BRITISH GENERIC MANUFACTURERS ASSOCIATION

BRITISH BIOSIMILARS ASSOCIATION

Biosimilars:

Supporting a competitive medicines market that widens patient access and saves the NHS money

August 2023

Foreword

Biosimilar medicines are integral to the National Health Service (NHS). Their use provides significant savings to the NHS and widens access to more medicines for patients earlier. As UK-focused businesses, British Biosimilars Association (BBA)[1] members are proud to deliver these dual benefits to the NHS. Our members can do this because they generate and operate in a competitive medicines market. Given the increasingly constrained fiscal environment the NHS must operate in, it is critical there are no barriers to this. The current Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)[2] negotiations present a risk to this competitive market thriving and delivering ongoing benefits to the NHS.

There is clearly a growing market for biosimilar medicines in the UK; however, there is more to do to ensure it thrives. In the last five years, the growth of the biosimilars market has, in volume terms, increased by nearly six times. Over the next VPAS period, more than 80 biological medicines will lose their exclusivity – with more than 40 not currently facing any competition – meaning this growth trend should continue.

However, this can only be the case if the medicine pricing schemes (both voluntary and statutory) that are set to be finalised this year do not act a disincentive to early market entry in the UK. Earlier this year the British Generic Manufacturers Association (BGMA)[3] published its position paper[4] to inform the VPAS negotiations. It included calls for branded off-patent generic and biosimilar medicines to be treated more favourably where competition has delivered discounts of 30% or more.[5]

As suppliers of medicines to the NHS, we recognise the importance of our ongoing partnership with them and key stakeholders, including the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), the Commercial Medicines Unit (CMU)[6] and the Office of Life Sciences (OLS), in ensuring the UK market remains attractive and competitive. This matters because it shows that our partners recognise the benefits of a strong market for biosimilars that delivers:

- Improved outcomes and quality of life for patients who have access to better treatments earlier, and
- Cost savings for the NHS when the Government is looking for efficiencies.

As well as the above, our members help ensure the UK realises its ambition to be a science and technology superpower. Innovation is not the preserve of the on-patent sector; the off-patent sector is also at the forefront of life sciences innovation and pharmaceutical research and development.

---

[1] Please see the 'About Us' section on page 6 for more information.
[2] VPAS requires companies selling branded medicines to the NHS of a value above £5 million to pay a percentage of these sales back to the Department of Health and Social Care whenever the branded market sales grow at a rate higher than the allowed rate. For the current VPAS period, it is set at 2% per annum. In 2023, the payment percentage is a 26.5% tax on revenues, nearly five times what it was two years ago. Companies pay an amount in proportion to their branded net sales to the NHS.
[3] Please see the 'About Us' section on page 6 for more information.
[4] 2023, Delivering a financially sustainable VPAS that supports widened medicines access to patients: The BGMA's position for the 2024-2028 VPAS negotiations. British Generic Manufacturers Association.
[5] When compared to the originator list price pre-loss of exclusivity.
[6] Part of NHS England.

As the voice of the biosimilar industry in the UK, I am proud the BBA is leading the way in ensuring the pharmaceutical industry is more diverse and reflects the society it serves, including an increasing proportion of women taking leading roles in the industry and its representative bodies.

This report makes clear the impact biosimilar medicines are already having on patients' lives and the NHS, and the potential for us to achieve more via its vision for a National Biosimilar Strategy. I look forward to continuing to work alongside our members and key partners to ensure biosimilars continue to deliver better outcomes for patients and the NHS.

Mark Samuels
Chief Executive, BGMA and BBA

Executive Summary

This report clearly sets out the positive impact that biosimilar medicines have, not only for patients through widened access to treatments, but also for the NHS through very substantial discounts and savings. Over the last six years there has been significant growth in the uptake of biosimilars in the UK, and it is clear there is significant development potential in the coming years.

Mitigating the risks

Independent analysis earlier this year by Europe Economics, commissioned by the BGMA and BBA, lays bare the potential economic cost if the UK is not an attractive and competitive market for biosimilar and branded generic manufacturers.

It shows that the effect of deterring just one company from entering these biosimilar markets (that is, new biosimilar medicines in a treatment area where exclusivity of the original biologic medicine has been lost between 2023 and 2028) is that in 2028 the NHS is projected to have lost around £100 million per year in savings. If a lack of competition means that two new entrants are deterred from entering the markets, the annual NHS losses by 2028 rise to £250 million.[7] These calculations are only on products that will lose their patent protection in the coming five years and do not consider the impact of reduced competition in existing biosimilars already on the market because of VPAS. This is a conservative forecast; the reality is that a high VPAS payment percentage may result in reduced and lost competition if the UK is not seen by global decision makers as an attractive market. Assessment of the analysis shows that lost NHS savings on new products alone could total £1.25 billion in the next five years, if not more.

To rationalise this possible loss, biosimilars were grouped according to their current on-patent annual value. Based on this, and our knowledge of the market, we were able to gain an informed view about the level of competition that might be expected in the market. This allowed us to predict expected price erosion levels. It is also true that the greater the market and competition, the greater the price erosion. The model used by Europe Economics calculates the impact and cost of one and two fewer players based on the price erosion caused by biologics with a smaller annual market, since smaller markets will generally experience less competition. In the absence of other forms of measurement, this was considered the best way of projecting a biosimilar's potential on the market, including the potential lost savings based on reduced competition.

Maximising the opportunity

There are clear opportunities to maximise the biosimilar industry's potential NHS and patient benefits in the UK. The BGMA and BBA call on the Government, the MHRA, NICE, officials in the Department for Health and Social Care (DHSC), NHS England (NHSE) and other decision makers to:

[7] 2023. Impacts of Changing VPAS Rules in Respect of Biosimilars. Europe Economics.

- Develop a clear strategy to promote biosimilar uptake and widen patient access in England,
- Work with their colleagues in Scotland, Wales and Northern Ireland to ensure a cohesive and holistic approach to widened access for patients, and
- Agree a medicine pricing scheme that recognises the key differences between how the on- and off-patent sectors operate and the benefit that competition in the off-patent medicine market brings.

