Glossary

The terms listed below are defined specifically for the purposes of this Guide. They may be defined differently in other documentation, including referenced documents and annexes, which were, in certain cases, published some years ago.

**Adherence.** Compliance with treatment; strictly following the drug regimen.

**Accountability.** Being required to account for one’s conduct and actions, usually to an individual or group but ultimately to the public. Both individuals and organizations may be accountable. There is some overlap between accountability and *transparency*.

**Active pharmaceutical ingredient.** A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).

**ARVs.** Antiretroviral drugs, used for treating symptoms related to AIDS.

**Bioequivalence.** Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability), after administration in the same molar dose, are similar to such a degree that their effects can be expected to be essentially the same.
**CD4 Test.** A test to measure the CD4+ cell count—a vital measure of the state of a person’s immune system. According to the Center for Disease Control and Prevention, any person who has a CD4+ count of lower than 200 has AIDS.

**Compulsory licensing.** An authorization by the government to itself or to a third party to use a patent without the permission of the patent holder. A compulsory license authorizing the government to use the patent for its own purposes is also referred to as a “government use” authorization (in British terminology, “Crown use”). The term “compulsory licensing” is used in this report to refer to compulsory licensing and government use authorization, unless expressly indicated otherwise.

**Container labelling.** All information that appears on any part of a container, including that on any outer packaging such as a carton.

**Differential pricing.** Sometimes called “equity pricing,” or tiered pricing, this is a system whereby medicines are sold at prices that relate to the income of consumers. In rich countries, prices will be higher, in poor countries, prices will be lower.

**Dosage form.** The form of the completed pharmaceutical product—for example, a tablet, capsule, injection, elixir, or suppository.

**Drug.** Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

**Drug product.** See pharmaceutical product.

**Drug regulatory authority (national).** A national body that administers the full spectrum of drug regulatory activities, including at least the following functions:

- Marketing authorization of new products and variation of existing products
- Quality control laboratory testing
- Adverse drug reaction monitoring
- Provision of drug information and promotion of rational drug use
- Good manufacturing practice inspections and licensing of manufacturers, wholesalers, and distribution channels
Enforcement operations

Monitoring of drug utilization.

**Equity pricing.** See differential pricing.

**Essential drugs.** Drugs that satisfy the health care needs of the majority of the population. As indicated by the Expert Committee on the Use of Essential Drugs, each country may generate its own list of essential drugs.

**Evaluation report.** A critical summary and interpretation of the data, with conclusions, prepared by or on behalf of the drug regulatory authority.

**Excipient.** Any component of a finished dosage form other than the claimed therapeutic ingredient or ingredients.

**Finished product.** A product that has undergone all stages of production, including packaging in its final container and labelling.

**Formulation.** The composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.

**Generic products.** The term “generic product” has somewhat different meanings in different contexts. *Generic product* and *multisource pharmaceutical product* (see below) are terms used interchangeably. Generic products may be marketed either under the approved international nonproprietary name or under a brand (proprietary) name. They may be marketed in dosage forms and/or strengths different from those of the innovator products. Where the term generic product is used, it means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiration of the patent (or under an exception to patent rights) or other exclusive rights. The term should not be confused with generic names for active pharmaceutical ingredients. *Generic* can also be used in a more limited sense of off patent.

**Grandfathered.** A product that is grandfathered is one that has been granted marketing authorization because it was already being marketed at the time the marketing authorization system was established. The terms “provisional registration” or “provisional marketing authorization” are preferred, but some countries do not have a separate category of provisional marketing authorization.
**Intellectual property rights.** Intellectual property rights include patents, trademarks, copyrights, and rights in data assembled for regulatory purposes (rights in data are not strictly “intellectual property”). HIV/AIDS medicines may be subject to claims based on any of these rights, which may affect medicine procurement in different ways.

**Interchangeability.** An interchangeable pharmaceutical product is one that is therapeutically equivalent to a comparator (reference) product.

**Labelling.** The word “labelling” has been avoided in this manual because its meaning is not consistent between Member states. See *container labelling* and *product information*.

**Licence.** See registration.

**Limited-source pharmaceutical products.** Drugs available from only a few manufacturers.

**Manufacture.** All operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products and the related controls.

**Marketing authorization.** See registration.

**Medicine.** See drug.

**Medicinal product.** See *pharmaceutical product*.

**Multisource (generic) pharmaceutical product.**Pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable.

**New drug.** Any drug that does not match the definition of *well-established drugs* (see below).

**Originator or innovator pharmaceutical product.** The first product authorized 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 authorization). When a substance has been available for many years, it may not be possible to identify an innovator pharmaceutical product.
Parallel importation. The purchase of a patented medicine from a lawful source in an exporting country and its importation without seeking the consent of the “parallel” patent holder in the importing country. The sale of the patented medicine in the exporting country is deemed to “exhaust” the patent holder’s right in the importing country.

