Generic medicines – integral to the drug discovery life cycle

The history of industrial pharmaceutical production has advanced through the decades aided by competition and official guidance. Companies now have a wealth of opportunities to develop and produce medicines in response to market demand. Generic medicines are an important part of the range of medicines available today.

Under EU legislation and the Finnish Medicines Act, medicines can only be produced under license granted by the relevant national authority (Fimea in Finland). As with all sectors of manufacturing and innovation, the industrial production of medicines is governed by the twin forces of competition and profitability.

The pharmaceutical industry is a high technology industry. The considerable research and development costs necessitate lengthy periods of market protection to safeguard the discovery of new medicines. The pharmaceutical industry is therefore characterised by its efforts to seek patent protection before a medicine, indication or formulation is subjected to open competition.

Finnish pharmaceutical industry increasingly international

Since the 18th century, Finland has undergone a gradual transition away from the traditional model of medicines produced on-site at individual pharmacies towards an international model of pharmaceutical manufacturing. In the 21st century, we are now faced with the fear that Finland's self-sufficiency in pharmaceutical supply and indeed the country's skills base have been jeopardised as industrial production to a large extent has migrated abroad.

The pharmaceutical industry of today is strongly international. Finland finds itself in competition with large and commercially considerably more profitable market areas.

The internationalisation of Finland's pharmaceutical industry has followed the general trend seen across the sector as a whole. As early as the 1950s, Finland's policymakers came to the understanding that developing and maintaining a comprehensive medicinal product range even for the purpose of meeting domestic need would not be feasible on the strength of domestic resources and requirements. Partnerships were created and licensing agreements were concluded with international pharmaceutical companies for the purpose of manufacturing their products in Finland. The "Finnish" products made under these agreements went on to claim significant shares of the market, in which their main competition came in the form of other Finnish licensed products.

The 1970s were a difficult decade for the Finnish pharmaceutical industry, particularly in terms of profitability. Competition increased and the new production, research and product development environment called for significant new investment. Strategies were updated and it became clear that expansion outside of Finland's own borders was necessary. Domestic research activity was channelled towards emerging technologies and molecules, often in collaboration with international research teams. Licensing agreements continued to thrive for short while longer. A market for both medicinal substances and medicinal products remained thanks to the Finnish process patent, which remained in force until 1988.

In the following decades, the Finnish pharmaceutical industry too was faced with the need to streamline its product range. Each industry player now had to focus its research and development resources towards original products in their particular areas of specialism. A period of internal mergers ensued, licensed production fell and the need for international partners grew.

The slow rise of generic medicines that had been apparent across the industry for some time began to gather pace and served to alter the nature of competition. The number of big name Finnish pharmaceutical manufacturers dropped to just a few. One international merger after another took place and as a result, the Finnish pharmaceutical industry came to be run and managed by international players. Thus far, Finland has retained several production plants, and a significant number of jobs, thanks to the country's highly skilled workforce.

Open competition promotes R&D

Medicines, and the pharmaceutical industry more widely, prompt strong reactions and demands for strict moral codes of conduct. In the popular opinion, the pharmaceutical industry should not be associated with such perceived ills as profit or dependence on the free market. A new and significant discovery is perceived as a positive thing but from that point onwards the industry is viewed far more critically than other manufacturing industries. Particularly trenchant criticism is directed at manufacturers who only produce new versions of already existing pharmaceutical innovations.

Different forms of free enterprise and the availability of a range of pharmaceutical products are essential if new pharmaceutical innovation is to take place, R&D activity is to continue and the supply of medicines is to remain steady. The development of new drugs is a lengthy, expensive and risky undertaking. Long periods of market protection and patents exist for a reason but there comes a point when products must be opened up to competition to ensure that the motivation for new pharmaceutical innovation remains.

Medicines manufactured under license and new versions of an existing preparation created in-house are part and parcel of competition. The biggest driver of competition in the past few decades has been so-called generic medicines, whose bioequivalence to the original drug is demonstrated through clinical trials.

An additional and relatively new competitor on the market are so-called parallel imports. Parallel importing describes a situation where a medicine subject to a marketing authorisation in another EU member state is marketed in another part of the community when the differences in price between the countries make this a viable alternative.

Demand for both innovative and generic medicines

It is a fact that a pharmaceutical market requires all its constituent parts to remain fully functional. Innovation will not happen without an industry willing to invest in R&D but even an innovative industry would wither if it were not for competition pushing it towards new discoveries. Conversely, there would be no generic pharmaceutical sector without innovative medicines and the generic medicines industry certainly cannot survive for very long without new innovative medicines on which to reference their generic alternatives.

Generic medicines and other alternative preparations are thus inextricably a part of the life cycle of new drug discoveries and the mutual dependence should not be seen as a hindrance to any one sector of the industry. Indeed, the division to innovative and generic medicine manufacturers is no longer as clear cut as before. Most innovative medicine manufacturers also produce generic medicines as part of their wider product offering, which allows them to remain competitive and to fund their R&D activities. All legal means of competition are available to all industry players.

