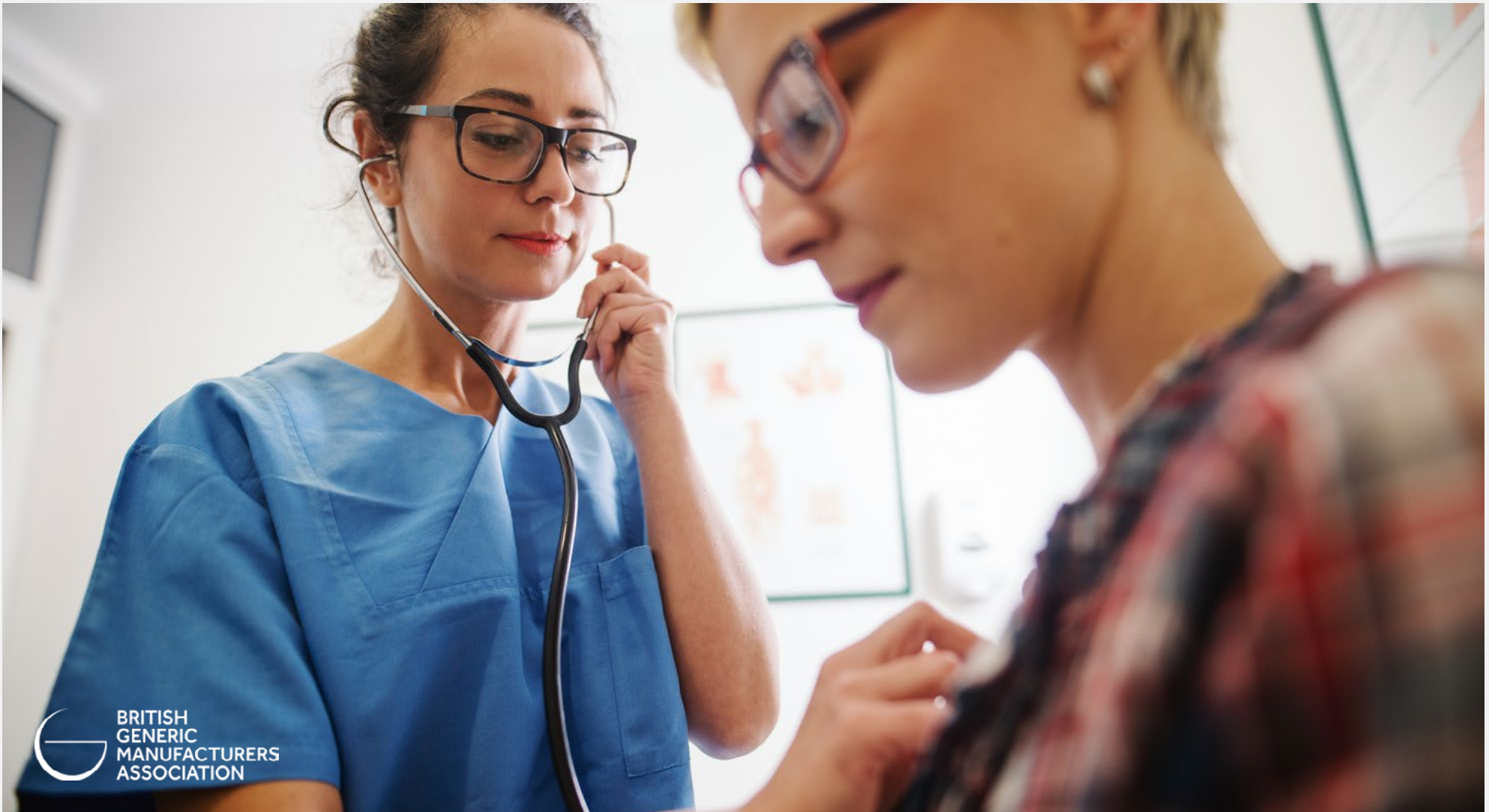


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# Off-patent savings watch: H1 2025

By the British Generic Manufacturers Association (BGMA)

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## Introduction

The principal benefits of a well-functioning off-patent medicines market are savings and access. When a patent product loses its protection, generic or biosimilar competitors enter the market providing alternative avenues of supply.

This competition for supply results in the price paid by the NHS tumbling as manufacturers seek to gain market share. Not only does this save the NHS money but it also adds important resilience to supply chains. It also means the NHS can treat more patients making stretched budgets reach further. Currently, generic and biosimilar competition saves the NHS around £18bn a year<sup>1</sup>. Over the next five years, around 250 additional products or molecules will lose their patent protection creating further potential for vital savings on top of what already exists<sup>2</sup>.

However, we cannot assume or be complacent about these savings being delivered. There are finite amounts of medicines in the world and the UK has to compete to enable adequate supplies to arrive and for new launches to take place.

