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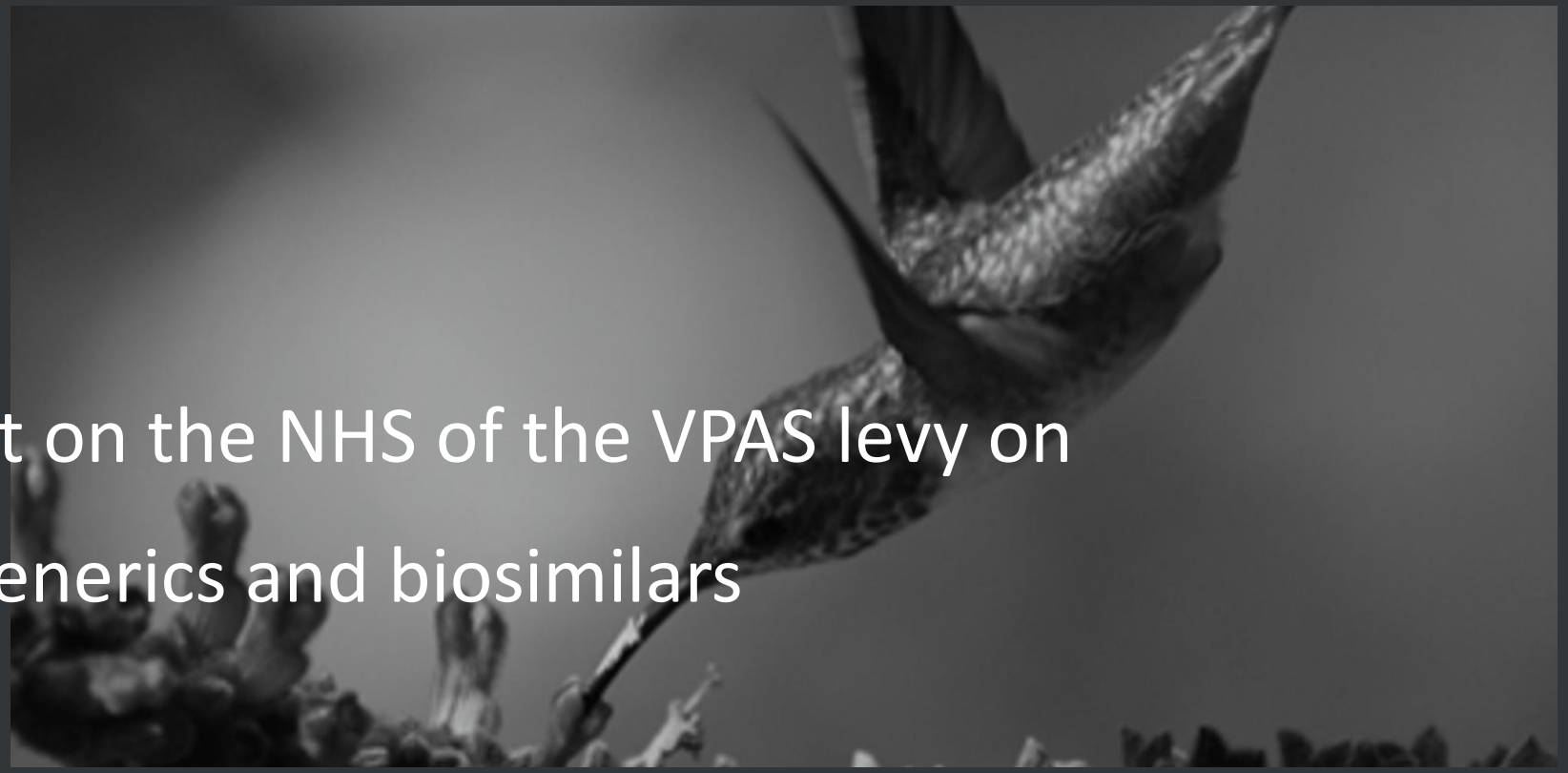

The impact on the NHS of the VPAS levy on branded generics and biosimilars

BRITISH GENERIC MANUFACTURERS ASSOCIATION

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Aim of this report

To

1. characterise the market of branded generics and biosimilars by identifying relevant publications.
2. report on the answers to the BGMA member survey on commercial information and hypothetical scenarios supporting the assumptions and key parameters used in the development of a market tracking tool and simulations.
3. create a market tool to track the operation of generics and biosimilars markets and simulate prices and volumes.
4. measure the impact of potential scenarios on the market and the NHS and suggest potential policy recommendations.

Content overview

Introduction

Foreword: Professor Alistair McGuire, LSE

- The impact of the changed pharmaceutical pricing and reimbursement regulation has been modelled against a background of existing literature that shows regulation in this market can have indirect consequences.
- Extensive simulation modelling is undertaken of the likely impact on sales revenue of the VPAS as it rolls out across the generic brand equalised market, the branded pharmaceutical market and the biosimilar market over the period 2023-2028.
- The simulations are built around past experiences, assumptions and potential reactions to variations in the VPAS rebate scheme and the likely impact this will have on competition levels within the various markets, through the expected price and volume shifts predicated by the scheme.
- The simulation model is applied to each of the markets based on the existing market valuation seen within each market in 2022, the VPAS rebate is then applied with various scenarios outlining different levels of rebate.
- The impact of these various levels of rebate on each of the markets on market competition is then assessed and the subsequent price adjustments outlined to determine the resultant market valuations for each of the individual markets for each year over the study period.

Foreword: Professor Alistair McGuire, LSE

- The simulation model results strongly suggest that the VPAS regulation will have a detrimental impact on the generic brand equalised market and the branded pharmaceutical market over the study period with competition levels falling, 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.

Foreword: Professor Alistair McGuire, LSE

- Overall, for the generic brand equalised market and the branded pharmaceutical markets, the simulations report that the increased government revenue from raising the VPAS rebate may be more than offset by higher prices and costs for the NHS.
- Moreover, if the reduced competition becomes a reality, this raises issues of continuity of supply in these markets.
- For the existing biosimilar market and under some scenarios, the impact appears not to be so harsh, while the impact of even a 5% rebate for new biosimilar launches following originator loss of exclusivity would dampen biosimilar competition and limit NHS savings. Still, the scenarios are motivated by emerging competition levels, and there may remain concerns that the VPAS levy may have on the product development incentives.
- These conclusions arise from an extensive simulation exercise, partly based on market suppliers' expected responses. Clearly, these expected responses should be considered in any deliberations over changes to the rebate levy as these will determine the levels of competition and price and volume changes going forward.

Executive Summary

- The main aim of this report is to create a market tool to track the operation of generics and biosimilars 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 in terms of additional costs for the NHS for the life of the next VPAS for various rebate rates ranges from £3.4bn for a rebate rate of 5% to £9.47- £9.76bn for 25%-30%.
- This simulation shows that while the VPAS rebate level does raise revenue for the government, based on estimates of rebates received from branded generics and biosimilar markets, 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 characterized by lower volumes (reducing general market access) and higher prices. As an example, even with the revenue from the VPAS rebate, a 25% levy would cost the NHS nearly £8bn extra over the lifetime of the next VPAS (2024-28). And while a 5% levy may initially bring in nearly as much as the projected lost savings at the start of the next VPAS period, the lost savings from 2025 become far more than the revenue raised from a 5% levy.
- These higher NHS costs or/and lost NHS savings comprise of three things:

1. Increases in reimbursement prices stemming from higher medicines costs.
2. Reductions in discounts offered to CCGs, meaning less local NHS savings.
3. Higher secondary care tender prices.

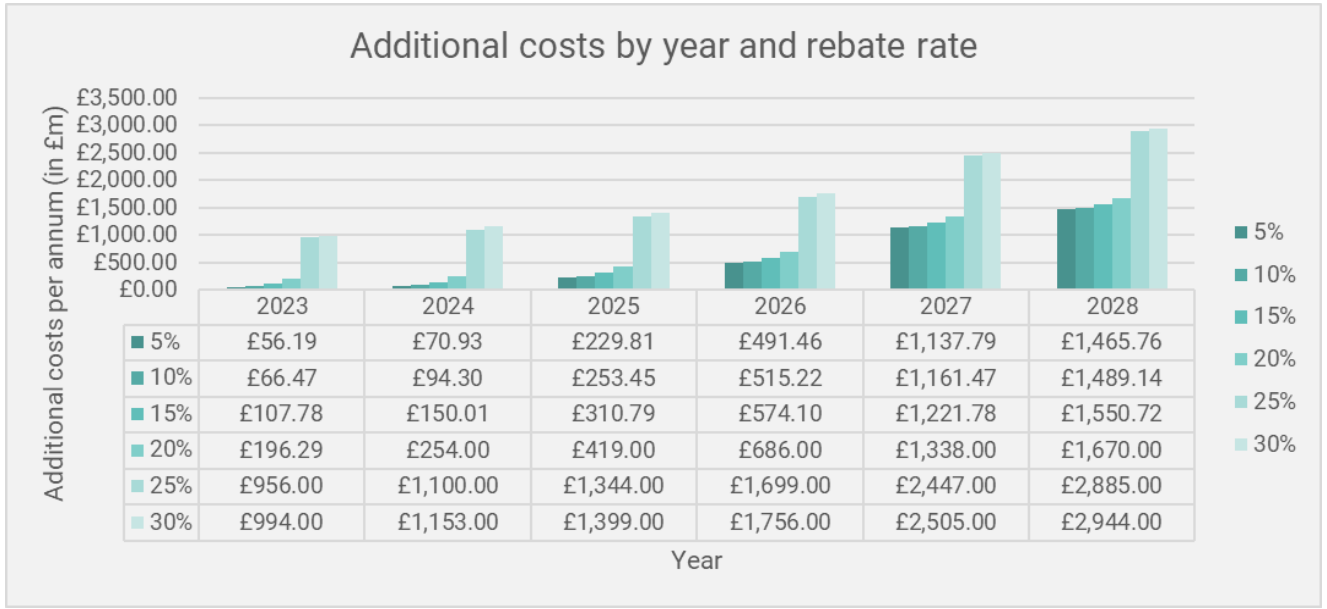
- Finally, the survey documents a prevalent expectation amongst members that market product costs* will rise by 17% over the next 5 years. Moreover, that this is accompanied by existing price discounts, varying by 10%-75% across the branded generic and biosimilar markets, which puts further pressure on producer revenues.

Note: In this analysis when we refer to brands dispensed as generics is the case "where a branded medicine is dispensed against a generic Rx and there is a generic alternative available. In these cases the NHS will reimburse the generic price, not the brand". Brand dispensed as brands is the case "where either the brand name is stated on the Rx and has to be dispensed or a generic alternative is not available and if written generically a brand will be dispensed".

**Market costs include costs that are not only at the discretion of the manufacturer. These costs may include marketing costs, including costs that promote access or services that support the product usage (e.g., a homecare package).*

Summary of impact by rebate level

- The chart shows additional costs associated with various rebate rates for the life of the next VPAS, as a result of less competition and fewer launches.
- The table shows the net impact in terms of additional costs for the NHS for the life of the next VPAS for various rebate rates. Ranging from £3.4bn for a rebate rate of 5% to £9.47- £9.76bn for 25%-30%.



	2023	2024	2025	2026	2027	2028
5%	£56.19	£70.93	£229.81	£491.46	£1,137.79	£1,465.76
10%	£66.47	£94.30	£253.45	£515.22	£1,161.47	£1,489.14
15%	£107.78	£150.01	£310.79	£574.10	£1,221.78	£1,550.72
20%	£196.29	£254.00	£419.00	£686.00	£1,338.00	£1,670.00
25%	£956.00	£1,100.00	£1,344.00	£1,699.00	£2,447.00	£2,885.00
30%	£994.00	£1,153.00	£1,399.00	£1,756.00	£2,505.00	£2,944.00

	Impact over life of VPAS (2024-2028) 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	£3,514	£3,807	£4,367	£9,475	£9,757

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

Market Tracking Tool, Policy Simulations and Solutions

Summary of impact by rebate level

- The chart shows additional costs associated with various rebate rates for the life of the next VPAS, as a result of less competition and fewer launches.
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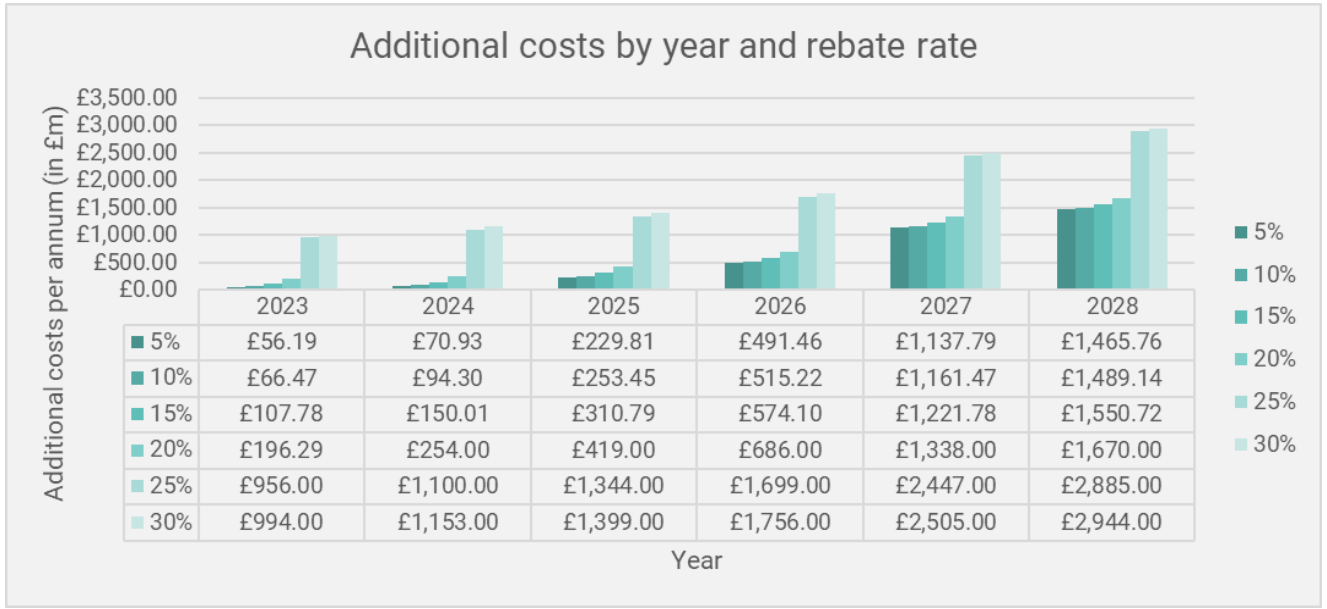

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Note: In the analyses, we have accounted for inflation.

Estimates of rebates received from branded generics and biosimilar markets.

- Using historic rates of rebate paid associated with levels of eligible spend (2019-2021) we have estimated the amount of rebate associated with branded generics and biosimilars.
- This has been inflated for 2024 - 2028 and estimated for various rates of rebate.