The Office of Health Economics (OHE) has forecast that NHS biosimilar sales will total £26 billion between 2023 and 2028[8] and that more than 40 originator biological medicines with no competition are set to lose their exclusivity over the next five years.[9] The potential savings that could be realised by the NHS by using new biosimilars instead of the original biological medicine are very real and very significant. In 2017, six of the ten most expensive medicines in the UK by cost were biological medicines;[10] by 2021, that number had risen to eight.[11] Biosimilars such as adalimumab accounted for a third of the £1.2 billion that the NHS saved on medicines over three years to 2022 and ensured that more than 45,000 patients were able to access treatment earlier.[12] The message from this report is clear: we cannot lose the opportunity to maximise the potential benefits of biosimilar medicines.

An uncompetitive market threatens supplies to the NHS

The Government must work with the industry and wider stakeholders to ensure a competitive market for biosimilar medicines. If it does not, there is a risk that biosimilar manufacturers will withdraw existing medicines used by the NHS and prioritise other markets for new biosimilar medicines. Already, we have seen the impact of the current VPAS payment percentage with BBA member Celltrion stopping marketing its breast cancer biosimilar trastuzumab.[13]

The BBA and its members stand ready and look forward to continuing to work hand in glove with key partners in delivering an overarching vision for biosimilars in England. However, more than rhetoric and ambition are needed to ensure an attractive and competitive market for new products. The licensing and approvals environment within which the sector operates – that is, MHRA approvals and NICE guidance – are both factors that must be considered by the Government and addressed.

If the current VPAS negotiations fail to recognise the key role of biosimilars in saving the NHS money, there could be significant negative consequences. VPAS requires companies selling branded medicines to the NHS of a value above £5 million to pay a percentage of these sales back to the DHSC whenever the branded market sales grow at higher than the allowed rate. For 2023, the levy is 26.5%. OHE analysis reveals

[8] 2022. A consulting report: The impact on the NHS of the VPAS levy on branded generics and biosimilars. Office of Health Economics, supported by Professor Alistair McGuire of the London School of Economics (LSE), October.
[9] 2022. IQVIA Patent Intelligence, Pipeline Intelligence, and IQVIA Forecast Link analysis, November; 2022. Historic analysis sourced from IQVIA Institute report, Protection expiry and Journey into the Market.
[10] 2017. As NHS approaches 70 it is time to unleash the potential of innovation to transform patient care, says Simon Stevens. NHS.
[11] Samuels, M. 2021. New regulatory guidance could lead to UK biosimilar boom. European Pharmaceutical Review.
[12] 2022. NHS saves £1.2 billion on medicines over three years. NHS.
[13] Milmo, C. 2023. Breast cancer drug withdrawn from UK after row over NHS funding. The i.

that a VPAS payment percentage of 25% would cost the NHS £7.8 billion more than any levy revenue obtained from biosimilars and branded generics between 2024 and 2028.

There is a window in which to send a clear message that the UK wants to support a competitive and sustainable biosimilar market, but that window is closing. Warm words and rhetoric must now be followed through, and the industry wants tangible measures through a Biosimilar Strategy for England and the finalisation of a VPAS that recognises the role of the off-patent sector.

Contents

About Us

The British Biosimilars Association is the expert sector group of the British Generic Manufacturers Association exclusively focused on biosimilars. We represent the interests of biosimilar medicines manufacturers who are active in the development and production of new biosimilars. We are dedicated to furthering confidence in and education on the benefits of biosimilars for the NHS, patients and healthcare professionals.

The UK medicines market is one where generics and biosimilars account for four in every five NHS prescription medicines.[14] In English community pharmacy alone, this equates to nearly 2.2 million packs of medicines a day.[15] BGMA and BBA members directly employ and support nearly 30,000 jobs in the UK.

Our goal is to improve the business environment of our members and sustain an attractive and competitive UK medicines market. This will keep prices affordable for the NHS and widen access to medicines, giving more patients access to more treatment options earlier. It also enables headroom to allow the NHS to invest in innovation from new patent-protected medicines to meet unmet need.

We advocate our members' views to regulators and stakeholders relevant to the supply of medicines, including the UK Government and devolved administrations, the NHS, the MHRA and NICE, as well as in the media.

The BBA's four pillars are:

- **Access:** Ensuring earlier access for more patients.
- **Uptake:** Making the UK a leader in biosimilar uptake.
- **Market:** Realising a competitive market that allows biosimilar manufacturers to thrive.
- **Sustainability:** Supporting the Net Zero ambitions of the NHS and member companies.

Our members

accord We make it better

Biogen

CELLTRION

Dr.Reddy's

FRESENIUS KABI caring for life

SANDOZ A Novartis Division

teva

T R Thornton & Ross

ZENTIVA

[14] NHS Digital, Prescriptions Dispensed in the Community, Statistics for England.
[15] Ibid.

Biosimilars in the UK

What are biosimilars?

Biosimilars are a type of biological medicine and are widely used in the UK for many conditions. Biological medicines are complex medicines made or derived from a biological source. The biosimilar contains a version of an active substance of an already approved biological medicinal product, known as the reference product. Offering the same clinical effectiveness and safety as their reference products, biosimilars are interchangeable with the original biological medicine and other biosimilars when approved.[16]

Biosimilars are used in clinical practice for many different conditions including:

- Cancers,
- Diabetes,
- Arthritis,
- Psoriasis,
- Neutropenia,[17]
- Macular degeneration,
- Kidney conditions, and
- Enzyme or hormone deficiencies.

More biosimilars are expected to come to market in the coming years, with the patents of more than 80 biological medicines set to expire between 2023 and 2027.[18] Biological medicines are the largest cost and growth areas in the NHS medicines budget. To realise greater savings, NHSE wants to drive greater uptake of biosimilars and, by making biosimilar medicines available more quickly, believes they can take advantage of up to £300 million in savings each year.[19]

Why biosimilars matter

We know the NHS is facing a £7 billion budget shortfall this year[20] and must make difficult decisions in an increasingly constrained fiscal environment. Biosimilars mean the NHS can treat more patients (often earlier than they would be able to with more expensive medicines) while saving the NHS money through significant discounts.

