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OHE

A consulting report: *The impact on the NHS of the VPAS levy on branded generics and biosimilars*

October 2022



The study

- The Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), was commissioned by the British Generic Manufacturers Association (BGMA) in January 2022 to carry out a study to:
 - Analyse and model what will happen to the supply of branded generics and biosimilar medicines in the UK for the duration of the next Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) agreement (scheme explained overleaf).
 - Build a model based on the responses of BGMA members to a detailed survey and analyse the markets for branded generics and biosimilars up to 2028, including originator products scheduled to lose their exclusivity in that time.
 - Carry out a literature review into branded generics and biosimilars to support the analyses, assumptions and modelling in this study.
- This document assembles the key pieces of analyses and the conclusions from the report. The full study report is available on request.



What is VPAS?

Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)

- *The Voluntary Scheme is an agreement between the Department of Health and Social Care (DHSC), NHS England and the Association of the British Pharmaceutical Industry (ABPI) on getting the best value and most effective medicines into use more quickly. * It has two parts:*
- *“First, it sets out a range of measures for England, unless otherwise stated, to support innovation and better patient outcomes through improved access to the most transformative and cost-effective medicines; and*
- *Second, it sets out a UK-wide affordability mechanism under which Scheme Members make a financial contribution to the Department for sales of Branded Health Service Medicines above the agreed allowable growth rate.” ***
- The VPAS requires companies selling branded medicines to the NHS of a value above £5m to pay a percentage of these sales back to the DHSC (a “rebate”) whenever the branded market sales grow higher than the allowed rate, set for the period of the current VPAS at 2% per annum.
- Companies pay an amount in proportion to their branded net sales to the NHS. The payment percentage (“rebate rate”) in 2022 is 15% of companies’ sales of branded medicines to the NHS and is currently projected to increase to 23.7% in 2023. ***
- 2023 is the final year of the present five-year VPAS. The next VPAS will be from 2024 to 2028 inclusive, subject to negotiations. Despite branded generics and biosimilars falling within the scope of the VPAS, BGMA was not an official negotiating party to the current scheme. BGMA’s status as a formal negotiating party to the 2024-28 scheme is not yet clear.

* <https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access>

** https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf

*** <https://www.gov.uk/government/consultations/update-to-the-statutory-scheme-to-control-the-costs-of-branded-health-service-medicines/outcome/proposed-changes-to-the-statutory-scheme-to-control-the-costs-of-branded-health-service-medicines-consultation-response>



What is the statutory scheme that shadows VPAS?

Statutory scheme

- A statutory scheme for branded medicines exists for companies not joining the VPAS. It has an associated higher rebate rate to incentivise joining the VPAS.
- *“The statutory scheme acts alongside the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) to limit the growth in costs of branded health service medicines. This is done to safeguard the financial position of the NHS, while taking into account the need for medicinal products to be available for the health service on reasonable terms, the costs of research and development, and impacts on the UK life sciences industry, wider economy, and patients. Companies that have opted not to join the current VPAS, a non-contractual agreement, which replaced the previous Pharmaceutical Price Regulation Scheme (PPRS 2014) between the Government and industry, are members of the statutory scheme. The 2019 VPAS began on 1 January 2019 and will run until the end of 2023.” **



*Department of Health and Social Care, 2018. Voluntary scheme for branded medicines pricing and access. [Policy paper] Available at: <https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access> [Accessed 28 Jul. 2022].

What are branded generics and biosimilars?

A branded generic medicine:

- A generic may be branded for two reasons. The first is where it is required by the regulator (the MHRA) because it recommends that a patient should be maintained on a single manufacturer's brand. Prescribers are free to make their own decision as to whether to require a pharmacist to dispense a particular brand or whether to enable interchangeability and allow the pharmacist to dispense a version of their choosing.
- 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.

A biosimilar medicine:

- According to NHS England, *“Biological medicines are derived from living cells or organisms and consist of large, highly complex molecular entities, which may be difficult to characterise. Due to the variability of the biological system and the manufacturing process, biological medicines may show a certain degree of variation, even between batches of the same product.*
- *“A biosimilar medicine is a biological medicine that is developed to be highly similar and clinically equivalent to an existing medicine. A biosimilar contains a version of an active substance of an already approved biological medicine, which is referred to as the reference medicine.*
- *“Similarity to the reference medicine must be established based on a comprehensive biosimilar comparability exercise, such that they do not have any meaningful clinical differences from the reference medicine in terms of quality, biological activity, safety, efficacy and immunogenicity.” **



* <https://www.england.nhs.uk/wp-content/uploads/2019/05/what-is-a-biosimilar-medicine-guide-v2.pdf>

