal products do not have a marketing authorization.

Composition

In relation to a medicinal product means an ingredient of which it consists, proportions, degree of strength, quality, and purity in which those ingredients are contained.

Distribution

The procuring, purchasing, holding, storing, selling, supplying, importing, or exporting of medicinal products, with the exception of the dispensing or providing them directly to a patient.

Donor

An individual/organization or country that provides assistance in form of a medicinal product supplies to an individual, organization or country.

Dosage Form

The pharmaceutical form in which the active pharmaceutical ingredient, excipients and physical formulation of a medicinal product is presented e.g. tablet, capsule, solution for injection, cream, inhalation etc..

Drug

See medicinal product

Drug Product (DP)

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.

Synonym: finished pharmaceutical product but specific for biotherapeutic products.

Drug Substance

Is synonymous to Active Pharmaceutical Ingredient but specific for biotherapeutic products.

Effectiveness

The performance of a medicinal product under 'real-world' conditions.

Efficacy

The ability of a medicinal product to produce the intended effect as determined by scientific methods, for example in pre-clinical research and/or clinical research studies.

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.

Excipient

Any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Expiry Date

The date stated on the label of a medicinal 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.

Extension application/ line extension

An extension application is an application for a marketing authorization in the name of the same marketing authorization holder, for example if the pharmaceutical form and/or strength, therapeutic indication of the product differs from one or more other medicinal products having the same active

ingredients, for which this marketing authorization holder already has a marketing authorization.

Finished (Pharmaceutical) Product (FPP)

Product that has undergone all stages of production, including packaging in its final container and labelling. A FPP may contain one or more active pharmaceutical ingredients.

Formulation

The process by which different chemical substances including the active pharmaceutical ingredient, are combined to produce a final pharmaceutical product.

Generic Drug

See Generic medicine

Generic Medicine / Medicinal Product

Is a medicinal product, which has the same qualitative and quantitative composition in active pharmaceutical ingredients and the same pharmaceutical form as the authorized reference medicinal product and which bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.
Synonym: Generic Drug / Multisource Medicine

Generic Name

See International Non-proprietary Name

Generic product

See Generic medicine

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the study 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 or distribution network, so that authorized medicines are distributed to retail pharmacists and others selling medicines to the general public without any alteration of their properties.

Good Manufacturing Practices (GMP)

A standard concerning the production, processing, packing, release, and holding of a medicine which ensure that medicinal products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorization.

Hybrid application (BE)

Hybrid medicines are medicinal products whose authorization depends partly on the results of tests on the reference medicine and partly on new data from clinical trials. This happens when a manufacturer develops a generic medicine that is based on a reference medicine, but has a different strength, a different route of administration or a slightly different indication from the reference medicine.

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 (including all possible risks and benefits)that are relevant to the subject's decision to participate.

Innovative Medicine

See innovator medicinal product

Innovator Medicinal Product

A novel medicine, which was the first product authorized for marketing by any country (normally as a patented product) on the basis of

documentation of efficacy, safety and quality according to requirements at the time of the authorization.

Synonym for originator product/ originator brand/ Innovative Medicine / Innovator finished pharmaceutical product.

Innovator finished pharmaceutical product.

See innovator medicinal product

International Non-proprietary Name (INN)

An official, unique name given to a pharmaceutical ingredient recommended by World Health Organization and that is globally recognized and public property used to identify the active ingredient in a medicine. Synonym: generic name.

Investigational Medicinal Product

A medicinal product or placebo being studied or used as a reference in a clinical trial, including a product with a marketing authorization 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.

Label

Is a descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a packaging of any medicinal product.

Licence Holder

See Marketing Authorization Holder

Licencing

See Marketing Authorization

Local agent

A person or company authorized by the marketing authorization holder to act as agent for one or more companies in a particular community and usually paid by commission.

Local Technical Representative

A person or company with sufficient pharmaceutical expertise that is incorporated within the specific country and who is responsible for facilitating communication between the NMRA and the Applicant and when the product is authorized shall assume all legal responsibilities.

Lot

See batch

Lot number

See Batch number

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 with responsibility in manufacturing activities including implementation of oversight and controls over the manufacture of the medicinal product or active pharmaceutical ingredients or excipients to ensure quality.

Manufacturing site

The location where the manufacturing process of a medicinal product is undertaken.

Marketing Authorization (MA)

Approval to market a medicinal product in the NMRA's country. MA is issued by the NMRA with a legal document for the purpose of marketing or distribution of a product within the country after evaluation for safety, efficacy and quality in the marketing authorization assessment process. Synonym: licensing/ registration/ approval.