Since 2018, there has been a push for biosimilar uptake from across Government, resulting in growing levels of switching. It is clear the NHS sees the value in biosimilars. NHSE Chief Executive Amanda Pritchard last year said, "*The NHS has once again shown our commercial power to secure cutting-edge treatments for patients while freeing up £1.2 billion of taxpayers' money, through negotiating better prices for high volumes of branded and non-branded drugs.*"[21]

---

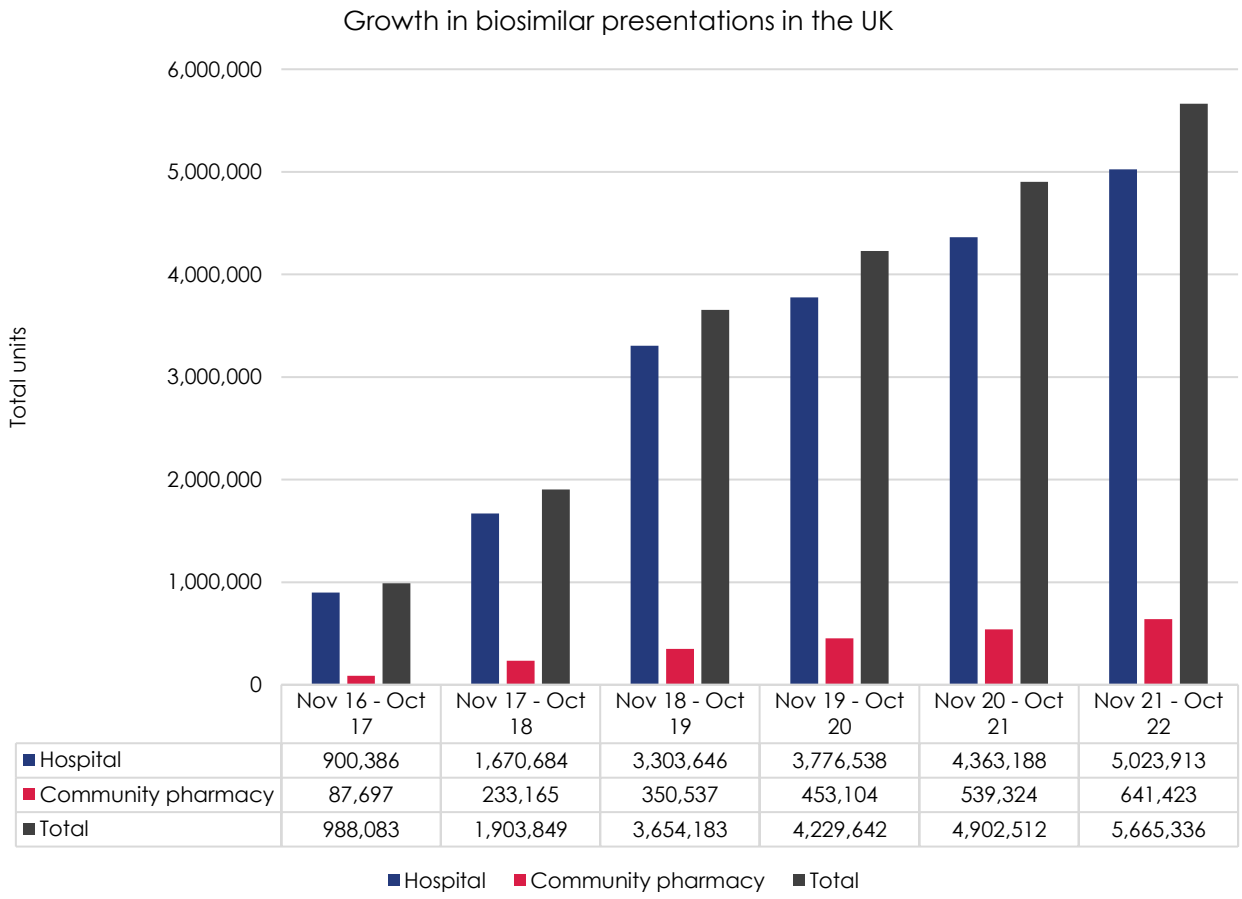
[16] 2022. Guidance on the licensing of biosimilar products. MHRA.
[17] A low number of white blood cells called neutrophils in the blood. This weakens the immune system, making it harder for the body to fight infection.
[18] 2022. IQVIA Patent Intelligence, Pipeline Intelligence, and IQVIA Forecast Link analysis, November; 2022. Historic analysis sourced from IQVIA Institute report, Protection expiry and Journey into the Market.
[19] 2023. Biosimilar medicines. NHS.
[20] Campbell, D. 2022. NHS England could face £7bn budget shortfall next year, finance chief warns. The Guardian.
[21] 2022. NHS saves £1.2 billion on medicines over three years. NHS England.

Growth in biosimilar use delivering savings to the NHS

The NHS has published the savings it attributes to deploying biosimilars in the 2017/18 financial year:

- Used to treat inflammatory conditions such as rheumatoid arthritis, Crohn's disease and ankylosing spondylitis, **infliximab** uptake **delivered £99,400,000 in savings**,
- Used to treat autoimmune conditions such as plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis and ankylosing spondylitis, **etanercept** uptake **delivered £60,300,000 in savings**, and
- A targeted cancer drug for non-Hodgkin's lymphoma and B-cell acute leukaemia, **rituximab** uptake saw **£50,430,000 in savings delivered**.[22]

The following chart demonstrates the very significant growth that has been seen in biosimilar presentations in the UK since November 2016. The significant growth in their use in secondary care settings is a result of increased market competition after an original biological medicine has lost its exclusivity. This growth trend is expected to continue over the next five years, meaning even greater savings for the NHS and widened patient access.[23]