Foreword: Professor Alistair McGuire, LSE

- The simulation model results strongly suggest that the VPAS payment percentage will have a detrimental impact on branded generics and biosimilars markets up to 2028 over the study period, with competition levels falling and subsequent changes in price and volume levels reacting to this lowered competition.
- The mechanism through which this occurs is primarily through incentives for firms to withdraw from the market, lowering competition and raising prices over time.
- Overall, the simulations indicate that the increase in government revenue from raising the VPAS rebate rate may be more than offset by higher prices and costs for the NHS.
- Moreover, if the reduced competition becomes a reality, this will raise issues of continuity of supply in these markets.
- The results show higher NHS costs for branded generics, borne through rising reimbursement prices and, to a larger extent, reductions in discounts to the NHS locally. For the existing biosimilars market, there is an impact on NHS costs at the higher rebate levels, while the impact of even a rebate of 5% for launches of new biosimilars following the originator's loss of exclusivity would dampen biosimilar competition and limit NHS savings. The scenarios are motivated by emerging competition levels, and concerns may remain about the effect of the VPAS rebate on the product development incentives.
- These conclusions arise from an extensive simulation exercise (explained overleaf), partly based on market suppliers' expected responses. Clearly, these expected responses should be considered in any deliberations over changes to the rebate rate as these will determine future levels of competition and price and volume changes.



Foreword: Professor Alistair McGuire, LSE

- Covering branded generics (branded as a regulatory requirement and by choice) and biosimilars, extensive simulation modelling has been undertaken of the likely impact on sales revenue of the VPAS as it rolls out over the period 2023-28. This covers the last year of the current VPAS and the next VPAS, spanning 2024-28 inclusive.
- The simulations are built around past experiences, assumptions and potential reactions to variations in the VPAS rebate scheme and the likely impact these will have on competition levels within the various markets, through the expected price and volume shifts predicted by the scheme.
- The simulation model is applied to the following markets based on the existing valuation within each market in 2022: brands dispensed as generics (often regulatory branded generics), brands dispensed as brands (often generics branded by choice), and biosimilars. The VPAS rebate is then applied with various scenarios for different rebate rates.
- The impact of these various rebate rates on each of the markets and on market competition is then assessed and the subsequent price adjustments are outlined to determine the resultant valuations for each of the markets for each year over the study period.

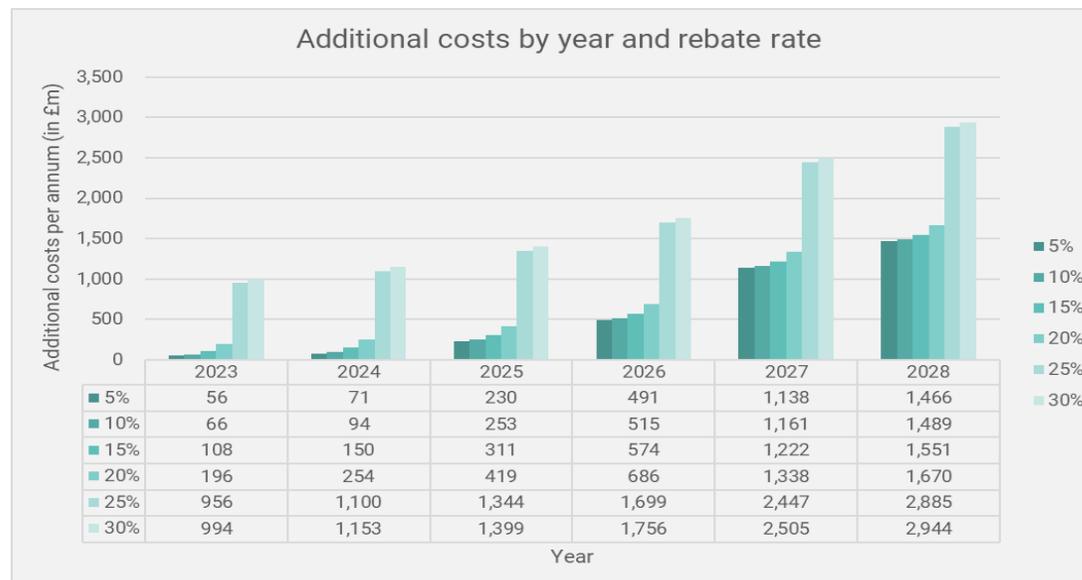


Executive summary

- The main aim of this report is to create a market tool to track the operation of the branded generic and biosimilar medicines markets and simulate prices and volumes. Moreover, it measures the impact of potential scenarios on the market and the NHS and suggests potential policy recommendations.
- The net impact is measured in terms of additional costs for the NHS over the life of the next VPAS for various rebate rates. Taking into account the five-year income to the Government from the VPAS rebate, the net cost to the NHS of charging a levy on branded generics and biosimilars spanning the lifetime of the next scheme (2024-28) ranges from £3.07bn for a rebate of 5% to £7.81bn for a rebate of 30% (page 11). This is based on subtracting the estimated VPAS Government revenue in applying a rebate to branded generics and biosimilars (page 10) from the projected additional NHS costs in applying a sales levy to those categories of medicine (page 9).
- The simulation shows that while the VPAS rebate does raise revenue for the Government, this is potentially more than offset by the aggregate effect of an increase in market product prices, as competition in these markets is stymied and the markets are increasingly characterised by lower volumes (reducing generic and biosimilars market access) and higher prices.
- These higher NHS costs or/and lost NHS savings comprise three components:
 1. Increases in reimbursement prices stemming from higher supplier selling costs.
 2. Reductions in discounts offered to clinical commissioning groups, meaning less local NHS savings.
 3. Higher secondary care tender prices.
- Finally, and in step with the above findings, the survey of BGMA members suggests that if the VPAS rebate covering years 2024-28 is between 0 and 5%, then this will encourage suppliers to market more branded generics and biosimilars in the UK.

