SEEING RED:

is VPAS Good for the Nation's Health?

BRITISH GENERIC MANUFACTURERS ASSOCIATION
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INTRODUCTION

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£37m

more per year on medicines

With the NHS continuing to face fiscal pressures, integrated care boards (ICBs)[1] are increasingly being tasked with finding efficiencies and cost savings while being asked to enhance population health and reduce healthcare inequalities. The medicines spend is a significant component of local budgets. **This paper, based on both NHS and pharmaceutical industry perspectives, finds that over the next five years, each ICB is at risk of spending an average of £37m more per year on medicines than budgeted.**

More specifically, this paper examines the effect of the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), an agreement between the government and the Association of the British Pharmaceutical Industry (ABPI) to control growth in pharmaceutical expenditure. In particular, it looks at how VPAS is projected to impact competition of medicines no longer under patent, the subsequent impact of reduced competition on ICB budgets over the next five years, and the benefits that these treatments[2] provide to a wide range of patients. VPAS is more fully explained later in this document.

This paper has been prepared by Conclusio and commissioned by the British Generic Manufacturers Association (BGMA). Conclusio is a market access and engagement agency creating strategic partnerships between the NHS and its supply chain where innovation can flourish. The paper's genesis can be found in a national roundtable meeting, convened by BGMA and facilitated by Conclusio, held in January 2023. This roundtable was chaired by an ICB Finance Director and attended by a number of senior NHS leaders including two NHS CEOs, an Acute Trust Director of Pharmacy, a recent ICB Medical Director, an Acute Trust Consultant, a Local Pharmacy Committee Chief Officer and a senior representative of retail pharmacy. Its purpose was to examine the unintended consequences of the current VPAS model and the payment percentage rebate on the supply of branded generic and biosimilar medicines.

An outcome from the roundtable was the commitment to create two task and finish groups, one looking at the commercial and financial considerations and the other taking a clinical perspective. Conclusio developed a report based on feedback from the two groups, and this paper is informed by those discussions.

Each group was co-chaired by a senior NHS leader. The groups consisted of an even split between NHS and pharmaceutical industry figures, largely those leading generic and biosimilar manufacturers. The participants are listed in the executive summary and we thank them for sharing their insight and expertise to inform this paper.

1. https://www.nhs.uk/nhs-services/find-your-local-integrated-care-board/
2. That is, branded generic and biosimilar medicines

(NHS) Foreword

As leaders in health systems, it was illuminating to understand more about the complex pricing arrangements governing the sale of medicines as we embarked on this work to review their impact on the NHS at a local level.

Medicines spending is likely to amount to approximately

10-15%

of total ICB spending.

The contributions from the subject matter experts involved in the task and finish groups, which inform this white paper, have been of particular value in highlighting the opportunities to ensure that people continue to get the medicines they depend on, are supported appropriately in how they take them and get the optimal health outcomes they deserve.

As negotiations between the government, NHS England and the pharmaceutical industry representative bodies continue, we will inevitably approach a time when it is appropriate and beneficial for each to engage with ICBs. The nature of the successor VPAS scheme will matter to all ICBs, so being able to engage with industry as a precursor to its finalisation has been useful. To facilitate such discussion, BGMA commissioned Conclusio to engage with the ICB community.

ICBs have been in existence for little more than a year and, thus far, much of that time has been dominated by the need to build the right clinical and management structures; develop an integrated care culture; and determine, plan and deliver both locally driven and national health objectives and strategies – all of which have to be achieved within a mandate of best use of finite resources and value for money. This white paper acknowledges some of the possible unintended consequences if the negotiations do not find an equitable and mutual settlement. The budgetary impact modelling posited in this paper will, if it manifests, raise significant concern across ICBs.

Despite the worrying prospect of medicine shortages due to pharmaceutical companies withdrawing from the market or having to reduce the volumes they supply, resulting in the increased cost of medicines, there are some positive trends. The strength of the relationship between the NHS and industry has grown considerably over the last few years. In addition, medicines are more than ever before seen as an investment in the health of our communities. At both local and national levels, the NHS and industry are working collaboratively to find solutions for keeping people well and preventing sickness.

Increasing access to medicines that make a real difference to people's lives is a common endeavour; this paper reveals that generic and biosimilar medicines account for four out of every five medicines prescribed. A proportion of these fall within VPAS. Indeed, the use and accessibility of medicines will significantly impact and shape all four ICB objectives: improving outcomes in population health; tackling inequalities in outcomes, experiences and access; enhancing productivity and value for money; and helping the NHS support broader social and economic development. In addition, medicine optimisation offers a crucial way of moving healthcare to a more preventative footing and enabling patients to better manage conditions at home instead of treating them in hospital, which is more expensive and may result in worse outcomes for patients.

Looking to the future, we cannot ignore the savings to the NHS that off-patent medicines offer, nor can we dismiss the benefits they bring to people every day. We believe that setting a balanced and equitable approach for all parties will create the space for continuing NHS and industry collaboration. This will deliver clinical innovation through medicines and transform our capacity and capability to keep people well, treat them when they are not well and sustain the NHS for everyone's benefit.

Dean Westcott
Chief Finance Officer
Bedfordshire, Luton
and Milton Keynes ICB

Prof. Ashok Soni OBE
Non-Executive Director, Sussex ICB
President,
National Association of Primary Care

Executive summary and conclusions

The 42 ICBs in England are responsible for the delivery of health and social care in their localities, yet there appears little understanding about how the renegotiation of VPAS[3], to take effect from January 2024, could significantly affect their ability to achieve the following stated objectives:

- Improve outcomes in population health.
- Tackle inequalities in outcomes, experiences and access.
- Enhance productivity and value for money.
- Help the NHS support broader social and economic development.

How the review was conducted and who participated

Based on this backdrop, BGMA asked Conclusio to bring together NHS and industry leaders to consider what the impact of VPAS, particularly a continuing high rebate or clawback on the sales of branded medicines for the next five years, could mean for ICBs and their patients. This was done by bringing together two task and finish groups.

The Commercial Task and Finish Group reviewed the impact of VPAS on ICBs' financial sustainability, new launches of off-patent medicines, the incentivisation of treatments that improve access to the right medicine to more patients and the broader life sciences agenda.