Patent. Granted to the inventor of a product or process giving the inventor the right to exclude others from making, using, selling, offering for sale, and importing1 a product covered by a product patent, and from using a process covered by a process patent.2 Patents are granted on a country-to-country basis, and sometimes on a regional basis.

Periodic review. The regular process, usually occurring every five years, by which the validity of a marketing authorization is renewed and information on a product is reviewed (validated), consolidated, and sometimes expanded.

Pharmaceutical equivalents. Products that contain the same amount of the same active substance(s) in the same dosage form, that meet the same or comparable standards, and that are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients or the manufacturing process can lead to differences in product performance.

Pharmaceutical product. Any preparation for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Pooled procurement. Several procurers pooling their buying needs through one source. It can work either nationally (many health systems together) or internationally (many countries together). It is often used when there is either low-volume need or insufficient capacity to procure.

Prequalification. A system whereby specific products of a specific pharmaceutical or medical company, or laboratory (in this context), may be

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1 The right to prevent importation does not prevent “parallel importation” of a patented medicine when a rule of international exhaustion of patent rights is followed. See chapter 2.

2 A patent is also used to exclude others from using, selling, offering for sale, and importing a product produced by a patented process.
certified for quality. For example, the WHO certifies a range of pharmaceutical manufacturers for ARVs.

**Procurement.** In this context, the act of buying medicines and related products.

**Product information.** A document defining information that may be supplied with or about a pharmaceutical product by or on behalf of the marketing authorization holder. The minimum information in the product information is that defined by the WHO’s sample product information sheet. The content of the product information is agreed between the marketing authorization holder and the drug regulatory authority at the time the market authorization is issued.

**Product selection.** The act of choosing the correct regimen of medicines and related products for a particular health problem.

**Quality control.** Sampling, specifications, and testing, and the organization, documentation, and acceptance and rejection procedures that ensure that the necessary and relevant tests are completed, and that starting materials, intermediates, and finished products are not accepted for use, sale, or supply until their quality has been judged to be satisfactory.

**Quantification.** Establishing the quantity of medicines to be procured for any given health problem.

**Register.** A list of all the pharmaceutical products authorized for marketing in a particular country. The register is maintained by the drug regulatory authority of the country in question.

**Registered drug products.** Pharmaceutical products that have a marketing authorization.

**Registration.** An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, and quality. It must set out, *inter alia*, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using international nonproprietary or national generic names where they exist), the shelf life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (for example, “The
product(s) must conform with all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products (the register) and is often said to be “registered” or to “have registration.” Marketing authorization may occasionally also be referred to as a licence or product licence.

**Single-source pharmaceutical product.** A pharmaceutical product only available from one source (the originator). Usually, the product is protected by a patent, and is very new (that is, generic versions are not yet available).

**Specification—expiry, check, or shelf life.** The combination of physical, chemical, biological, and microbiological test requirements that an active ingredient must meet up to its retest date or a drug product must meet during its shelf life.

**Specification—release.** The combination of physical, chemical, biological, and microbiological test requirements that determine whether a drug product is suitable for release at the time of its manufacture.

**Stability.** The ability of an active ingredient or a drug product to retain its properties within specified limits throughout its shelf life. The chemical, physical, microbiological, and biopharmaceutical aspects of stability must be considered.

**Starting material.** Any substance of a defined quality used in the production of a pharmaceutical product, excluding packaging materials.

**Therapeutic equivalence.** Two pharmaceutical products are therapeutically equivalent if they are pharmaceutically equivalent and, after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same, as determined from appropriate bioequivalence, pharmacodynamic, clinical, or *in vitro* studies.

**Unregistered drug products.** Pharmaceutical products that do not have a marketing authorization.
**Validation.** The demonstration, with documentary evidence, that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

**Viral load test.** A test establishing the amount of HIV virus in a person’s blood.

**Well-established drugs.** Usually active pharmaceutical ingredients (not products) that:

- Have been marketed for at least five years in countries that undertake active postmarketing monitoring.
- Have been widely used in a sufficiently large number of patients to permit the assumption that safety and efficacy are well known.
- Have the same route of administration and strength, and the same or similar indications as in those countries.

Because this definition refers to active pharmaceutical ingredients and not products, it does not take into account possible sensitivities to excipients and other factors that are relevant to therapeutic equivalence.

**Well-established drug products.** Pharmaceutical products that contain well-established drugs that:

- Have been marketed for at least five years in countries that undertake active post-marketing monitoring.
- Have been widely used in a sufficiently large number of patients to permit the assumption that safety and efficacy are well known.
- Have the same route of administration and strength, and the same or similar indications as in those countries.

**WHO-type certificate.** A certificate of pharmaceutical product of the type defined in the World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.
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