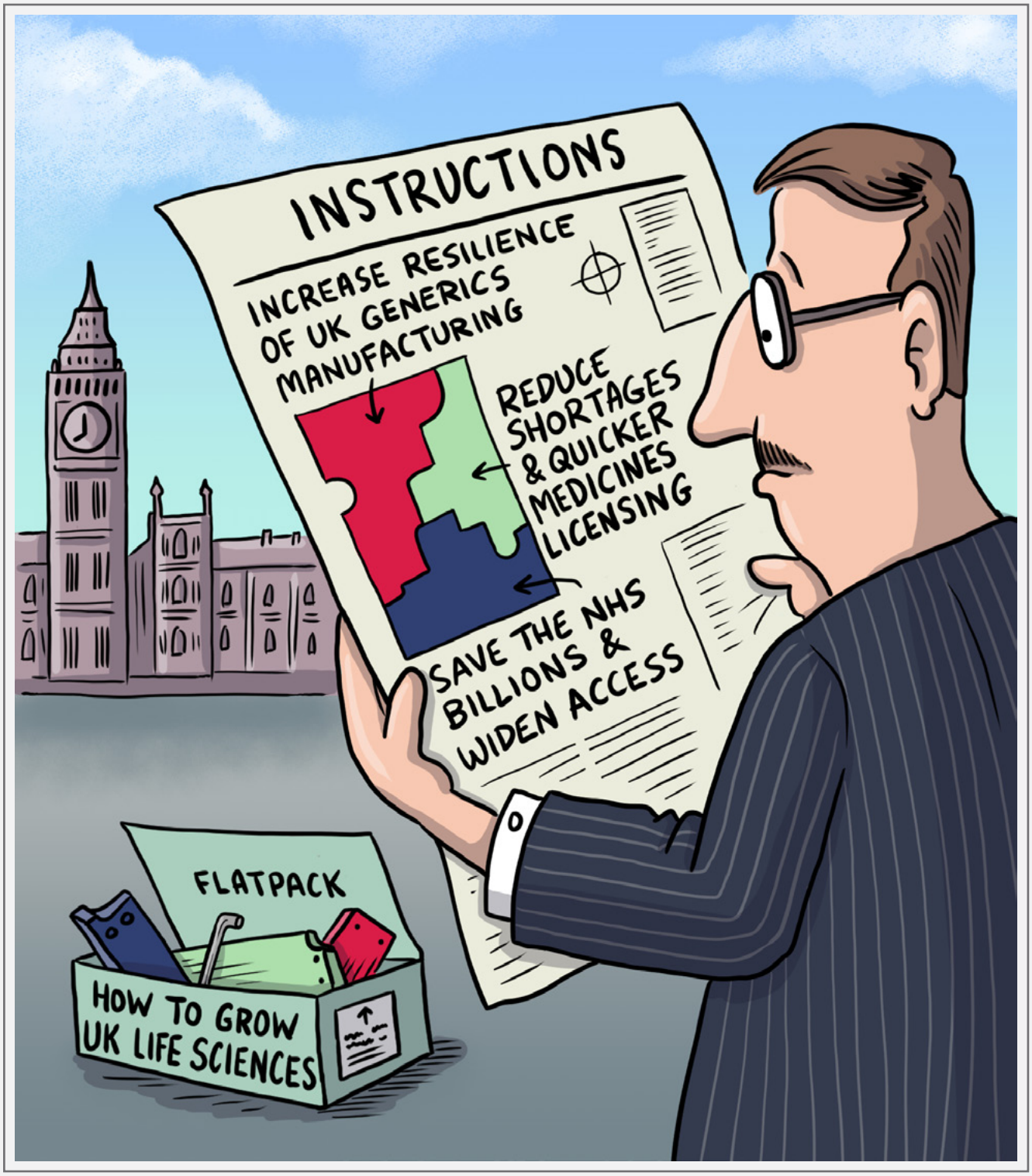
A BGMA WHITE PAPER March 2024

MANIFESTO

for building a resilient UK medicines industry

Recommendations from the British Generic Manufacturers Association



BRITISH GENERIC MANUFACTURERS ASSOCIATION

Off-patent products deliver £16.5bn of annual savings to the NHS budget.

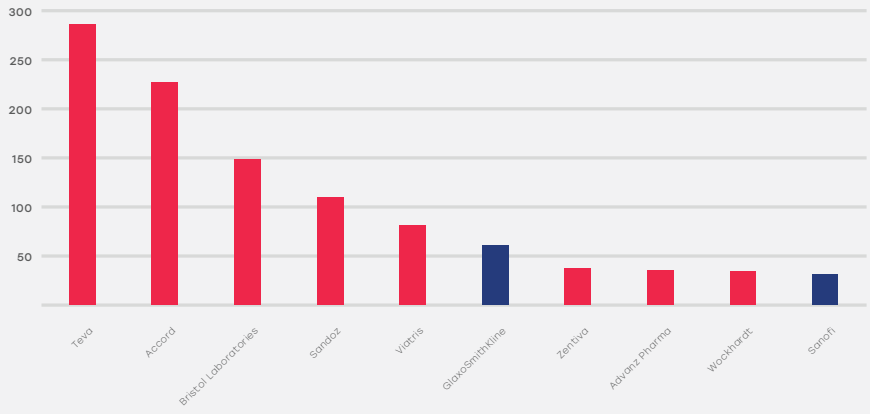
Introducing our manifesto

Generic and biosimilar medicines matter: they represent four out of five NHS prescriptions. They are fundamentally inherent to the well-being of all patients in the UK. Their importance to NHS finances is also significant, as competition from off-patent products lowers medicine prices, delivering over £16bn of annual savings to the NHS budget[1].