	Estimate of rebate paid (£m)						
Rebate rate	1%	5%	10%	15%	20%	25%	30%
2024	£11.74	£58.72	£117.44	£176.16	£234.88	£293.61	£352.33
2025	£12.33	£61.66	£123.31	£184.97	£246.63	£308.29	£369.94
2026	£12.95	£64.74	£129.48	£194.22	£258.96	£323.70	£388.44
2027	£13.60	£67.98	£135.95	£203.93	£271.91	£339.89	£407.86
2028	£14.28	£71.38	£142.75	£214.13	£285.50	£356.88	£428.26

We present 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*.

* Often but not always, these products will typically be products required to be branded for regulatory reasons, but which nonetheless, prescribers have prescribed by INN to enable competition at dispensing level.

2

Primary care – brands dispensed as brands.

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

* Often but not always, these will be products where suppliers have branded by choice, and which prescribers would consciously prescribe, therefore requiring the chosen brand's dispensing.

3

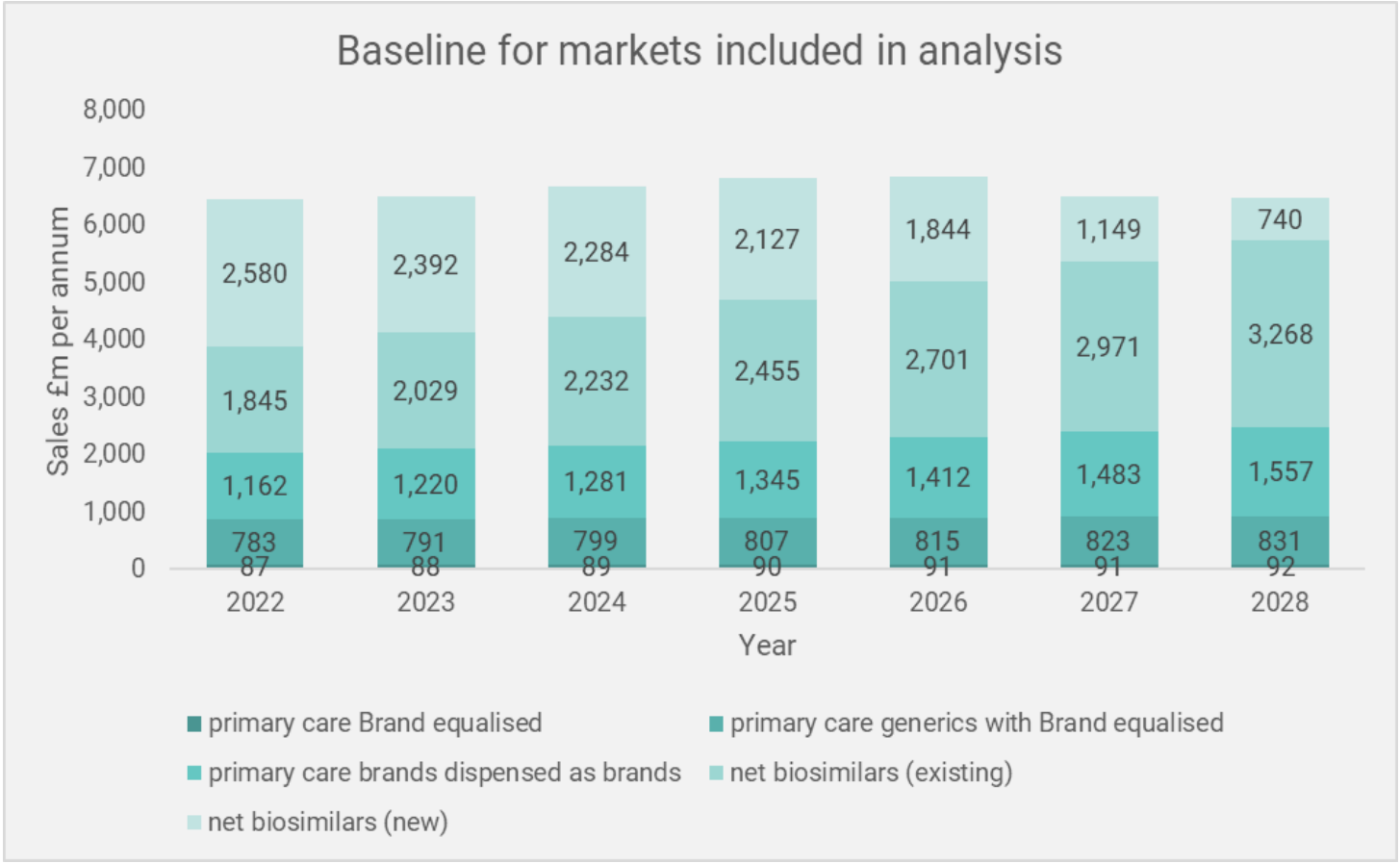
Secondary care – biosimilars

1. Medicines which are procured through competitive NHS-run tenders.
2. Medicines facing biosimilar competition 2022-2028.

- For each market, we present the **mechanism of effect**; the **assumptions** applied; a **summary table** with the projections for reimbursement prices and volumes; the **effect mechanism** populated with our estimates; and a **diagram of the impact**.
- Projections for prices and volumes are based on our forecast exercise - provides reasonable assumptions for sales in the next VPAS period – 2024-2028.

Forecast

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



Note: Chart values are rounded.

1

Primary care – brands dispensed as generics (BDAG).

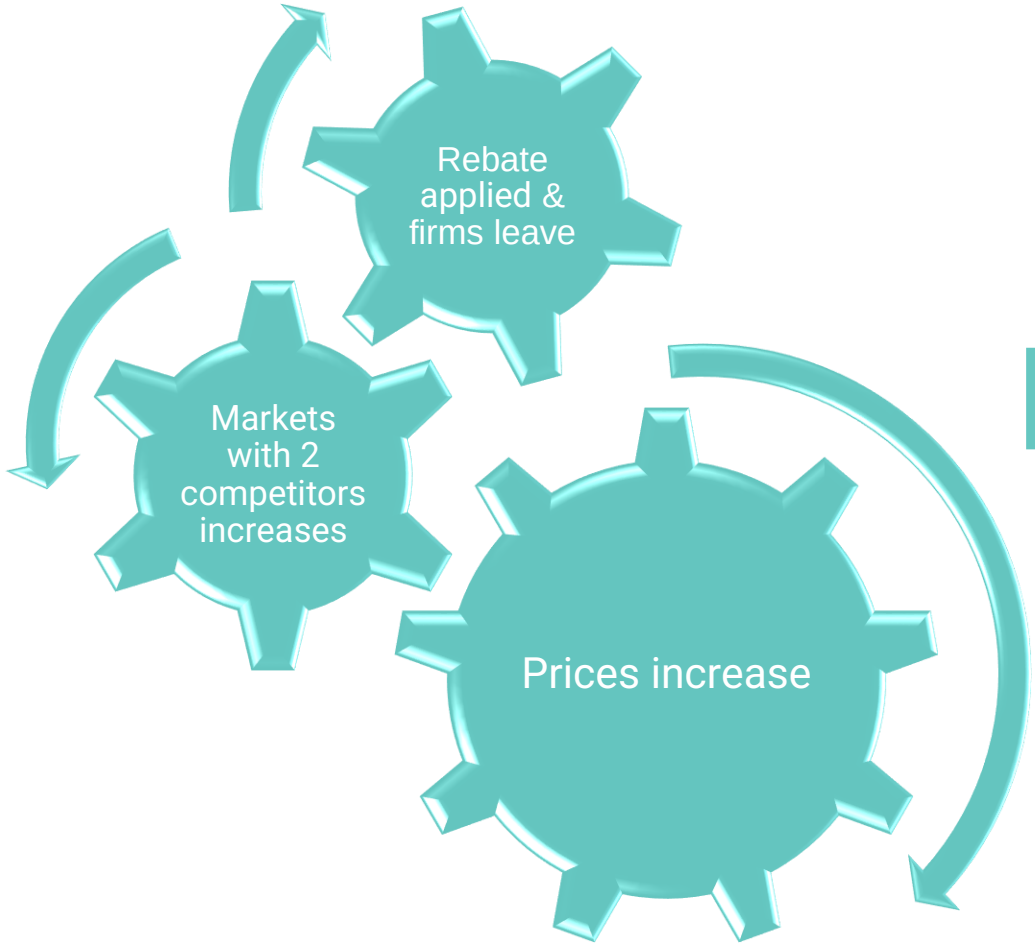
1. Brands dispensed as generics (brand equalised).
2. Generics in markets with brands dispensed as brands.

We present:

- the mechanism of effect;
- the assumptions applied;
- a summary table with the projections for prices and volumes;
- the effect mechanism populated with our estimates;
- a diagram of the impact.

Market characterisation: brands dispensed as generics

Value of generic reimbursement for medicines where brands dispensed as generics 2024-2028



Additional NHS costs associated with higher reimbursement prices

Value of generic reimbursement for medicines where brands dispensed as generics 2024-2028

Brands dispensed as generics:

Main Assumptions:			Level of impact
Assumption	Rationale	Source	
1. Estimate of share of generics reimbursed and met by branded generics (BDAG).	NHSBSA reimbursement data does not identify the manufacturer. We have identified and matched branded generic equivalents for generics and assumed that, on average, 10% of generic reimbursement is satisfied by branded generics.	Estimates based on previous analysis of Brand equalisation.	MED/LOW
2. Share of products/markets exiting the market related to anticipated average level of rebate for next VPAS scheme.	This key assumption estimates number of markets (i.e. individual products rebimbursed where Brand equalisaiton occurs) that will face a reduction in competition, due to high levels of rebates affecting branded generics but not generics.	BGMA survey of members. Approximately half of respondents said that for a specific product it would be withdrawn if there were a rebate of 25%.	HIGH
3. Share of products where withdrawal of branded generic means that there will be two suppliers remaining.	A key finding from the literature, and the survey returns, was that markets where there are 2 manufacturers face less price pressure than markets where there are 3 or more suppliers. We asume that one quarter of markets, where the branded generic exits, will drop to 2 suppliers.	Based on educated estimates.	MED-HIGH
4. Price increase associated with a decrease in competition.	Assuming that in the medium term the generic reimibursement system will ensure that reimbursment tracks discounting we have compared the difference in reported disounting where 3 or more competitiors to those with 2 or fewer and assumed this would be the increase in price. NHS costs also include where CCGs might receive less rebates, and where tender prices for secondary care procured biosimilars are projected to rise.	Calculation based on BGMA survey.	MED

BDAG assumptions

- These are the assumptions currently used to estimate the impact of changes to the rebate on BDAG.

Brand Equalisation	Current rebate levy	Change in rebate levy	New rebate levy	Market exit	Products that drop to having fewer than 2 competitors	Increase in price on effected products	Average changes to prices across markets
	15%	-15%	0%	0%	0.0%	35%	0.0%
	15%	-10%	5%	11%	2.8%	35%	1.0%
	15%	-5%	10%	13%	3.2%	35%	1.1%
	15%	0%	15%	23%	5.7%	35%	2.0%
	15%	5%	20%	43%	10.7%	35%	3.7%
	15%	10%	25%	50%	12.5%	35%	4.3%
	15%	15%	30%	50%	12.5%	35%	4.3%

Market characterisation: brands dispensed as generics (mechanisms)

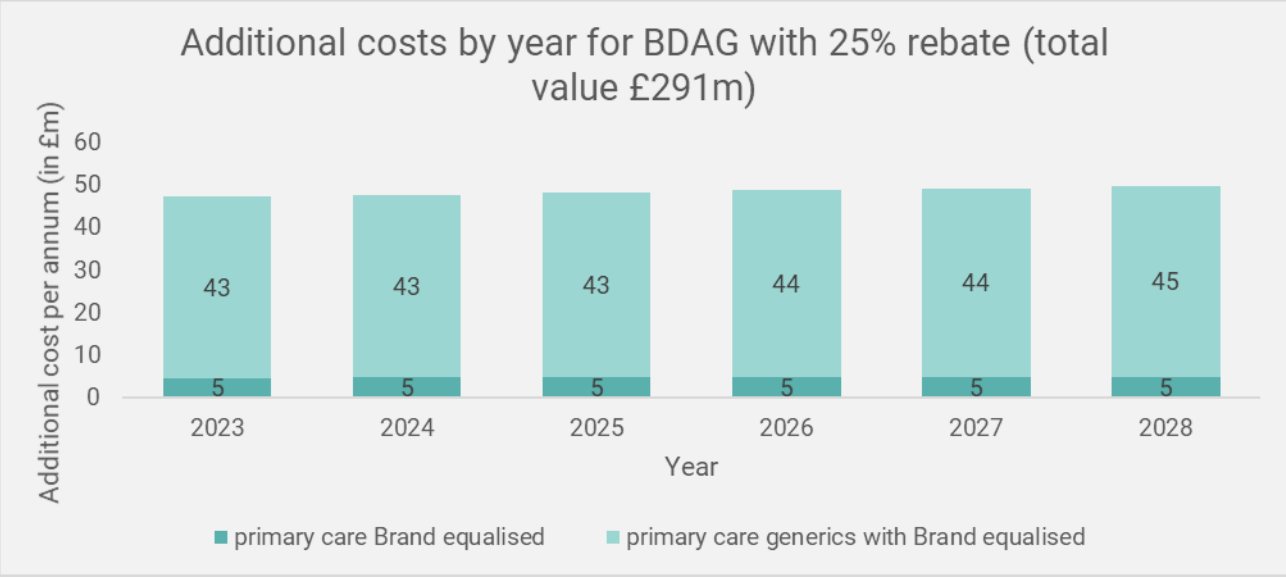
Value of generic reimbursement for medicines where brands dispensed as generics 2024-2028

Additional NHS costs associated with higher reimbursement prices

Value of generic reimbursement for medicines where brands dispensed as generics 2024-2028

Results: brands dispensed as generics

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



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

This represents modelling produced to show higher reimbursement prices, which can flows through from suppliers charging higher actual selling prices.

Note: Chart values are rounded.

	Impact over life of VPAS (2024-2028) 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

2

Primary care – brands dispensed as brands.

1. Brands dispensed as brands.

We present:

- the mechanism of effect;
- the assumptions applied;
- a summary table with the projections for prices and volumes;
- the effect mechanism populated with our estimates;
- a diagram of the impact.
- This section looks at the impact on rising reimbursement prices which can flow through from increasing actual selling prices.

Market characterisation: brands dispensed as brands (prices)

Brands dispensed as brands (prices):

Main Assumptions:			Level of impact
Assumption	Rationale	Source	
1. Estimate increase in market costs.	Increase in costs associated with maintaining market presence of branded generic medicines.	BGMA survey of members.	MED
2. Reduced profitability associated with long term application of VPAS rebate.	Assuming that longer term application of a rebate will reduce the profitability of companies producing branded generics and trigger pressure for price increases.	Assumption used to assess policy implications.	MED
3. Share of products applying for price increase and share achieving price increase.	Due to reduced profitability share of companies that apply for, and are successful in, price increases.	Assumption based on comparsion of increased costs compared with return on capital VPAS profit mechanism. Number of companies successful in achieving a price increase based on BGMA survey of members.	MED-HIGH
4. Level of price increase.	Calculation based on comparison of increased costs compared with return on capital VPAS profit mechanism.	Assumption based on previous steps and in the context of the VPAS profit mechanism.	MED

Brands dispensed as brands (prices) assumptions

- These are the assumptions currently used to estimate the impact of changes to the rebate on the prices of brands dispensed as brands.