In Finland generic medicines represent less than half of sales

The number of marketing authorisations issued to generic medicines has increased steadily in Finland (Table 1). Currently, approximately half of all marketing authorisations are granted to generic medicines. The number of generic medicines available on the Finnish market increased significantly following the adoption of the generic substitution policy in 2003 as well as the reference price system introduced in 2009.

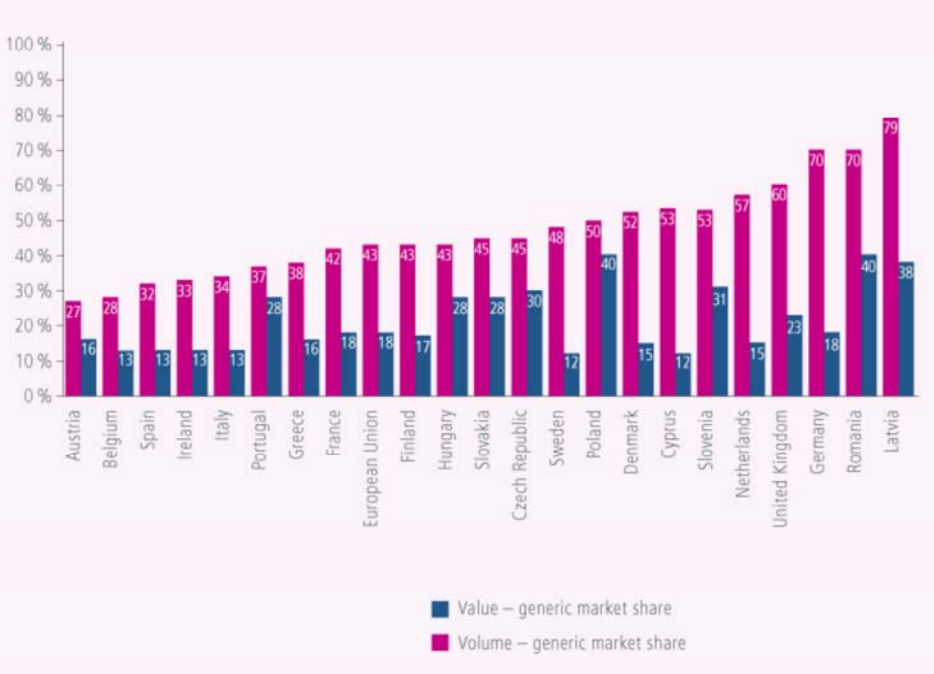
Generic medicines suitable for substitution and parallel imports are available in Finland across all disease categories. The largest number of generic medicines is available for neurological, psychiatric as well as cardiovascular diseases, in keeping with the commonest medical conditions.

Some of the potential offered by non-branded preparations remains untapped as the market share of generic medicines by volume remains below 50%, the equivalent of less than 20% by value (Figure 1). Parallel imports represent just 1% of total sales in Finland.

Table 1. Marketing authorisations issued in Finland 1995–2013 and marketing authorisations issued to generic medicines.
SOURCE: FIMEA MARKETING AUTHORISATION REGISTER.

Year	Marketing authorisations for generic medicines	Total marketing authorisations
1995	457	3 423
2000	938	4 210
2005	2 906	6 406
2013	3 586	7 595

Figure 1. Total sales of generic medicines by value and volume across EU member states in 2010.
SOURCE: CARONE ET AL. 2012, 41.



Ensuring security of supply through sensible mix of branded and generic medicines

A distinctive feature of the pharmaceutical market is that the person prescribing, using and covering the cost of the medicine are rarely one and the same. In terms of prescription only medicines, a significant proportion of the cost is borne by society. The reimbursement of medicine expenses and price setting are both highly regulated.

The current government programme includes in its aims the promotion of cost-effective pharmacotherapies and seeks a significant reduction in spending on medicines. The Finnish population is ageing and the demand for treatments for chronic illnesses is rising. Medicines, including biologic agents, are becoming technologically more sophisticated. Our aim is to be able to offer the latest, often very cost intensive, treatment options to those who need them. Correspondingly, we will also need to maximise opportunities for reducing spending on medicines where high-quality alternatives are available. Cheaper generic medicines and parallel imports generate savings both in terms of their lower cost and a competitive market environment driving down costs further.

It is a good thing that a wide selection of medicines that have been shown to be of high quality, effective and safe and which are in receipt of a marketing authorisation is available on the market. Thanks to legislation supporting competition, we have at our disposal a wide range of preparations that thrive in a symbiotic relationship with one another and which we can make use of wisely to ensure the secure and comprehensive availability of medicines for the end user at a reasonable cost.

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