Summary of impact on NHS costs by rebate level

- The chart shows additional costs associated with various rebate rates up to the end of the next VPAS. The model shows the impact of reduced competition leading to higher prices paid by the NHS as the rebate rate increases.
- The table shows the net impact in terms of additional costs for the NHS, compared with the case that no levy was in place for branded generics and biosimilars, measured over the next VPAS for various rebate rates.
- The net impact ranges from £3.396bn for a rebate of 5% to £9.757bn for a rebate of 30%.



	Impact over life of VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	33,376	33,376	33,376	33,376	33,376	33,376	33,376
Revised (adjusted)	33,376	29,980	29,862	29,569	29,009	23,901	23,619
Net impact (additional cost to the NHS)	0	3,396	3,512	3,808	4,367	9,475	9,757

Note: Chart values are rounded.

Note: In the analyses, we have accounted for inflation.

Estimates of rebates received from biosimilars and branded generics markets

- Using historical rates of rebate paid associated with levels of eligible spend (2019-21), we have estimated the amount of rebate associated with the supply of branded generics and biosimilars.
- This has been adjusted for inflation for 2024-28 and estimated for various rebate rates.

	Estimate of rebate paid (rounded to nearest £m)						
Rebate rate	1%	5%	10%	15%	20%	25%	30%
2024	12	59	117	176	235	294	352
2025	12	62	123	185	247	308	370
2026	13	65	129	194	259	324	388
2027	14	68	136	204	272	340	408
2028	14	71	143	214	286	357	428

Total projected additional NHS costs vs estimated Government income from VPAS rebate

Projected extra NHS costs from applying a range of rebate levels to branded generics and biosimilars vs estimated Government rebate income (rounded to nearest £m)												
Rebate rate	5%		10%		15%		20%		25%		30%	
	Extra NHS costs	VPAS rebate Gov't income	Extra NHS costs	VPAS rebate Gov't income	Extra NHS costs	VPAS rebate Gov't income	Extra NHS costs	VPAS rebate Gov't income	Extra NHS costs	VPAS rebate Gov't income	Extra NHS costs	VPAS rebate Gov't income
2024	71	59	94	117	150	176	254	235	1,100	294	1,153	352
2025	230	62	253	123	311	185	419	247	1,344	308	1,399	370
2026	491	65	515	129	574	194	686	259	1,699	324	1,756	388
2027	1,138	68	1,161	136	1,222	204	1,338	272	2,447	340	2,505	408
2028	1,466	71	1,489	143	1,551	214	1,670	286	2,885	357	2,944	428
Total 2024-28 costs and income	3,396	325	3,512	648	3,808	973	4,367	1,299	9,475	1,623	9,757	1,946
Total 2024-28 costs vs income	-3,071		-2,864		-2,835		-3,068		-7,852		-7,811	

Note: This slide brings together the data from the graph on page 9 and the table on page 10. It compares the extra NHS costs incurred as a result of a rebate, across all rebate levels and years covering the next VPAS scheme (page 9), with the income that the Government is estimated to receive across each rebate level and year in applying a rebate to branded generics and biosimilars (page 10).

Projected sales for three markets

1

Primary care – brands dispensed as generics (BDAG)

1. Brands dispensed as generics (brand equalised)
2. Generics in markets with brands dispensed as brands

* These products will typically, but not always, be required to be branded for regulatory reasons. These brands are often prescribed by an international nonproprietary name (INN) to enable competition at the dispensing level.

2

Primary care – brands dispensed as brands

1. Brands dispensed as brands
2. Brands dispensed as brands – NHS discounted

* These products will typically, but not always, have been branded by choice by suppliers and consciously prescribed by prescribers, therefore requiring dispensing of the chosen brand.