Brands Dispensed as Brands				based on 150% MOT on 21% aka VPAS	32%		
	Rebate levy	Market cost increase (commercial and regulatory)	Share of products applying for price increase (use 21% MOT)	Share achieving price increase	Level of price increase	Net change to prices	Increased cost plus rebate
	0%	12%	0%	50%	0%	0.0%	12%
	5%	12%	0%	50%	0%	0.0%	17%
	10%	12%	0%	50%	0%	0.0%	22%
	15%	12%	20%	50%	0%	0.0%	27%
	20%	12%	40%	50%	1%	0.1%	32%
	25%	12%	60%	50%	6%	1.7%	37%
	30%	12%	80%	50%	11%	4.2%	42%

Market characterisation: brands dispensed as brands (prices)

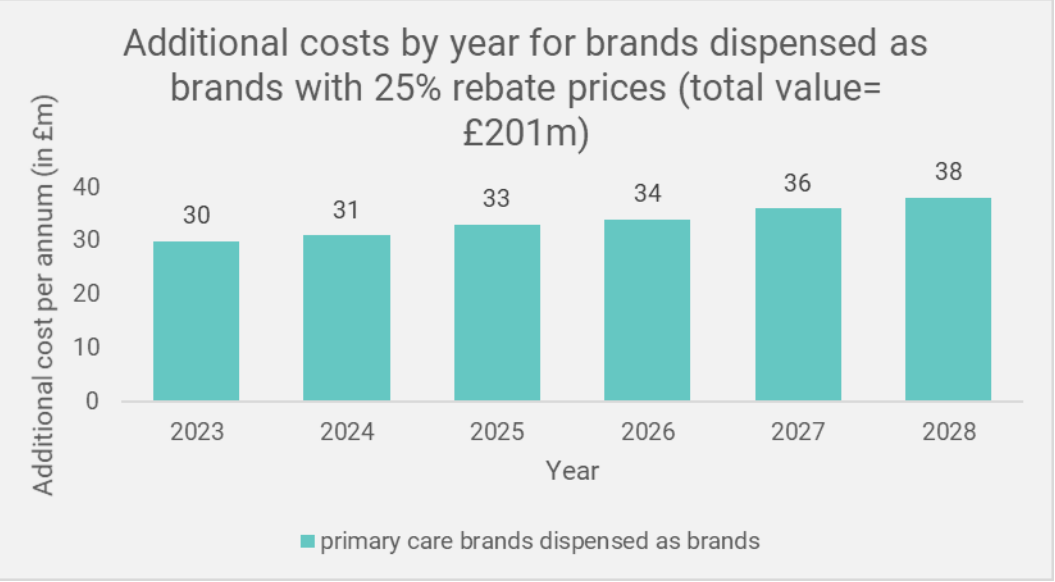
Value of reimbursement for branded generic medicines dispensed as brands 2024-2028

Additional NHS costs associated with higher reimbursement prices

Value of reimbursement for branded generic medicines dispensed as brands 2024-2028

Results: brands dispensed as brands (prices)

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



	Impact over life of VPAS (2024-2028) 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

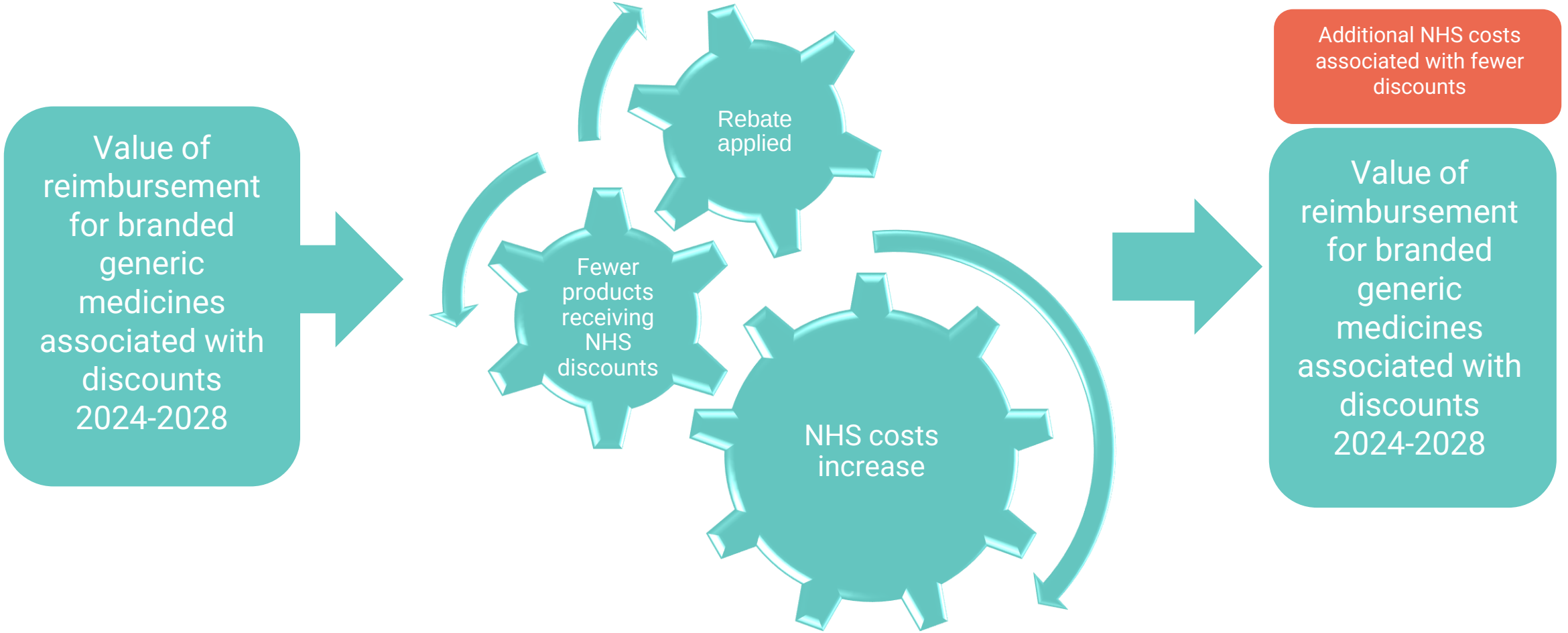
Primary care – brands dispensed as brands.

2. Brands dispensed as brands – NHS discounted.

We present:

- the mechanism of effect;
- the assumptions applied;
- a summary table with the projections for prices and volumes;
- the effect mechanism populated with our estimates;
- a diagram of the impact.
- This section looks at the impact of reduced discounts to the NHS locally as result of rising actual selling prices.

Market characterisation: brands dispensed as brands (NHS discounting)



Brands dispensed as brands (NHS discounts):

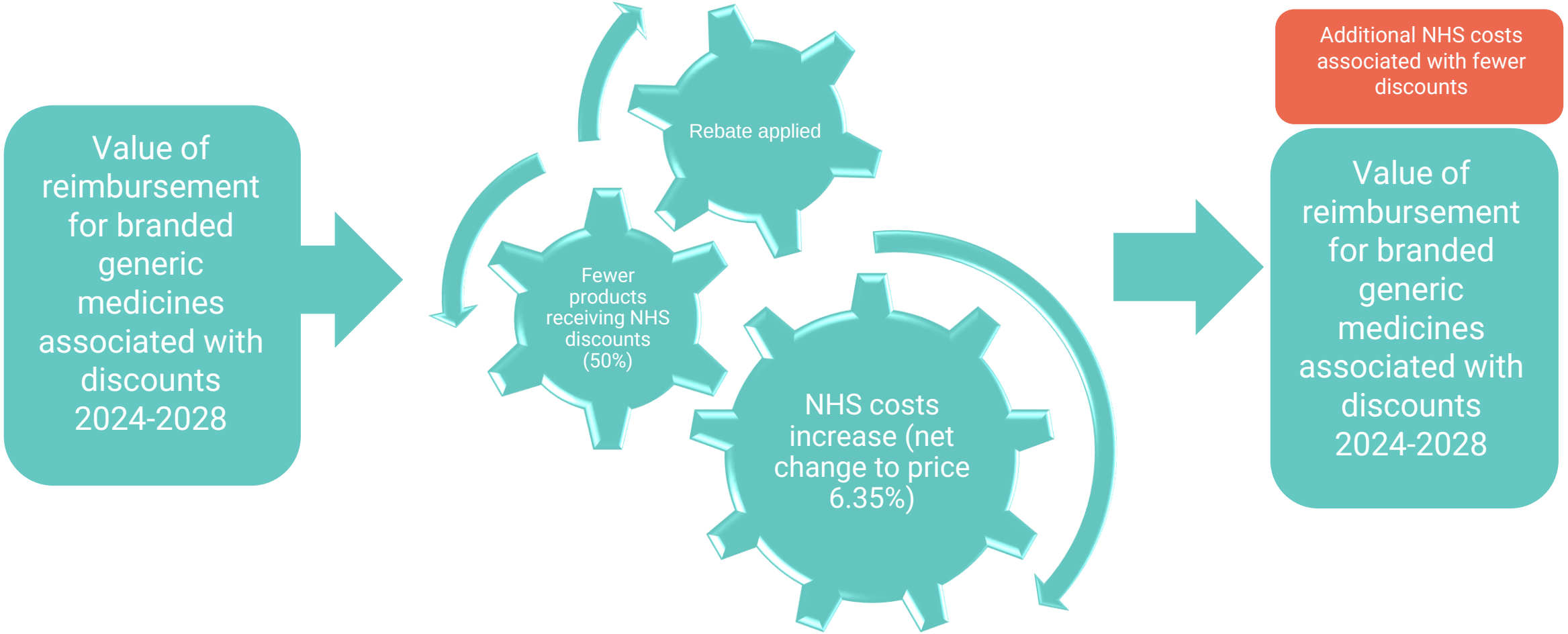
Main Assumptions:			Level of impact
Assumption	Rationale	Source	
1. Share of products/markets exiting the market related to anticipated average level of rebate for next VPAS scheme.	This fundamental assumption estimates the number of markets (i.e. individual products reimbursed where Brand equalisation occurs) that will face a reduction in competition due to high levels of rebates affecting branded generics but not generics.	BGMA survey of members. Approximately half of respondents said that for a specific product it would be withdrawn if there were a rebate of 25%.	**MED-HIGH**
2. Net change to prices.	Discount forgone due to products stopping offering discounts or reducing them.	BGMA survey of members. Average discount applied to products.	**MED-HIGH**

Brands dispensed as brands (NHS discounts) assumptions

- These are the assumptions currently used to estimate the impact of changes to the rebate on the NHS discounts for brands dispensed as brands.

Brands Dispensed as Brands (NHS)	Rebate levy	Change in rebate levy	New rebate levy	Share of products exiting the market	Net change to prices	Impact on prices generics
	0%	-15%	0%	0%	25.08%	0.00%
	5%	-10%	5%	11%	25.08%	2.83%
	10%	-5%	10%	13%	25.08%	3.24%
	15%	0%	15%	23%	25.08%	5.67%
	20%	5%	20%	43%	25.08%	10.68%
	25%	10%	25%	50%	25.08%	12.54%
	30%	15%	30%	50%	25.08%	12.54%

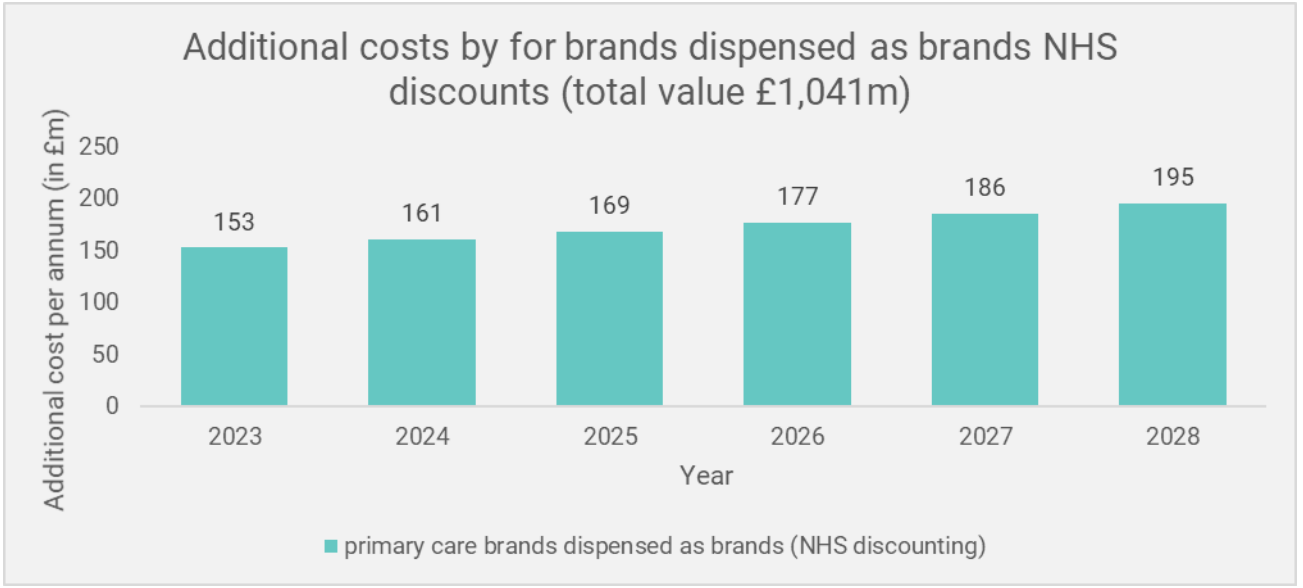
Market characterisation: brands dispensed as brands (NHS discounting)



Results: brands dispensed as brands

- The chart shows the impact of applying an average 25% rebate over the period of the next VPAS.

- The table shows the net impact for additional costs for the NHS for the life of the next VPAS for various rebate rates. These are the savings lost locally through lower discounts received by the NHS



	Impact over life of VPAS (2024-2028) 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

Secondary care – biosimilars.

1. Medicines which are procured through competitive NHS-run tenders.

We present:

- the mechanism of effect;
- the assumptions applied;
- a summary table with the projections for prices and volumes;
- the effect mechanism populated with our estimates;
- a diagram of the impact.
- Modelled on existing biosimilars.

