GENERIC MEDICINES

an overview

Generic and biosimilar medicines represent four out of five drugs prescribed by the NHS. These critical medicines are exact equivalents of existing originator (original) products and can be supplied to the NHS when the period of patent protection ends on originator products, known as loss of exclusivity. At this point, the NHS moves from paying one supplier's monopoly price to having a choice of manufacturers who compete for market share.

The sudden injection of competition sees prices paid sharply tumble – often by as much as 90% – providing annual savings of £16.5 billion to the NHS budget. The more affordable medicines also mean that more patients can access treatments, and with more suppliers making medicines, the resilience of market supply is also improved. In addition, the lower prices delivered by off-patent products allow the National Institute for Health and Care Excellence (NICE) to reappraise a medicine, potentially approving its wider use and allowing more patients to benefit.

Every day, more than 2.2 million off-patent generic and biosimilar prescription products are given to patients. Around a quarter of these medicines used in the UK are manufactured here. The UK's competitive market delivers the lowest medicine prices in Europe.

BRITISH GENERIC MANUFACTURERS ASSOCIATION

What are generic and biosimilar medicines?

A generic medicine is created to be exactly the same as an already marketed brand-name drug. For example, lenalidomide is a generic of the cancer treatment Revlimid™ and atorvastatin is a widely used generic of the originator product Lipitor™ and helps prevent cardiovascular disease.

A biological medicine consists of complex molecules derived from living cells, instead of chemicals. A biosimilar medicine is an almost exact copy of a biological medicine. Making a biosimilar is like getting a spare key cut. Biosimilars have the same therapeutic effect as the originator branded medicines and provide better value for the NHS.

The Medicines and Healthcare products Regulatory Agency (MHRA) ensures that generic and biosimilar medicines meet stringent quality, safety and efficacy standards. Significant investments in manufacturing, regulatory compliance and quality assurance are essential to meet its high standards and gain market approval.

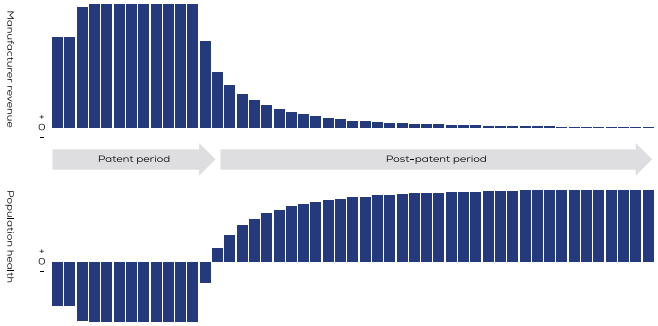
How generics and biosimilars save the NHS money

It takes more than a decade of research and clinical trials to develop an originator medicine. In recognition of this upfront investment, manufacturers are given exclusive rights to sell and market their new drug, typically for around 15 years, before the market is opened up to other manufacturers. To recoup the development costs, the price of medicines during this period of exclusivity is often quite high.

Once exclusivity is lost, other manufacturers can freely develop, manufacture and supply a medicine. Its generic and biosimilar versions are approved by the MHRA and are recognised as being equally safe and of the same effectiveness and quality as the more expensive, original medicine. Because the development costs are lower, a manufacturer's selling price to the NHS is significantly reduced, especially if several suppliers enter the market and competition pushes prices down.

The UK has robust systems for pricing and reimbursement through both community pharmacy and NHS hospitals, which encourages the use of generic medicines. Manufacturers transparently provide their pricing and sales data every three months to DHSC as input to the NHS Drug Tariff, which is updated monthly. Generic medicines for use in the hospital service are procured through regular competitive tenders. These mechanisms keep generics cost-effective for the NHS, patients and taxpayers.

The value profile of new pharmaceuticals from a manufacturer and NHS perspective



The LSE, York University and the London School of Hygiene and Tropical Medicine, June 2023