Marketing Authorization Certificate

An official document issued by NMRA for the purpose of marketing and distribution of a product within the country after evaluation for safety, efficacy and quality.
Synonym: registration certificate, license.

Marketing Authorization Holder (MAH)

A person or entity whose product has been authorized by a national medicines regulatory authority to be on the market.

Synonym: license holder

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

The term “medicinal products” in the context of these guidelines include finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, in-vitro diagnostics, blood products and animal products, if not indicated otherwise.

Medicine

See medicinal product

Multisource Medicine

See Generic medicine

National Essential Medicines List (NEML)

The list of essential medicines that has been defined, adopted, and published at country level.

National Medicines Regulatory Authority (NMRA)

A National medicines regulatory authority is a country's entity responsible for the registration, marketing authorization, and other regulatory functions concerning medicinal products.

New active substance

See new Molecular Entity

New Chemical Entity

See new Molecular Entity

New Drug

New drug: a generic copy of an innovator product, that has not been previously registered as a pharmaceutical or biological product in <Country> or which has been marketed in <Country> for a period of not more than ten (10) years or any other period to be determined by the Authority from time to time, for public health reasons.

New Molecular Entity (NME)

A New Molecular Entity (NME) is an active ingredient that contains no active moiety that has been previously approved by the Agency in an application submitted or has been previously marketed as a drug in the country.
Synonym: New Chemical Entity / New active substance

Originator brand

See innovator product

Package

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

Patient Information Leaflet (PIL)

A leaflet in every pack of medicine containing information on the medicine for the user, such as patients.

Pharmaceutical Form

See Dosage Form

Product Information

Product information refers to the summary of product characteristics (SmPC), labelling and patient information leaflet.

Product owner

See Marketing Authorization Holder

Proprietary Name

See Brand Name

Protocol Amendment

A written description of a change or formal clarification of a clinical trial protocol

Recall

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

Recipient

An individual, organization, government, NGO, or health facility that receives assistance in the form of medicinal product supplies from an individual, institution or country (donor).

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

Reference Institution

An authority or institution which assessment and its outcome serve as basis for regulatory reliance. As per WHO guidance (https://www.who.int/news/item/29-04-2021-who-publishes-new-guidance-to-promote-strong-efficient-and-sustainable-regulatory-systems) this encompasses different levels of reliance.

In this document this term relates to a list of authorities/institutions determined by the NMRA including the transitional WHO listed authorities referred to as group B+C (https://www.who.int/publications/m/item/list-of-transitional-wlas) and WHO Prequalification Programme.
Synonym: Reference regulatory authority

Reference Medicinal 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.

Registration

See Marketing Authorization

Reliance (partial and full)

The act whereby the National Medicines Regulatory Authority (NMRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NMRA 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. Full reliance means that the authority relies on the entire assessments/inspection and quality control reports performed by another regulatory authority. Partial reliance means that the authority relies on certain documents/parts of the assessments performed by another regulatory authority, while for the other part(s) an independent, full assessment of the documentation submitted by the Applicant is conducted.

Renewal

The process of extending the validity of a marketing authorization based on an application by the marketing authorization holder when the validity of the current authorization is due to expire.

Revocation

Action taken by the NMRA, if a marketing authorization was granted unlawfully from the outset, e.g., due to deception or the like.

Risk-benefit analysis

Evaluation of the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, in relation to known and potential risks as defined above.

Risks

Any known and potential risks relating to the quality, safety or efficacy of the medical product as regards patients' health or public health.

Sample

A sample is a portion of a material collected according to a defined sampling procedure.

Shelf life

The period of time during which a medicinal product, 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.

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.

Storage

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

Strength

The content of the active substances in a medicinal product 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

Suspension

Action taken by the NMRA, if a ground for refusal as defined in the legal provision developed or if one of the conditions imposed pursuant to maintaining the marketing authorization has not been met and the flaw has not been corrected within a reasonable period of time that is to be specified by the NMRA.

Trade Name

See Brand Name

Variation

A change to the terms of a marketing authorization. There are different types of variations with different regulatory requirements and procedures.

Withdrawal

The permanent discontinuation of the marketing authorization by the marketing authorization holder (MAH). Reasons for withdrawal could be manifold, including administrative or commercial. The MAH shall declare the reason for withdrawal, particularly if his/her action concerns the quality, safety and/or efficacy of the medicinal product.