Therefore, ensuring that international manufacturers view the UK as an important supply market for their portfolios is vital. This means the operating environment needs

to be conducive for suppliers who typically thrive on a model of high volumes and razor thin margins.

Delay, duplication or additional costs are all major factors in preventing supply and over the past few years there have been a number of issues such as these which have made the UK less attractive in supply terms. The possibility of an expanded patient cohort can also make supply more attractive.

Despite being four out of every five prescription medicines used by the NHS, successive Governments have failed to create any targeted policy for the off-patent sector. Neither has there been any recognition of their contribution in the UK's Life Sciences Vision.

This has to change otherwise the loss of exclusivity events which are set to occur in the next few years as patents expire will not deliver their full potential leading to a drop in NHS savings and a less resilient supply market. Over the next few years, we will review and release data about the cumulative effect of expected patent expiries every six months. We will also attempt to show the impact of these patent expiries to understand whether competition is delivering value to the NHS.

1. Based on if all scripts were fulfilled at the average brand reimbursement price; Prescription Cost Analysis for England, 2023/24; 6 June 2024

2. For some the main product patent may have already expired, but further patents on the molecule remain (for an additional indication, way of taking the medicine or even manufacturing step) and are due to end before 2029



## Overview

This is the first in a new series of short reports looking at what money the NHS could save from medicines set to lose their patent expiry in the next six months.

The Chief Executive of the NHS, Amanda Pritchard, recently pointed out: *“We need you (NHS organisations) to act on the unacceptable variation in uptake. Because every penny you spend on branded medicines over generics or biosimilars...is a penny that should be spent on improving care elsewhere<sup>3</sup>”.*

In fact, based on NHS Prescription Cost Analysis data<sup>4</sup>, a 1% switch from brand to generic dispensing can annually save over £228m nationally or £5.43m on average per Integrated Care Board (ICB).

This short report series will raise awareness of the savings that generic and biosimilar medicines can provide as the patent or other protection lapses from the original producer of the drug (or originator). It ignores the thousands of existing generics and biosimilar products that are already providing billions of pounds in savings and enabling widened access.

The report utilises IQVIA NHS sales data, with adjustments made on the basis of feedback

from our members<sup>5</sup> around potential patent expiry timings and competition delays. Timings as to when products may lose exclusivity protection can change and so this analysis is only ever intended to be indicative.

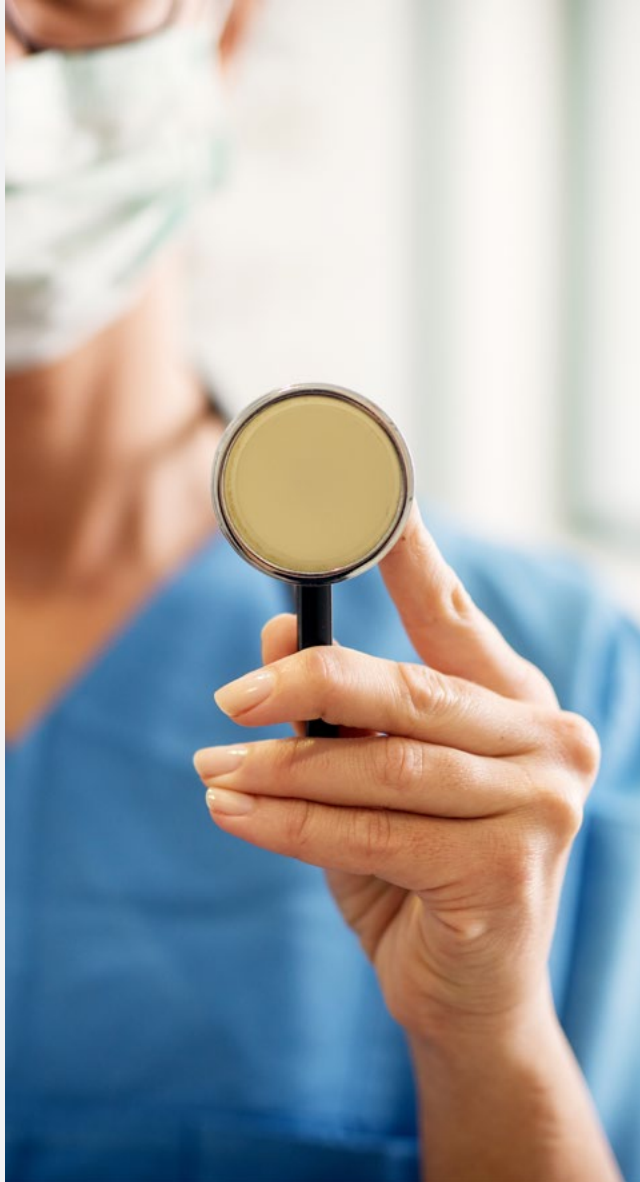
We project a price erosion level of 80% for generic medicines against the originator’s NHS Drug Tariff price, and 70% for biosimilars. For some high value lines, the rate of price erosion will be much more. For some, it will be less. The propensity for higher value lines to deliver a far bigger saving we think balances the variance on a macro level.