	Nov 16 - Oct 17	Nov 17 - Oct 18	Nov 18 - Oct 19	Nov 19 - Oct 20	Nov 20 - Oct 21	Nov 21 - Oct 22
Hospital	900,386	1,670,684	3,303,646	3,776,538	4,363,188	5,023,913
Community pharmacy	87,697	233,165	350,537	453,104	539,324	641,423
Total	988,083	1,903,849	3,654,183	4,229,642	4,902,512	5,665,336

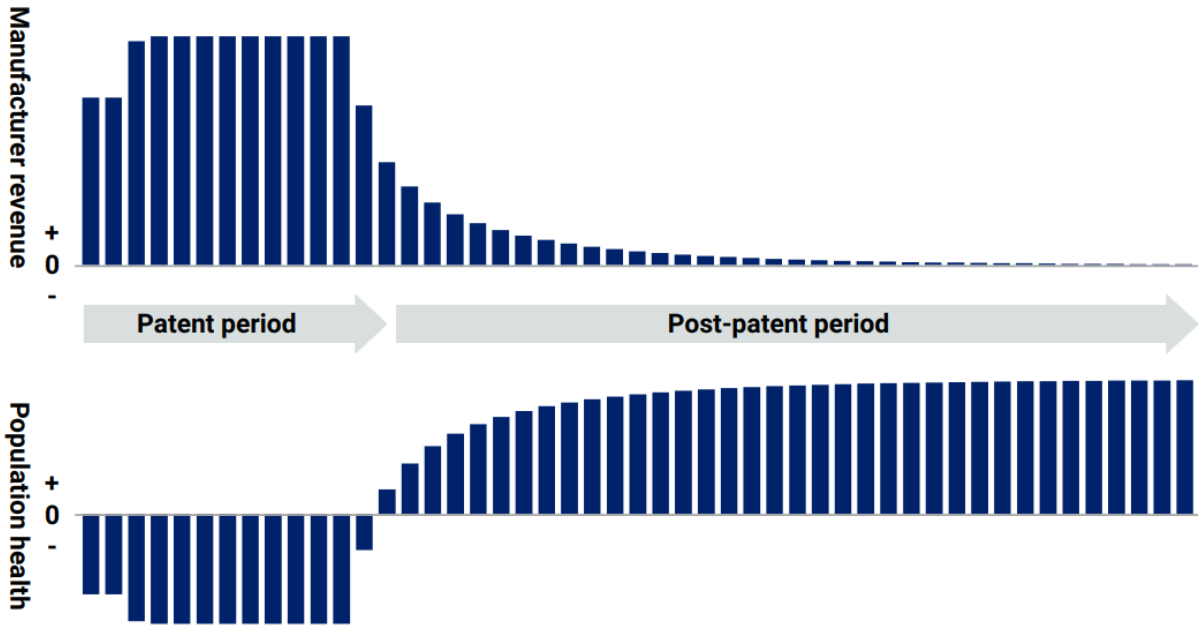
[22] 2018. The NHS saves £324 million in a year by switching to better value medicines. NHS England.
[23] Based on IQVIA data.

Generic and biosimilar medicines account for around 80% of the drugs used by the NHS. The UK has benefited from the lowest average selling prices of generic medicines in Europe because our members have generated a competitive market.[24] NHS efforts to promote switching to the best-value biologics have enabled price erosion for certain biologics on a par with the 80-90% price erosion rates typically achieved for generics. By working closely with the BBA, NHSE can ensure maximum benefit from investment in innovations and efficiencies across its operations.

NHS patient benefits

In June this year, the London School of Economics, the University of York and the London School of Hygiene and Tropical Medicine published its report "Promoting population health through pharmaceutical policy: The role of the UK Voluntary Scheme".[25] It sets out how a medicine's value is distributed between the manufacturer and NHS patients over its life cycle. 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 because the new medicine's benefits are outweighed by the impact on other NHS services. However, after loss of exclusivity, NHS patients start receiving significant net benefits because competition results in the availability of cheaper generic or biosimilar versions of the medicine.

The report sets this out in two graphs. Taken together, they show why it is so important that the Government fosters a competitive and healthy off-patent market since as the patent period expires and competition can take effect, what the NHS pays goes down (the top graph) while the benefit to NHS patient goes up (the bottom graph).



[24] 2019. The supply of generic medicines in the UK. Oxera.
[25] 2023. Promoting population health through pharmaceutical policy. London School of Economics, the University of York and the London School of Hygiene and Tropical Medicine.

Expected biosimilar growth

The OHE forecasts that NHS biosimilar sales will total £26 billion between 2023 and 2028.[26] The calculation covers existing biosimilars as well as opportunities stemming from the originator biologic version expiring. The chart below sets out the breakdown of sales into predicted sales from existing biosimilars and those expected following originator biologics losing their exclusivity. It highlights the strong growth (by volume) expected in the biosimilar market over the coming years.[27] The positive impact that competition can have is evident; however, the Government needs to send a clear message to biosimilar manufacturers that the UK market is an attractive one and set out a clear plan to address potential barriers to growth and increased competition.

Breakdown of sales between predicted sales from existing biosimilars and those expected following loss of exclusivity

	2023	2024	2025	2026	2027	2028
New	2,392	2,284	2,127	1,844	1,149	740
Existing	2,029	2,232	2,455	2,701	2,971	3,268

Life-changing effects

In addition to reducing NHS medicine spend and increasing patient access, biosimilars have a positive effect on people's lives each and every day.

Louis: I can live my life again and not feel fear

"Don't be afraid, biosimilars are fantastic. I can live my life again and not feel fear."

Louis has ankylosing spondylitis, which is an advanced form of rheumatoid arthritis, where the rheumatoid attacks the spine and hips. Louis has lived with it for 10 years, and it impacts his life

[26] 2022. A consulting report: The impact on the NHS of the VPAS levy on branded generics and biosimilars. Office of Health Economics, supported by Professor Alistair McGuire of the London School of Economics (LSE), October.
[27] Op. cit., Office of Health Economics.

every single day; most mornings he can barely get out of bed. He was on the original product for two and a half years before switching to a biosimilar. When he first switched, he was worried about whether the biosimilar was as good as the original. Now that he's on the medication, he can once again play bass, walk his dogs and use the gym.