The Clinical Task and Finish Group reviewed the role of branded generics and biosimilars in the patient pathway, focusing on several examples. It also considered the effect that VPAS could have on ICBs' attempts to enhance population health, reduce inequalities and shift healthcare delivery away from acute hospital treatment.

Commercial Task and Finish Group

Co-chairs:

Dr John Niland
Recent NHS Chief Executive and current Non-Executive Director

Mark Samuels
Chief Executive, BGMA

Attended by:

NHS Finance Director

Former DHSC Turnaround Director

Public Health Director

BGMA member company MDs and leads from Accord and Aspire

Clinical Task and Finish Group

Co-chairs:

Dr Steve Lloyd
GP and recent CCG/ICB Executive and Medical Director

Paul Fleming
Technical Director, BGMA

Attended by:

Chief Officer, Cheshire and Wirral Community Pharmacy

Consultant Gastroenterologist, Barts and London NHS Trust

Head of Market Access, Sandoz

External Affairs Lead, Viatris

3. https://www.gov.uk/government/publications/the-2019-voluntary-scheme-for-branded-medicines-pricing-and-access-payment-percentage-for-2023

VPAS

Voluntary Scheme for Branded Medicines Pricing and Access

What is VPAS?

VPAS is the Voluntary Scheme for Branded Medicines Pricing and Access and is the main scheme for controlling the price of medicines in the UK. It is an agreement between the Department of Health and Social Care (DHSC), NHS England (NHSE) and the ABPI. It requires companies selling branded medicines to the NHS of a value above £5 million to pay a percentage of these sales back to DHSC whenever the branded market sales grow faster than the allowed rate. 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%, which is over five times what it was two years ago.

Pharmaceutical companies that supply the NHS with branded medicines are members of VPAS or the parallel statutory scheme[4], which sets an overall growth limit capped at 2% per annum, with companies collectively paying the NHS for any overspend based on an annually determined percentage of their sales. For 2023, companies must pay back 26.5% of their NHS sales (not profits). This rebate currently applies to on-patent medicines and off-patent medicines like branded generics and biosimilars, but not unbranded generic products.

The projected impact on ICBs and their objectives

Both VPAS and the parallel statutory scheme apply to branded generics and biosimilar medicines even if they are, in many cases, in a competitive market and suppliers are already selling them to the NHS at a price more than 80% off the originator price pre-patent expiry. Because of their relatively low cost, generic and biosimilar medicines already save the NHS billions of pounds each year, meaning that it can offer better treatments to patients earlier. Indeed, the findings in the report clearly show how patients with conditions such as ulcerative colitis, rheumatoid arthritis and asthma benefit from branded generics and biosimilar medicines. Looking forward to 2028, the opportunity to make savings and widen patient access looks set to increase with numerous on-patent biologic medicines losing their exclusivity[5].

Yet manufacturers say that if the variable and high payment percentage rate continues for another five years, it will no longer be viable to supply many branded generic medicines or biosimilars, particularly at the same volume levels. The alternative will be to increase their prices to cover the rebate.

Indeed, modelling by the OHE and LSE projected that if the VPAS rate is set at 25% for the next five years for branded generics and biosimilars, the reduction in competition will result in the NHS spending an additional £7.8bn through higher prices[6]. This is over and above any revenue that central government will receive from collecting the VPAS rebate. This roughly means that every year, each ICB faces a projected £37m rise in what it pays for branded generics and biosimilars. In many cases, this increase will wipe away any projected surplus. We calculate that £37m is roughly 10-20% of the entire pharmaceutical spend of an ICB depending on its size.

This will not only make it harder to deliver ICBs' population health objectives, but it is likely to impact efforts to fund more preventative treatments that enable condition management. The number of shortages is also expected to rise as a result of a more volatile market stemming from fewer suppliers, potentially less stock being earmarked for the UK, and product withdrawals. This will likely not only increase the prices that the NHS pays, but also impact pharmacy contractors' cashflow position, with pharmacists spending up to a third of their working week mitigating shortages as opposed to supporting the NHS in advising patients and prescribing specific prescription treatments.

4. https://www.gov.uk/government/consultations/review-of-the-scheme-to-control-the-cost-of-branded-health-service-medicines#:~:text=The%20statutory%20scheme%20is%20set,branded%20medicines%20to%20the%20NHS.
5. Impacts of Changing VPAS Rules in Respect of Biosimilars. Europe Economics, May 2023.
6. The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), commissioned by BGMA, October 2022.

We calculate that **£37m** is roughly **10-20%** of the entire pharmaceutical spend of an ICB depending on its size

A proportionate contribution that supports the NHS and protects ICBs from unintended consequences

Nevertheless, there is a shared understanding that the generics and biosimilar industry should make a contribution to supporting the sustainability of the NHS financial position. With the negotiations only having a few months to run until the end of the year, to try to finalise a new VPAS, as well as the statutory scheme governing the pricing of branded medicines, we suggest that ICBs' concerns may be best alleviated through the following recommendations:

- **Differentiate between patent-protected medicines,** where competition doesn't exist, and off-patent medicines, where competition very often does exist.
- **Introduce a lower, fixed rate for off-patent medicines** where competition exists, or require a minimum rate of discount compared to when the product was patent-protected.
- **If this differentiation based on competition cannot be reliably implemented,** introduce a progressive or tiered VPAS rebate rate so that companies with higher NHS sales make a larger proportionate contribution.
- **If a voluntary agreement can be agreed that moves beyond setting a pricing framework,** we support targets, levers and incentives across the NHS system that utilise the prescribing of biosimilars, thereby widening access and bringing down costs.

All biosimilars and some generics are required to be branded by the MHRA... those products cannot "de-brand" and have no choice but to pay this levy.

The current VPAS and the medicines it covers

The table[7] below shows the percentage payment, namely the percentage of each company's branded sales that they must pay to the government, since the start of the current VPAS. The third column shows how much all branded manufacturers combined have paid the government each year.