Market characterisation: Current biosimilars

Value of reimbursement for medicines currently facing biosimilar competition 2024-2028

Additional NHS costs associated with higher tender prices

Value of reimbursement for medicines currently facing biosimilar competition 2024-2028

Current biosimilars:

Main Assumptions:			Level of impact
Assumption	Rationale	Source	
1. Level of discount.	Discount relative to list prices for existing biosimilar medicines.	BGMA survey of members, average minimum discount evident through stated tender prices offered.	MED-HIGH
2. Share of products/markets exiting the market related to anticipated average level of rebate for next VPAS scheme.	This key assumption estimates the number of markets (i.e. individual products reimbursed where brand equalisation occurs) that will face a reduction in competition due to high levels of rebates affecting branded generics but not generics.	BGMA survey of members. Approximately half of respondents said that for a specific product it would be withdrawn if there were a rebate of 25%.	MED-HIGH
3. Average number of competitors per market.	Number of suppliers for each existing biosimilar.	BGMA survey of members.	MED
4. Price increase due to reduced competition.	As firms exit the market the number of markets that drop below 2 suppliers with estimated price increase using BGMA member returns.	BGMA survey of members.	MED-HIGH

Current biosimilars assumptions

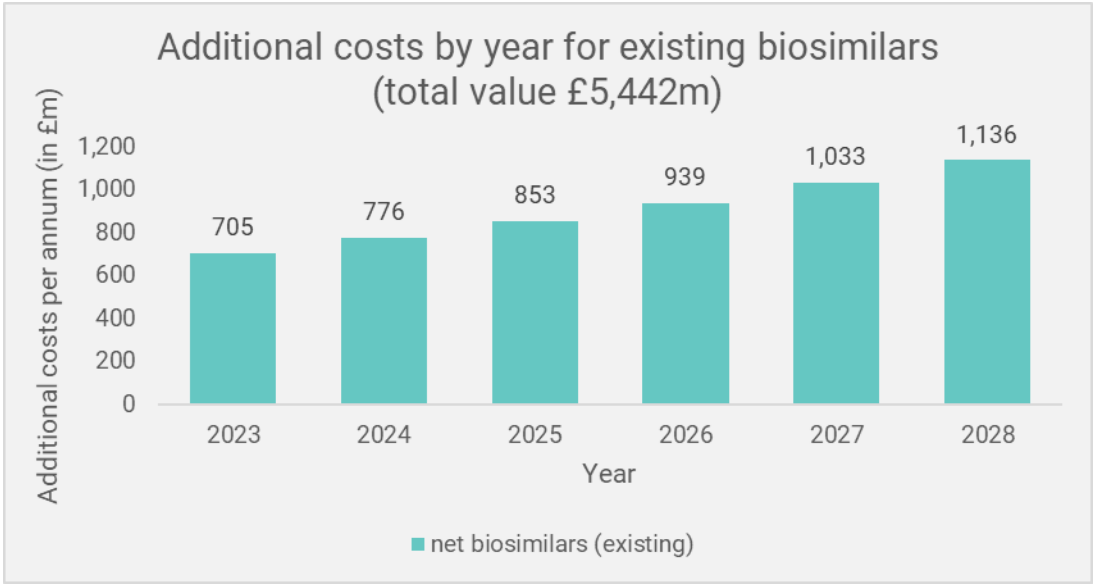
- These are the assumptions currently used to estimate the impact of changes to the rebate on the prices of current biosimilars.

Existing Biosimilars	Rebate levy	Level of discount	Cost plus rebate	Avg # competitors	Share leaving	Remaining competitors	Price increase
	0%	61.7%	6.02%	3.12	0%	3.12	0%
	5%	61.7%	11.02%	3.12	14%	2.67	0%
	10%	61.7%	16.02%	3.12	6%	2.93	0%
	15%	61.7%	21.02%	3.12	12%	2.73	0%
	20%	61.7%	26.02%	3.12	18%	2.55	0%
	25%	61.7%	31.02%	3.12	50%	1.56	35%
	30%	61.7%	36.02%	3.12	50%	1.56	35%

Results: Current biosimilars

- The chart shows the impact of applying an average 25% rebate over the period of the next VPAS.

- The table shows the net impact for additional costs for the NHS for the life of the next VPAS for various rebate rates. The additional NHS cost is in the form of higher tender prices offered.



	Impact over life of VPAS (2024-2028) 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

* Low participation of biosimilar companies.

Note: Chart values are rounded.

3

Secondary care – biosimilars.

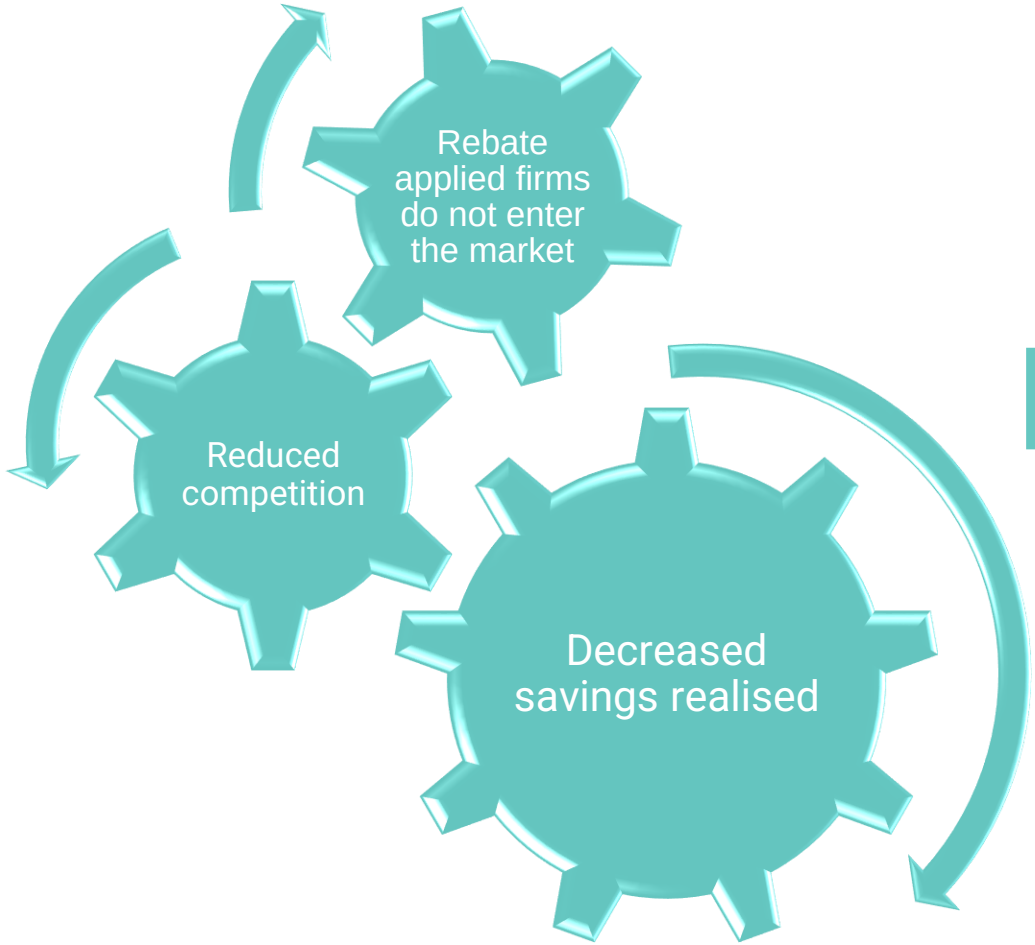
2. Medicines facing biosimilar competition 2022-2028.

We present:

- the mechanism of effect;
- the assumptions applied;
- a summary table with the projections for prices and volumes;
- the effect mechanism populated with our estimates;
- a diagram of the impact.
- Modelled on biosimilars forecast to be launched up to 2028 as a result of originator loss of exclusivity.

Market characterisation: Future biosimilars

Value of reimbursement for medicines facing biosimilar competition from 2022 2024-2028



"Savings" forgone due to reduced competition

Value of reimbursement for medicines facing biosimilar competition from 2022 2024-2028

Future biosimilars:

Main Assumptions:			Level of impact
Assumption	Rationale	Source	
1. Post loss of exclusivity erosion curve	Price erosion, relative to brand price at LOE, used to calculate savings	BGMA survey of members, average minimum discount applied for year 1, maximum discount applied for year 3, interpolated for year 2.	**MED-HIGH**
2. Adjustment to erosion due to reduced competition	Based on number rebate rate reduced level of competition and hence lower level of price erosions (expressed as a percentage adjustment to baseline erosion curve)	BGMA survey of members. Approximately half of respondents said that for a specific product it would be withdrawn if there were a rebate of 25%.	**MED-HIGH**

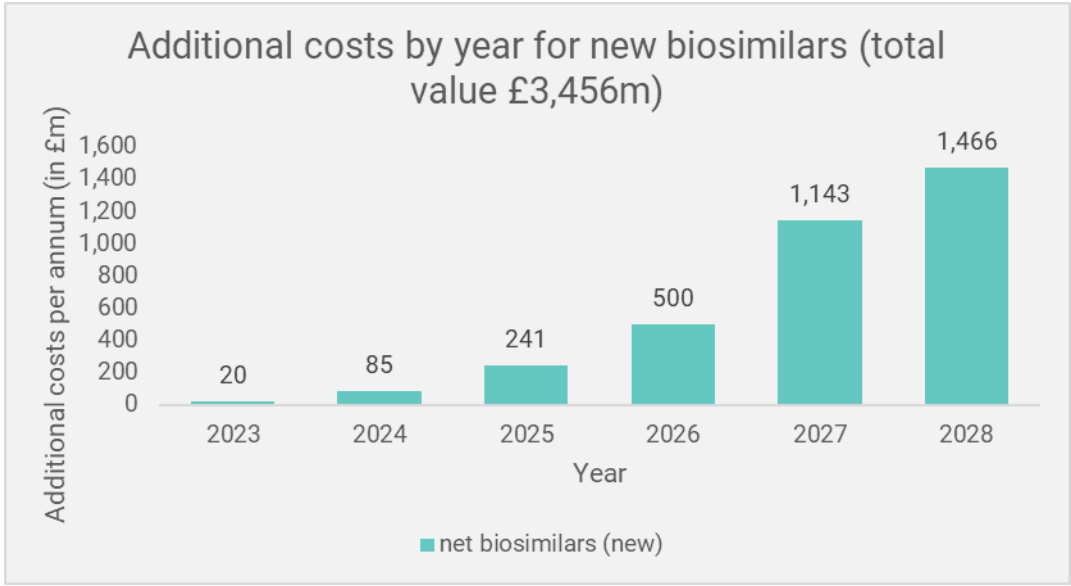
Future biosimilars assumptions

- These are the assumptions currently used to estimate the impact of changes to the rebate on the prices of medicines facing biosimilar competition to 2028.

		Base erosion	Modelled rebate levy	Adjustment to LOE	Adjusted erosion	Rebate assumption	Adjustment to erosion
New Biosimialrs	Year 1	60.00%	15%	70%	42.00%	0%	100%
	Year 2	65.0%	15%	70%	45.50%	5%	90%
	Year 3	70.00%	15%	70%	49.00%	10%	80%
	Year 4	75.00%	15%	70%	52.50%	15%	70%
	Year 5	80.00%	15%	70%	56.00%	20%	60%
	Year 6	85.00%	15%	70%	59.50%	25%	50%
	Year 7	90.00%	15%	70%	63.00%	30%	40%

Results: New biosimilars

- The chart shows the impact of applying an average 25% rebate over the period of the next VPAS.
- ➢ Higher NHS costs occur in the form of high tender prices paid by NHS trusts.
- The table shows the net impact for additional costs for the NHS for the life of the next VPAS for various rebate rates.



	Impact over life of VPAS (2024-2028) 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.

Policy Implications

- In the context of markets, mechanisms that *deliver savings to the government* by *increasing rates of rebates* will **reduce competition** and will end up **rising prices** for the buyer (NHS).
- In this context according to the calculations:

➢ Once we account for the markets' reactions to *increased rebate levels* (revised estimates), the losses are larger than when we do not (baseline-unadjusted).

➢ The increased government revenue from raising the VPAS rebate is more than offset by higher prices and costs for the NHS and has other longer-term implications due to continuity of supply.

- i.e., the positive impact on government revenue is cancelled out by the future losses to the NHS.
- Notwithstanding that the rebate is collected by government and higher prices are borne by NHS payers, the case for not levying a VPAS payment on branded generics and biosimilars can be made by comparing the net loss between higher prices and the payment percentage revenue across the different VPAS rebate levels.
- Overall, reduced stability of prices faced by the NHS is to be expected.

- **The VPAS effects are very likely to be compounded by *the rise of overall market costs due to inflation*, which will amplify the negative consequences on competition and prices faced by the NHS.**

Concluding remarks

Postscript: Professor Alistair McGuire, LSE

- The three distinct but interrelated markets covering generic brand equalised products, branded pharmaceutical products, and newer biosimilars are highly complex.
- This complexity means that simulating the impact of regulatory change through the potential changes to the VPAS is not straightforward.
    - However, starting from the basis that any increase in the pricing (rebate) levy through the VPAS scheme will increase product costs leading to lower product market entry and thereby reducing competition, we can reasonably expect that these markets will be exposed to lower production volumes and higher prices.
    - This is the general conclusion of the presented simulation of the impact of changes to the price (rebate) levy incorporated within the existing VPAS scheme over the next few years (2024 – 2028).
        - The aggregate impact of the existing VPAS levy rate of 15% leads to a net increased impact of £3.8 billion over this period (£4.3 billion if the levy is raised to 20%; and higher still with higher levy rates).
        - In other words, the simulation shows that while the VPAS rebate level 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 general market access) and higher prices.

Postscript: Professor Alistair McGuire, LSE

- While the simulation is based on a range of assumptions (as any prediction of the future has to be), it is founded upon (amongst other information) data drawn from a survey of BGMA members outlining their expected reactions to increases in the price levy.
  - The survey documents a prevalent expectation amongst members that market product costs will rise substantially over the next five years.
  - Moreover, this is accompanied by existing price discounts across the branded generic and biosimilar markets, which puts further pressure on producer revenues.
    - Such price discounts have a wide variance, but around 30% across these products on average.
    - Although around a third of surveyed providers have no local CCG discounts in place within these markets.

APPENDIX

APPENDIX 1

Economics of Generics and Biosimilars Markets: A Review of the Literature

Summary of key messages

1. The likelihood of generic entry is influenced by several factors.
2. Regulation can negatively impact generic markets.
3. Generic entry leads to a reduction in the market share of originator products.
4. The impact of generic entry on prices varies across countries.
5. Generic prices are associated with several market and product characteristics.
6. In specific countries, the prices of branded medicines increase after generic entry (the generics paradox).
7. Some generic markets are subject to delayed market access.
8. Some markets are considered to face more barriers than others.
9. Biosimilar markets face high development and marketing costs and less government support.
10. Physician behaviour is key to successful substitution.
11. The various effects of generic and biosimilar uptake are complex, and further research on measuring them is needed.

Implications

- **Reductions in incumbent prices prior to generic entry can be an effective deterrent for generic entry.**
- Prices of generics charged by manufacturers in the UK are, on average, lower than in other countries.
- **Generics are more successful in markets with more flexible pricing policies.**
- **The literature supports the case that the UK has established a generic market where:**
  - the reimbursement system for generics effectively encourages competition, and
  - the DHSC tracking actual prices paid for generics enables the amendment of reimbursement costs. This is for unbranded medicines or branded medicines dispensed against a generic script. The reimbursement price for brands will stay more stable and be more reflective of list prices.
- Policies that deter manufacturers from entering the market, or induce them to leave, might increase costs to the NHS through increased prices due to diminished competition.

Literature Review Methodology

- We conducted a **pragmatic literature review**.
- We exploited three electronic bibliographic databases (**Google Scholar, EconLit, and PubMed**).
  - ★ The search used combinations of the following **keywords and terms**: "economics of generics drugs", "economics of generics drug competition", "price regulation and generics drugs", and "economics of generics drugs the UK".
- A preliminary search was carried out to analyse primary keywords in the title and abstracts of the papers.
- We assessed the studies' **eligibility** and kept 25 of those focusing on the **economics of generics and biosimilar markets with the ultimate aim to provide evidence on i) the structure of these markets, ii) the price regulation and iii) competition effects**.