Professor Peter Taylor, Chief Medical Advisor, National Rheumatoid Arthritis Society

Rheumatoid arthritis is painful and progressive. It is a systemic autoimmune disease that has an impact on every aspect of a person's life. Until recently, only patients with severe disease had access to biosimilar medicines. This has now changed.[28] *Professor Peter Taylor has said that the widening of access to treatments such as adalimumab, etanercept, infliximab and abatacept for adults with moderate rheumatoid arthritis is the biggest change to its treatment since the introduction of biologics nearly 20 years ago. These biosimilar medicines will now be accessible at an earlier stage than has previously been possible. Professor Taylor believes that ensuring more patients with moderate rheumatoid arthritis have access to treatment earlier than they previously would has the potential to improve the lives of thousands of people in England and Wales.*

Harnessing biosimilars' potential

It is critical that the potential of biosimilars is not lost. The significant savings already delivered by biosimilar medicines is clear. The potential for new biosimilar medicines to enter the UK market over the next five years, coupled with the significant potential annual losses where there is no competition, necessitate urgent action to promote uptake. This is why the BGMA and BBA are using this report to call on the Government, regulators and other decision makers to:

- **Publish a Biosimilar Strategy for England** that sets out a clear plan to promote biosimilar uptake and widen patient access in England, and
- **Negotiate a sustainable VPAS** that works for all by recognising the key differences between how the on- and off-patent sectors operate and the benefit that competition in the off-patent medicine market brings.

[28] 2021. Guidance: Evidence-based recommendations on adalimumab, etanercept, infliximab and abatacept for adults with moderate rheumatoid arthritis who have tried conventional DMARDs but they have not worked. NICE.

Biosimilar Strategy for England

To maximise the potential of biosimilar medicines, we call on the Government and NHSE to publish an ambitious strategy to establish the right conditions for a competitive biosimilar medicines market in England. As the voice of biosimilar manufacturers who supply the NHS, the BBA would welcome the opportunity to work with NHSE and other key partners on this. There is precedent for this, with NHS Wales publishing a National Biosimilar Strategy for Wales.[29] Doing so would address any misapprehension in the sector, in the UK and globally by sending a clear message about continued support for biosimilars.

It must include:

- An **ambition to be a world-leading market** for biosimilar adoption, uptake and innovation,
- A plan to **empower and resource the MHRA and NICE** to incentivise new biosimilars,
- A tangible **set of actions** to deliver it, and
- A **plan for delivery**, with a timeline and checks and balances for accountability.

Developing a world-leading market

An IQVIA white paper[30] published last year highlights the potential for biosimilar market growth in Europe – and by dint of the regulatory landscape before Brexit – the UK. There are more than 80 biologics that will lose exclusivity between 2023 and 2027; within that cohort, more than 40 do not presently have competition.[31]

This represents significant opportunities. To maximise these opportunities, we are committed to working in partnership with key stakeholders including the MHRA, NICE, NHSE, the CMU, NHS Trusts and the devolved administrations to develop and publish a Biosimilar Strategy for England that will position England as an attractive market for biosimilars.

The BBA believes a national strategy must include:

- A joint BBA and Government **working group to identify the key barriers to biosimilar uptake** and a clear plan to address them,
- A clear **directive that there will be a greater focus on hospital compliance** with tenders,
- **Biosimilar adoption as a key performance indicator (KPI)** for funding of regional Pharmacy Procurement Specialists,
- An **incentive mechanism** for smaller volume biosimilars,
- An **education and empowerment plan** for prescribers, and
- A commitment to **invest in research on biosimilars** to maximise their potential.

[29] 2023. Maximising the opportunity presented by biosimilar medicines: A national strategy for Wales. All Wales Therapeutics and Toxicology Centre and Welsh Government.
[30] 2022. White Paper: The Impact of Biosimilar Competition in Europe. IQVIA.
[31] Ibid.

Joint working group

We are already working with partners to address the challenges that a Biosimilar Strategy should, with a long-standing record of working with medicines policy teams across DHSC and NHSE to ensure we are working in concert, not at cross purposes. Additionally, the BBA and CMU recently agreed to join up to identify what barriers to biosimilar uptake could be jointly worked on and to develop a strategy to address them. Critical though this working group will be, its existence with other piecemeal working groups will mean a lack of cohesion across the stakeholders who matter, which would limit the impact these activities could have, compared to a holistic approach as part of a wide-reaching national strategy.

A clear directive

NHSE's Commissioning Framework for biological medicines[32] has a stated ambition of 90% of new patients being on the best-value biological within three months of product launch, and 80% of existing patients within 12 months for Clinical Commissioning Group (CCG)-commissioned services. To realise this ambition, a clear directive is needed – via a national strategy – that there will be a greater focus on hospital compliance with tenders. This will help ensure uptake is as predicted and, as a result, these targets for best-value biologics can be achieved. Such a directive necessitates oversight and clear consequences if there is no reasonable justification for not following it.

Setting KPIs

The strategy should also cement biosimilar adoption as a KPI for NHSE's funding of regional Pharmacy Procurement Specialists. This will be a positive move that can lead to wider access for patients and greater savings for the NHS.

Incentive mechanisms

A national strategy must include an incentive mechanism for smaller volume biosimilars to ensure competition. The system and its processes are set up for blockbusters, that is, large-volume products which have rightly attracted NHS priority and communications programmes to promote switching. However, there many smaller volume products in the pipeline which will be a large proportion of the future market. Without incentives for these smaller volume biosimilars, there will be no competition. While launches in the coming years may be smaller in volume, there will be more of them, meaning their cumulative impact will be significant and must be considered. Without the right environment in place, the NHS risks overpaying for these medicines.

[32] 2017. Commissioning framework for biological medicines (including biosimilar medicines). NHS England.

