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# Glossary

## **Active pharmaceutical ingredient (API)**

The chemical substance responsible for a product's effect. In this manual, it is called "substance".

## **Affordability**

The cost of treatment in relation to peoples' income. In this survey, the daily wage of the lowest-paid unskilled national government worker is used for comparison with the cost of a defined course of treatment for a specific condition.

## **Brand name**

Name given to a pharmaceutical product by the manufacturer: e.g. Valium is the originator brand name (also called trade name) for diazepam. The use of this name is reserved exclusively to its owner as opposed to the generic name e.g. diazepam.

Brand names may also be used for generic products; they are then often called "branded generics". These brand names are different from innovator brand names. See Generic medicine.

## **Cost, insurance, freight (CIF)**

Shipping term meaning the seller must pay the costs, insurance and freight charges necessary to bring the goods to the port of destination.

## **Dispensing fee**

Normally a fixed fee that pharmacies are allowed to charge per prescribed item instead of or in addition to a percentage mark-up. The fee more accurately reflects the work involved in dispensing a prescription; a percentage mark-up makes profit dependent on the sale of expensive medicines.

## **Dosage form**

The administration form of the completed pharmaceutical product: e.g. tablet, capsule, suspension, injection. Also called dose form or dosing unit.

## **Drug**

See Medicine.

## **Essential medicines**

Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual

and community can afford. The WHO Model List of Essential Medicines (WHOML) is intended to be flexible and adaptable to many different situations; the precise definition of the medicines that are regarded as essential remains a national responsibility.

**Free on board (FOB)**

Shipping term meaning the buyer must pay all costs and insurance against risks of damage once goods are loaded for shipping.

**Generic medicine**

A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights.

Generic medicines are marketed either under a nonproprietary name (INN), for example diazepam or occasionally another approved name, rather than under a proprietary or brand name. However, they are also quite frequently marketed under brand names, often called “branded generics”. Many different branded generic products of the same medicine can be on the market in a country along with the originator brand product.

The manual Marketing Authorization of Pharmaceutical Products with Special Reference to Multi-source (Generic) Products (WHO/DMP/RGS/98.5) defines and uses the term “multi-source pharmaceutical product” for generic products. This includes even an originator brand for which the patent has expired. This definition of a generic is used in some countries, but this manual distinguishes between originator brand, regardless of its patent status, and lowest-priced generic equivalents.

**Innovator brand**

See Originator pharmaceutical product/originator brand

Note: in the first edition of this manual the originator brand was referred to as the innovator brand. This was changed in the second edition primarily to clarify that the product was the original (normally patented) one worldwide.

**International Nonproprietary Name (INN)**

A common, generic name selected by designated experts for the unambiguous identification of a new pharmaceutical substance. The selection process is based on a procedure and guiding principles adopted by the World Health Assembly. INNs are recommended for worldwide use. This manual uses INNs.

The system was introduced by WHO in 1950 as a means of identifying each pharmaceutical substance or active pharmaceutical ingredient by a unique name that is universally accessible as public property (non-proprietary). It is often identical to the generic name: e.g. diazepam. A brand name (trade name) should not be derived from the INN name.

More information is available on the WHO website: <http://www.who.int/medicines/services/inn/en/index.html>

**Interchangeable pharmaceutical products**

Products within a therapeutic class, but with different active ingredients are interchangeable if they have equivalent therapeutic effect.

**Mark-up**

A certain percentage added to a purchasing price to cover the cost and profit of the distributor, wholesaler, retailer, medical store etc.

**Marketing authorization**

An official document issued by a competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. "Registration" is another term used for this purpose.

**Median**

There are three ways of expressing the average value: mean, median and mode. The mean is simply the sum of the values divided by the number of values. The median is the value that divides the distribution in half. If the observations are arranged in increasing order, the median is the middle observation. The median is a useful descriptive measure if there is an asymmetrical distribution of the data or there are one or two extremely high or low values, which would make the mean unrepresentative of the majority of the data.

The median is correctly used with the interquartile range to summarise markedly non-normally distributed (asymmetrical) data. See Percentile.

**Medicine**

Any dosage form containing a substance approved for the prevention and treatment of disease. The term "medicine" is increasingly used to distinguish it from a drug as a substance that is misused. See also Pharmaceutical product.