3

Secondary care – biosimilars

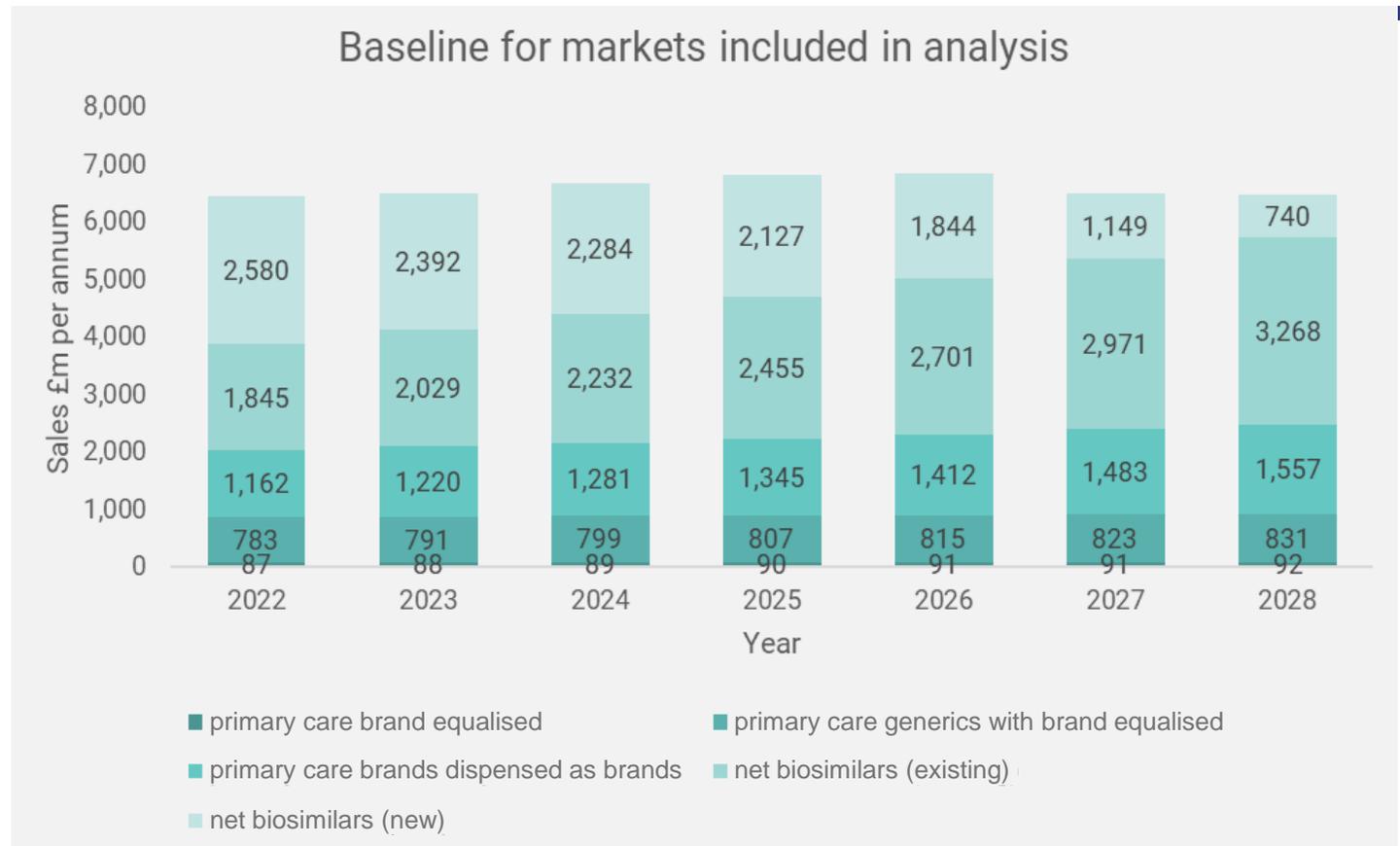
1. Medicines procured through competitive NHS-run tenders
2. Medicines facing biosimilar competition in 2023-28

* Biosimilars have typically, but not always, been supplied to patients in a hospital setting.

- For each market, we present a summary table with the projections for reimbursement prices and volumes and a diagram of the impact.
- Projections for prices and volumes are based on our forecast exercise with reasonable assumptions provided for sales up to and including 2028.

