Questions and answers on generic medicines

What are generic medicines?
A generic medicine is an alternative to a medicine that has already been placed on the market, the so-called reference, or innovative, medicine. The generic and reference medicines contain the same active substance in the same dose and are administered via the same route.

When do generic medicines become available?
When the patent on a reference medicine has expired (when the period of exclusivity is over) other pharmaceutical manufacturers can introduce their own generic preparation to the market.

How can marketing authorisation be obtained for generic medicines?
A marketing authorisation is required for all generic medicines. In order to secure a marketing authorisation, the applicant must provide detailed information on the manufacturing methods and the quality of the ingredients used as well as the product itself, in accordance with EU legislation. This is in keeping with the requirements on the manufacturer of the original reference medicine. In addition, the applicant must demonstrate that the generic medicine is absorbed as effectively as the reference product (this requirement applies to orally administered solid medicines, such as tablets, only). This information is used to ensure that the generic medicine offers the same efficacy, safety and quality as the reference medicine.

Are generic medicines too easy to develop?
Manufacturers are not required to re-investigate the efficacy and safety of the active ingredient used in generic medicines as this has already been done in conjunction with the development of the original reference medicine. When the innovator company's period of exclusivity ends, others can utilise the information without the need to carry out unnecessary duplicate clinical trials. This speeds up the development of generic medicines and makes the process more cost-effective.

The generic medicine itself must be developed using the same methods and is subject to the same documentation requirements as the original reference medicine. All relevant information regarding the product development and manufacturing process and quality assurance methods as well as comparative studies on absorption (so-called bioavailability) must be provided in conjunction with a marketing authorisation application. The development of a generic medicine requires significant pharmaceutical and medical expertise.

Are generic medicines the same quality as reference medicines?
Generic medicines must meet the same strict criteria with regard to the ingredients used, the manufacturing process and the final medicinal product as the reference medicine. Strict quality standards have been set by the EU and are monitored by national regulatory authorities (the Finnish Medicines Agency Fimea in Finland), the European Medicines Agency (EMA) and the European Commission. This promotes consumer confidence in generic medicines.

Why do generic medicines look different from the reference medicine?
The generic medicine may differ from the reference medicine in terms of its appearance, colour or shape. Different generic medicines may also look different from one another. Manufacturers may use different inactive ingredients and colouring agents and the final product may also have a different shape. Despite these variations, all generic preparations must meet the same strict regulatory requirements, designed to ensure the safety of the products.

Can the generic medicine or the ingredients used in it originate in China or India?
Not only generic medicines or the ingredients used to produce them but also original reference medicines and their constituent parts can come from anywhere in the world. What matters, however, is that the Finnish and EU regulatory authorities are familiar with the pharmaceutical plants where the medicinal products or ingredients destined for the Finnish market originate.

Inspectors from Finland and other EU member states conduct inspections in production facilities across the world. The real question is not where the products are manufactured but what quality standards and testing methods are applied. Both China and India have a highly sophisticated pharmaceutical industry – comparable to their electronics research and industry.

What are the benefits of generic medicines to the patient?
Generic medicines are usually cheaper than reference medicines but offer the same efficacy. Patients with chronic conditions in particular will benefit from lower prices when generic medicines enter the market. In addition, the pricing competition prompted by generic medicines also forces the manufacturer of the reference medicine to lower their prices.

How much cheaper are generic medicines?
When the first generic medicine appears on the market alongside the reference medicine, the generic medicine is usually priced at 20–30% lower. Initially, the markets will determine the exact price. As further generic preparations enter the market, the competition between providers intensifies. In Finland, the generic substitution policy also exerts further downward pressure on prices. Thus, generic medicines may be priced at up to 70–90% lower than reference medicines.

What are the benefits to society?
Due to their lower price, generic medicines bring direct cost savings both to the patients and the Social Insurance Institution of Finland (Kela). In Finland, some 50 million prescriptions are issued every year. The more generic medicines are prescribed, the higher the savings. Finnish pharmacies also offer generic substitution, where customers are given the option of purchasing a more affordable alternative, whenever available.

Have generic medicines already generated cost benefits?
Following the introduction of the generic substitution policy in 2003, several hundred million euros have been saved through the use of

generic medicines. At the same time, the Finnish population continues to age and consume more medicines, which are subject to the national medicine reimbursement system administered by Kela. The savings generated by generic preparations have served to balance the rising cost of medical reimbursements.

Will the development of new innovative medicines stop when patents expire and the cost of medicines falls?

No. The patent granted to the innovator company, like all patents, applies for a fixed period and during this time the patent holder can commercially exploit their discovery. After the patent expires, commercial competitors can enter the market. Savings in drug expenditure arise as they produce the equivalent product at a lower cost. The funds saved can in turn be used to fund the reimbursement of new innovative medicines (the so-called Kela-korvaus). The free competition also drives innovation and the discovery of new medicines and pharmaceutical companies producing new innovative medicines may develop their own range of generic medicines to fund their research activity.

Why does the information provided in the package leaflet vary between generic products?

The information provided on the package leaflet provided with a generic medicine may differ slightly from that of the reference product or another generic product. This is due to the requirements imposed during the marketing authorisation application process. Under the EU arrangements, one member state will be responsible for assessing marketing authorisation applications for a single generic product on behalf of the other member states. The member state in question will compare the information provided on the generic package leaflet to the information provided in the reference medicine package leaflet in that country. Thus, the information provided may vary between member states unless the information has already been harmonised.

Are the Finnish authorities responsible for monitoring generic medicines that have been granted marketing authorisation in another EU member state?

The Finnish Medicines Agency (Fimea) is responsible for monitoring the efficacy, safety and quality of some 450 generic medicines granted marketing authorisation by different EU member states. The responsibility usually remains for the duration of the marketing authorisation period.

What are parallel imports?

Parallel importing is the import of a medicine with an existing Finnish marketing authorisation from another EU member state by a pharmaceutical company independent of the Finnish marketing authorisation holder.

Is marketing authorisation required for parallel imports?

Yes, a marketing authorisation for parallel import is required. Further information on the requirements for parallel import is set out in the Fimea administrative regulation on parallel imports.

What is parallel distribution?

Parallel distribution is the distribution of a medicine granted marketing authorisation centrally by the European Medicines Agency (EMA) from another EU member state by a pharmaceutical company independent of the marketing authorisation holder. EMA authorisation is required for parallel distribution.

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