Year	Percentage payment	Resulting aggregate scheme payments
2019	9.6%	£845m
2020	5.9%	£594m
2021	5.1%	£562m
2022	15%	£1.821bn
2023	26.5%	TBC

The scheme covers medicines that are marketed with a brand name. In addition to the drugs sold by originator companies – those who invent and patent medicines – the scheme also includes manufacturers and suppliers of branded generic and biosimilar medicines. All biosimilars and some generics are required to be branded by the Medicines and Healthcare products Regulatory Agency (MHRA) for clinical reasons. Manufacturers of those products cannot "de-brand" and have no choice but to pay this levy. The OHE and LSE[8] also noted, "Branded generics may also be branded by choice where the manufacturer wants to differentiate its product. This can be to draw attention to and promote certain features of the product."

The scale of the levy is exacerbated by manufacturers of blockbuster patented medicines containing new active substances being exempted for three years, the costs of which other VPAS member companies must bear.

There are a number of possible reasons why the medicines budget has grown in recent years, which has driven the rise in the amount companies must pay the government. These include the impact of Covid-19 creating delayed demand for healthcare and arguably leading to less focus on cost-effective prescribing, NHSE signing more agreements for higher cost on-patent medicines and the impacts of inflation. The scheme runs for a five-year period and the agreement will be renewed in 2024.

Negotiations between DHSC, NHSE and ABPI are currently underway for the next VPAS. Presently, nearly half of medicines to which the current scheme is made up of branded generics and biosimilars, which typically face competition. Despite BGMA representing manufacturers who supply 80% of the medicines used in the NHS, and whose membership includes eight out the ten largest suppliers to the NHS by volume, it is not included in the negotiations.

Operating in parallel with VPAS, there is a statutory branded medicines pricing scheme. It is updated each year to ensure that it is broadly commercially comparable with VPAS and is for companies that choose not to be members of the voluntary scheme. In the absence of any voluntary scheme being agreed, all suppliers of branded medicines would automatically fall into the statutory scheme.

7. https://www.gov.uk/government/publications/voluntary-scheme-aggregate-net-sales-and-payment-information-february-2023/aggregate-net-sales-and-payment-information-february-2023
8. The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), commissioned by BGMA, October 2022.

the growth of patented medicine sales as a proportion of total growth **was far higher than its VPAS contribution**

The UK pharmaceuticals market and VPAS in figures

The NHS spent £17.8bn[9] on medicines from April 2021 to March 2022, most of which was on NHS-prescribed branded drugs. Including the NHS England Innovative Medicines Fund[10], the NHS spent nearly £13bn on branded medicines. The remainder, approximately £4-5bn, was spent on unbranded medicines. This includes the £800m community pharmacy margin for dispensing unbranded generics.

Of that £13bn spent on branded medicines, the vast majority (£12.125bn) was payable through VPAS, with the Innovative Medicines Fund making up the remainder. In actual fact, NHS branded medicines spending was £1.819bn more than this £12.125bn figure, but the VPAS agreement – capping branded medicines sales growth at 2% – meant that branded medicines suppliers returned £1.819bn to central government (row 6 in the table below).

This table, compiled by BGMA, shows the volume and value of on- and off-patent NHS medicine sales in 2022. (Note that the Drug Tariff price, the price of medicines that the government uses to reimburse pharmacies, is on average around double the value that the medicines are sold for.) The table shows that the level of sales growth that the off-patent sector is responsible for (row 4) is far less as a proportion than the contribution it paid to the VPAS last year (rows 7 and 8). In contrast, the growth of patented medicine sales as a proportion of total growth was far higher than its VPAS contribution.

Row	Characteristics of market	Patented	Off-patent sector		
			Branded generic	Biosimilar	Legacy originator
1	Number of medicine packs[11]	152.41m	215.51m	7.44m	201.3m
			Total: £424.25m		
2	Percentage of medicine packs	26.43%	37.37%	1.29%	34.91%
3	Drug Tariff price cost of medicine packs sold to NHS[12]	£14.95bn	£2.32bn	£1.84bn	5.96bn
			Total: £10.12bn		
4	Actual year-on-year sales growth rate from 2021 to 2022	15.8%	0.83%		
5	VPAS rate	15%	15%		
6	VPAS payment across industry[13]	1.819bn			
7	Share of VPAS payment	£1.085bn	£0.168bn	£0.134bn	£0.432bn
8	Share of VPAS payment across on- and off-patent sectors	£1.085bn	£0.734bn		

9. https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202122
10. https://www.england.nhs.uk/2021/07/nhs-england-announces-new-innovative-medicines-fund-to-fast-track-promising-new-drugs/
11. IQVIA, 2023.
12. IQVIA, 2023.
13. https://www.gov.uk/government/publications/voluntary-scheme-aggregate-net-sales-and-payment-information-may-2023/aggregate-net-sales-and-payment-information-may-2023

ICBs

Integrated care boards

The integrated care board perspective:
Why does VPAS matter?

Integrated care boards are statutory organisations that bring the NHS and care organisations together to establish, fund and implement local shared strategic health and care priorities. There are 42 ICBs in England, each with their own governance arrangements, constitution and specific priorities, but all are centred around the objectives to[14]:

- Improve outcomes in population health
- Tackle inequalities in outcomes, experiences and access.
- Enhance productivity and value for money.
- Help the NHS support broader social and economic development.

ICBs multiple challenges:

ICBs must operate within an NHS that faces multiple challenges:

Access to frontline services is becoming more delayed for patients, with over 40% of NHS patients having waited more than 18 weeks from referral to treatment in June 2023[15] and millions waiting over two weeks to see a GP[16].

Financial constraints are a significant challenge faced by the NHS. Increasing demand, an ageing population and rising healthcare costs exert immense pressure on system resources.

Health inequalities persist as a pressing challenge within the NHS. Socio-economic factors, geography and demographic disparities contribute to differential access to healthcare services and health outcomes.

The NHS built estate is in need of repair. While digital care in the form of virtual appointments and clinics could reduce the dependence on bricks and mortar, the need for a clinical estate will remain. Some estimates suggest a £9bn backlog of building repairs due to limited resources being redirected into frontline services.

Staff shortages exist in many clinical settings. In nursing roles alone 46,000 posts lie vacant, with overall clinical staff shortages of 6-11% depending on the region[17].

there is limited recognition and understanding of the issues caused by VPAS at ICB level... these issues may therefore not be a feature in the negotiations and discussions.