Limitations

1. The review is carried out across countries where very different health and medicines reimbursement systems are in place, so hard to always read across to other nations.
2. Finding the true or actual generic pricing is difficult in many countries, so reports tend to assume proxies or use imperfect data. This then impacts the veracity of the reports.
3. While there is a greater body of research on the triggers, benefits and challenges with generic competition, this is less apparent for branded generic products.

The likelihood of generic entry is influenced by several factors.

- Price regulation significantly reduces the time to launch of generics, with faster adoption in higher-priced markets. The speed of entry of generics is dependent on the degree of competition and the expected market size. (1)

- When the analysis takes market size into consideration, then intermolecular substitution, *and* the projected high generic prescribing rate increase the likelihood of generic entry. The difficulty of manufacturing will be a factor in generic entry; hard to say if it helps or hinders generic entry. (2)

- The regulator's decision to require a brand will affect generic prescribing levels, which in turn affects generic entry.

- Reductions in incumbent prices prior to generic entry can be an effective deterrent, as observed in drug markets*. (3,4)

- NICE recommendations may affect generic uptake, but there is limited evidence they will affect generic entry. (2)

1. Costa-Font, J., McGuire, A. and Varol, N., 2014. Price regulation and relative delays in generic drug adoption. *Journal of Health Economics*, 38, pp.1–9. 10.1016/j.jhealeco.2014.04.004.
2. Serra-Sastre, V., Bianchi, S., Mestre-Ferrandiz, J. and O'Neill, P., 2021. Does NICE influence the adoption and uptake of generics in the UK? *The European Journal of Health Economics*, 22(2), pp.229–242. 10.1007/s10198-020-01245-1.
3. Tenn, S. and Wendling, B.W., 2014. Entry Threats and Pricing in the Generic Drug Industry. *The Review of Economics and Statistics*, 96(2), pp.214–228. 10.1162/REST_a_00382.
4. Saha, A. and Xu, Y., 2021. The 'Generic Competition Paradox' Revisited. *International Journal of the Economics of Business*, 28(3), pp.363–375. 10.1080/13571516.2021.1880252.

*In (3) the reduction in prices was only found in small drug markets.

Generic entry leads to a reduction in market share of originator products.

US:

- The share of generic retail prescriptions in the US has grown from 18.6% in 1984 to 74.5% in 2009, with a notable acceleration in recent years. (1)
- For generic drugs entering in 2011/12, the average brand unit share after 1 year was 16% (11% for new molecular entities with sales greater than $250m). (2)

England:

- In 2021/22, 80% of prescriptions in the community were written generically. (3)

Germany:

- Market share increased with time since generic entry. 48 months after generic entry the average market share was 75%. (1)

1. Berndt, E.R. and Aitken, M.L., 2011. Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation. *International Journal of the Economics of Business*, 18(2), pp.177–201. 10.1080/13571516.2011.584423.
2. Grabowski, H., Long, G. and Mortimer, R., 2014. Recent trends in brand-name and generic drug competition. *Journal of Medical Economics*, 17(3), pp.207–214. 10.3111/13696998.2013.873723.
3. NHS, 2022. *Prescription Cost Analysis – England – 2021/22 | NHSBSA*. Available at: https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202122.
4. Fischer, K.E. and Stargardt, T., 2016. The diffusion of generics after patent expiry in Germany. *The European Journal of Health Economics*, 17(8), pp.1027–1040. 10.1007/s10198-015-0744-3.

The impact of generic entry on prices varies across countries.

- In the Netherlands, the median drug price after patent expiration decreased by 41% after 4 years. (1)
- In the US, following the 1984 Waxman-Hatch legislation, the weighted mean reduction in pharmaceutical daily treatment cost across nine therapeutic areas equalled 35.1% 24 months post-generic entry. (2)
- Prices charged by manufacturers in the UK are, on average, lower than other countries. (3,4)
- On average, in the UK, six months after loss of exclusivity the generic price is 70% lower, falling to 80–90% lower over a four-year period. (4)

1. van der Schans, S., Vondeling, G.T., Cao, Q., van der Pol, S., Visser, S., Postma, M.J. and Rozenbaum, M.H., 2021. The impact of patent expiry on drug prices: insights from the Dutch market. *Journal of Market Access & Health Policy*, 9(1), p.1849984. 10.1080/20016689.2020.1849984.
2. Berndt, E.R. and Aitken, M.L., 2011. Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation. *International Journal of the Economics of Business*, 18(2), pp.177–201. 10.1080/13571516.2011.584423.
3. Wouters, O.J., Kanavos, P.G. and McKEE, M., 2017. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. *The Milbank Quarterly*, 95(3), pp.554–601. 10.1111/1468-0009.12279.
4. OXERA, 2019, The supply of generic medicines in the UK. A study by Oxera Prepared for The British Generic Manufacturers Association

Generic prices are associated with several market and product characteristics.

- Generic drug prices are strongly associated with the market competition levels.
  - Generic drugs in quadropoly markets experienced changes in prices of -31.7%; duopoly markets -11.8%; near monopoly markets 20.1% and monopoly markets 47.4% (1)
  - Variation in prices after generic entry depend on the level of revenue prior to patent expiration and the time of patent expiration. (2)
  - Generic market share and price are simultaneously determined. (3)
  - The level of generic competition is a key determinant of generic market share and the generic-to-brand price ratio. (3,4)
  - **Generic competition is more intense for 'blockbuster' drugs,** following the originator's loss of exclusivity. They experience significantly more generic entry, price erosion, and generic penetration than other drugs. (3) Nevertheless, this will depend on the number of generic entrants and the feasibility/difficulty of producing generics of blockbuster drugs.

1. Dave, C.V., Kesselheim, A.S., Fox, E.R., Qiu, P. and Hartzema, A., 2017. High Generic Drug Prices and Market Competition. *Annals of Internal Medicine*, 167(3), pp.145–151. 10.7326/M16-1432.
2. van der Schans, S., Vondeling, G.T., Cao, Q., van der Pol, S., Visser, S., Postma, M.J. and Rozenbaum, M.H., 2021. The impact of patent expiry on drug prices: insights from the Dutch market. *Journal of Market Access & Health Policy*, 9(1), p.1849984. 10.1080/20016689.2020.1849984.
3. Saha, A., Grabowski, H., Birnbaum, H., Greenberg, P. and Bizan, O., 2006. Generic Competition in the US Pharmaceutical Industry. *International Journal of the Economics of Business*, 13(1), pp.15–38. 10.1080/13571510500519905.
4. Fischer, K.E. and Stargardt, T., 2016. The diffusion of generics after patent expiry in Germany. *The European Journal of Health Economics*, 17(8), pp.1027–1040. 10.1007/s10198-015-0744-3.

Regulation can impact negatively generic markets.

- Generics are more successful in markets with more flexible pricing policies. (1)
- **Price caps introduced Ontario, Canada, reduced incentives for generic manufacturers:**
  - The price caps impacted how likely generic firms were to enter the market. (2)
  - Lowering the price-cap was associated with a higher incidence of generic firms' exit from markets. The exit rate ratio during the 25% price-cap period compared with the 70%/90% price-cap period was 2.42 with small manufacturers. Older markets or manufacturers in a market with ≥ 3 competitors were more likely to exit. (3)
- **Price regulation can result in higher prices through reduced incentives to set prices lower than those imposed by the regulation.** (4,5)

Free markets of wholesalers and retailers can enhance competitive markets, providing strong purchasing power to distributors and stimulating the success of unbranded generics. (1)

1. Garattini, L. and Tediosi, F., 2000. A comparative analysis of generics markets in five European countries. *Health Policy*, 51(3), pp.149–162. 10.1016/S0168-8510(00)00061-0.
2. Zhang, W., Sun, H., Guh, D. and Anis, A.H., 2017. The impact of price-cap regulations on market entry by generic pharmaceutical firms. *Expert Review of Pharmacoeconomics & Outcomes Research*, 17(2), pp.231–238. 10.1080/14737167.2017.1271717.
3. Zhang, W., Guh, D., Sun, H., Marra, C.A., Lynd, L.D. and Anis, A.H., 2016. The Impact of Price-cap Regulations on Exit by Generic Pharmaceutical Firms. *Medical Care*, 54(9), pp.884–890. 10.1097/MLR.0000000000000577.
4. Puig-Junoy, J., 2010. Impact of European Pharmaceutical Price Regulation on Generic Price Competition. *PharmacoEconomics*, 28(8), pp.649–663. 10.2165/11535360-000000000-00000.
5. Dylst, P. and Simoens, S., 2010. Generic Medicine Pricing Policies in Europe: Current Status and Impact. *Pharmaceuticals*, 3(3), pp.471–481. 10.3390/ph3030471.

In specific countries, the prices of branded medicines increase after generic entry (*the generics paradox*).

- The generic paradox has been found to hold in the US and 6 European prescription drug markets. (1)
- However, there is also evidence that the generic paradox does not always hold in the US. (2)

1. Vandoros, S. and Kanavos, P., 2013. The generics paradox revisited: empirical evidence from regulated markets. *Applied Economics*, 45(22), pp.3230–3239. 10.1080/00036846.2012.703313.
2. Saha, A. and Xu, Y., 2021. The 'Generic Competition Paradox' Revisited. *International Journal of the Economics of Business*, 28(3), pp.363–375. 10.1080/13571516.2021.1880252.

Some generic markets are subject to delayed market access.

- Delayed market access puts at risk the long-term sustainability of the generic manufacturing industry. (1)

- However, in the long run, prices and shares will be unaffected and any potential costs to consumers from delayed generic entry will be minimal. (2)

1. Dylst, P., Vulto, A., Godman, B. and Simoens, S., 2013. Generic Medicines: Solutions for a Sustainable Drug Market? *Applied Health Economics and Health Policy*, 11(5), pp.437–443. 10.1007/s40258-013-0043-z.
2. Berndt, E.R. and Aitken, M.L., 2011. Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation. *International Journal of the Economics of Business*, 18(2), pp.177–201. 10.1080/13571516.2011.584423.

Biosimilar entry impacts prices.

- **Governments will be more likely to achieve long-term savings through the competition due to biosimilar entry** than through one-off cuts in originator prices. [1]

1. Mestre-Ferrandiz, J., Towse, A. and Berdud, M., 2016. Biosimilars: How Can Payers Get Long-Term Savings? *PharmacoEconomics*, 34(6), pp.609–616. 10.1007/s40273-015-0380-x.

Biosimilar markets face high development and marketing costs and less government support.

- There are different judgments as to whether biosimilars are deemed automatically substitutable. [1,2] Biosimilars are approved by the regulator as equivalent in terms of efficacy, safety, and quality with their reference product. But while some in countries in Europe are promoting automatic substitution policies [1,2,3], in other markets, such as the UK, this is not a policy that is supported.
- Biosimilars incur higher development and marketing costs than generics. [1]

- To support biosimilar entry, governments should support and incentivise collecting high-quality, comprehensive outcomes data on safety and effectiveness and ensure incentives are in place for budget holders to benefit from price competition. [4]

1. Duerden, M.G. and Hughes, D.A., 2010. Generic and therapeutic substitutions in the UK: are they a good thing? *British Journal of Clinical Pharmacology*, 70(3), pp.335–341. 10.1111/j.1365-2125.2010.03718.x.
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3. Derbyshire, M., 2014. Reducing the European healthcare budget with generics and biosimilars. *Generics and Biosimilars Initiative Journal*, 3(4), pp.200–202.
4. Mestre-Ferrandiz, J., Towse, A. and Berdud, M., 2016. Biosimilars: How Can Payers Get Long-Term Savings? *PharmacoEconomics*, 34(6), pp.609–616. 10.1007/s40273-015-0380-x.

Physician behaviour is key to successful substitution.

- There is an increasing trend in favouring financial incentives for physicians' prescribing behaviour as opposed to pharmacists. (1)
- In countries like Switzerland, **patient health status impacts whether substitution to generics** takes place, with patients with worse health status being offered generics less often. Large regional variation suggests that prescribing behaviours and beliefs were likely to be a greater determinant of generic substitution rates than economic incentives. (2)
- **There have been cases of implementing policies requiring generic prescribing and substitution**. (3)

1. Garattini, L. and Tediosi, F., 2000. A comparative analysis of generics markets in five European countries. *Health Policy*, 51(3), pp.149–162. 10.1016/S0168-8510(00)00061-0.
2. Decollogny, A., Eggli, Y., Halfon, P. and Lufkin, T.M., 2011. Determinants of generic drug substitution in Switzerland. *BMC Health Services Research*, 11(1), p.17. 10.1186/1472-6963-11-17.
3. Wouters, O.J., Kanavos, P.G. and McKEE, M., 2017. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. *The Milbank Quarterly*, 95(3), pp.554–601. 10.1111/1468-0009.12279.

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7. Dylst, P. and Simoens, S., 2010. Generic Medicine Pricing Policies in Europe: Current Status and Impact. *Pharmaceuticals*, 3(3), pp.471–481. 10.3390/ph3030471.
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10. Garattini, L. and Tediosi, F., 2000. A comparative analysis of generics markets in five European countries. *Health Policy*, 51(3), pp.149–162. 10.1016/S0168-8510(00)00061-0.
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12. Grabowski, H.G., Kyle, M., Mortimer, R., Long, G. and Kirson, N., 2011. Evolving Brand-Name And Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act. *Health Affairs*, 30(11), pp.2157–2166. 10.1377/hlthaff.2010.0270.
13. Mestre-Ferrandiz, J., Towse, A. and Berdud, M., 2016. Biosimilars: How Can Payers Get Long-Term Savings? *PharmacoEconomics*, 34(6), pp.609–616. 10.1007/s40273-015-0380-x.

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14. OXERA, 2019, The supply of generic medicines in the UK. A study by Oxera Prepared for The British Generic Manufacturers Association
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APPENDIX 2
Survey:
VPAS and Statutory Scheme

Summary of key messages

1. Almost 72.5% of respondents bring to market between 1-30 branded generics or biosimilar SKUs.
2. Over 40% spend 1-5% of branded generics' revenues on market costs when they brand by choice.
3. Over 42% spend 1-5% of branded generics' revenues on market costs when branded because of regulatory requirements.
4. Over 23% spend 10-15% of biosimilars revenues on market costs.
5. Market costs are expected to increase on average by 17.13% over the next five years.
6. Respondents identified several different factors that can influence market costs.
7. 32% of the respondents had no local CCG discount commercial agreements associated with any products in their portfolio.
8. Respondents' opinion is split on whether the impact of competition and discounting on local CCGs changes across therapeutic areas.
9. The average CCG discount or rebate as a percentage of the final selling price of branded generics and biosimilars is between 10-75%. The average CCG discount or rebate is 29.5%.
10. Some companies seek formularies at the CCG level, but others do not.
11. Experiences and opinions on the costs of the negotiations with the CCG varied.
12. Higher VPAS rates increase the percentage of projected product withdrawals, which will reduce competition.
13. A lower VPAS rate increases the prospect of new launches in the UK, thereby strengthening competition.
14. The decision to apply for a price increase in at least one product varies across companies.
15. Almost all respondents agree that commercial viability is critical in applying for a price increase.
16. Processes can act as barriers when seeking price increases.