In addition, to ensure that we project conservative generic and biosimilar savings estimates, we assume that prior to the originator losing exclusivity for its presentation, that they were making NHS sales with a 35% price discount from the Drug Tariff price. While there is a variance in the extent to which these discounts are applied, notably whether the presentation is used in a primary or secondary care setting (where different pricing / procurement systems are in place), we have applied this figure for all presentations losing exclusivity. Indeed, the report does not distinguish between medicines supplied to community pharmacies or NHS hospitals.

3. 12 November 2024, NHS Providers.

4. Prescription Cost Analysis for England, 2023/24; 6 June 2024

5. This feedback, following Secretariat requests to members on an individual basis, is only ever supplied to the Secretariat, which treats the information as commercially sensitive and not for further distribution.



## KEY DATA INSIGHTS FOR H1 2025:

The first half of 2025 appears a comparatively quiet six months for high value patent expiry opportunities, even if there are broadly the same number of molecules with presentations expiring in H2 2025. Even so, the data tells us the following:

- Number of molecules<sup>6</sup> with presentations<sup>7</sup> where the patent is set to expire during January-June 2025 = 31. This compares to 28 in H2 2025.
- Total annual value of all presentations paid for by the NHS, measured by NHS Drug Tariff value, where the patent is set to expire during January-June 2025 = **£341 million**. This compares to **£1.43 billion** in H2 2025.
- The potential financial saving to the NHS in 2025 arising from generic and biosimilar competition for all presentations where the patent is set to expire during January-June 2025 = **£150 million**
- And the NHS saving figure if we estimate average pre-patent expiry discounts offered by the originator at 35% for all presentations paid for by the NHS = **£97million**
- The potential average financial saving to each Integrated Care Board (ICB) in 2025 arising from generic and biosimilar competition for all presentations where the patent is set to expire during January-June 2025 = **£2.3 million**<sup>8</sup>
- The potential financial saving to the NHS from 2025-2029 arising from generic and biosimilar competition for all presentations where the patent is set to expire during January-June 2025 = **£1.234 billion**
- And the NHS saving figure if we estimate average pre-patent expiry discounts offered by the originator at 35% for all presentations paid for by the NHS = **£802 million**
- The potential average financial saving to each ICB from 2025-2029 arising from generic and biosimilar competition for all presentations where the patent is set to expire during January-June 2025 = **£19.1 million**<sup>9</sup>

6. The unique active ingredient of a drug, irrespective of strength of dose, method of administration (e.g. tablet or injection) and pack size.

7. There can be many presentations containing the same molecule, but each presentation may vary according to the strength, method of administration and pack size.

8. Based on dividing £97m saving in 2025 from H1 2025 loss of exclusivity products by 42.

9. Based on dividing £802m saving from 2025-2029 from H1 2025 loss of exclusivity products by 42.



## Summary of what the data tell us

These figures show the importance of the NHS utilising generic and biosimilar competition and consciously promoting appropriate switching processes.

**Even in a quiet half-year for high value patent expiries, the NHS savings cumulatively add up to over £800 million by the end of 2029, or nearly £20 million per ICB.** This means that the right prescribing decisions taken today really add up over the next five years.

Indeed, over this period, we estimate an additional several billion a year of savings could be secured for the NHS for presentations losing patent protection between 2025-29. This is on top of the already significant sums generated via generic or biosimilar competition for presentations that are already off-patent (those lapsing prior to 2025).

For this to be realised, it is important that the UK remains a viable place to supply from a commercial perspective. As part of that, we need to encourage the uptake of off-patent medicines and incentivise supply and new launches.

## About us

The British Generic Manufacturers Association (BGMA) represents the manufacturers of 4 out of every 5 prescription medicines used by the NHS. Generic and biosimilar medicines are off-patent treatments covering the vast majority of conditions. Biosimilar medicines are similar, but they are biologic medicines, which are complex molecules derived from living cells.

Generics and biosimilars are produced by many different manufacturers, creating price competition which pushes prices down. While they have the same therapeutic effect as their on-patent counterparts, they are far more affordable, typically 80-90% less in the case of generics. Generic and biosimilar competition saves the NHS £18 billion each year, or 11% of the NHS' entire operating budget for England.

The NHS would be unaffordable without generics and biosimilars. They also mean more patients can be treated with more effective medicines to help them recover and manage their conditions.