When comparing ICBs' broad objectives and the present challenges facing the NHS, the Commercial Task and Finish Group was concerned that an unreformed VPAS risks the NHS:

- Paying more for everyday, often preventative treatments at ICB level, leading to greater financial pressures and reduced access to population health medicines.

- Having to manage more shortages stemming from fewer suppliers, diverting precious NHS and pharmacy contractor staff time as well as costing more money to find alternatives.

Before looking at both these connected risks and their consequences, it should be noted that the NHS representatives in the task and finish groups highlighted that ICB leaders are either largely unaware of VPAS or have little understanding or working knowledge of the scheme. ICB leaders are also unsure about the level of understanding held by NHSE regional leaders. Moreover, there is a lack of communication between the centre (where the decision on VPAS is made) and ICB level – where the direct impact on medicine cost pressures and supply issues will be most acutely experienced.

At a national level, anecdotal evidence suggests that VPAS is not wholly understood. In a recent visit to one ICB, a DHSC official asked how much VPAS was saving in that particular area. In reality, VPAS does not directly benefit the taxpayer via investment in local healthcare systems. Rather, the VPAS revenue goes back to the Treasury to cover public sector expenditure. Funds may be recycled back into healthcare expenditure, but it may not cover medicine cost increases due to a rising VPAS rebate rate, as suggested by the OHE and LSE modelling commissioned by BGMA.
As such, there is limited recognition and understanding of the issues caused by VPAS at ICB level, which could be exacerbated if the status quo is broadly maintained for the next five years, and these issues may therefore not be a feature in the negotiations and discussions.

Paying more for everyday, preventative treatments at ICB level

OHE and LSE modelling, commissioned by BGMA, illustrates the effect of a sustained high VPAS rate on ICBs. The modelling projected that applying a 25% rate to branded generics and biosimilars – less than the current 26.5% – over five years would cost the NHS £7.8bn more than any government income received from VPAS[18]. This is in part

14. Integrated Care Systems: design framework, version 1, June 2021.
15. https://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2023/08/Jun23-RTT-SPN-publication-version-V3-PDF-K-25787.pdf
16. https://digital.nhs.uk/data-and-information/publications/statistical/appointments-in-general-practice/february-2023
17. https://www.nuffieldtrust.org.uk/resource/the-nhs-workforce-in-numbers
18. The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), commissioned by BGMA, October 2022.

"An overspend of £37m on medicines would potentially turn the efficiency savings identified into a cost pressure, placing at risk the balanced budget.

"Celltrion, the biosimilar manufacturer of the off-patent breast cancer drug Herzuma, has signalled a ceasing of supply should VPAS continue unchanged"

because IQVIA[19] has identified 85 biologics that will lose their exclusivity between 2023 and 2028. According to modelling by Europe Economics, [20]just for these products alone, a reduction of two suppliers per product owing to a persisting high VPAS rate – a fairly conservative assumption – would cost the NHS over £1bn in the five years up to 2028 as a result of less competition leading to higher prices.
If this extra £7.8bn cost were to apply to all 42 ICBs evenly, then each year, every ICB would spend over £37m extra in higher medicines prices for which there would be no government reimbursement. We now look at how this could impact several ICBs spread across England.

The North Cumbria and North East ICB (NCNE) has set a balanced financial plan for 2023-24[21]. The plan outlines allocations of around £6.81bn and associated expenditure of around £6.78bn, leaving a surplus of around £32m. The budget assumes around £24m of efficiency savings associated with prescribing. An overspend of £37m on medicines would potentially turn the efficiency savings identified into a cost pressure, placing at risk the balanced budget. NCNE has a population of around 3.15 million, more than double the average ICB population in England of around 1.47 million. In addition, NHSE identifies NCNE as having the third highest prescribing need among the ICBs in England. The population size and prescribing need indicate an above average impact of VPAS on NCNE.

Elsewhere, North Devon ICB has a £2.3bn a year budget, which covers two thirds of the county's population health needs[22]. For Norfolk and Waveney ICB, the budget is £2bn a year[23]. Nottingham & Nottinghamshire ICB estimates that around 14% of the total ICB budget is spent on medicines[24]. If this percentage was to apply to both North Devon and Norfolk and Waveney ICBs, their annual medicines spending would be around £322m and 280m respectively. Applying the £37m figure to each ICB suggests that the current VPAS could create 12% and 13% overspends on their medicine budgets respectively, for which there will be no earmarked central government funding.

A reformed VPAS might support the implementation of current NHS reviews, for example, the Hewitt Review. Reducing the avoidable additional financial pressures on ICBs projected to be caused by VPAS will help increase the share of the budget at ICB level that can be allocated to preventative health.

Having to manage more shortages

Some ICBs are already experiencing cost pressures from medicine supply shortages impacting on prescribing costs, and this issue is featuring on ICB risk registers. A financially well-performing ICB in the South of England reports a current in-year cost pressure from shortages of £8 million relating to medicines spend. This figure could be significantly higher for ICBs in a less favourable financial position. Of course, any emerging cost pressure from prescribing will impact the ability of an ICB to deliver a medicine optimisation QIPP[25] and could have a follow-on effect on its end-of-year budgetary control total. This would undermine ICBs' performance in both balancing the books and improving outcomes in population health.

There are many reasons why a shortage may exist, including regulatory problems, supply chain difficulties and increased demand. For branded off-patent medicines, VPAS is increasingly being cited as a problem that makes supply unviable, particularly where the company is unable to increase its selling price to counterbalance the high rebate.

Some companies have scaled back volumes, with finite capacity prioritised for other international markets. Celltrion, the biosimilar manufacturer of the off-patent breast cancer drug Herzuma, has signalled a ceasing of supply should VPAS continue unchanged[26]. Although there are other producers of off-patent alternatives, they may not be able to fill the vacated market share or may themselves be forced to reduce supply in the UK due to more favourable market conditions in other countries. The resulting risk to patients is manifest; the five-year survival rate for women treated with Herzuma is 97%.