Sales forecast for branded generic and biosimilar medicines

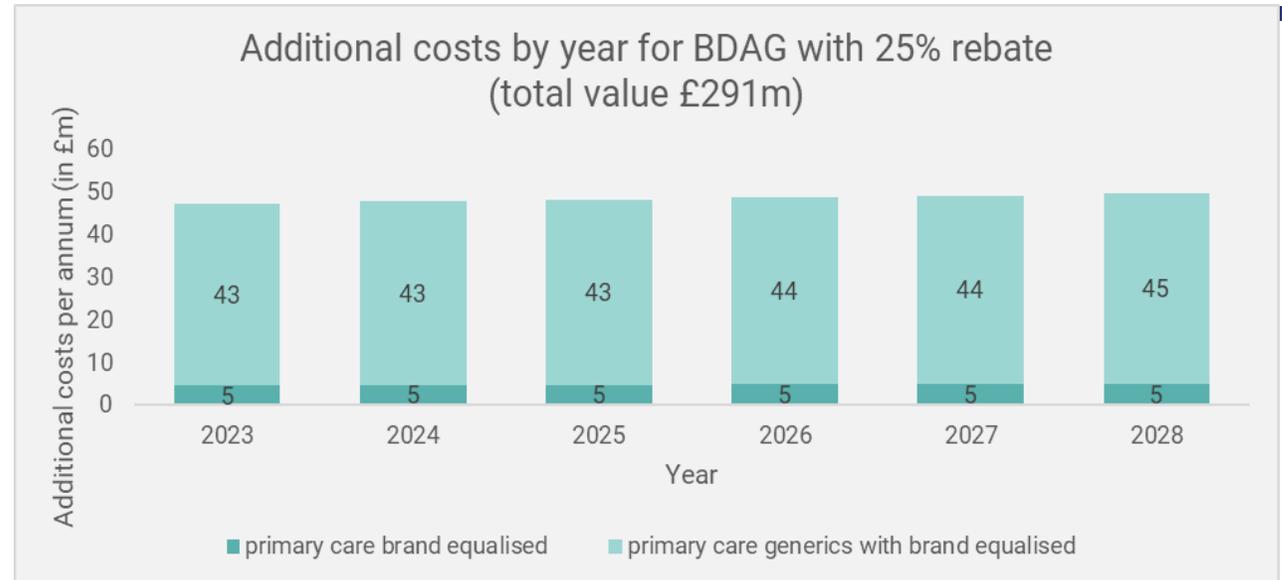
- Using NHSBSA and IQVIA data, we have created an estimate for the various branded generic and biosimilars markets for the next VPAS.
- This baseline does not include any adjustments due to market reactions.
- Each market segment has been treated separately, enabling the market tool to assess the impact of rebates in each segment.
- Both primary care and secondary care markets are analysed.



Note: Chart values are rounded.

1. Brands dispensed as generics

- The chart shows the impact of applying an average rebate of 25% over the next VPAS.
- The table shows the net impact of additional costs for the NHS over the next VPAS for various rebate rates.
- The additional costs are a result of higher reimbursement prices, which can flow through from suppliers charging higher actual selling prices.



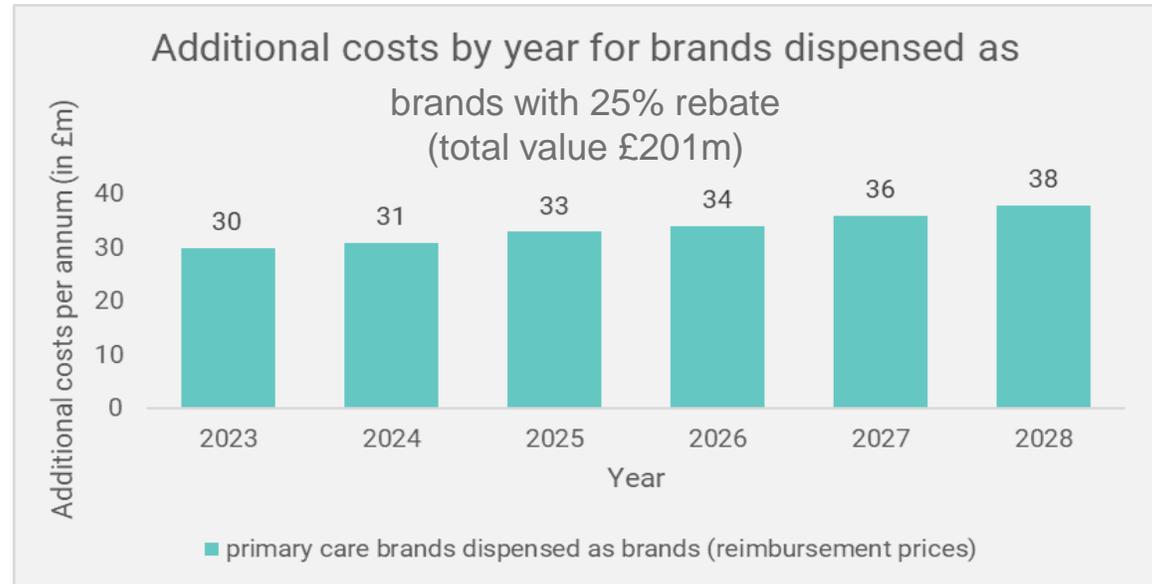
	Impact over VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	4,527	4,527	4,527	4,527	4,527	4,527	4,527
Revised (adjusted)	4,527	4,437	4,430	4,392	4,312	4,283	4,283
Net impact (additional cost to the NHS)	0	90	97	135	215	244	244

Note: In this and subsequent slides, we have graphed out using a 25% VPAS rebate as an indicator, since it is the nearest value to the projected 2023 rate (23.7%), to show how the costs fall across years up to 2028.

Note: Chart values are rounded.

2. Brands dispensed as brands: (a) reimbursement prices

- The chart shows the impact of applying an average rebate of 25% over the next VPAS.
- The table shows the net impact of additional costs on reimbursement prices for the NHS over the next VPAS for various rebate rates.