Education and empowerment plan

While many parts of the system understand the benefits of biosimilars, there is a missing link in the chain: prescribers do not always understand the impact of their decisions – whether that be significant savings to the NHS or widened access for more patients. This is not their fault; they are busy clinicians doing their best to treat patients and address backlogs in the NHS post-Covid.

We must make it as easy as possible for prescribers and give them the tools that enable a conversation with patients about switching and provide an understanding of why it is needed. We know that the conversation can sometimes be awkward and seem bureaucratic. It is important, though, that these discussions are had. To guide and support a switching process with patients, we recommend a series of information guides for prescribers that set out the benefits of switching to a better value product for the NHS, their patients and other patients. We recommend these guides be produced in partnership with NICE and reflect their most recent and up-to-date guidance.

Investment in biosimilar research

As set out earlier in this report, innovation is not the preserve of the on-patent sector. Our members and the wider off-patent sector remain at the forefront of life sciences innovation and pharmaceutical research and development; however, they want to be able to do more. To ensure the UK is a world leader in biosimilar uptake, the BBA believes it is essential that any wide-reaching national strategy demonstrates a commitment to investing in and incentivising biosimilar research to create a 'super cluster' here in the UK. There are two ways this can be achieved: through a change in National Institute for Health Care and Research (NIHR) competition applications, and UK Research and Innovation (UKRI) support for research into biosimilar repurposing.

We believe there is a simple mechanism that will allow the NIHR to address this market failure in biosimilar research. The NIHR has a fixed budget for its competition grants to biomedical research centres. While we recognise that this budget is unlikely to significantly increase in the next few years, the BBA believes this should not preclude a consideration of how it can support further biosimilar research. Presently, the NIHR distributes between 70 and 75% of its funding through competition grants. These are incredibly competitive and demonstrate the high quality of research being done in the UK. We are calling on the NIHR to include a question asking to what extent they have considered biosimilar research in preparing their application. The BBA believes this simple addition to the application form will have a significant impact on the focus of research in the next funding round. For example, NIHR biomedical research centres could address clinical evidence gaps needed by NICE to ascertain if an extended patient population could benefit from the biosimilar or work on repurposing the biosimilar for areas of unmet clinical need. Additionally, considering finite NHS finances, the NIHR should consider socioeconomic issues that could be researched to inform wiser and more visionary long term health resource planning.

To complement this, there should also be a focus on biosimilar research for NIHR themed calls. Research areas for previous themed calls include dementia, long-term

conditions in children and multimorbidities in older people.[33] These are areas where research into the use of biological and biosimilar medicines could have proved useful. Indeed, there has been much recent media coverage of research in America into the use of biological medicines in the treatment of Alzheimer's disease and dementia. The BBA believes the Government and funding agencies should be doing all they can to support and incentivise similarly groundbreaking research here in the UK.

To harness the potential of biosimilars already used the UK, the BBA is calling for UKRI and Innovate UK to support collaborations between industry and research partners to understand the potential for biosimilars to be repurposed. We know that clinicians already consider how existing biosimilars can have a potentially life-prolonging effect for their patients in treating conditions other than those which they are licensed for.[34] Focusing research efforts on repurposing could allow the MHRA to widen the scope for which medicines are licensed, widen access for patients and potentially provide further savings to the NHS.

Removing barriers to a thriving market

Following the UK's departure from the European Union (EU), full applications are now reviewed and approved by the MHRA. Before this, biosimilars were licensed by the European Medicines Agency (EMA), whose processes the MHRA had helped to inform. In the period immediately following Brexit, the MHRA continued to recognise the EMA's processes; this period was extended until the end of 2023.

Last year the MHRA published its guidance on a licensing pathway for biosimilar medicines.[35] It enables companies to submit for UK regulatory approval about one year earlier than in the EU. However, due to MHRA backlogs, it is little used, meaning the 'Brexit benefit' of the bespoke UK regulatory pathway, which the BBA strongly supports, is wiped out by regulatory delays and backlogs.

The UK's departure from the EU was an opportunity to put in place a regulatory framework that incentivised early movers, rewarded manufacturers that chose to bring their new products to the UK market first and kept the UK as a tier 1 global launch market that can punch above its weight as 6% of the global pharmaceutical market. Notwithstanding platitudes, this opportunity appears to have been lost.

The BBA believes a national strategy must include:

- A commitment to **better resourcing** of the MHRA and NICE,
- A plan to **promote the MHRA's world-leading plan** to approve applications for new medicines within six months,
- A strategy to **increase awareness of interchangeability** and the MHRA guidelines around this,
- **Incentives** for first movers,
- A commitment to **review NICE's remit and scope** to ensure it is fit for purpose for biosimilars, and

[33] Themed Calls. NIHR.
[34] Ledwith, M. 2023. Cancer drug fundraiser buys time for couple to marry. The Times.
[35] 2022. Guidance on the licensing of biosimilar products. MHRA

- A plan for **mutual recognition** of medicine licensing decisions.

Resourcing the MHRA and NICE

A thriving life sciences sector depends on a timely, predictable approvals process to allow new products to come to market and benefit patients. The UK derives most benefit from the life sciences sector when our NHS maximises its uptake of the most cost-effective versions of treatments to improve outcomes for patients and free up resources to fund additional treatments. The bodies that approve and license medicines and that publish guidelines for their use must be adequately resourced to support this need.

Promoting the MHRA's six-month approvals plan

The MHRA has a world-beating and ambitious plan to approve applications for new medicines within six months.[36] Its purpose is to accelerate regulatory approvals for a broader biosimilars portfolio, leading to faster access for more patients and savings for the NHS. At present, the commitment to six-month approvals for biosimilars is little known and unlikely to be universally adhered to. Moreover, the MHRA is not able to ensure the UK is an attractive market for first movers. Without sustained investment to ensure that it is properly resourced, the MHRA cannot deal with its significant backlogs and meet its world-beating ambition.