Responding to reports in the media relating to challenges over the availability of Herzuma, the leading UK charity Breast Cancer Now said it wanted the next version of VPAS, due to come into force next January, to ensure that patients receive rapid and fair access to treatment. Melanie Sturtevant, the charity's Associate Director of Policy, said[27]:

"We know that timely access to effective drugs can be life-changing for people with breast cancer – from reducing the risk of the cancer returning to potentially increasing the time people with incurable secondary breast cancer live. It's now critical the next VPAS has a firm focus on delivering quick and equitable access to new, innovative and effective medicines to those who could benefit from them."

In recent years, medicine supply shortages have increased in the UK, particularly for hormone replacement therapy (HRT), an off-patent branded treatment. This was, in part, driven by a sudden

19. A leading pharmaceutical industry provider of data and consultancy services.
20. Impacts of Changing VPAS Rules in Respect of Biosimilars. Europe Economics, May 2023.
21. item-9-2-1-icb-financial-plan-budgets-23-24-v3-final.pdf (northeast-northcumbria.nhs.uk)
22. https://devon.icb.nhs.uk/
23. https://improvinglivesnw.org.uk/about-us/our-nhs-integrated-care-board-icb/
24. https://www.nottinghamshiremedicinesmanagement.nhs.uk/ commissioned by BGMA, October 2022.
25. Locally prepared Quality, Innovation, Productivity and Prevention (QIPP) plans to help the NHS deliver its objectives more cost-effectively: https://www.bennett.ox.ac.uk/blog/2019/02/qipp-planning-how-to/#:~:-text=Every%20year%20in%20the%20NHS,more%20for%20the%20 same%20funding
26. https://inews.co.uk/news/breast-cancer-drug-withdrawn-uk-row-nhs-sales-levy-vpas-2414832#:~:text=Celltrion%2C%20a%20South%20 Korean%20drug%20manufacturer%2C%20told%20i,losses%20asso-ciated%20with%20the%20NHS%E2%80%99s%20drugs%20procure-ment%20system.
27. https://inews.co.uk/news/breast-cancer-drug-withdrawn-uk-row-nhs-sales-levy-vpas-2414832

"It's now critical the next VPAS has a firm focus on delivering quick and equitable access to new, innovative and effective medicines to those who could benefit from them."

and unexpected increase in demand. BGMA's monthly supply issues dashboard, charting primary and secondary care supply issues on the Specialist Pharmacy Service's online medicine supply tool, shows that nearly 100 products are facing supply issues[28], most of which are off-patent medicines. Of those, branded generics make up 48%.

Last year The Pharmaceutical Journal highlighted the risks to patient safety, a situation that still exists and could get worse.

"More than half of pharmacists warn medicine shortages have risked patient safety in the past six months. *Results from The Pharmaceutical Journal's annual salary and job satisfaction survey show that 54% of UK-based pharmacists said medicines shortages have put patients at risk in the past six months."*

Article at: https://pharmaceutical-journal.com/article/news/more-than-half-of-pharmacists-warn-medicine-shortages-have-risked-patient-safety-in-the-past-six-months

As the focus of Integrated Care Systems shifts to reducing inequalities, their ability to achieve this with medicines will be hampered by supply issues for existing medicines. As rates of prescribing are higher in more deprived areas due to higher rates of multi-morbidity, it reasonably follows that medicine shortages will impact patients and the local NHS more in those areas.

The impact of medicine shortages can drive additional resource burdens on local health systems. A recent example from a Local Pharmaceutical Committee in the North-East demonstrated that pharmacists could spend up to 12 hours a week sourcing replacements due to medicine shortages. In addition, community pharmacies sometimes do not receive full reimbursement quickly enough for the alternative medicine, and this has a significant impact on contractor cashflow.

Overall, continuing to apply a high rebate rate to branded generics and biosimilars risks negatively impacting on all the macro-objectives of ICBs, whether that is improving population health, tackling health inequalities, ensuring greater value for money or supporting economic development.

28. https://www.britishgenerics.co.uk/view-news/bgma-supply-issues-dashboard-july-2023.html

PATIENT SAFETY

What is the impact of VPAS on the patient?

As we have commented, supply issues such as with HRT do impact patients and The Pharmaceutical Journal has reflected pharmacists' views that shortages have impacted patient safety. The Clinical Task and Finish Group noted that this can lead to condition exacerbation, symptom flare and other clinical complications for individual patients. Potential consequences from supply disruption also include:

- Delays in starting or continuing therapy
- Reduced adherence
- Potential loss of access to a medicine-specific patient support programme