Implications- primary care

Primary care market

1. Brands dispensed as generics
    a. Brand Equalisation: Market withdrawal leads to reduced competition and higher generic prices

2. Brands dispensed as brands
    a. Impact of VPAS rebate and market costs on prices – VPAS profit mechanism
    b. Impact of VPAS rebate and market costs on scope for CCG rebates
    c. Impact of VPAS rebate and market costs on supply

Income from VPAS rebate, which is received by the central government, more than offset by higher reimbursement prices and costs for NHS

Other implications due to continuity of supply

Reduced stability of prices in the context of increasing inflation for NHS

Implications- secondary care

Secondary care market

1. Current biosimilars

a. Reduced competition due to market withdrawal – impact on future tendering cycles and scope for maintaining low net prices

2. Future biosimilars

a. Significant number of biologics facing loss of exclusivity (LOE) in the next VPAS cycle
b. VPAS rebate and market costs = reduced number of market entrants
c. Savings realised are lower than those achieved through recent LOE events e.g., Humira

Income from VPAS rebate, which is received by the central government more than offset by higher prices and costs for NHS

Other implications due to continuity of supply

Reduced stability of prices in the context of increasing inflation for NHS

Role of the Survey

- To get information on critical parameters of the market tracker: market costs, market expectations, competition, and strategy.
- To generate evidence for the assumptions to be used in the market tracking tool and the simulations. Including those developed outside of survey answers.
- Each combination of assumptions leads to a *scenario*, reflecting the resulting market under those circumstances.

Survey Design

- The survey questionnaire was designed based on i) the initial RfP, ii) meeting and discussion with the steering group consisting of the BGMA member companies and iii) discussion with the project representative of the BGMA.
- The survey questionnaire was composed of 25 main questions + 6 additional clarification questions.
- The survey was separated into 5 main parts.

1. Introduction and personal/company information.
2. Questions around market costs.
3. Questions about local CCG discounts.
4. Strategic decisions and VPAS.
5. Questions around pricing.

Overview of the Survey (1)

- **Survey software:** SurveyMonkey.
- **Survey time:** between the 8th of March and the 3rd of April (additional survey: May-June).
- **Number of participants:** 31
- **Number of companies:** 22
- **Type of products sold:**

❖ Branded generics: 43.33%

❖ Biosimilars: 3.33%

❖ **Both: 50%**

❖ Other (Biosimilars & Originator molecules): 3.33%

Overview of the Survey (2)

- **Department of the respondent:**

Pricing	17.24%
Market Access	31.03%
Health Economics and Outcomes Research	0.00%
Sales	41.38%
Marketing	24.14%
Governmental Affairs	3.45%
Other: External affairs, general management, commercial operations	13.79%

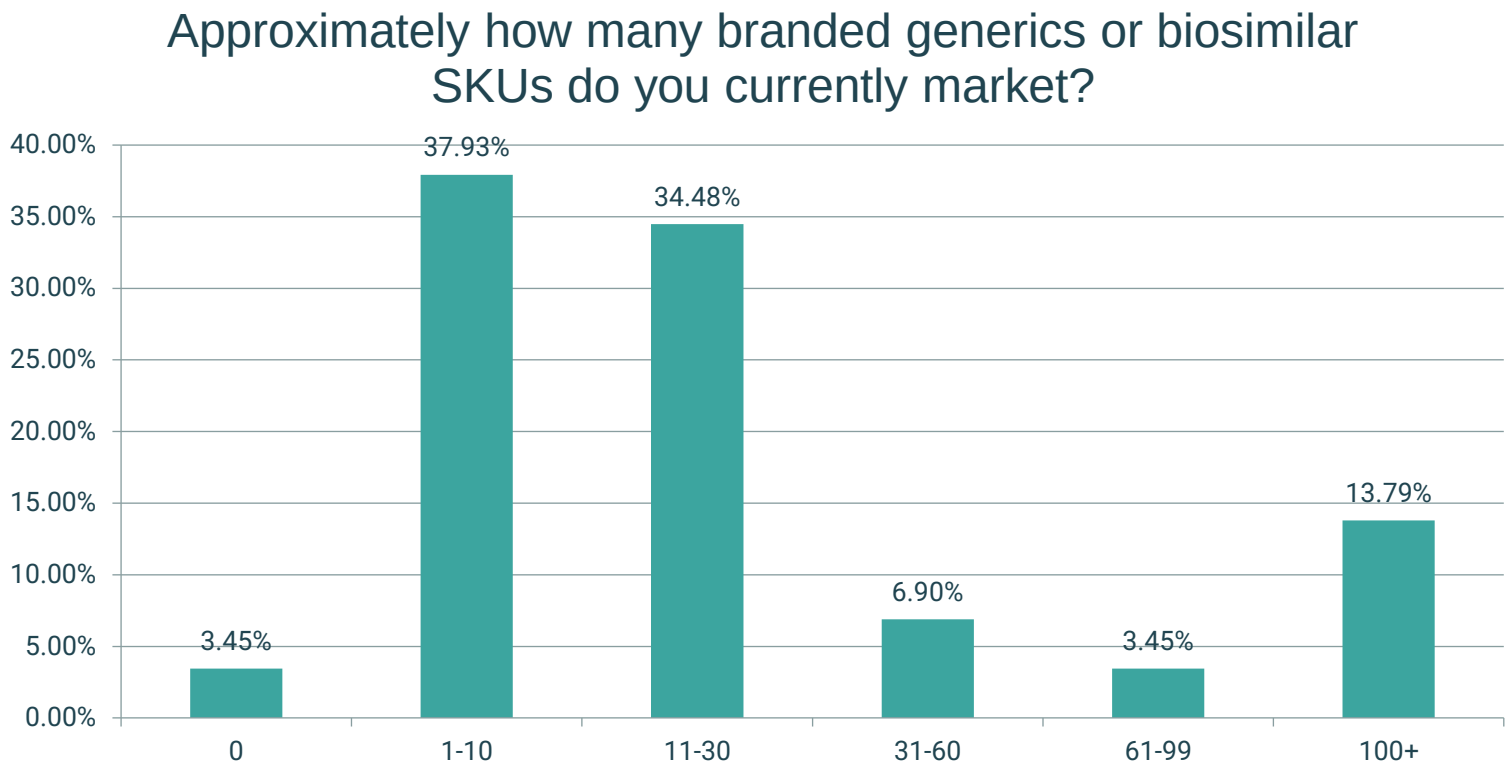
- **Work responsibilities:**

National level (single country)	89.66%
Regional level (selection of multiple countries)	10.34%
Global level (all relevant countries)	0.00%
Other (please specify)	0.00%

- **Therapeutic areas companies operate:**

Cardiovascular	51.72%
Dermatological	41.38%
Obstetrics	17.24%
Gynaecology and Urinary-Tract	48.28%
Central Nervous System	68.97%
Endocrine System	37.93%
Respiratory System	62.07%
Malignant Disease and Immunosuppression	44.83%
Other: Rheumatology Dermatology Gastroenterology Ophthalmology Multiple Sclerosis SMA Alzheimer's, Cancer Immunology, Pain Management, Nutrition)	24.14%

Over 72% of respondents bring to market between 1-30 branded generics or biosimilar SKUs.

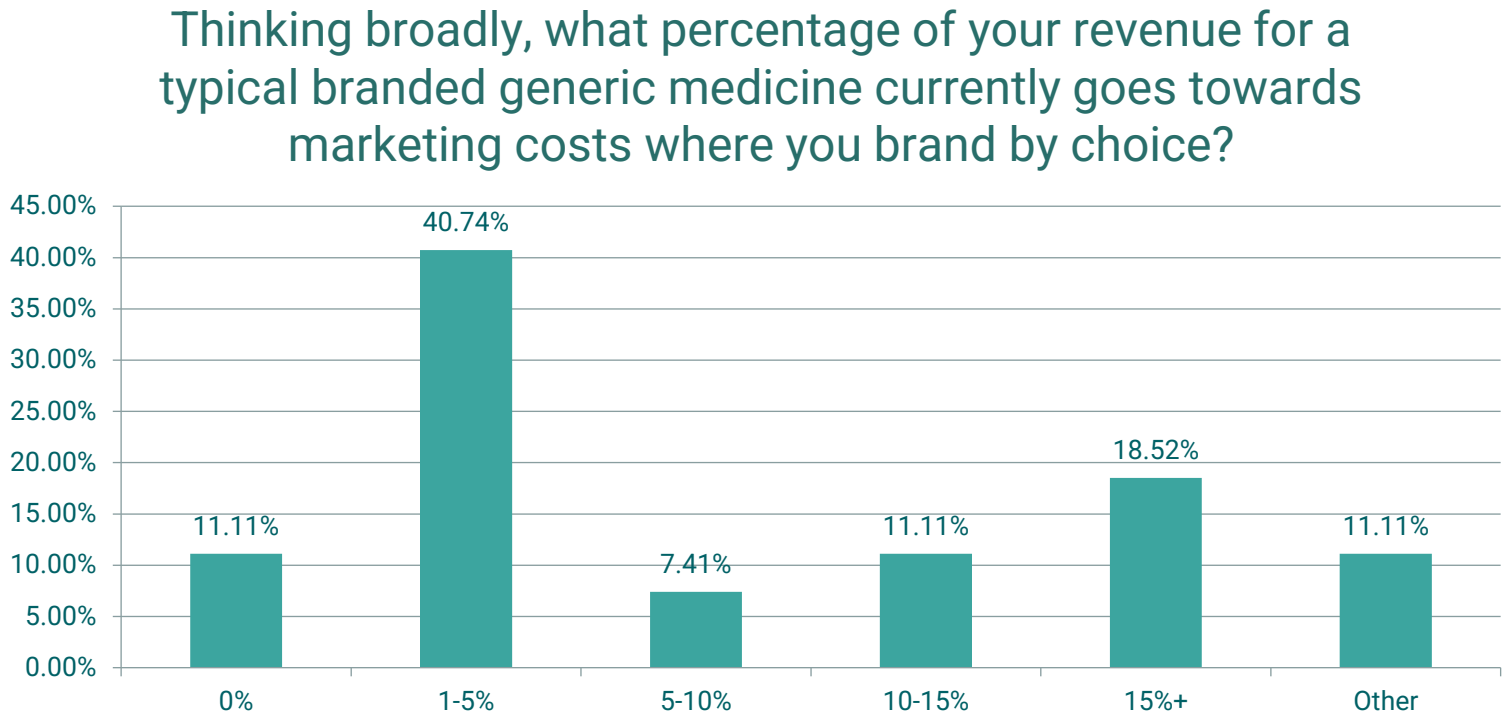


Over 40% spend 1-5% of branded generics' revenues on market costs when they brand by choice.

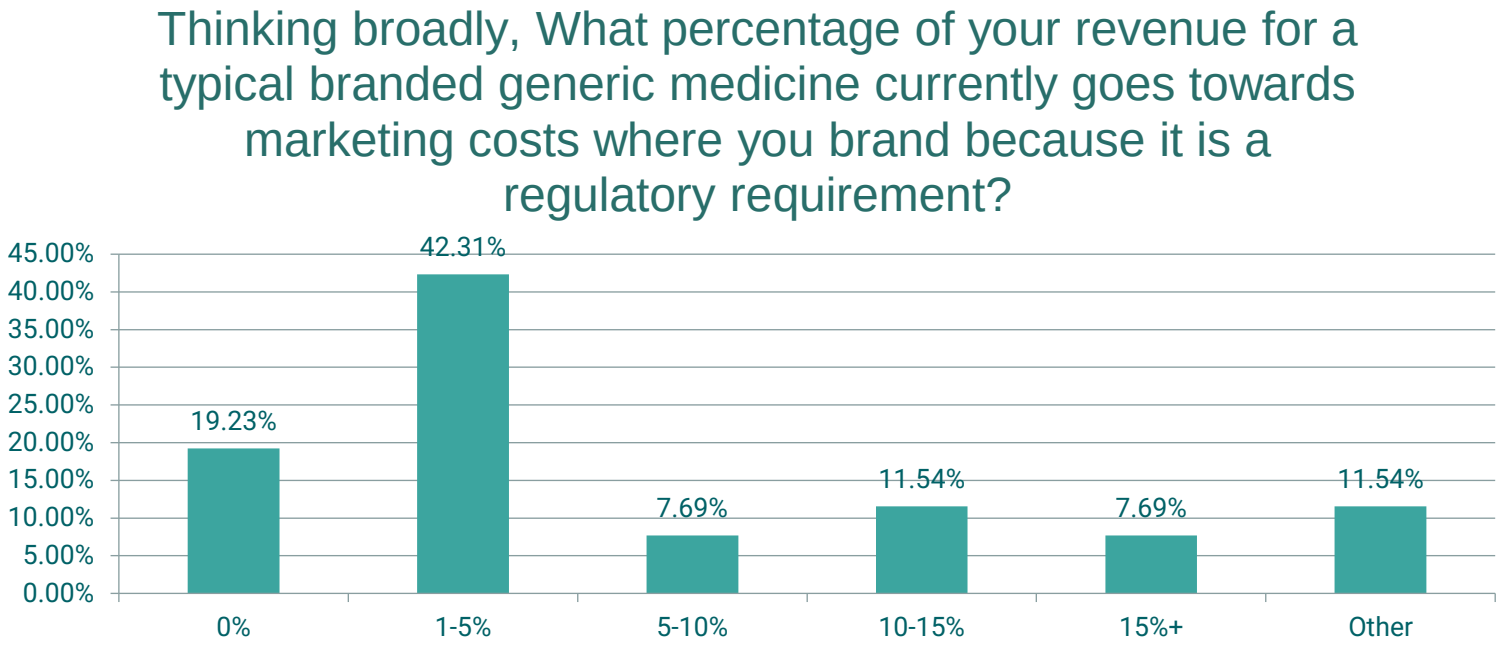
Note: Market costs include costs that are not only at the discretion of the manufacturer. These costs may include marketing costs, including costs that promote access or services that support the product usage (e.g., a homecare package).

Indicative respondent comment:

- No branded generics where we brand by choice.