The British Generic Manufacturers Association (BGMA) represents the interests of UK-based manufacturers and suppliers of off-patent generic and biosimilar medicines. We represent eight of the top ten suppliers (by volume) to the NHS (Figure 1), with our members providing more than two million packs of medicines to patients every day. We are proud to be a key partner to the NHS.

Despite their importance to the success of the UK healthcare system, the benefits from generic and biosimilar medicines have been taken for granted by UK governments for too long. A lack of investment or bespoke strategy for the sector, coupled with worsening regulatory challenges and post-Brexit disadvantages, has created an environment which makes the UK an increasingly difficult and commercially unattractive market to supply. Some of the world's largest generic companies do not provide their complete portfolios to the NHS.

This matters as a finite amount of medicines are available, and the UK competes with other countries to ensure patients can access the necessary treatments. The resilience of the UK off-patent sector, which has long been its core strength and is the fundamental principle of the competitive market, delivering the lowest prices in Europe, is now increasingly under threat.



Eight of the top ten NHS suppliers are BGMA members.

Figure 1: Packs dispensed by the top NHS suppliers per million

For example, medicine shortages are becoming increasingly common and are symptomatic of a system which needs fresh policy thinking and consideration. With European countries collaborating and coordinating on access to critical medicines, the UK faces a much tougher environment in which to obtain the products it needs.

This manifesto outlines the challenges facing this most vital of UK sectors. It provides key policy areas which need greater focus from whichever political party forms the next UK government.

1. Prescription Cost Analysis for England, 2022-23, if all prescriptions dispensed as a generics had been reimbursed at the annual brand price, NHS BSA

Foreword

Mark Samuels, Chief Executive, BGMA

The UK's off-patent medicines sector has a universal impact on public health. However, it does not command corresponding levels of policy attention despite increasing media interest in key issues such as generic medicine shortages. The vast majority of prescription medicines taken by UK patients are generics or biosimilars, which, via competition, save the NHS many billions of pounds every year. These savings increase patient access, meaning that hundreds of thousands more people can be treated with the right medicine earlier.

This sector is an economic success story, with around 25% of the over one billion packs of generic medicines used by the NHS each year made in the UK by a high-tech industry that supports more than 26,000 good-quality jobs in a dozen major facilities around the country. The remainder primarily come from India and the European Union (EU).

Yet it is a sector that goes under the policy radar when it comes to government, which focuses almost exclusively on tomorrow's potential new treatments.

In spite of being vital to the health and well-being of the UK's citizens, this sector has been unrecognised over many years and has received virtually no consideration or support from a policy perspective. This must change.

Based on research, we estimate that some 250 medicine patents will expire in the next five years. The potential savings to the NHS –based on current market levels of competition in generics and biosimilars – could be as much as £18bn. This is on top of the annual savings of £15bn from already patented expired products. This is a significant commercial opportunity which will make a huge difference to NHS finances. However, its full realisation is under threat.

We have written to successive health ministers, Secretaries of State and even the Prime Minister to warn of the consequences of failing to place off-patent medicines at the heart of policy. Yet the government's own Life Sciences Vision fails to acknowledge the off-patent side of the supply chain despite the sector accounting for four out of five medicines patients take.

The result is that many of the issues we have flagged time and again to successive governments are now being experienced by patients in pharmacies, who are struggling to access the treatments they need. The long-standing mission of our sector has been to ensure that the right medicines are available for the right patient at the right time. This is increasingly becoming an ambition rather than a promise, as policy has failed to protect this industry's resilience.

In this manifesto, we provide a range of solutions across four policy areas that will help safeguard UK stocks and restore the resilience of our medicines supply chain, which has become critically eroded.

These savings increase patient access, meaning that hundreds of thousands more people can be treated.

We examine:

01 How the off-patent sector can save the NHS more money

02 Economic and domestic growth to encourage inward investment

03 Health and access and what to do about shortages

04 Global partnerships and why intellectual property matters

As the sector that supplies most prescription medicines, the generics and biosimilars industry is an important strategic supplier to the NHS and a central part of the the UK life sciences ecosystem. On this basis, we call for equal representation in how a future government treats the pharmaceutical industry's on-patent and off-patent sectors. Unlike the recent Life Sciences Vision, this will help develop a more durable and resilient life sciences industry whereby the rhetoric can be delivered and felt on the ground.

Medicines resilience should also be viewed as a regional security issue, not just a UK-specific one, and we should look at areas of collaboration with European counterparts, notably the issue of batch testing.

We implore the next government to recognise the critical importance of a well-functioning and resilient, off-patent medicines sector. We need a bespoke industrial strategy and supportive policy environment that allow our sector to thrive again.

The lessons from Brexit and the pandemic also need to be heeded, and we must promote and protect an industry which ultimately protects us all.

We implore the next government to recognise the critical importance of a well-functioning and resilient off-patent medicines sector.