Example of branded generic use

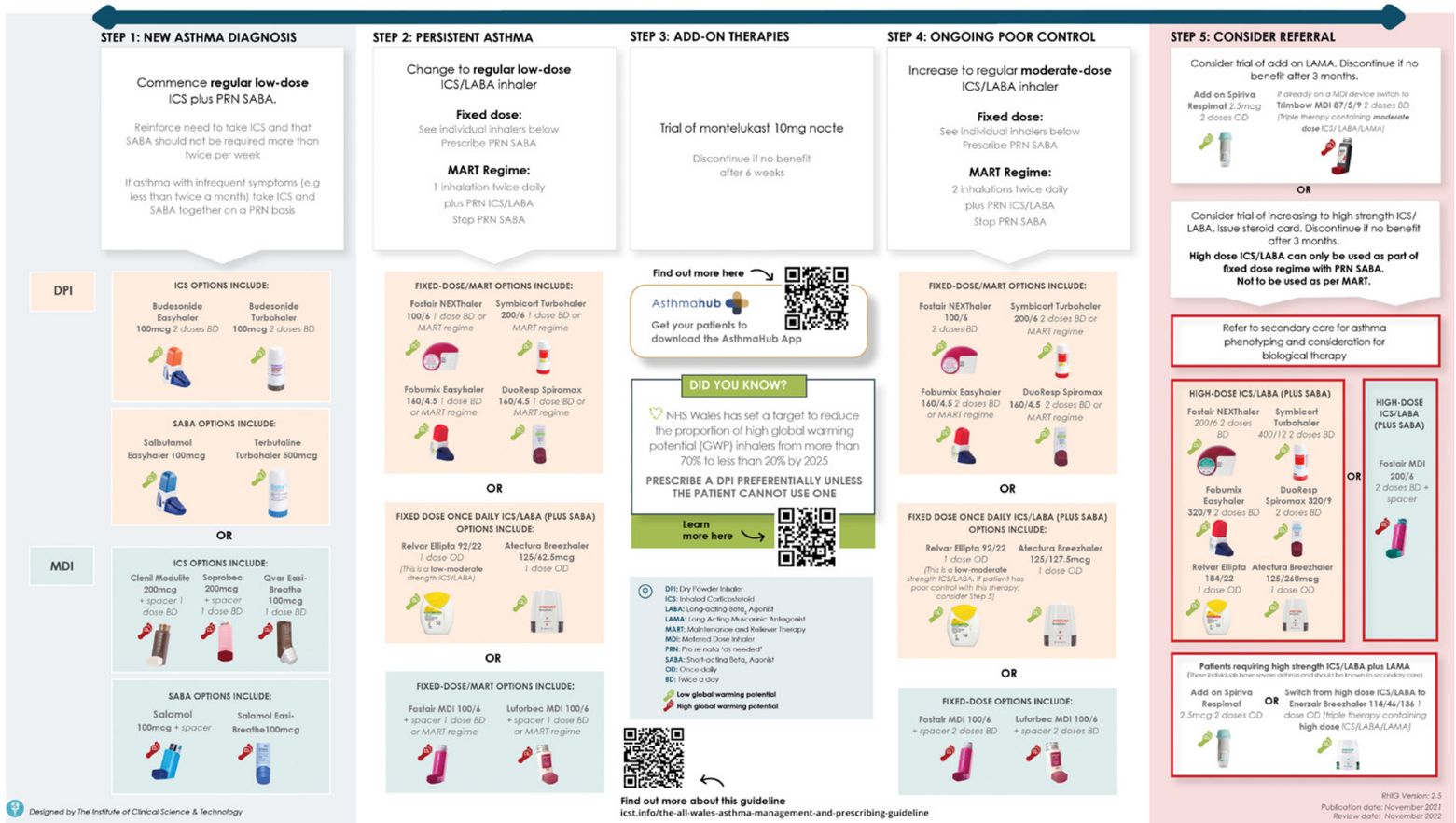
Like unbranded generics, branded generics treat a variety of the most common chronic conditions for which patients seek help from the NHS in managing. Because of this, branded generics are central to ICBs' population health objectives.

As an example, the Clinical Task and Finish Group looked at the pathway for a patient with asthma and the need to both step-up and step-down medicine use within the pathway. The All Wales Asthma Management and Prescribing Guideline (see diagram below) exemplifies the dominant role of branded generic medicines in the care of people living with the condition[29].

Inhaled asthma therapies include a device to ensure the drug reaches the targeted part of the respiratory system. MHRA requires that such medicine/device combinations carry a brand name because the various presentations are not interchangeable. Similarly, the current joint British Thoracic Society – Scottish Intercollegiate Guidelines Network – NICE guidance[30] supports the necessity to prescribe branded generic asthma medicines on clinical grounds:

29. https://awttc.nhs.wales/files/guidelines-and-pils/all-wales-adult-asthma-management-and-prescribing-guideline-pdf/
30. https://www.brit-thoracic.org.uk/quality-improvement/guidelines/asthma/

"Generic prescribing of inhalers should be avoided as this might lead to people with asthma being given an unfamiliar inhaler device which they are not able to use properly."



"earlier access to biosimilars has the potential to improve the lives of thousands of people in England and Wales."

Examples of the types of medicine or treatment where a brand may be required by MHRA.

- Solid Oral Dose Antiepileptic Medicines
- Asthma pressurised metered dose inhalers
- Oral modified release products
- Long acting injectables
- Antipsychotic agents
- Enzyme replacement
- Hormone Replacement Therapy
- Transdermal patches
- Anaphylaxis

Example of biosimilar use

With 85 biologics losing their exclusivity up to 2028, the opportunities for further expansion of the biosimilars market will deliver further savings and allow more people to access medicines and treatment sooner.

Professor Peter Taylor, Chief Medical Advisor at the National Rheumatoid Arthritis Society, has noted the impact of using biosimilar medicines to treat rheumatoid arthritis. He said that the widening of access to treatments for adults with moderate rheumatoid arthritis is the biggest change to its treatment since the introduction of biologics nearly 20 years ago. Until recently, only patients with severe disease had access to biosimilar medicines. This has now changed. These biosimilar medicines are now accessible at an earlier stage than has previously been possible. Professor Taylor believes that ensuring more patients with moderate rheumatoid arthritis have earlier access to biosimilars will improve the lives of thousands of people in England and Wales.

If the NHS is to avoid losing this potential opportunity in other treatments, it is vital that NHS leaders within ICBs can rely on a thriving biosimilars market. Indeed, according to the OHE and LSE, the sales forecast of new biosimilars launched between 2024 and 2028 is £8.1bn, during which existing biosimilar sales are projected to be £13.6bn[31]. As such, biosimilars are a big market opportunity for suppliers, but their development takes 6-9 years and it requires £50-300m investment to bring a biosimilar to market[32]. We therefore believe that competition can provide very significant savings in the price the NHS pays compared to that when the treatment was under patent protection.

The Clinical Task and Finish Group took a deep dive review into the role of biosimilars in the ulcerative colitis (UC) pathway. An audit by the hospital consultant participant in the group demonstrated how the development of biosimilars had increased the pool of patients who can benefit from them and reduced the need for significant surgery, thus improving patients' quality of life and outcomes while also improving the efficiency of the wider system.

The management and prescribing guidelines for UC again show a dominance of biosimilar medicines[33].

Example of biosimilar pathway – UC (proctitis) and induction of remission

Medical treatment for UC has two main goals: achieving remission (control or resolution of inflammation, leading to symptom resolution) and then maintaining remission.

Over the last several years, biosimilars have become available for the treatment of inflammatory bowel disease (IBD) such as UC and other inflammatory

"Data from clinical studies suggest that

30-65%

of UC patients will achieve remission after taking these medications for one year"

diseases. Biologic therapies offer a distinct advantage in IBD treatment because their mechanisms of action are more precisely targeted to the factors responsible for IBD. For example, biologic agents act more selectively than corticosteroids, which affect the whole body and may produce major side effects. These therapies target proteins that have already been proven to be involved in IBD. While it is not possible to determine which biologic will work best for an individual patient, they have an increasingly important role in early intervention to maintain remission and avoid complications and to reduce the risk of surgical intervention.

