Lääketeollisuus
Pharma Industry Finland

New therapy options from biological innovative medicines and biosimilars

Biological medicines have revolutionised the treatment of many serious diseases. They are used to treat diseases such as asthma, diabetes and rheumatism as well as many types of cancer. A significant part of novel medications under development are based on biological products.

Biological medicines are an extremely versatile group; their size and complexity vary significantly. Biological medicines are produced in living cells, and therefore the manufacture is more demanding and more costly compared with conventional chemical medicines. Ensuring the high and uniform quality of each medicine batch plays a particularly important role.

Once the patent protection of a biological medicine expires, it is possible to start producing " new versions" of the same medicine, so-called biosimilars. However, a biological medicine and its biosimilar are not the same medicine, and a biosimilar is not a generic substitute for the original biological medicine or for another biosimilar.

The manufacturing process of biosimilars is equally complex and subject to risks. Therefore, the product development and manufacturing costs of biosimilars are also higher than is the case with generics. The marketing authorisation requirements are also more extensive than those applied to generics even if they are less extensive than the requirements imposed on original innovative biological medicines.

Research-based pharmaceutical companies develop and bring to the Finnish market both innovative (original) biological medicines and biosimilars that can be launched once the patent protection of the original medicine expires.

To provide the Finnish patients with the opportunity to use the novel medications, we need a predictable and transparent operating environment and active dialogue between the industry, authorities and decision-makers.

According to Pharma Industry Finland PIF:

The administration of the products and patients' adherence to treatment must be taken into consideration when the biological medicine is chosen

Biological medicines are normally administered using a unique medical device specific to the product. The usability of different devices may vary significantly from the patient perspective, and the differences may have an impact on the success of the therapy and adherence to treatment. It is therefore important to consider the patient's individual needs in selecting the medicine and provide the patient with sufficient instruction for proper use of the medicine and the device.

Lowering prices may give patients earlier access to medications

Once the patent protection of an original biological medicine expires and biosimilars start to appear on the market, price competition that tends to lower the therapy costs may start, provided that the preconditions for competition are met. Factors that impact competition include the size of the market, medicine price regulation and its predictability as well as the various parties' expected advantages drawn from price competition.

Hospitals are efficiently exploiting the price competition mechanism in making their medicine selection. However, in hospital medicine procurements, it is important to ensure that the decisions for the pharmaceutical products chosen for the procurement period are made in a timely manner well in advance. This is the only way that allows the pharmaceutical companies to forecast the demand for their products, ensure their availability and prevent unnecessary medicine wastage.

The reimbursability regulation of outpatient medicine, in turn, ensures that the price of the innovative biological medicine drops significantly as soon as the first biosimilar enters the market. When treatment costs go down, this will give many more patients the opportunity to benefit from biological medicines.

The savings from price competition also make it possible for the patients to have the novel innovative medicines more rapidly in use, both in hospitals and in outpatient care, reimbursed by the health insurance system.

Legislation must ensure savings from competition as well as incentives for development and introduction to the market of new medicines

We support the development which leads to increased price competition after the expiry of the innovative medicine's patent protection and promotes the controlled introduction of biosimilars.

The market must function in a way to ensure continued incentives for the development, introduction to and keeping on the market of novel biological medicines and biosimilars in Finland. The regulation on patented products must not discourage companies from introducing novel medicines to the Finnish market in situations where some of the products used for the treatment of the same disease are already covered by the biosimilar competition.

Moreover, the continuous availability of the medicinal products must be ensured to safeguard the continuity in patient therapies.

Changes and substitutability of medicinal products must be done with due attention to therapy expertise, patient safety, therapy follow-up and traceability

Due to patient individuality as well as the differences in various medicine alternatives and the devices required for their administration, it is important that the attending physician makes the product choice in collaboration with the patient. A specialised nurse also plays an important role in the selection of the suitable device and the induction to its use. The patient must be able to know which product is chosen and how to use it.

Lääketeollisuus ry
Porkkalankatu 1, PL 206, 00181 Helsinki | kotipaikka Helsinki | Y-tunnus 0881821-0 | puhelin (09) 6150 4900 | sähköposti etunimi.sukunimi@laaketeollisuus.fi | www.laaketeollisuus.fi
Pharma Industry Finland (PIF) Porkkalankatu 1, P.O.Box 206, FI-00181 Helsinki, Finland | Domicile Helsinki | Business ID 0881821-0 | Tel. +358 9 6150 4900 | E-mail firstname.lastname@pif.fi

Original biological medicines and biosimilars are not substitutable at the pharmacy which means that the criteria related to the generic substitution of chemical medicines are not applied to them. This must also be the principle followed in the future.