How does the current market work?

Generic and biosimilar medicines, which are regulated to the same standards of quality, safety and efficacy as originator versions, are supplied to the market after the patent on the originator medicine has expired. Once the patent expires, the NHS no longer needs to pay a monopoly supplier for the originator product, and a competitive market is created in which multiple manufacturers compete on price for market share.

Because generics and biosimilars are typically up to 90% less expensive than the originator versions, they make up 80% of NHS-prescribed medicines and save the NHS over £16bn per year on its medicines bill. This makes generic – and, increasingly, biosimilar – medicines the bedrock of the NHS, providing life-saving and life-enhancing treatments to millions of people every day.

The UK benefits from the lowest average manufacturer selling prices in Europe[2]. This is because the UK typically enjoys high levels of competition and low barriers to entry once a marketing authorisation or medicines licence application has been secured. Having a competitive market does not just deliver lower prices; the plurality of supply acts as a safety net when manufacturers encounter supply problems.

Generics and biosimilars save the NHS approximately over £16bn per annum.

2. The supply of generic medicines in the UK– A study by Oxera

Around 80 biologics are due to expire before the end of 2028.

Biosimilar medicines – are they a magic wand to save NHS money and increase patient access to treatments?

We estimate that every year, the UK saves over £16bn from generic and biosimilar medicines. This is a great success story but is under threat due to incoherent or – worse – non-existent government policy.

To continue to realise the best value from generics and biosimilars, we need to ensure that the NHS procures the most cost-effective medicines, meaning more patients have access to treatments and there is more headroom to pay for truly innovative treatments. As much as 80% of the UK's prescriptions are for generic medicines. However, this proportion has remained fairly static for a decade. The big opportunity to realise more savings from off-patent drugs in the next five years comes from biosimilars. Around 80 biologic off-patents are due to expire before the end of 2028. Biosimilars produce considerable cost savings and enable more patients to access medicines earlier, leading to better health outcomes.

The potential savings the NHS could realise by using new biosimilars instead of the original biological medicines are very real and very significant. In 2017, six of the ten most expensive medicines in the UK by cost were biologic medicines; by 2021, that number had risen to eight. The biosimilar adalimumab, used to treat rheumatoid arthritis, saved the NHS £400m over the three years to 2022 and ensured that more than 45,000 patients were able to access treatment earlier. The message is clear: we cannot lose the opportunity to maximise the potential benefits of biosimilar medicines.

The National Institute for Health and Care Excellence (NICE) is essential for evaluating biosimilars when biological patents expire. NICE's role is crucial because switching to a biosimilar medicine is more complex than switching to a conventional generic. NICE should update its guidance in anticipation of biological medicine patent expiries when biosimilar competition is expected to lower prices. New or revised NICE guidance can widen patient access. This could be of particular benefit where initial NICE appraisals had been negative because the patented medicine was too expensive to be cost-effective for the NHS, resulting in patients in England missing out on these treatments. Biosimilar treatments, typically 72% cheaper, can improve patient access with appropriate NICE guidance.

Creating a national strategy for biosimilars like the one championed by the Welsh Government should also be considered. A strategy and plan that is collaborative and focused on jointly working with all relevant stakeholders must be created.

The big opportunity to realise more savings from off-patent medicines in the next five years comes from biosimilars.

The National Institute for Health and Care Excellence (NICE) can play an important role in promoting and increasing biosimilar uptake.

What we need

NICE to publish a process for re-appraising post-patent biologic and generic medicines where the original decision was not to recommend funding or to recommend funding for a population smaller than the licensed indication.

A bespoke national strategy for biosimilars for England to realise the enormous potential of these critical medicines given that it may be harder to unlock than for conventional generics.

Government figures show that life sciences manufacturing volumes fell by 29% between 2009 and 2021, leading to the loss of 7,000 well-paid jobs.

Economic investment and domestic growth

Generic manufacturing in the UK – like medicines manufacturing more broadly – is in decline. Government figures show that life sciences manufacturing volumes fell by 29% between 2009 and 2021, leading to the loss of 7,000 well-paid jobs. Recently, 500 medicines research and manufacturing jobs moved from Kent to India and the US. Less visible are the investments that failed to come to the UK: we know of two major potential investments by our members for which the UK was considered but which went elsewhere. The large scale of generic manufacturing means thousands of new highly skilled UK jobs have been forgone.

Over the past six years, no significant new generics manufacturing capacity has been created. By contrast, across Europe in the same period, work has started on almost 40 new or expanded generics pharmaceutical plants, representing up to £4bn in investment and creating thousands of jobs. In addition to creating jobs and tax revenue, increased medicines manufacturing in the UK supports preparedness for another pandemic, when vaccines and treatments may be required in very large quantities. The value of this onshore capacity was shown in the COVID-19 pandemic, when Wockhardt (a BGMA member company) provided crucial manufacturing capacity for the AstraZeneca vaccine. The nature of generic businesses means their manufacturing sites are often flexible, which is a vital advantage for national resilience.

To combat this decline, the government has launched many different fast-changing and often short-lived initiatives – some targeted specifically at the medicines sector, others aimed at more generally encouraging business investment. But current initiatives are complex to navigate, apply for and win funding from. Each scheme focuses on different areas of activity, different conditions are attached to every tranche of funding, and no current initiatives (to our knowledge) focus on general UK medicines manufacturing as a goal in itself.