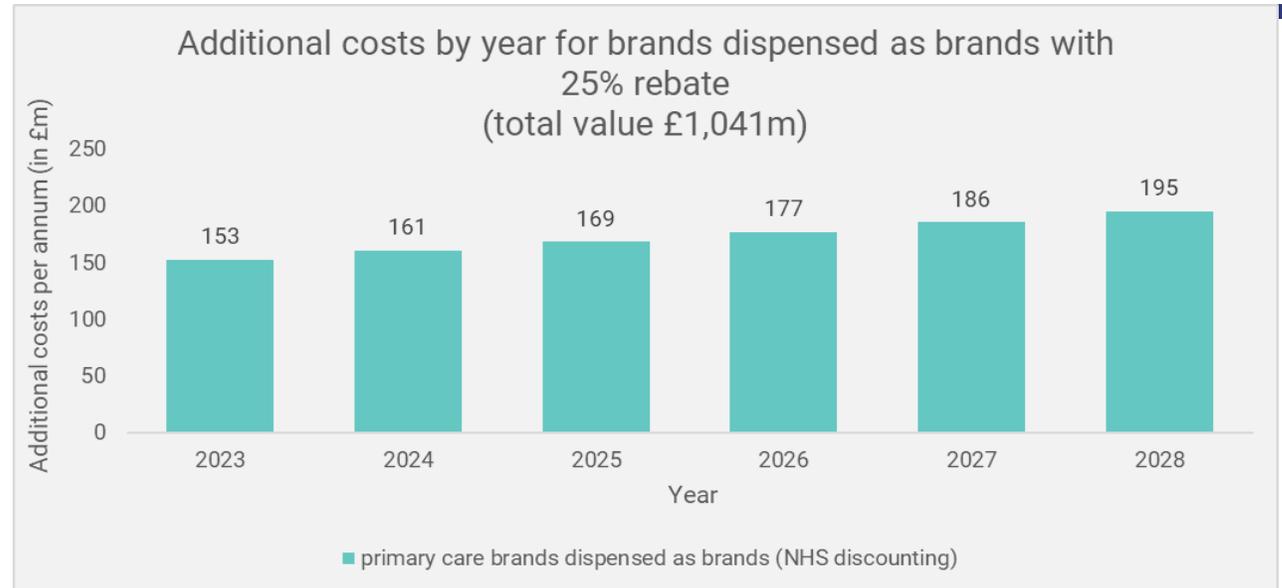


	Impact over VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	7,079	7,079	7,079	7,079	7,079	7,079	7,079
Revised (adjusted)	7,079	7,079	7,079	7,079	7,035	6,907	6,709
Net impact (additional cost to the NHS)	0	0	0	0	44	172	370

Note: Chart values are rounded.

2. Brands dispensed as brands: (b) NHS discounts

- The chart shows the impact of applying an average rebate of 25% over the next VPAS.
- The table shows the net impact of additional costs for the NHS over the next VPAS for various rebate rates. These are savings lost locally through lower discounts received by the NHS.

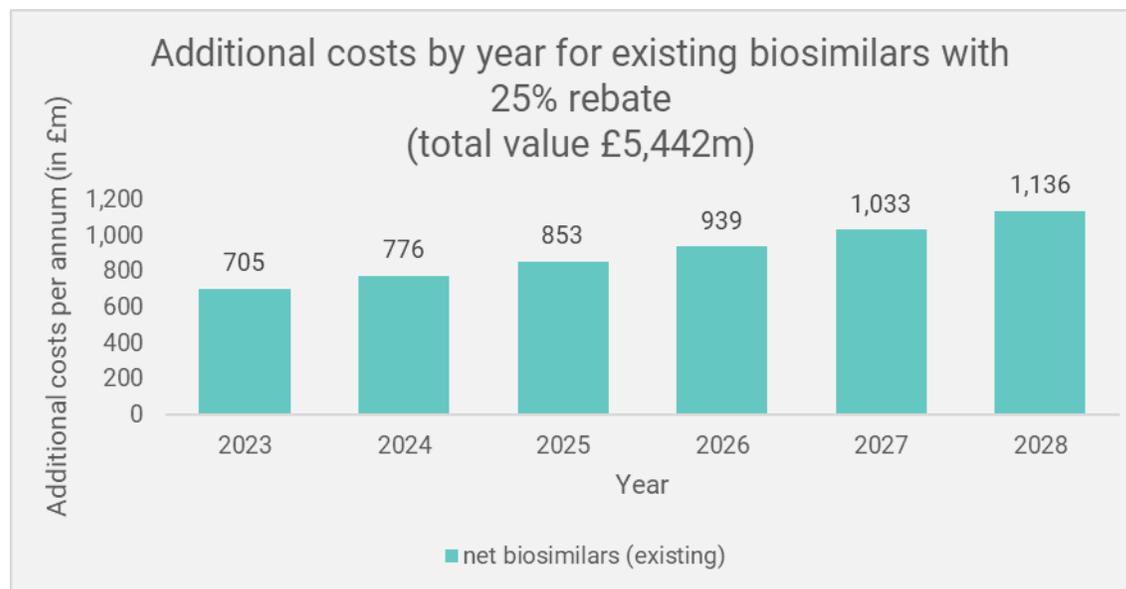


	Impact over VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	7,079	7,079	7,079	7,079	7,079	7,079	7,079
Revised (adjusted)	7,079	6,878	6,850	6,678	6,323	6,191	6,191
Net impact (additional cost to the NHS)	0	201	229	401	756	888	888

Note: Chart values are rounded.