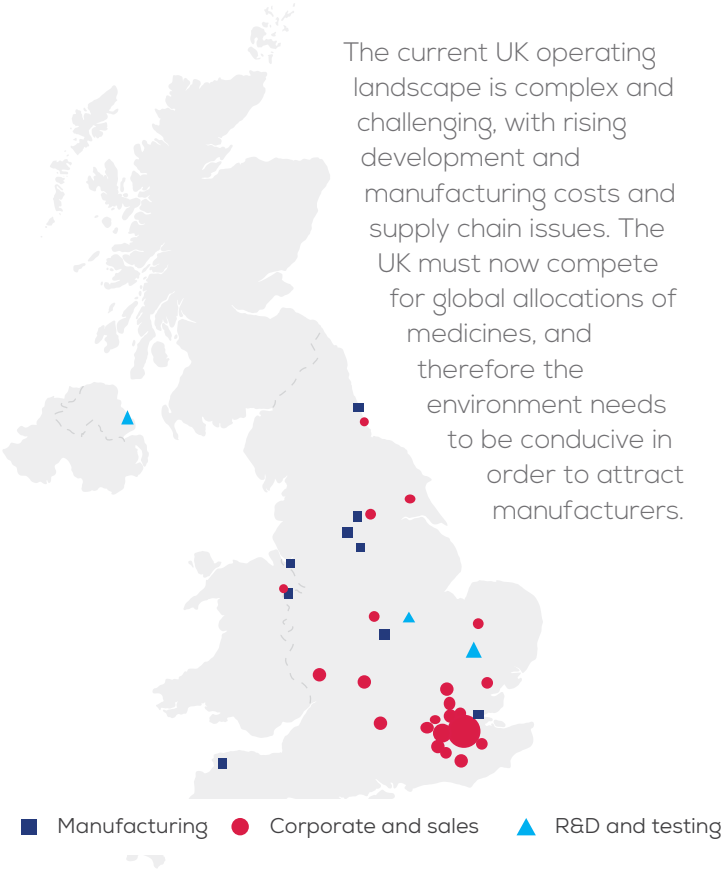
Biosimilars not only produce big cost savings, but they enable more patients to access the medicine earlier, which leads to better health outcomes. This was recently set out emphatically by the country's foremost three leading academic bodies on medicines policy, as stated in the following and depicted in the graph above:

> "During the on-patent period, revenue mainly accrues to the manufacturer due to the

drug's monopoly protection. During this period, NHS patients experience a health deficit as the new medicine's benefits are outweighed by the impact on other NHS services. After the patent period, NHS patients start receiving significant net benefits from the availability of cheaper generic or biosimilar versions of the medicine."

The UK generics and biosimilars industry

The UK's generic and biosimilars industry is essential for access to affordable medication and underpins the NHS. Eight of the ten largest medicine suppliers to the NHS are generic or biosimilar manufacturers, which play a key role in ensuring early and affordable access to essential treatments.



The current UK operating landscape is complex and challenging, with rising development and manufacturing costs and supply chain issues. The UK must now compete for global allocations of medicines, and therefore the environment needs to be conducive in order to attract manufacturers.

Without supportive and targeted policies, manufacturers will prioritise other markets before the UK for new generic and biosimilar medicines. Any government life sciences strategy should recognise and support the supply of generic and biosimilar medicines.

Conclusion

Generic and biosimilar medicines play a pivotal role in ensuring the NHS has access to affordable medicines, meaning that more patients are treated, and often earlier. The UK generics and biosimilars industry is a well-regulated, competitive market that supports the NHS through significant cost savings and widened access to life-saving and life-changing medicines. In developing its medicines, the industry invests significantly in innovation, enhancing products and creating patient-friendly devices that are complemented by personalised patient support services.

Generic and biosimilar medicines and patented medicines are pieces of the same puzzle and essential for a sustainable NHS, necessitating a regulatory and operating environment which allows them both to thrive.

In the next five years, more than 250 products will lose their exclusivity. Based on current figures, this will generate an additional £18 billion of savings on top of the annual £16.5 billion currently in place.

However, for the UK to continue to benefit from a resilient and competitive off-patent market, the government must have a dedicated strategy for the generics and biosimilars sector that includes a supportive policy environment.

A lack of strategy will put in jeopardy the many financial and patient access benefits currently enjoyed as a result of the critical contribution from generics and biosimilars.

In summary, generic and biosimilar medicines are:

New versions of existing patented medicines that are just as clinically effective and safe

Typically 70–90% cheaper than the original medicines

The source of £16.5 billion of savings for the NHS

About the British Generic Manufacturers Association (BGMA)

The BGMA comprises members of the generic and biosimilars manufacturing supply industry, who account for approximately 85% of the total UK off-patent market by volume. BGMA members include eight of the ten largest medicine suppliers to the NHS. Our role is to represent the sector with all stakeholders including politicians, policymakers and regulators. We work in partnership with the government to ensure our sector continues to save the NHS significant amounts of money and widen patient access to vital medicines.