Increasing awareness of interchangeability

The MHRA updated its guidance in November 2022, in line with the EMA, to confirm that biosimilars are interchangeable, including with the reference product. However, awareness of this certainly is not universal. A national strategy should include a plan to promote awareness of interchangeability with clinicians and support confidence in and uptake of biosimilars, particularly in those treatment areas with a high prevalence of patented biologics losing their exclusivity over the next few years.

Incentives for first movers

McKinsey analysis makes clear that it costs up to US$300 million to develop and bring a biosimilar to market[37] and that a burden remains on the manufacturers first to bring a new biosimilar to the market. A national strategy must set out clear incentives to first movers. This might include a paused or discounted payment percentage under either the voluntary or statutory scheme, tax rebates for an agreed period or funding to support clinical research.

[36] 2022. Guidance: 150-day assessment for national applications for medicines. MHRA.
[37] Fontanillo, M., Körs, B. and Monnard, A. 2022. Three imperatives for R&D in biosimilars. McKinsey.

Reviewing NICE's remit and scope

We hold the view that NICE could do more, and that its remit and scope may need further consideration to ensure it is fit for purpose with respect to biosimilars. There is an onus on NICE to also clarify what actions it intends to take this year following an apparent decision to move away from a rapid approvals process. This should include a mandate that NICE provide updated guidance promoting wider usage once the biosimilar market has formed and competition has led to falling prices.

NICE action should not be tied to the CMU transition tender; however, its publications should coincide with the next tender opportunity so that any demand uptick can be considered and factored into NHS Trusts' committed volume estimates without adversely impacting supply mid-tender. The strategy must address a lack of clarity on how all partners and stakeholders can work with NICE to incentivise take up of biosimilars in the NHS. This might include a plan to help spotlight and actively promote revised NICE guidance.

Mutual recognition of licensing decisions

A benefit of Brexit should be that the UK is a rule-maker not a rule-taker regarding medicines marketed in the UK. The Government is currently working on an international recognition framework. The MHRA is expected to publish detailed guidance in August ahead of the new international recognition framework going live on 1 January 2024. It will include jurisdictions of comparative regulatory standing: Australia, Canada, the EU, Japan, Switzerland, Singapore and the United States.[38] This will not be a mutual recognition scheme, which is a missed opportunity. As part of a national strategy, the Government should set out its plans to realise the benefits of mutual recognition of medicine licensing decisions[39] to position the UK as a market leader.

A plan to deliver

However, none of the above proposals will realise any benefit if there is no clear plan for delivery. Such a plan is the final piece of the puzzle and key to supporting a competitive and attractive biosimilar market in the UK. One of the criticisms of the Welsh strategy is that it identifies the challenges but does not always provide a clear set of solutions. Given the opportunities that lie ahead, it is critical that any national strategy is more than lip service. To achieve this, there must be not only a plan for delivery, but also a timeline that the Government and other stakeholders can work toward, KPIs that they can measure success against and checks and balances for accountability.

[38] 2023. MHRA announces new recognition routes to facilitate safe access to new medicines with seven international partners. MHRA

[39] Among countries with comparable and complementary regulatory and approval processes.

VPAS

VPAS in its current form is a significant barrier to increased biosimilar uptake in the UK. For the current VPAS period, the allowable growth rate is set at 2% per annum and the payment percentage (levy) in 2023 is 26.5%. This is nearly five times what it was two years ago.

Earlier this year, the BGMA published its position paper "Delivering a financially sustainable VPAS that supports widened medicines access to patients".[40] We want to be constructive partners to the Government in negotiating and agreeing the next scheme and in contributing to the development of the statutory scheme that will sit alongside it.[41]

Currently, 39% of all branded products[42] are branded generic or biosimilar by volume. All biosimilars and some generics are required to be branded by the MHRA for clinical reasons. Manufacturers of those products cannot 'de-brand' and have no choice but to pay this tax. It is critical that the next VPAS, negotiations for which are currently underway, deliver a financially sustainable scheme that supports widened medicines access to patients.

Off-patent sector growth held back by one-size-fits-all VPAS

According to IQVIA, the sales growth in branded medicines is not from the off-patent branded generic and biosimilar sector; it is from the monopolistic patent-protected innovator sector. During this VPAS period, the maximum allowable sales growth for the two sectors combined was 2%, with a rebate payable for excessive growth. The average annual growth rate for off-patent medicines was 2%, and it was less than 2% in 2020 and 2022, compared with an average growth rate of 18% for on-patent medicines. These figures suggest that the off-patent sector should have been exempt from the rebate for those two years. However, it paid £282 million in 2020 and £735 million in 2022, cancelling out the industry's economic growth.

The scheme fails to recognise the unique operating model of the off-patent sector in the UK: that it thrives on competition. In doing so, it unfairly disadvantages manufacturers of branded generics and biosimilar medicines, forcing them to subsidise significant price increases in the on-patent originator sector. Biosimilars provide major savings, and so their subsidisation of on-patent originator medicines operating in monopolistic markets is inequitable. Furthermore, it reduces competition among companies producing biosimilars and discourages them from supplying biosimilars to the UK, which will ultimately increase the cost of biosimilars in the UK.

It is vital the Government ends the cross-subsidisation of high price and high profit medicines by heavily discounted branded generics and biosimilars in the next VPAS scheme. Not to do so would be illogical. The BGMA and BBA continue to call on the

[40] Op. cit., BGMA.
[41] Manufacturers can elect to be part of the voluntary scheme or the statutory scheme. The Government recently launched its consultation on the statutory scheme. If an agreement on the voluntary scheme is not reached before the end of the year, all manufacturers may be forced to be members of the statutory scheme in the interim.
[42] These are innovative on-patent medicines, legacy products post-exclusivity, biosimilars (which are required to be branded by the regulator) and branded generics (some of which are required to be branded by the regulator).

Government to treat competitively priced biosimilars more favourably in the next scheme. Doing so will not only ensure the UK remains an attractive market for biosimilars, but also help safeguard savings to the NHS achievable through price erosion in a competitive market.

