

► **What exactly is a generic medicine?**

A generic medicine is the **therapeutic equivalent** of an originator pharmaceutical product whose patent has expired. It contains the same active substance as, is essentially similar to, and is therefore interchangeable with the originator product.

A generic medicine is produced and marketed in compliance with international patent law. It is identified either by its scientific International Nonproprietary Name (INN) or, less frequently, by its own brand name. Generic medicines are widely used in many countries in cost-effective treatment programmes, and are increasingly prescribed by general practitioners as effective alternatives to higher-priced originator pharmaceuticals.

► **Is there a difference between a generic medicine and an originator pharmaceutical?**

There is no therapeutic difference between a generic medicine and an originator pharmaceutical. Where there *is* a difference is on price, where generics are 20% to 80% less expensive than the originator, depending on the national pricing policy and the pricing strategy of originators when facing price competition. Equivalent generic medicines may contain different non-active ingredients (such as colourings, starches, saccharose, etc) which have no therapeutic effect. In certain cases generics and originators may also differ in salts and esters, but these must not affect therapeutic equivalence between the two products. Originator products may also change their non-active ingredients, salts and esters over periods of time.

► **Who checks the quality, safety and efficacy of a generic medicine?**

As with all other medicines, the **quality, safety and efficacy** of a generic medicine in Lebanon is assured, by the Ministry of Public Health. To receive market approval, the product must be "bioequivalent", that is, "essentially similar", to the originator product. Generic medicines are carefully scrutinised by the competent authority.

Are generics really as good as their originals?

Yes. Generic medicines must comply with exactly the same controls over quality, safety and efficacy as all other medicinal products. They are produced in inspected plants under what is known as "GMP" or "Good Manufacturing Practice". And, just like originator products, once a generic is sold on the market, it must be monitored by the manufacturer in case any adverse reactions are reported.

Are generic medicines really less expensive?

Yes, and the savings are significant. Generic medicines cost 20% to 80% less than the original price of their band-name equivalents. In addition, competition from rival generic products forces originators to reduce their own prices after — *or even before* — patent expiry.

How do generic medicines benefit patients and the national healthcare systems?

When, as patients, we use generic medicines, we immediately notice the difference in the savings over more expensive originator products. In the same way, our national healthcare systems save money by promoting the use of cost-effective generics, as this frees up money to pay for other, more expensive treatments and services that patients need.

How many years does a patent last on an original brand pharmaceutical product?

Pharmaceutical patent protection is longer than in other industries, lasting up to 25 years.

Can a medicinal product have more than one patent?

Yes. Pharmaceutical products are covered by a number of patents, sometimes by as many as 30-40 patents or more. In addition, a patent on a "new use" can block the registration or marketing of a generic for treatments where the base patent has already expired. This is a strategy used in "evergreening".

Do generics companies "use" the data of originator products?

Generic applications do not make use of any data of the originator registration file and are approved under the same EU requirements as originals. Since generic medicinal products contain well-known, safe and effective substances, the pre-clinical tests and clinical trials performed by the originator are not repeated. Indeed, it would be unethical and contrary to international convention to do so. The safety and efficacy of a the generic product is cross referenced with the originator product's dossier by the medicines authorities who alone have access to these files. The data of originator products are never revealed to third parties, and so cannot be used by generics companies.