**Medicine outlet**

A term sometimes used to describe a shop that is not owned or run by a pharmacist and that has a limited licence. However, in this survey "medicine outlet" is used more broadly to identify any place in which medicines are sold, including private retail pharmacies, outpatient pharmacies/dispensaries in public and NGO health facilities etc.

**MSH (Management Sciences for Health) reference prices**

MSH issues an annual International Drug Price Indicator Guide (<http://erc.msh.org>). It lists two types of prices:

- supplier prices: prices offered by not-for-profit and for-profit suppliers to developing countries for multi-source generically equivalent products. Most supplier prices do not include insurance and transportation charges.
- buyer prices: these are usually government international competitive bidding, or tender, prices. They are actual prices obtained by the organizations listed, and usually do include insurance and transportation charges.

In both lists, the number of suppliers listed for each product may vary. For each product, a mean and a median unit price is calculated. The median price is used in this manual as the international reference price. The tender price is used only for products that have no supplier price.

**Multi-source product**

See Generic medicine.

**Originator brand premium**

The difference in price between the originator brand and a generic equivalent (in this case the lowest-priced generic equivalent).

**Originator pharmaceutical product/originator brand**

Generally the product that was first authorized world wide 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: e.g. Valium. The originator product always has a brand name; this name may, however, vary between countries.

Some substances (eg. prednisolone and isoniazid) are so old that no originator can be identified and the patent was probably never claimed. In these cases you only survey the lowest priced generic equivalent.

**Patent**

A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

**Patient co-payments**

Payments by patients of a fixed amount per prescribed medicine, even if reimbursed.

**Percentile**

The range of values containing the central half of the observations: that is, the range between the 25th and 75th percentiles (the range including the values that are up to 25% higher or down to 25% lower than the median) is called the interquartile range. It is used with the median value to report data that are markedly non-normally distributed.

**Pharmaceutical equivalence**

Medicines with identical amounts of the same active ingredient in the same dosage form and route of administration, that meet the standards of strength, quality, purity and identity.

**Pharmaceutical product**

Any medicine intended for human use, presented in its finished dosage form that is subject to control by pharmaceutical legislation (registered). A product may be sold under a brand name (e.g. Valium) or under the generic name (e.g. diazepam).

**Procurement price**

The price paid by the government, wholesalers, retailers and other purchasers to procure medicines. Different prices may be paid for the same product by a public sector purchaser, such as the Ministry of Health, the medicine outlet that supplies the medicine to the patient, and the individual who purchases the medicine.

**Rebate**

Pharmacies may receive a bulk refund from a wholesaler, based on sales of a particular product or total purchases from that wholesaler over a particular period of time. It does not affect the price the patient pays, but the retailer's profits will be higher.

**Retailer**

A company that sells goods to consumers. In the pharmaceutical sector, the retailer is the pharmacy or any other medicine outlet.

Many low- and middle-income countries have at least two different types of shops in which medicines can be purchased: pharmacies with a registered pharmacist and drug stores, chemists or medicine outlets with paramedical staff or lay people.

**Retail mark-up**

A percentage added to the purchasing price to cover the retailer's costs and profit.

**Standard deviation**

The standard deviation measures how spread out a set of data is around the average (mean) value. Normally, about two-thirds of the values in a set of data will fall within one standard deviation above or below the average, and only one in 20 will fall more than two standard deviations above or below the average.

When you get a very low standard deviation about the mean it indicates that the majority of the values are close to the mean (little spread) thus the mean is a good indicator for the sample as a whole. Conversely, when there is a large standard deviation there is a lot of spread and the value of the mean as an indicator is reduced, as a lot of observations are going to be a long way off the mean.

**Substance**

See Active pharmaceutical ingredient.

**Trade name**

See Brand name.

**Trade-Related Aspects of Intellectual Property Rights (TRIPS)**

An agreement annexed to the World Trade Organization convention aimed at strengthening and harmonizing aspects of the protection of intellectual property at the global level. It includes trademarks and patents as well as other forms of intellectual property.

**Wholesaler**

A company that buys goods from a manufacturer or importer and sells it to retailers.

The number of wholesalers in the pharmaceutical sector varies between countries, from one state wholesaler to more than 500. The wholesaler may be an agent for one company only or deal with products from several companies. Manufacturers may also be wholesalers for their own products. In some countries, pharmacies may also have a wholesaler licence.

**Wholesale mark-up**

A percentage added to the purchasing price to cover the wholesaler's costs and profit.