The lack of visibility of accessible, long-term grant funding means investment decisions cannot factor in UK government support with any confidence. This, in turn, means the government's aim of using its funds to attract more investment to the UK is unlikely to be achieved on any scale.

In addition to creating jobs and tax revenue, increased medicines manufacturing in the UK supports preparedness for another pandemic, when vaccines and treatments may be required in very large quantities.

Governments such as those in France, Germany and the US have prioritised reshoring of the production of essential generic medicines and devoted large-scale investment to make this happen.

In the Autumn Statement, the UK government announced £520m to support life sciences manufacturing. How this sum will be made up is not yet clear to us. Additionally, the new investment fund, stemming from the December 2023 conclusion of a five-year medicines pricing scheme and beginning in January 2024, may include £75m to support medicines manufacturing. The funding for this will come from the generics and biosimilars sector as well as those supplying on-patent drugs.

The limited support for medicines is in stark contrast to other industrial sectors in the UK and overseas initiatives. Governments such as those in France, Germany and the US have prioritised support for their domestic production of essential generic medicines and devoted large-scale investment to make this happen.

We believe that there is a clear public policy interest in supporting more domestic manufacturing which supports the UK's resilience in the face of future supply chain shocks or potential health emergencies.

Governments such as those in France, Germany and the US have prioritised support for their domestic production of essential generic medicines and devoted large-scale investment to make this happen.

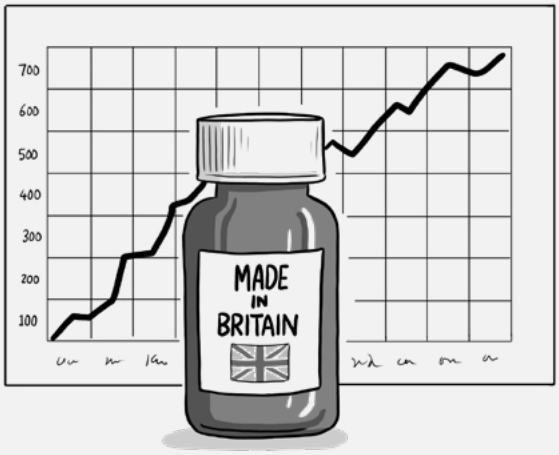
Lack of mutual recognition a blocker to UK manufacturing investment

The absence of EU recognition of UK decisions on medicines licensing and batch testing is another critical disincentive to invest in UK manufacturing. When a batch is manufactured, samples must be randomly taken to ensure the safety and efficacy of the medicine. This takes nearly a month and is an expensive lab-controlled process. The UK recognises batch testing done on EU soil but not vice versa. This means that medicines manufactured and tested in the UK would have to be tested again in the EU, costing time and money.

The UK's recognition of EU decisions has made us a rule-taker. Moreover, it is a significant disincentive to investing in manufacturing here rather than in EU states. The market for EU-approved medicines without further approvals is the whole EU plus the UK. In contrast, the demand for UK-approved medicines without further approvals is limited to the UK.

The absence of EU recognition of UK decisions on medicines licensing and batch testing is another critical disincentive to invest in UK manufacturing.

What we need



Given the volume of medicines supplied by the generics and biosimilars industry, the on- and off-patent sectors should be afforded equal policy input representation and opportunities to bid for government funding, since both are essential in driving and paying for innovation and widening access to medicines.

The government should use at least half of the £520m announced in the 2023 Autumn Statement to support UK manufacturing of generic and biosimilar medicines in long-term, straightforward schemes which are easy to apply for and are not hamstrung with many, often conflicting, conditions. The Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) Investment Fund, which will be partly funded by our members' contributions, should be capable of funding generics and biosimilars.

Resilience and national security of supply should be given greater priority as reasons for awarding funds for domestic manufacturing. Investment relief is needed for generic medicines manufacturing to support the NHS's supply of "business as usual" drugs and strengthen the UK's export competitiveness.

When the next government sets its life sciences industrial strategy and aims to deliver it, there must be equal consideration and representation of the on- and off-patent sectors.

UK supply issues have grown in number since the start of 2022.

Health and access

The ultimate embodiment of the policy vacuum around the UK generics industry is the rise of medicine shortages.

UK supply issues have grown in number since the start of 2022 and are now double what they were in 2021. Although historically high (101 medicine shortages in February 2024), this number needs to be put in context: it represents 2.41% of all presentations in the Drug Tariff and used in the NHS. Often an alternative is available, such as a different form or strength, or a second-line treatment. There are also well-developed policies and levers in place to mitigate shortages.

However, the growing incidence of supply issues is in part due to an underestimation by some in government of the importance of generics to the NHS. We track the incidence of supply issues based on the data compiled by the Department of Health and Social Care (DHSC) and NHS England, which is then presented on the Specialist Pharmacy Service website for use by pharmacists and NHS commissioners.

On a local level, we know that medicine shortages are among the top items of some Integrated Care Board risk registers. Figure 2 shows the number of supply issues since January 2021[3], where the index on the vertical axis tracks the number of medicinal products with supply issues.

On a local level, we know that medicine shortages are among the top items of some Integrated Care Board risk registers.