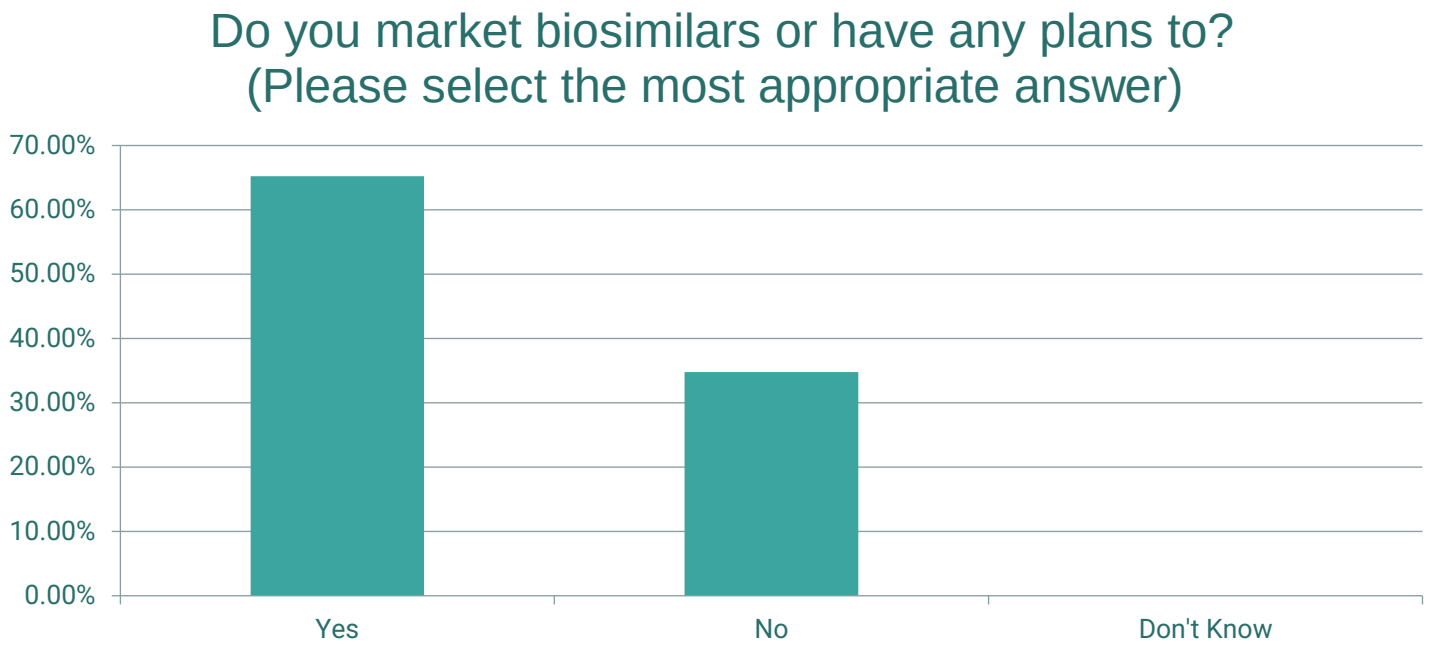
Over 42% spend 1-5% of branded generics' revenues on market costs when branded for regulatory requirement.



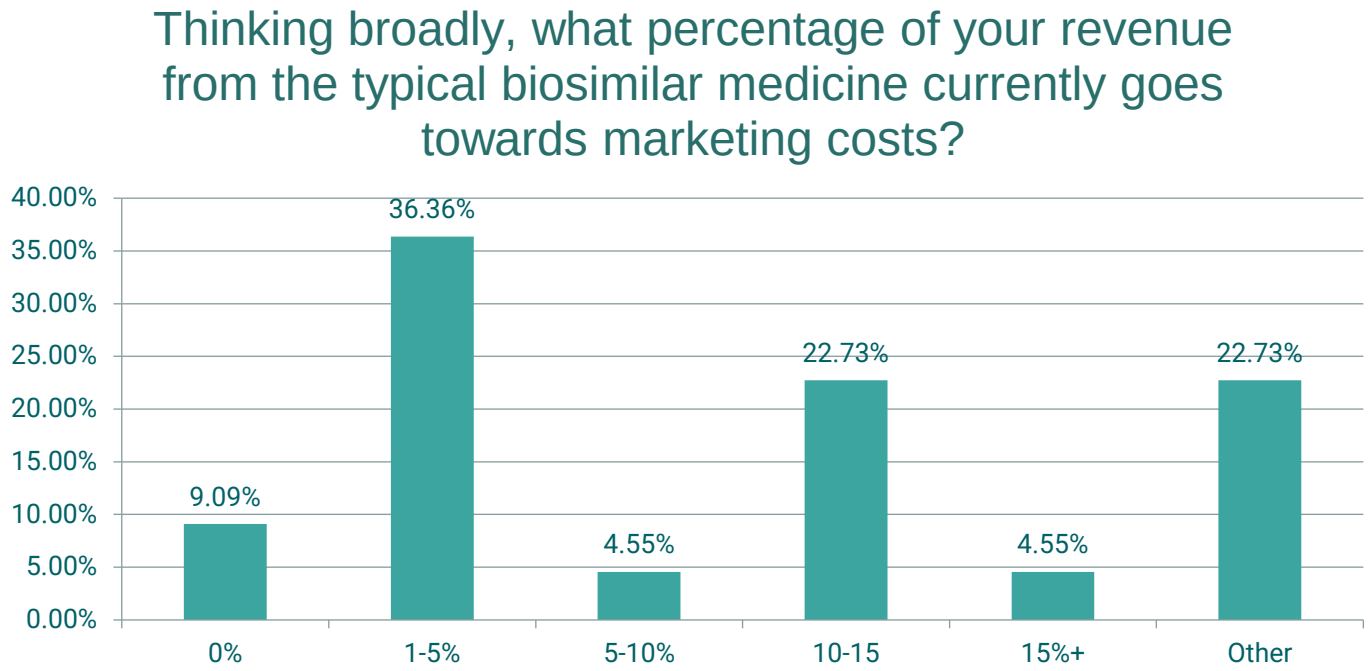
Indicative respondent comment:

- A much greater % of promotional spend in the earlier years of launch.

65% of the respondents market or have plans to market biosimilars.



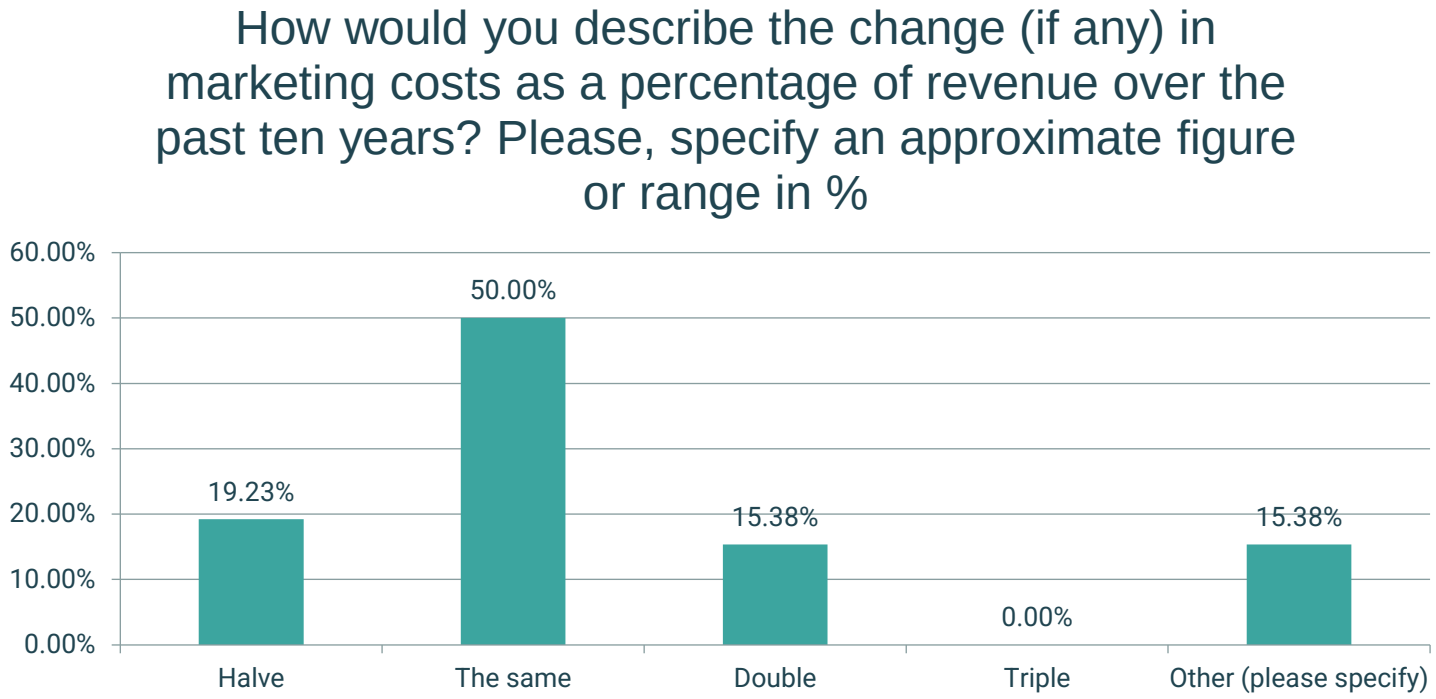
Over 23% spend 10-15% of biosimilars revenues on market costs.



The market costs as a percentage of revenue have doubled for 15.4% of the respondents.

Market costs will decrease or remain the same for 69.2% of respondents.

These results are likely to be driven by the firm size and their product portfolio.



Indicative respondent comment:

- Circa a 9 fold this year.
- Difficult to quantify as very much depends on level of sales/marketing resource a company decides to put behind a product (e.g. KAM's - number of sales people in team), congress sponsorship, number of marketing assets developed etc).

Market costs are expected to increase on average by 17.13% over the next five years.

How much do you expect market costs to increase over the next five years? Please, specify an approximate figure or range in %

- 0%, 5%, 5%-7%, 5%-10%,
- 10%+inflation, 10%-20%, 15%-20%,
- 30%, 100%

Average: 17.13%

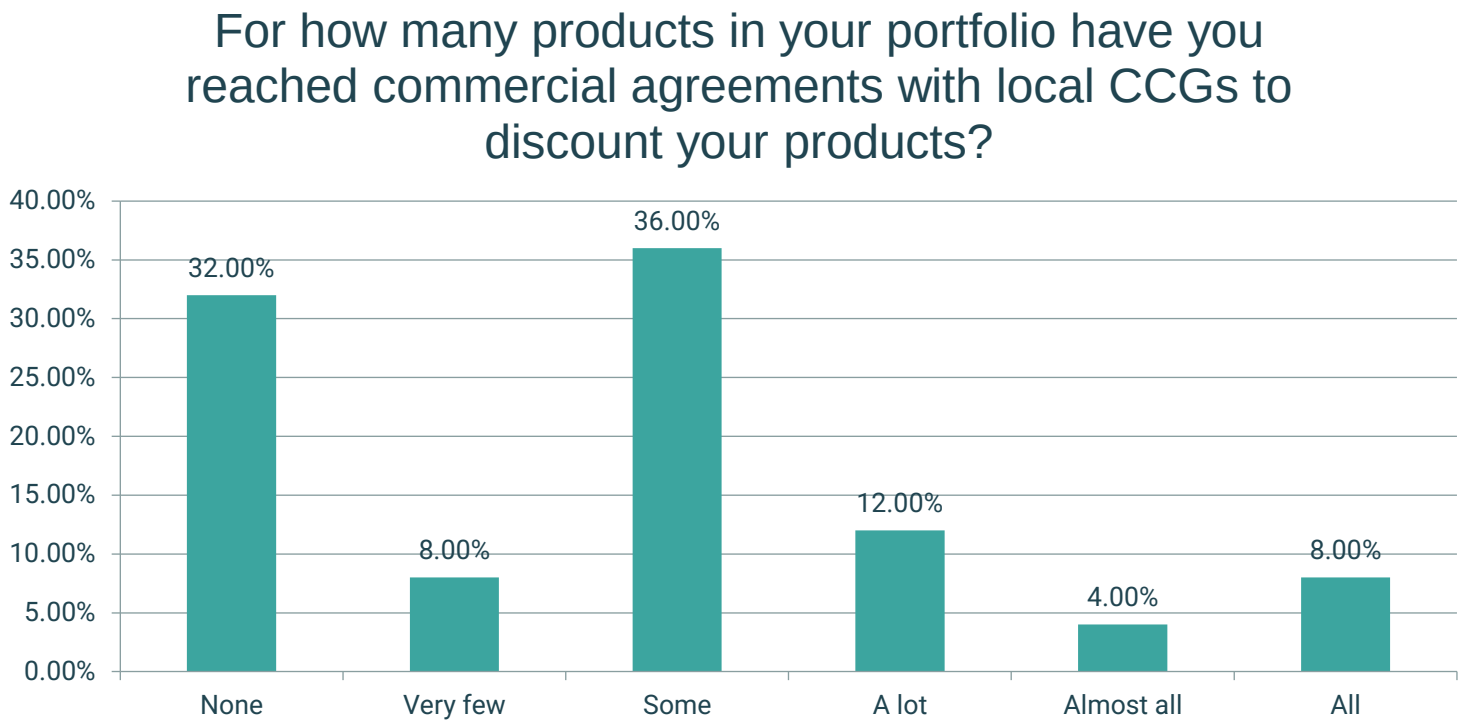
Respondents identified several different factors which can influence market costs.

What do you see as the key factors that drive your company's marketing costs?

- Profitability, Increased Competition
- Payers, Prescribing behaviour, Clinician engagement, Growth forecast
- Medical and regulatory approval
- Stakeholder access and engagement
- Complexity of the disease and technology used to treat patients
- Complexity of National & Local commissioning requirements and implementation
- Complexity and differing prioritisation within multiple local commissioning to drive change
- Therapy area experience/reputation
- Value to customers/prescribers/NHS/devolved
- The cost of moving towards a net zero organisation and the high current inflation and forecasted inflation rate

32% of the respondents didn't have any local CCG discount commercial agreements associated with any products in their portfolio.

44% of the respondents had a local CCG discount commercial agreement associated with some or very few products.



Respondents' opinion is split on whether the impact of competition and discounting on local CCGs changes across therapeutic areas.

Does the impact of competition and discounting on local CCGs change across therapeutic areas, and if so, how?
• Not in my experience - if they are willing to influence prescribing based on price, it's a fairly broad approach, apart, possibly, from epilepsy. • Yes, more competition drives greater discounts and savings for CCGs. • Yes - Respiratory and diabetes are very competitive. Where more players and competition then more price pressure and discount expected. Shared care pathways in our experience result in system inertia to change. • Relative to payer budget and product costs for that population. • The cheaper the product to produce, and the easier it is to switch between brands, and the greater the competition, will to an extent determine the net price. A branded generic asthma/ COPD inhaler might be more expensive to produce and more expensive to promote due to the high complexity of driving prescribing change than perhaps other disease areas. The higher the complexity of the brand "switch" is also likely to determine the resistance of the originator to significantly price compete.

The average CCG discount or rebate as a percentage of the final selling price of branded generics and biosimilars is between 10-75%. The CCG discount or rebate is 29.5%.

What is the average CCG discount or rebate, as an approximate percentage of the final selling price of the branded generic or biosimilar?

10%, 15%, 20%, 10%-30%, 15%-30%, 30%, 10%-40%, 40%-60%, 50%, 70%, 75%

Average: 29.5% (This may only represent part of the total discount offered in actual sales prices when compared against products' NHS List Prices)

Some companies seek formularies at the CCG level, but others do not.

To what extent does your company seek formularies at the CCG level?

- To a large extent across all Primary Care products. Formulary is key to the success of all Primary Care brands.
- Historically yes but currently no activity in that regard.
- To a great extent.
- At every opportunity.
- Highly with branded generics.
- Rarely. Most conversations take place at regional level.