3. (a) Existing biosimilars

- The chart shows the impact of applying an average rebate of 25% over the next VPAS on biosimilars currently on the market.
- The table shows the net impact of additional costs for the NHS over the next VPAS for various rebate rates. The additional NHS costs are in the form of higher secondary care tender prices offered.



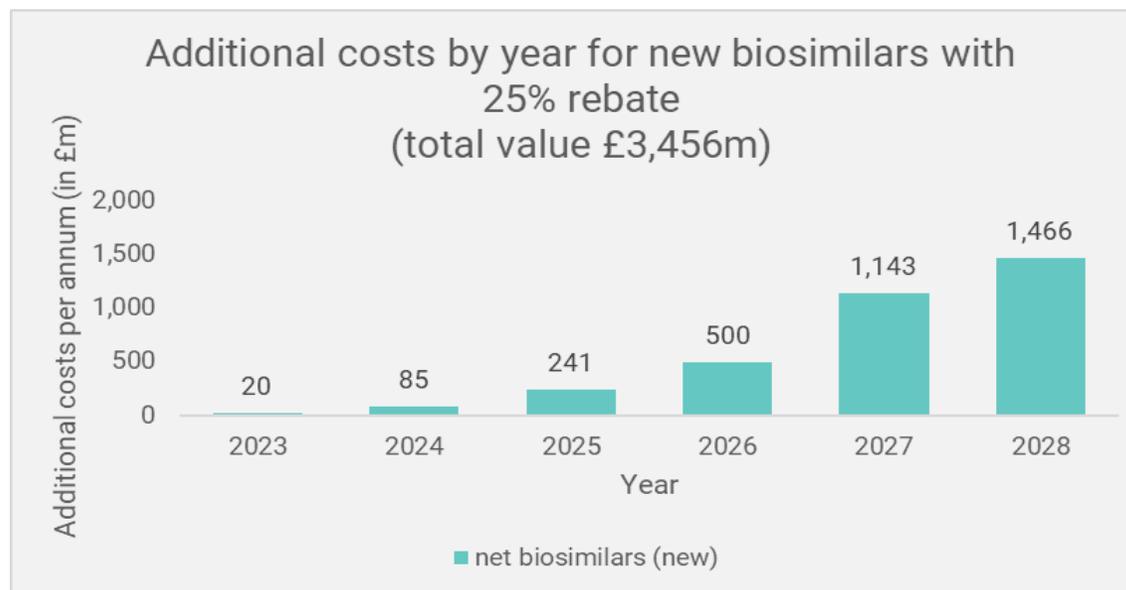
	Impact over VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	13,626	13,626	13,626	13,626	13,626	13,626	13,626
Revised (adjusted)	13,626	13,626	13,626	13,626	13,626	8,890	8,890
Net impact (additional cost to the NHS)	0	0	0	0	0	4,736	4,736

Note: There was less participation in the survey by companies selling biosimilars than by those marketing branded generics.

Note: Chart values are rounded.

3. (b) New biosimilars

- The chart shows the impact of applying an average rebate of 25% over the next VPAS on biosimilars where the originator product will lose its exclusivity up to and including 2028.
- The table shows the net impact of additional costs for the NHS over the next VPAS for various rebate rates.
- Higher NHS costs occur in the form of higher secondary care tender prices paid by NHS trusts.