3. We record instances where there is no equivalent licensed alternative available for the pharmacist to dispense automatically. There may be alternatives such as a similar strength, a different form of administration (capsules instead of tablets) or another pack size, but this would normally require the doctor to authorise a change in script.

Figure 2 - Supply issues since 2021

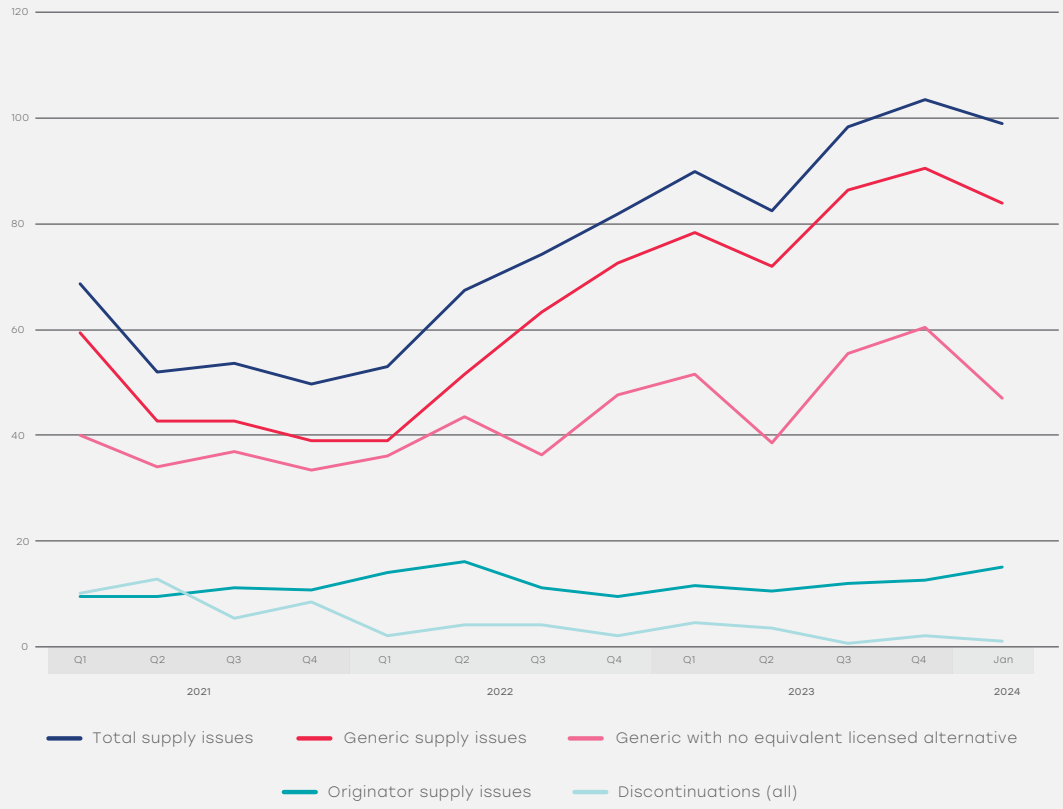


Figure 3 - Level of impact on the NHS from supply issues

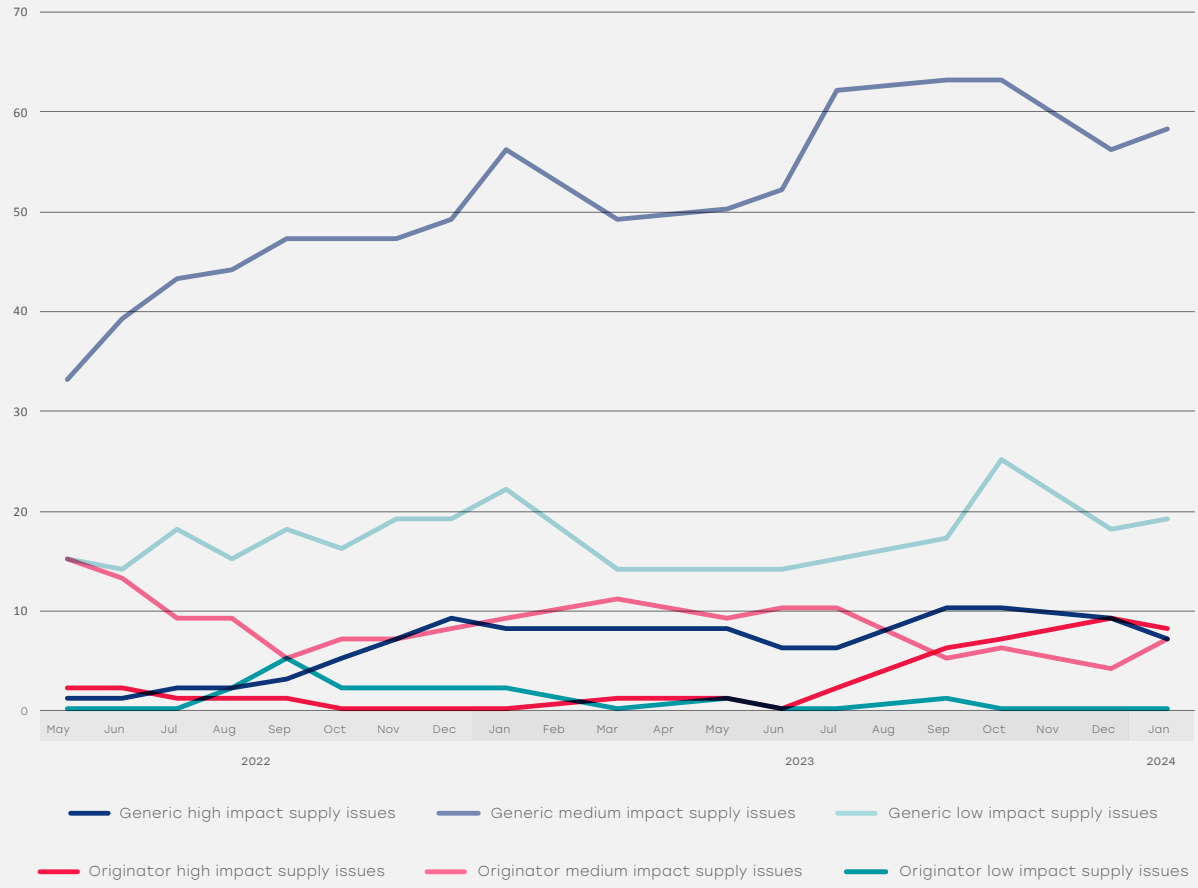


Figure 3 categorises the level of impact on the NHS, including potentially upon patients, due to these individual supply issues, with the same vertical axis as before. Here, the categorisation depends on the duration of the supply issue, alternatives available in the market supplied by other suppliers, alternatives available for the same molecule, whether other treatments can be used instead of the medicine in shortage, where and how the medicine is administered, whether a licensed version can be imported from another country and the risk or potential health risk to the patient.

While the impacts on individual patients are important and can be difficult for them and their families and carers to manage, they are, thankfully, rare. That is largely because the DHSC, NHS and supply chain work effectively to minimise shortages and find additional or alternative sources.

However, this can obscure the impact of supply issues and the effort taken in the supply chain to mitigate them, particularly for pharmacists. A recent example from a local pharmaceutical committee in the North-East demonstrated that pharmacists can spend up to 12 hours a week sourcing replacements due to medicine shortages. This time could be spent supporting patients in more productive ways.

Pharmacists can spend up to 12 hours a week sourcing replacements due to medicine shortages.

Other reasons for the growth in supply issues

Manufacturer and distribution costs have risen in the last few years, reflecting rising costs for other products and services. These include significant materials, packaging, energy and transport. Costs may stabilise as UK and global inflation ease.

Consequently, the supply chain – at all levels from manufacturers to wholesalers, hospitals and community pharmacies – has sought to become more agile and efficient. This can be at the cost of reduced resilience, including carrying less stock. This means that when a supply problem occurs, each part of the supply chain is less able to make up the shortfall.

In some cases, longer and more complex supply chains – devised to provide the NHS with the most affordable medicines – do not provide sufficient visibility to ensure that there is enough time for the NHS and community pharmacies to respond to and mitigate the issue.