The risk of reduced competition

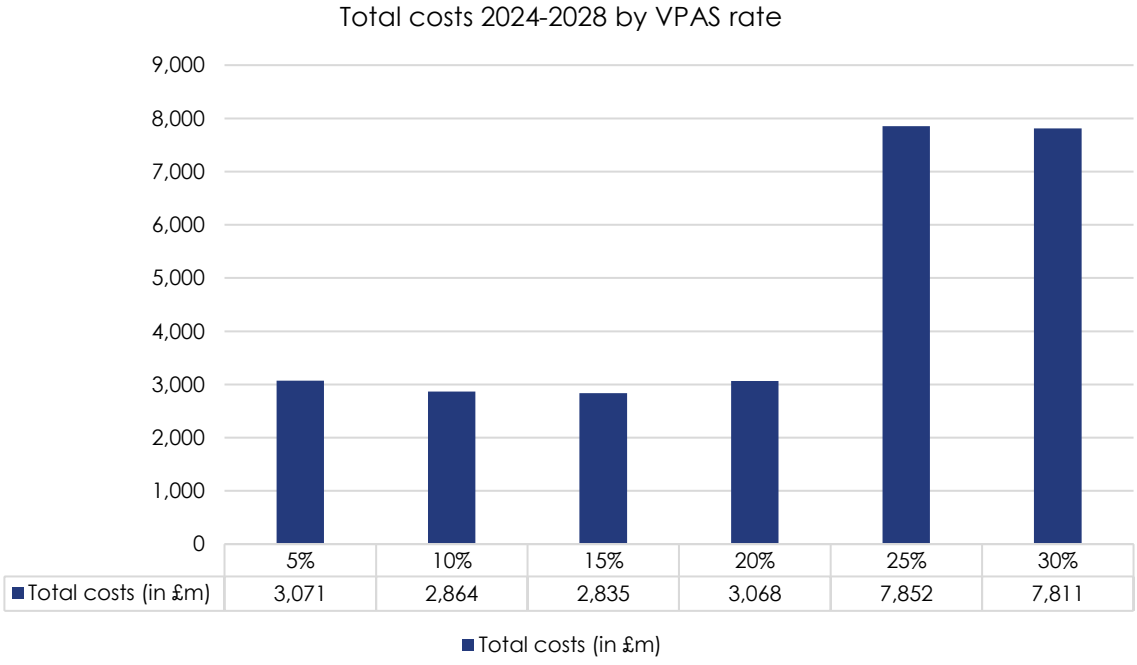
The potential impact on increasing costs to the NHS of a VPAS scheme which ignores the unique benefit of a competitive off-patent sector is clear. A higher tax burden will make the UK market less competitive for biosimilar manufacturers.

Ultimately this will lead to reduced competition and will mean:

- The NHS pays higher prices for medicines, and
- Patients will have reduced access.

Neither outcome is desirable.

The chart below details the additional costs over and above any revenue that the VPAS levy would provide the Government with from biosimilars and branded generics sold to the NHS. A 25% or 30% VPAS rate would cost £7.8 billion; this is illogical. Most of the additional costs originate from diminished biosimilar competition.



VPAS negotiations and the Statutory Scheme Consultation

As set out earlier, the manufacturers that the BGMA and BBA represent account for four out of five NHS drugs; this includes eight of the ten largest medicine suppliers (by volume) to the NHS. While not all these medicines are branded products, BGMA and BBA members supply four out of ten products that fall into VPAS.

Last year, the BGMA and BBA sought a seat at the negotiating table to agree the current VPAS's successor. We did so because our members felt there was a conflict

for the Association of the British Pharmaceutical Industry (ABPI) in representing both the competition-free patent-protected sector and the competition-driven off-patent sector. This concern was amplified when the ABPI published its VPAG proposals earlier this year which completely omitted branded generics and biosimilars.[43]

Following our request for equal status, the Government excluded the BGMA and BBA from being party to agreeing the next scheme, something we were not successful in overturning through judicial review. When the BGMA and BBA exercised their legal rights, the Government removed our status as an observer in the negotiations. While we are disappointed this has not been restored, we remain committed to working closely with the Government. We believe all parties must work together establish a long-term pricing system that works for the NHS, patients, taxpayers and the life sciences sector.

Concurrent with VPAS negotiations, the Government has now published its consultation on the Statutory Scheme that would operate alongside an agreed VPAS. The BGMA and BBA welcome the Government's consultation, which delivers on its commitment to listen to the wider industry. In particular, the proposal for Lifecycle Adjustment is both pro-innovation by rewarding the UK launch of innovative medicines and pro-competition as it encourages the launch of new and off-patent generic and biosimilar medicines. The BGMA and BBA will now seek to work through the proposal with the Department of Health & Social Care on how it can best work in practice and mitigate any supply risks by introducing a new way of seeking a rebate from the industry.

[43] 2023. At the crossroads: how a new UK medicines deal can deliver for patients, the NHS and the economy. The Association of the British Pharmaceutical Industry.

Next Steps

The potential for biosimilars to have significant and lasting impacts on the lives of more patients while saving the NHS billions of pounds is clear. However, it cannot be for the industry alone to ensure biosimilars realise their potential. It is clear there is a role for the Government, NHSE, NICE, the MHRA and the CMU to partner with the industry in achieving this.

For this to happen, the BBA is calling for:

- The development of a National Biosimilar Strategy for England that is focused on ensuring the UK is a competitive market that attracts early movers for new biosimilars,
- Recognition in the next VPAS scheme that the operating model of the off-patent market is grounded in competition and is distinct from the monopolistic market in which patent-protected innovators operate,
- Biosimilars to be treated more favourably through a reduced payment percentage, alongside branded generics, in both the next VPAS and the statutory scheme to ensure the UK is an attractive market for existing and new medicines, and
- The restoration of observer status for the BGMA, and through it the BBA, at the VPAS negotiations to ensure the voice of our sector is heard.

The BBA and its members remain committed to ensuring that the long-standing and constructive working relationships we have with key partners and decision makers continue to realise the potential for biosimilar medicines here in the UK.

British Biosimilars Association

https://britishbiosimilars.co.uk/