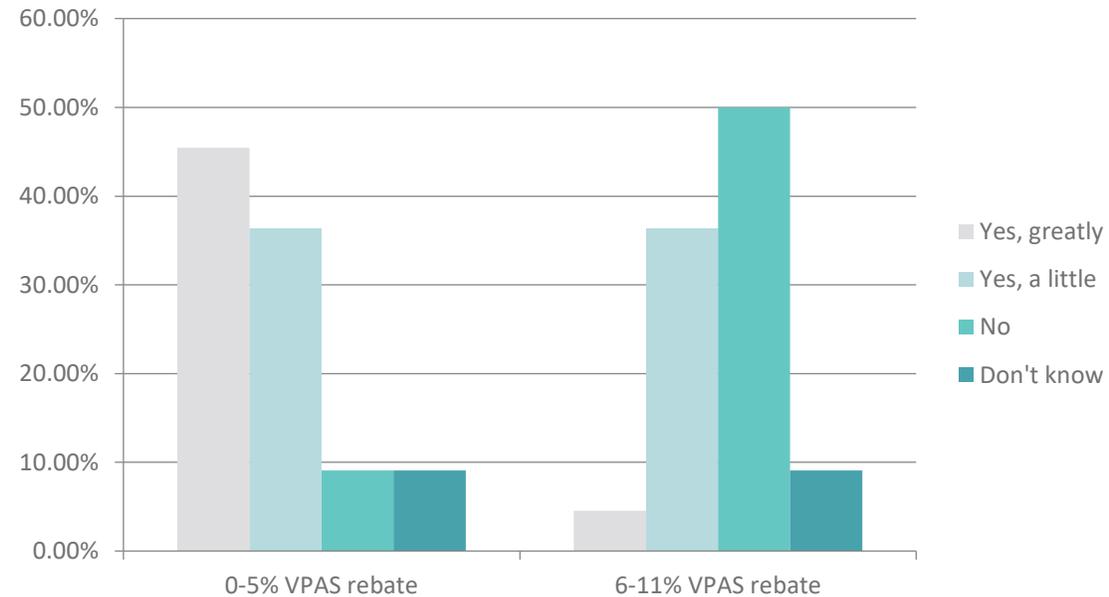
	Impact over VPAS (2024-28) by rebate rate (£m)						
	0%	5%	10%	15%	20%	25%	30%
Baseline (unadjusted)	8,144	8,144	8,144	8,144	8,144	8,144	8,144
Revised (adjusted)	8,144	5,039	4,957	4,874	4,791	4,708	4,626
Net impact (additional cost to the NHS)	0	3,105	3,187	3,270	3,353	3,436	3,518

Note: Chart values are rounded.

A VPAS rebate of 0-5% would encourage 82% of respondents to expand their portfolio of branded generics

A VPAS rebate of 6-11% would not encourage 50% of respondents to expand their portfolio of branded generics.

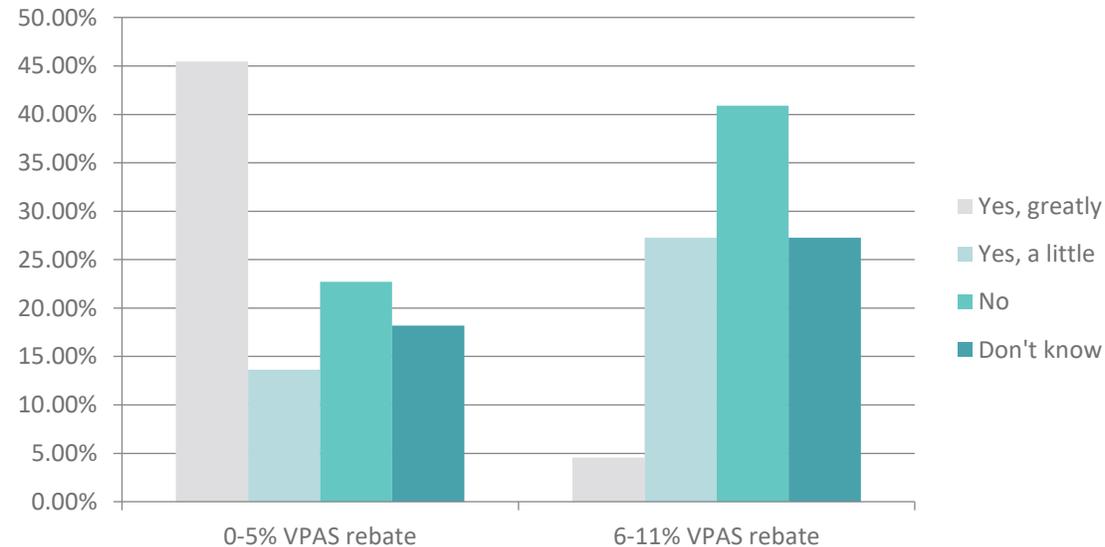
Would rebate rates in the following ranges over the entire VPAS (2024-28) encourage you to expand your portfolio of branded generics?



A VPAS rebate of 0-5% would encourage 59% of respondents to expand their portfolio of biosimilars

A VPAS rebate of 6-11% would not encourage 41% of respondents to expand their portfolio of biosimilars.

Would rebate rates in the following ranges over the entire VPAS (2024-28) encourage you to expand your portfolio of biosimilars?



Policy implications

- Mechanisms that deliver savings to the Government by increasing rebate rates will **reduce competition** and ultimately **increase prices** for the NHS.
- According to the calculations:
 - Once we account for the markets' reactions to increased rebate rates (revised estimates), the losses are larger than those when we do not (baseline-unadjusted).
 - The increased government revenue from raising the rebate rate over the VPAS is more than offset by higher prices and costs for the NHS and has other longer-term implications due to continuity of supply.
- Overall, we expect the NHS to face reduced stability of prices if the rebate rate is increased.
- **The effects of the VPAS are very likely to be compounded by the increased overall market costs due to inflation, which will amplify the negative consequences on competition and prices faced by the NHS.**





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