Over the past few years, community pharmacies have seen an increase in concessionary-priced products[4]. For these products, the DHSC provides a higher reimbursement price to pharmacies if the price of the product paid by them has gone up and is not sufficiently covered by the reimbursement price. We understand that this increase may have happened at a similar time as the recouping of the agreed overpayment to pharmacies during the COVID-19 pandemic through flatter reimbursement prices, which may have increased the number of concessionary-priced products.

NHS hospital tenders commonly do not provide sufficient time between the award notice and the start date for manufacturers to make and supply the product. At least 16 weeks is needed to secure sufficient manufacturing capacity and supply to fulfil contracts. Sometimes half that time or less has been provided, increasing the likelihood of supply problems.

There is insufficient transparency as to how suppliers gain licences and increase supply to meet the demand for NHS-prescribed controlled drugs, such as those for cancer and end-of-life pain relief. These medicines come under the ambit of the Home Office, and quotas are submitted to and agreed upon by the International Narcotics Control Board.

NHS hospital tenders commonly do not provide sufficient time between the award notice and the start date for manufacturers to make and supply the product.

4. Community Pharmacy England – Funding & Reimbursement –- Price Concessions

Regulatory reform

DHSC data published on the NHS Specialist Pharmacy Services medicines supply tool shows that shortages are becoming an increasing issue for patients. We estimate that the number of medicines facing shortages is nearly double that two years ago. There are multiple causes, but one critical factor is the deterioration in the performance of the MHRA, the regulator of medicines.

The MHRA's annual budget, which includes fees for medicines licence applications from industry, is a little over 1% of the total yearly savings that generic and biosimilar drugs create for the NHS.

Generic and biosimilar medicines provide these savings because the UK has a system of medicines pricing that encourages competition, which brings down prices significantly compared to the cost when the product was on-patent. This means the MHRA has an important job in reviewing medicines licences promptly.

However, a backlog in reviewing generic medicines licences, central government funding cuts and a reliance on outdated IT systems have left what was an internationally leading regulator struggling to deliver reliable quality performance.

We are calling for the MHRA to determine generic licences within 12 months and a new biosimilar pathway within 6 months. At the moment, there is a significant backlog, and this meant that by June 2023, only 21% of new applications were approved within 12–15 months, a timescale that used to be the accepted norm. Now licences commonly take 24–30 months, or sometimes longer. Due to these delays, the NHS is overpaying for medicines because new generic medicines are unable to enter the market and provide competition. Such delays exacerbate shortages as companies are left frustrated in their attempts to enter or re-enter a market with supply issues.

