



EGA *faq* on generic medicines



Frequently Asked Questions about Generic Medicines

What exactly is a generic medicine?

A generic medicine contains the same active medicinal substance as an originator pharmaceutical product. Because it acts in the same way in the human body, it is interchangeable with the originator product. Generic medicines are launched when the originator product's patent has expired.

In the EU a generic medicine is identified either by a company name plus its International Nonproprietary Name (INN), or by its own invented brand name. Generic medicines are increasingly used by general practitioners, specialists, and hospitals as equally effective alternatives to higher-priced originator pharmaceuticals.

Is there a difference between a generic medicine and an originator?

Generic medicines contain the same active ingredients as originator pharmaceuticals and act in the same way on patients. Equivalent generic medicines may contain different non-active ingredients (such as colourings, starches, sugars, etc) and they may differ in size, colour or shape, but none of these have any impact on the therapeutic effect, ie, the way they work in the patient's body. In some cases, the active ingredient in generics and originators may also differ in salts and esters. And just as when originators modify the non-active ingredients, salts or esters in their products, these differences must not affect the therapeutic equivalence between the different products.

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

In the EU, all medicines, originator or generic, have to be authorised before they may be produced and distributed to patients. The medicines agency of each EU Member State, or the European Medicines Agency (EMA) in London, does this by assessing the quality, safety and efficacy of the medicine. To receive market approval, a generic medicine must be "bioequivalent" to the originator product—ie, it must work in essentially the same way in the patient's body. Generic medicines are subject to the same European procedures as originator products and are carefully scrutinised by the competent authority.

Are generic medicines really as good as their originals?

Yes. Generic medicines must comply with exactly the same standards of quality, safety and efficacy as all 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 medicine 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 90% less than the original price of their brand-name equivalents. In addition, competition from rival generic products forces originators to reduce their own prices after - or sometimes before - patent expiry.

How do generic medicines benefit patients and national healthcare systems?

When we use generic medicines, our national healthcare systems save considerable sums of money—many billions of Euros. This frees up money to pay for other, more expensive treatments and services that patients need, including funding the research into new treatments and medicines. Generic competition also acts as an important stimulus for originator companies to focus on new research to create new patented medicines.

When can EU patients have access to generic medicines?

Generic medicines can be made available to patients in the EU only after the relevant patents on the originator product have expired.

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

As in other industries the standard patent is 20 years. But uniquely for pharmaceuticals and plant technologies this can be extended by up to a further 5 years by gaining a Supplementary Protection Certificate (SPC).

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 to 40 patents or more. In addition, a patent on a new use (“indication”), formulation, salt or ester can block the registration or marketing of a generic medicine for treatments where the base patent has already expired. This is a strategy known as “evergreening” which aims to prevent or delay competition for generic medicines by extending market protection through patents on minor changes to the original product.

How long does it take to register a generic medicine in the EU?

The registration of a generic medicine usually takes 1 to 2 years, but can sometimes take longer. Moreover, access to the market in many EU Member States is delayed for generic medicines—as for originator products—by having to wait for pricing and reimbursement status. Generic medicines manufacturers also spend considerable time and money on developing their products which are not, as sometimes alleged, mere “copies” of the originator product. It can take several years to bring a generic medicine to the market following the original commercial decision to do so.

What is “data exclusivity”?

Data exclusivity is a separate and additional provision to patent protection for the originator medicine. It defines a period of time during which the generics applicant is restricted from applying to the medicines authorities for market authorisation. Consequently generic medicines can only be evaluated and approved by the medicines authorities after the data exclusivity period has expired unless unusual and much more expensive procedures are used, which only happens very rarely.

Data exclusivity was introduced in 1987 to compensate for insufficient product patent protection in some countries at that time. Although strong product patents are now available in all EU Member States, data exclusivity was nevertheless maintained in the new EU pharmaceutical legislation which entered in force in 2005.

Do generic medicines companies have access to the data of originator products?

No. Generic medicines applications do not make use of any data from the originator registration file. In fact, the data of originator products are never revealed to third parties, and so cannot be used by generic medicines researchers. Instead, generic medicines producers research and develop their own formulation of the product which must then be 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 generic product is cross referenced with the originator product’s dossier by the medicines authorities who alone have access to these files.

Formed in 1993, the EGA is the official representative body of the European generic pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the global pharmaceutical sector.