Biologics known as anti-tumour necrosis factor (anti-TNF) agents bind and block a small protein called tumour necrosis factor alpha (TNF-alpha) that promotes inflammation in the intestine as well as other organs and tissues. All anti-TNF medications have been shown to not only reduce the symptoms of IBD, but also help heal the inflamed intestine. While anti-TNF medications are not effective for every individual, many patients benefit from this class of medication. It may take up to eight weeks after starting an anti-TNF to notice an improvement in symptoms, though many experience more immediate improvement.

Examples of classes of anti-TNF medications used in UC and Crohn's disease include:

- Anti-TNF agents
- Integrin receptor antagonists
- JAK inhibitors

In clinical trials, all the biosimilar drugs approved to treat moderate to severe UC[34] have been shown to be more effective than a placebo at decreasing symptoms (inducing remission) and preventing their return (maintaining remission).

Biosimilar medicines, as well as the original reference biologic versions in brackets, approved for UC include:

- Adalimumab (Humira)
- Infliximab (Remicade)
- Vedolizumab (Entyvio)
- Ustekinumab (Stelara)
- Golimumab (Simponi)

These treatments are an option when other, more standard therapies have failed to help, which occurs for about 20-40% of patients.

Adalimumab and infliximab are already available as biosimilars. The exclusivities on the other three treatments are all due to expire over the next VPAS period, between 2024 and 2028[35]. Therefore, more UC patients will be able to be treated and sooner, unless a high VPAS rate prevents biosimilar competition.

31. The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), commissioned by BGMA, October 2022.
32. https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars?stcr=26497786B91C4223AF46BF6237DE446F&cid=other-eml-alt-mip-mck&hlkid=0c37ee73617b4ca8b7c6b841017f3e9a&hctky=13496708&hdpid=709a0826-6e44-4c4b-88e0-f693b46118e9 McKinsey, August 2022.
33. https://www.nice.org.uk/guidance/ng130, NICE, 2019.
34. https://www.drugs.com/condition/ulcerative-colitis.html
35. IQVIA, 2023.

These medicines can prevent some patients with moderate to severe UC from requiring surgery or hospitalisation.

Data from clinical studies suggest that 30-65% of UC patients will achieve remission (the absence of symptoms and inflammation) after taking these medications for one year, with the rate of responders (patients who benefit from biologic drugs) versus non-responders varying depending on the treatment.

For example, in a study of 134 adults with UC carried out by the charity Crohn's & Colitis UK, researchers found that:

- 56.9% of those who took adalimumab were responders.
- 62.5% of those who took infliximab were responders.
- 47.5% of those who took vedolizumab were responders.

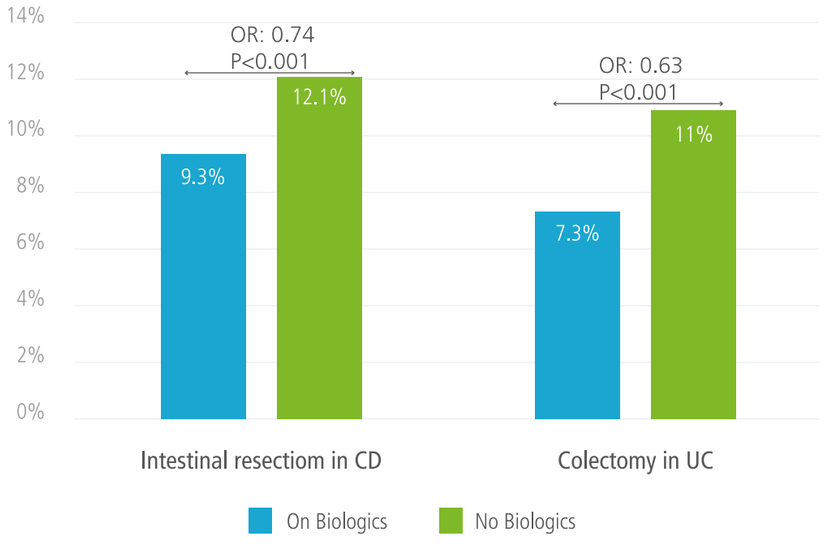
These medicines can prevent some patients with moderate to severe UC from requiring surgery or hospitalisation. The percentage of people with UC receiving biologic drugs has increased substantially since 1998, when infliximab became the first approved biologic. Now, about 16% of the patient population is estimated to use biologics – either the original reference product or the biosimilar treatments that have followed. According to a 2020 study of more than 500 patients with UC, the introduction and utilisation of biologics may be responsible for a marked decline in the number of patients who need to undergo surgery.

In the pre-biologics era, about 20% of patients with UC needed a colectomy (surgery to remove the colon) during their first hospitalisation, and 30% required a colectomy within a year of their first hospitalisation. Since the introduction of biologics, those rates have declined to 5.3 and 11.9% respectively, suggesting that biologics have spared many patients from losing their colons. And as more biologic treatments have lost their exclusivity, the NHS has been able to expand the treatment owing to the availability of biosimilars. This has led to the prevalence of biologics in UC, as can be seen by the orange bars in the chart below.

Not all patients with UC experience improvements while taking biologics. The drugs do not always bring about remission or prevent the need for surgery, or sometimes they have reduced effectiveness over time or even no benefits at all. However, there is no indication that the number of non-responders is different between originator biological medicines and the biosimilar alternatives. The UK medicines regulator MHRA[36] says:

"Once authorised, a biosimilar product is considered to be interchangeable with their Reference Product (RP), which means a prescriber can choose the biosimilar medicine over the RP (or vice versa) and expect to achieve the same therapeutic effect. Likewise, a biosimilar product is considered to be interchangeable with another biosimilar to the same RP."