Given the sums of money that the NHS can save, greater MHRA capacity and better systems should be regarded as an investment. The MHRA was making headway, but a decision was taken to prioritise the clinical trials application backlog, a decision that has cost local NHS bodies millions at a time when the money is most needed.

By June 2023, only 21% of new applications were approved within 12–15 months, a timescale that used to be the accepted norm. Now licences commonly take double this time or longer.

What we need

In 2024, the MHRA must prioritise reducing the generics licensing backlog and fund and commit to a return to most licences being determined within 12 months, with changes to existing licences completed within 3 months.

In community pharmacy, it will be important to ensure that the reimbursement received by pharmacies from the government for commonly dispensed medicines covers the cost of the medicine (plus the pharmacy margin).

In hospital pharmacy, tenders should be awarded in good time so that suppliers can make the product for the contract duration in the right quantity. If buffer stocks are required, then the build-up will take longer, which should also be factored in. Suppliers commonly need a 16 week lead time, moving out to 20.

Where contracted suppliers in other regions hold buffer stocks, incentives should be built in to encourage their use to fill a shortage elsewhere. Currently, suppliers can be penalised for dipping into their buffer stocks and not replenishing them quickly enough, which could affect future tender awards.

Suppliers should report supply issues to the NHS more quickly. The NHS should continue to encourage this through contract management and key performance indicators, and previous supply performance should become a more important factor in procurement award criteria.

The government must prioritise a return to 12 month application timelines. Companies are willing to pay more for applications if it will support a better, more reliable service. Over time, the MHRA could aim for 6 month application review timelines. This will help ensure that the UK remains a priority market for new launches and that UK patients are the first to access better treatments earlier, particularly where their use has been restricted when on-patent.

The creation of a new fast-track licence for products in shortage to allow companies to quickly enter or re-enter the market to help alleviate supply issues.

Mutual recognition of licensing decisions would be game changer.

Global partnerships

As Britain increasingly seeks to further its commercial ties globally, it is crucial to ensure that any trade deals a future government strikes do not change the UK's intellectual property (IP) balance while seeking to reduce duplicative regulatory activity.

There is a careful balance in the UK IP framework between rewarding innovation and enabling fair competition. The Intellectual Property Office notes: "The annual US Chamber of Commerce's Global Innovation Policy Centre Index provides a measure as to the strength of IP regimes. It places the UK second, narrowly behind the US." Governments need to support both sides of the balance to enjoy a thriving life sciences industry, particularly if the country has a state-funded healthcare system which pays for drugs spending.

The UK's IP system is well respected, fast-acting and balanced. In signing new trade deals, particularly with parties like the US, Canada and even Switzerland, we need to be very careful not to sign clauses pertaining to IP that would de facto delay the entry of generics to the NHS. The US system, for example, creates vastly more expense than the UK and delays generic entry because it considers litigation as business as usual when launching a generic or biosimilar; and often suppliers must settle with the originator to launch later in the US than in the UK.

The delay in competition of just one medicine for as little as several months can cost the NHS tens of millions of pounds. The Conservative Party pledged not to sign any trade deals that would increase the prices paid by the NHS and, ultimately, it has held firm, even if the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). The next government must also make the same commitment, given the potential effect of an increase in medicine prices on NHS finances.

On the flip side, trade deals can benefit the generics and biosimilars sector. A game changer would be to promote mutual recognition of licensing decisions and factory inspections with countries having respected top-tier international regulators. Making decisions based on international standards just once would allow the more rapid and ultimately more cost-effective flow of medicines around the world.

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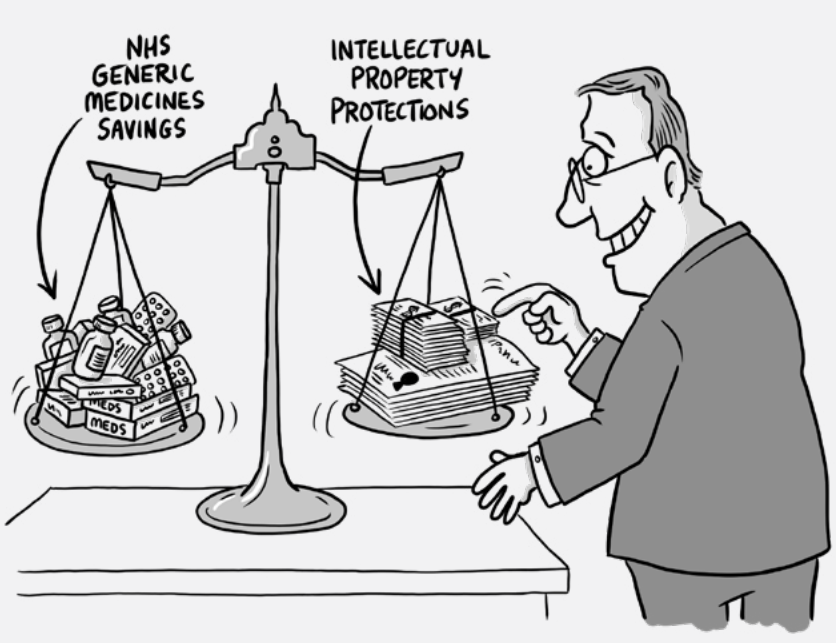
What we need



Protect the NHS from higher medicine prices in any post-Brexit trade agreements and push for reciprocity of regulatory decisions worldwide to put the finite regulatory time available to best use.