To ensure the treatment of patients, hospitals need to have a sufficient selection of biological original medicines and biosimilars. Procurement processes must

- be based on several criteria, not just price
- keep a sufficiently extensive product range that takes the patients' individual needs into account (including paediatric patients)
- make it possible for the therapy to continue uninterrupted at the interface between outpatient and inpatient care.

Biological medicines must be prescribed using their trade name

According to the instructions given by the authorities, all biological medicines must be prescribed based on their trade name, also indicating the batch number of the product in the patient records and pharmacy systems. These two types of data are indispensable in view of adverse effect or product defect cases so that the product used by the patient can be traced at batch level.

Biological medicine follow-up systems must be further developed

The range of innovative biological medicines and biosimilars is extensive. In the near future, it is expected that increasingly complex biological medicines and biosimilars will enter the market, with an even greater ensuing need to emphasise the safety considerations. The actors in the sector must actively provide unbiased information on the benefits and risks associated with biological medicines and take care of the safety follow-up.

Competition must be free to function on market terms

As far as possible, the competition between original biological medicines and biosimilars must be let to function on market terms. In choosing the regulatory pricing and steering measures, rather than imposing medicinal product changes, the alternative measures to boost competition should be favoured.

Predictability supports competition and ensures the availability of medicines, also reducing the volume of unnecessary medicine waste.

Lääketeollisuus ry
Porkkalankatu 1, PL 206, 00181 Helsinki | kotipaikka Helsinki | Y-tunnus 0881821-0 | puhelin (09) 6150 4900 | sähköposti etunimi.sukunimi@laaketeollisuus.fi | www.laaketeollisuus.fi
Pharma Industry Finland (PIF) Porkkalankatu 1, P.O.Box 206, FI-00181 Helsinki, Finland | Domicile Helsinki | Business ID 0881821-0 | Tel. +358 9 6150 4900 | E-mail firstname.lastname@pif.fi

Definitions

Biological medicine

The active ingredient of biological medicines has been extracted from or been produced with the help of a biological source. A biological source is a living organism, such as tissue or cell.

Normally, the biological medicine is a protein (or a longer-chained peptide) but it can also be another biological macromolecule (DNA, RNA or sugar structure) or part of the body (cell, blood product or even tissue). Compared with conventional chemical pharmaceutical substances, biological pharmaceutical substances are very large and complex molecules.

Biological medicines can be used to substitute for a molecule in the human body, with some disturbance in its volume or quality, or to adjust the body's own physiological functions, such as protective mechanisms. The impact mechanism of a biological medicine can also be based on the destruction of a target cell (the body's internal or external cell) or prevention of a molecule contributing to the disease. Vaccines are also biological medicinal products.

Biosimilar

A biosimilar is a medicinal product which contains a new version of the active ingredient of an original biological medicine (reference product), complete with a marketing authorisation and already on the EU market. The physicochemical, structural and biological properties as well as efficacy and safety of the biosimilar have been shown by comparative studies to be sufficiently similar to those of its reference product.

Marketing authorisation requirements of biosimilars

The marketing authorisation requirements imposed on biosimilars are substantially more extensive than those on generic medicines. In addition to the corresponding quality documentation required of original biological medicines, biosimilars must also be accompanied with evidence showing that the biosimilar has a similar activity, structure and purity profile as possessed by the original medicine. Biosimilars must also be backed by studies on clinical efficacy and safety, although much fewer are required compared with original biological medicines.

Generic

Generics are non-biological medicines that include the same amount of the same, identical active ingredient in the same pharmaceutical form as the original medicine.

Lääketeollisuus ry
Porkkalankatu 1, PL 206, 00181 Helsinki | kotipaikka Helsinki | Y-tunnus 0881821-0 | puhelin (09) 6150 4900 | sähköposti etunimi.sukunimi@laaketeollisuus.fi | www.laaketeollisuus.fi
Pharma Industry Finland (PIF) Porkkalankatu 1, P.O.Box 206, FI-00181 Helsinki, Finland | Domicile Helsinki | Business ID 0881821-0 | Tel. +358 9 6150 4900 | E-mail firstname.lastname@pif.fi