

Active moiety

In chemistry, a moiety is a group of atoms forming part of a molecule. In the case of a pharmaceutical product, the active moiety is that part of the molecule of an active substance which gives it its therapeutic effect.

Bioavailability

The rate and extent at which an *active moiety* or active substance is absorbed (both speed and amount) by the body when introduced in a given dosage form (capsule, tablet, injectable, suppository, etc).

Bioequivalence

Two medicines are bioequivalent when they contain the same amount of an identical active moiety, and when their bioavailability is the same when administered in equal doses under equal conditions. Strict scientific criteria exist for running bioequivalence studies.

Biogeneric/Biosimilar product

An off-patent biological medicinal product which is produced by manufacturers other than the originator and which is similar to the originator product. Biogenerics are sometimes called biosimilar products because biological products produced by different manufacturers are not strictly identical, but similar. Once approved by the competent authorities, biosimilar/biogeneric products are not significantly different in terms of quality, safety and efficacy from the originator product. See: *similar biological medicine*.

Biological medicinal product

A medicine where the active substance is a biological substance as opposed to a chemical substance. The biological substance is produced by or extracted from a biological source.

Biosimilar/Biogeneric product

An off-patent biological medicinal product which is produced by manufacturers other than the originator and which is similar to the originator product. Biogenerics are sometimes called biosimilar products because biological products produced by different manufacturers are not strictly identical, but similar. Once approved by the competent authorities, biosimilar/biogeneric products are not significantly different in terms of quality, safety and efficacy from the originator product. See: *similar biological medicine*.

“Bolar” provision

A legal provision which allows a generic company to perform the research and development needed to apply for marketing authorisation for a generic medicine before the patent has expired on the originator product without violating patent law. This allows the generic medicine to be available to patients immediately after the the expiry of the originator product’s patent and data exclusivity periods.

Budget headroom

Margin within a budget to pay for additional or increasing costs. The use of generic medicines saves an estimated €13 billion per year in the EU, which allows the necessary budget headroom for national healthcare systems to provide patients with more expensive treatments and services.

Data exclusivity

The period of time during which the medicines authorities are not allowed to consult the dossier of an originator pharmaceutical to verify the safety and efficacy of the active moiety in the application for marketing authorisation of a generic medicine. Data exclusivity periods may extend beyond the patent protection period of a pharmaceutical product, thus delaying the availability of lower-priced generic medicines to patients.

DDD

Defined Daily Dose

Dosage form

The physical form in which a pharmaceutical product is presented to patients for therapeutic treatment as determined by their intended route of administration. Well-known examples of different dosage forms include: capsules, tablets, injectables, suppositories, and liquids.

EMEA

The European Medicines Agency is responsible for evaluating medicinal products and providing advice on research and development programmes and maintaining various databases available to healthcare professionals and the public. It is also responsible for granting single European marketing authorisations for medicines through the Centralised Procedure and for arbitrating in case of disputes. The EMA is based in London and has been known as the EMA since May 2004.

EPAR

European Public Assessment Report

Essentially similar

Essentially similar is used to describe a pharmaceutical product which has the same amount of the active moiety in the same dosage form as the originator product, and has been shown to be bioequivalent to the originator product. Once essential similarity is established, the two products in question are therapeutically equivalent and, as such, are interchangeable in treating patients with a given illness. See: *bioequivalent*.

FDA

United States Food and Drug Administration

GCP

Good Clinical Practice

Generic medicine

Generic medicines are equivalent medicines demonstrating the same quality, safety and therapeutic efficacy as the originator product. They contain the same active substance under the same pharmaceutical form as the originator and are marketed after patent expiry. Generics are usually 20% to 80% less expensive than the originator, depending on national pricing policy and the pricing strategy of originators when facing price competition.

GMP - Good Manufacturing Practice

GMP ensures that pharmaceutical products are manufactured consistently and are controlled to the specific standards of quality set out in EU Directive 2003/94/EC. To be GMP certified, a company must show that its facilities and equipment are appropriate, its staff has the required levels of training, and that it manufactures according to approved procedures, maintains detailed manufacturing records, and follows EU norms on storage and transport.

INN

International Non-proprietary Name. This is the scientific name used to identify a specific molecule used in pharmaceutical treatment. Generic medicines are generally known by their INN rather than under a fantasy trade mark name.

Marketing Authorisation

A licence issued by a medicines agency approving the product for market based on a determination by the medicines agency that a pharmaceutical product meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.

Medicines agency

The national Member State or the European authority responsible for evaluating medicinal products, granting marketing authorisation and monitoring the safety of products through ongoing pharmacovigilance.

Originator medicinal product

The first version of a medicinal product, developed and patented by an originator pharmaceutical company which receives exclusive rights to marketing the product in the European Union for 15 years.

OTC

Over-the-Counter medicinal product, dispensed without prescription.

Patent

A document granting an inventor exclusive rights to exploit an invention for a given period of time in return for submitting to public access the complete information necessary to repeat the invention. The patent prohibits others from making, using or selling the invention without the permission of the

inventor in the territory where the patent was issued, whilst enabling the advancement of knowledge through the publication of the technical and scientific details of the patented invention.

Pharmacovigilance

The continuous monitoring of the safe use of medicinal products. Pharmacovigilance is generally regarded as all post-authorisation scientific and data-gathering activities aimed at detecting, assessing, understanding, and preventing adverse events or reactions (ie, side-effects) or any other problems related to the use of a pharmaceutical product. This enables an ongoing assessment to ensure that only those medicines presenting a positive benefit-to-risk ratio remain in use.

Reference product

The originator pharmaceutical product which is referred to in a generic medicine's application for marketing authorisation.

Second medical use patent

A patent granted for a new use of a medicine that is discovered for a product that already possesses another pharmaceutical use. The new use can, for example, be a new indication or a new method of administering a medicine.

Similar biological medicinal product

Official term used by the competent authorities for biogenerics or biosimilar products.

SOP

Standard Operating Procedure

Usage patent / use patent

A patent that has been granted to a pharmaceutical company for a new use that is developed for a specified medicinal product. A new use can, for example, be for a new indication, a new target population or a new mode of administration. See: *new indication*.

Well-established-use product

A medicinal product which has established a solid reputation of *quality, safety* and *efficacy* through at least 10 years of regular, documented therapeutic use in the European Union.

WHO

World Health Organisation

WTO

World Trade Organisation

WTO 30th of August Decision

This Decision implements Paragraph 6 of the Doha Declaration on Public Health. It will effectively allow developing countries with no pharmaceutical manufacturing capacity to import generic versions of patented products under compulsory licenses. It is essentially a temporary waiver until Article 31(f) of the WTO TRIPs agreement is amended in June 2004 by the TRIPs Council. Article 31(f) establishes that production under a compulsory license must be predominantly for the domestic market.