Ensure that any future trade deals do not change the UK's careful IP balance while seeking to reduce duplicative regulatory activity.

There is a sense of complacency around generic and biosimilar medicines and the benefits they bring.

Conclusion

The NHS runs on generic and biosimilar medicines – it simply couldn't function without them. The vast majority of prescription medicines relied on by patients are off-patent products that allow the NHS to make critical budget savings, which increase access.

These medicines are fundamental to a safe and successful NHS, yet from a policy perspective there is no strategy to safeguard a system which has consistently delivered to the UK the lowest medicine prices in Europe.

However, the operating environment has evolved. Brexit has polarised the UK in a medicines supply sense, adding regulatory and logistical complexity to an industry that thrives on simplicity and ease of access. This is an industry built on high volumes and razor-thin margins.

These factors, combined with a volatile government pricing system over the past few years and a doubling of domestic regulatory delays, have led to the UK becoming an increasingly unattractive market for international companies.

At the end of last year 16 leaders of some of the biggest global generic and biosimilar companies wrote to the UK government, expressing their concerns about the then VPAS pricing negotiations and their impact on future supply.

This letter went unanswered and did little to assuage growing concerns that there is a sense of complacency around generic and biosimilar medicines and the benefits they bring.

The broader policy environment supports this theory, with no strategy in place to maintain and grow this most vital of sectors.

This has to change. The UK is a contestant in a global competition for a finite supply of medicines. However, our ability to compete is being hampered and held back. The result is stock allocation of medicines being prioritised elsewhere, which will mean shortages becoming increasingly common.

This manifesto lays out workable and practical solutions which would provide the certainty this industry craves from a policy perspective. These measures can support growth and restore the UK's reputation as a key supply destination. The potential benefits are immense, with billions of pounds of savings at stake as well as the opportunity to extend treatment to more patients.

Whichever party is successful at the next general election, we would urge them to review the relationship with our sector and create a proactive policy strategy aimed at safeguarding and super-charging an industry that matters so much to so many people.

Summarised Recomendations

- NICE to publish a process for re-appraising post-patent biologic and generic medicines where the original decision was not to recommend funding or to recommend funding for a population smaller than the licensed indication.
- A bespoke national strategy for biosimilars for England to realise the enormous potential of these critical medicines given that it may be harder to unlock than for conventional generics.
- Given the volume of medicines supplied by the generics and biosimilars industry, the on- and off-patent sectors should be afforded equal policy input representation and opportunities to bid for government funding, since both are essential in driving and paying for innovation and widening access to medicines.
- The government should use at least half of the £520m announced in the 2023 Autumn Statement to support UK manufacturing of generic and biosimilar medicines in long-term, straightforward schemes which are easy to apply for and are not hamstrung with many, often conflicting, conditions. The Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) Investment Fund, which will be partly funded by our members' contributions, should be capable of funding generics and biosimilars.
- Resilience and national security of supply should be given greater priority as reasons for awarding funds for domestic manufacturing. Investment relief is needed for generic medicines manufacturing to support the NHS's supply of "business as usual" drugs and strengthen the UK's export competitiveness.
- When the next government sets its life sciences industrial strategy and aims to deliver it, there must be equal consideration and representation of the on- and off-patent sectors.
- In 2024, the MHRA must prioritise reducing the generics licensing backlog and fund and commit to a return to most licences being determined within 12 months, with changes to existing licences completed within 3 months.
- In community pharmacy, it will be important to ensure that the reimbursement received by pharmacies from the government for commonly dispensed medicines covers the cost of the medicine (plus the pharmacy margin).
- In hospital pharmacy, tenders should be awarded in good time so that suppliers can make the product for the contract duration in the right quantity. If buffer stocks are required, then the build-up will take longer, which should also be factored in. Suppliers commonly need a 16 week lead time, moving out to 20.
- Where contracted suppliers in other regions hold buffer stocks, incentives should be built in to encourage their use to fill a shortage elsewhere. Currently, suppliers can be penalised for dipping into their buffer stocks and not replenishing them quickly enough, which could affect future tender awards.
- Suppliers should report supply issues to the NHS more quickly. The NHS should continue to encourage this through contract management and key performance indicators, and previous supply performance should become a more important factor in procurement award criteria.
- The government must prioritise a return to 12 month application timelines. Companies are willing to pay more for applications if it will support a better, more reliable service. Over time, the MHRA could aim for 6 month application review timelines. This will help ensure that the UK remains a priority market for new launches and that UK patients are the first to access better treatments earlier, particularly where their use has been restricted when on-patent.
- The creation of a new fast-track licence for products in shortage to allow companies to quickly enter or re-enter the market to help alleviate supply issues.
- Protect the NHS from higher medicine prices in any post-Brexit trade agreements and push for reciprocity of regulatory decisions worldwide to put the finite regulatory time available to best use.
- Ensure that any future trade deals do not change the UK's careful IP balance while seeking to reduce duplicative regulatory activity.