Biologic-treated inflammatory bowel disease (CD & UC) patients are significantly less likely to undergo colectomy (7.3%) than UC patients not receiving biologic therapy (11.0%) (p <.001). The same is true for CD patients receiving biologic therapy, who are less likely to undergo colectomy (9.3%) than CD patients not receiving biologic therapy (12.1%) (p <.001). Khoudari et al., Clin Gastroenterol Hepatol 2022



Biosimilar medicines have already made a remarkable contribution to widening patient access to better, more consistent treatments that reduce health inequalities while also providing significant NHS savings.

As a result of interchangeability, switching patients from one product to another (RP or biosimilar) has become clinical practice. The decision rests with the prescriber in consultation with the patient, in line with the principles of shared decision making; both need to be aware of the brand name of the product received.

"All biological medicines, including biosimilars, should be prescribed by brand name."

The utilisation of biosimilars in UC has therefore meant:

- Admissions avoidance – Patients needing medicine through devices such as inhalers require consistency in delivery to support adherence and reduce exacerbations.
- Outpatient and elective admissions reduction – Biosimilars for the management of UC have reduced the need for surgery and improved patient outcomes.
- Supporting patients waiting for elective treatment – Patients waiting for treatment are being managed with the use of medicines to alleviate symptoms.
- Inequality reduction – Closing diagnosis gaps in circulatory, endocrine and respiratory conditions will help improve health outcomes for all and reduce inequalities.

Biosimilar medicines have already made a remarkable contribution to widening patient access to better, more consistent treatments that reduce health inequalities while also providing significant NHS savings. With so many biologics losing their exclusivity up to 2028, the next VPAS scheme should encourage a healthy biosimilar medicine market and strengthen the levers to drive uptake across the health service. Similarly, the use of branded generic treatments has the potential to help more people manage chronic conditions, leading to better outcomes and less strain on the NHS.

36. https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products

SUMMARY

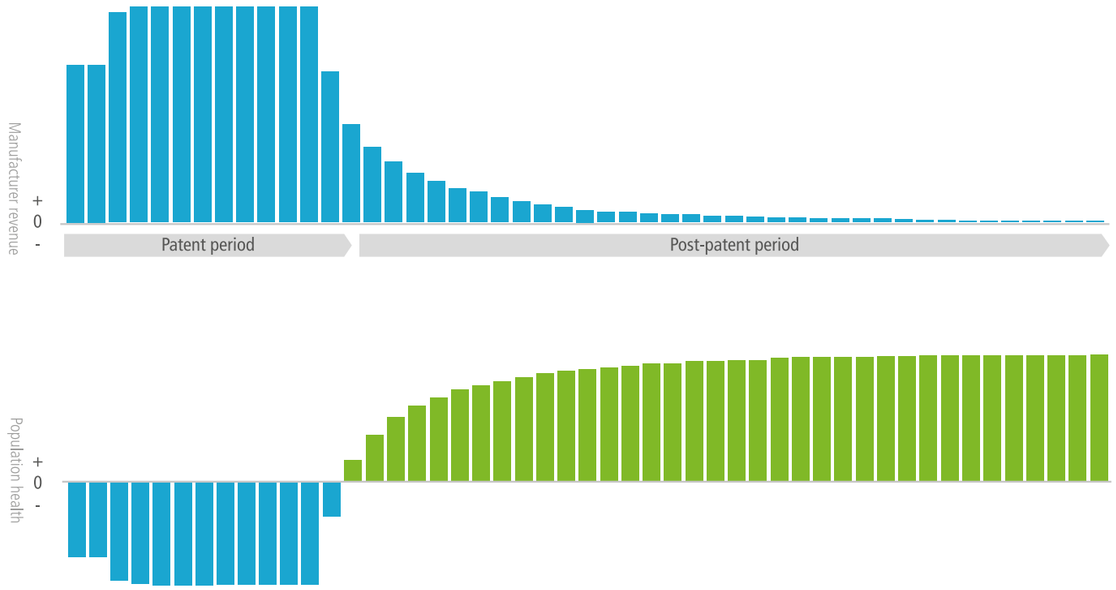
Closing remarks and summary

In June 2023, three very respected health policy institutions, the LSE, the University of York and the London School of Hygiene and Tropical Medicine, published a report entitled: "*Promoting population health through pharmaceutical policy: The role of the UK Voluntary Scheme*".

The report set 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 as the new medicine's benefits are outweighed by the impact on other NHS services. After the patent period, NHS patients start receiving significant net benefits from the availability of cheaper generic or biosimilar versions of the medicine*".

The 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.

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



The participants in the task and finish groups concluded that there was a balance to be struck in ensuring that the generic and biosimilar industry contributes to supporting the sustainability of the NHS financial position, while recognising the benefits of these medicines to the health service of billions of pounds of savings and widened patient access.

It was further recognised that if a high VPAS rate continues for the next five years, particularly where competition is already working for the NHS to deliver medicines at very significant discounts, then it may discourage some companies from supplying the UK. As the OHE and LSE report projects, this may paradoxically lead to far higher prices paid by the NHS. Indeed, it would mean an average-sized ICB paying £37m more each year for the next five years. This could also exacerbate supply issues, with fewer suppliers and reduced volumes allocated to the UK, as well as limit the time available for NHS colleagues and community pharmacists to concentrate on other healthcare priorities.

Rather, the design of VPAS should encourage the supply of medicines to enable widened access to treatments so that more patients can be treated with the right medicine earlier and for less. As such, we recommend that the next VPAS (and the statutory scheme for branded medicines) builds in the following measures to ensure that the financial and patient-focused objectives of ICBs can be best fulfilled:

Differentiate between patent-protected medicines, where competition doesn't exist, and off-patent medicines, where competition very often does exist.

Introduce a lower, fixed rate for off-patent medicines where competition exists, or require a minimum rate of discount compared to when the product was patent-protected.

If this differentiation based on competition cannot be reliably implemented, introduce a progressive or tiered VPAS rebate rate so that companies with higher NHS sales make a larger proportionate contribution.

Increase the exemption threshold for low-cost presentations to protect the supply of medicines least capable of subsuming a rebate on sales.

If a voluntary agreement can be agreed that moves beyond setting a pricing framework, we support targets, levers and incentives across the NHS system that utilise the prescribing of biosimilars, thereby widening access and bringing down costs.

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