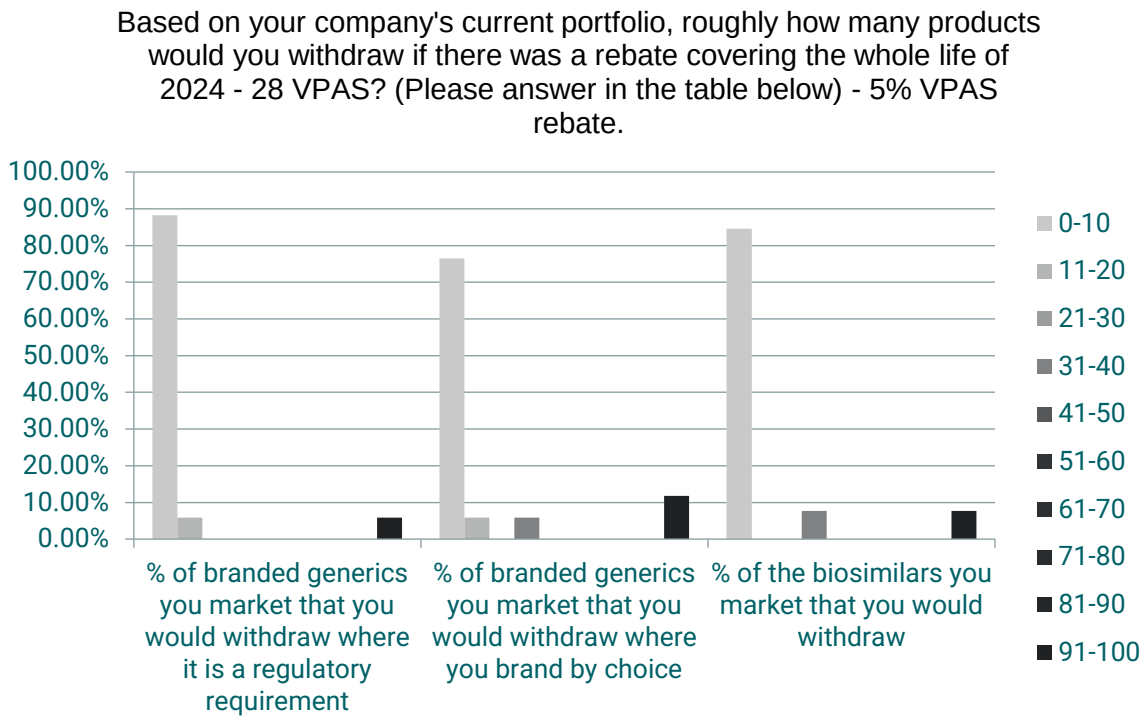
Experiences and opinions on the costs of the negotiations with the CCG varied.

What has been the cost of these negotiations, and how have the local CCGs benefited? Has this resulted in those CCGs buying at a discount?

- CCG's buy at a discount for branded generics where the list price is below the Drug tariff and the Rx is written by brand. This discount is a function of the headroom between Brand list and the Drug Tariff. VPAS rates will squeeze the manufacturer margin further.
- Difficult to quantify.
- There have been massive savings for the CCGs over a number of years, typically 20% of every product it replaced plus a rebate - which averages another 20%.
- Employment cost of market access team approx. £250k per annum which has resulted in savings to the CCG's over and above the innovator cost in most cases.
- Cost: Slow time to the uptake of branded generic. Benefit: lower Rx budget once implemented. Result: yes, always a benefit as the CCGs buy at a lower price than list price with additional rebates possible. Opportunity loss: Pull through of actions to achieve savings is often slow.

With 5% VPAS rebate, 88% and 76.5% of the respondents would withdraw 0%-10% of branded generics, where it is a regulatory requirement or they brand by choice, respectively.

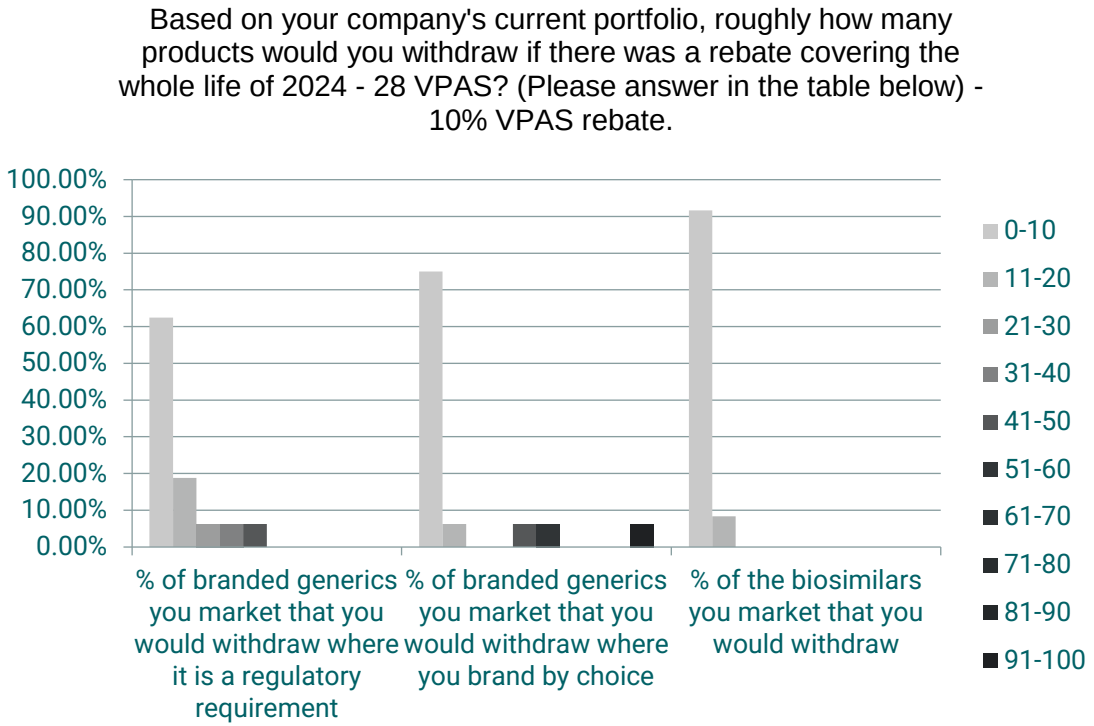
With 5% VPAS rebate, 84.6% of the respondents would withdraw 0%-10% of their biosimilars.



With 10% VPAS rebate, 62.5% and 75% of the respondents would withdraw 0%-10% of branded generics, where it is a regulatory requirement or they brand by choice, respectively.

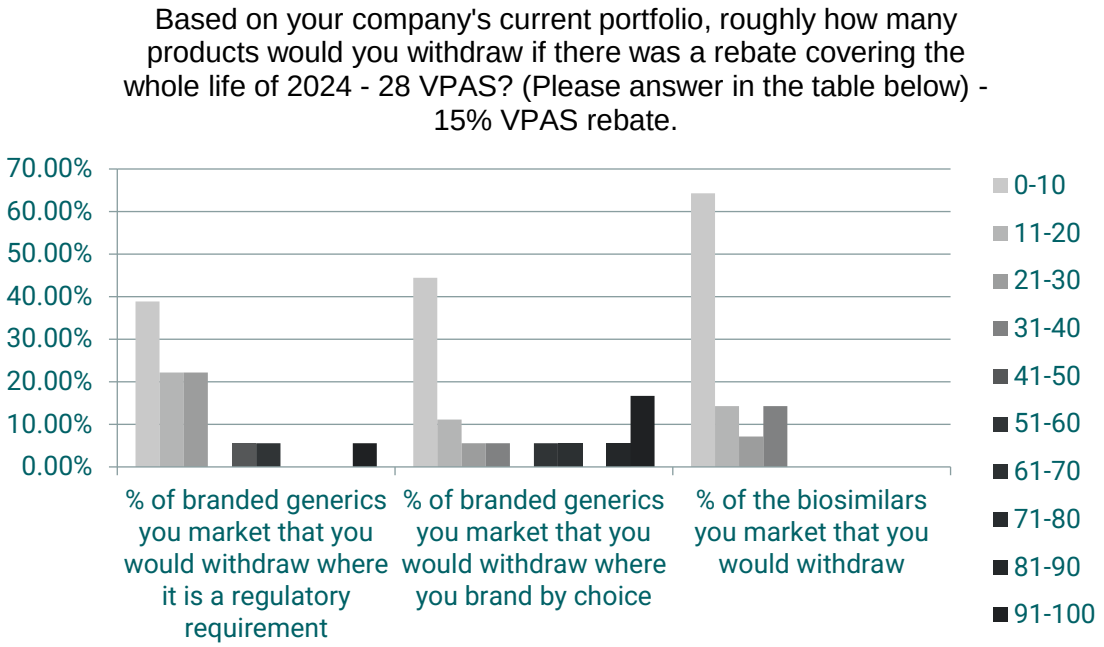
With 10% VPAS rebate, 18.75% of the respondents would withdraw 11%-20% of their branded generics where it is regulatory approval.

With 10% VPAS rebate, 91.7% of the respondents would withdraw 0%-10% of their biosimilars.



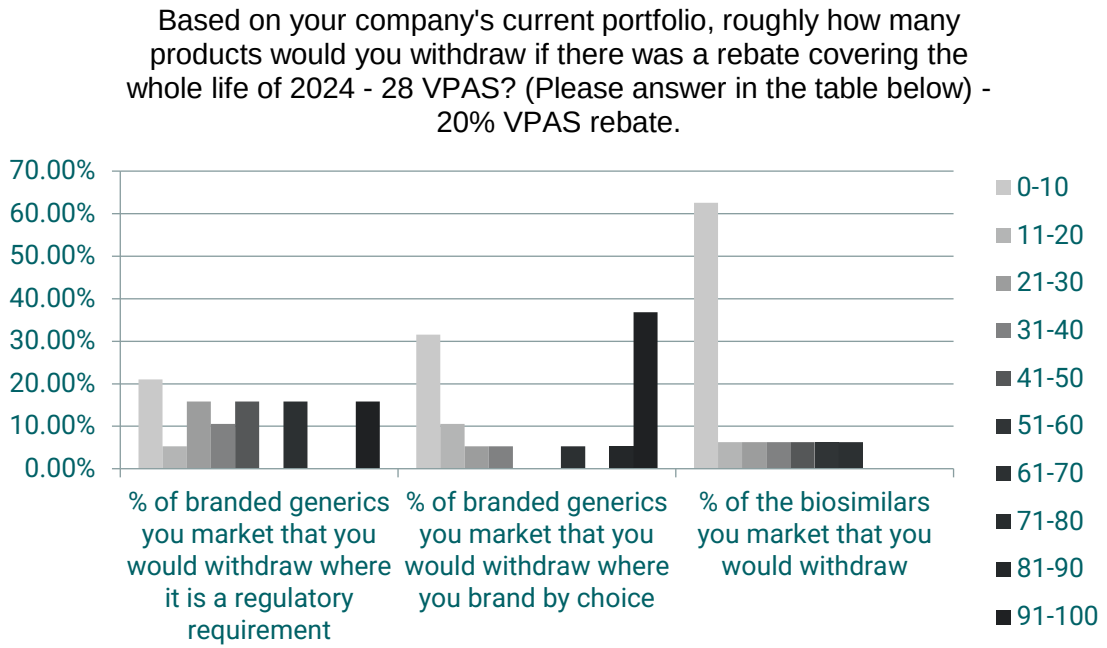
With 15% VPAS rebate, 44.44% of the respondents would withdraw 11%-30% of branded generics, where it is a regulatory requirement.

With 15% VPAS rebate, 78.5% of the respondents would withdraw 0%-20% of their biosimilars.



With 20% VPAS rebate, 42.1% of the respondents would withdraw 21%-50% of branded generics, where it is a regulatory requirement.

With 20% VPAS rebate, 37.5% of the respondents would withdraw 11%-70% of their biosimilars.



Different members would react differently on entering markets with biosimilars if the VPAS was 25%.

Which markets would or are you considering entering with biosimilars for biologics that are coming off patent or where the biologic has already lost its exclusivity, and would you still consider entering if the VPAS was 25%?

- Yes, we are still considering entering with biosimilars for biologics and we would still consider entering if the VPAS was 25%.
- None - prices are already too low and ANY rebate makes them unviable.
- Oncology and Rheumatoid Arthritis. Yes would still consider but would have to see if the costs for market access justified the return on our investment.
- Immunology, Oncology, Orthopaedics, Respiratory.
- Immunology, Oncology, Ophthalmology, Dermatology.
- Multiple markets are being considered for entering with biological products. We would still consider launching, but the higher VPAS percentage has a direct impact on commercial viability, which ultimately may result in not launching as there would be no commercially viability.

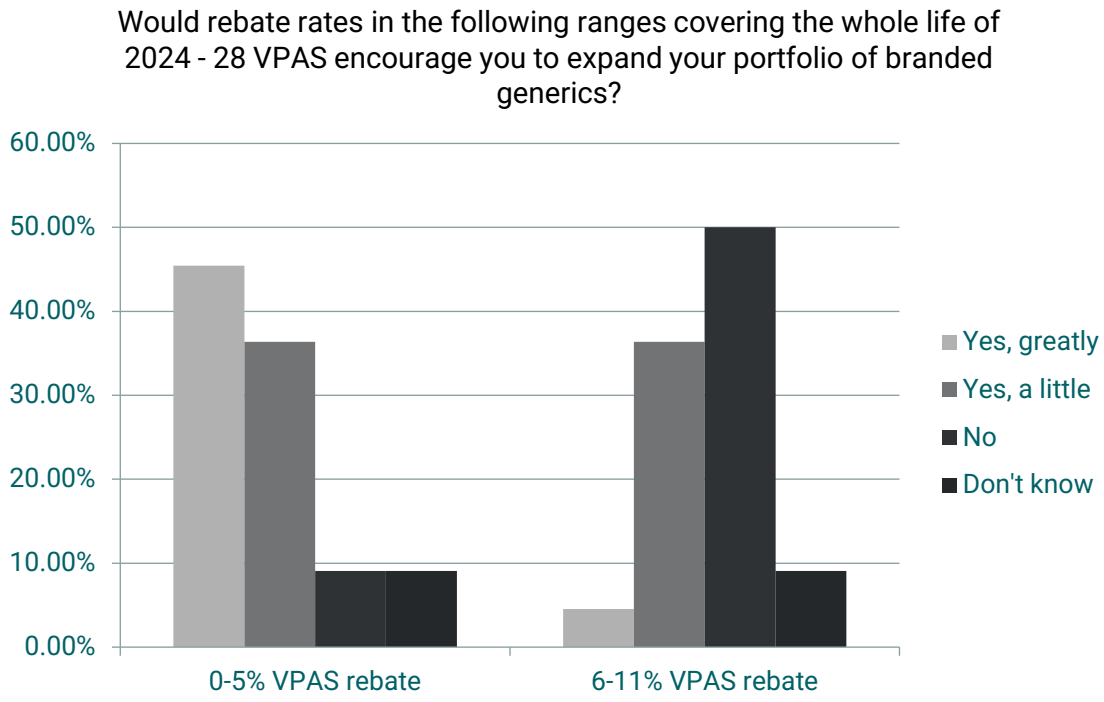
Different members would react differently on entering markets with branded generics if the VPAS was 25%.

Which markets would or are you considering entering with branded generics for drugs that are coming off patent or where the branded product has already lost its exclusivity, and would you still consider entering if the VPAS was 25%?

- None - I would enter with an INN + manufacturer to avoid VPAS. VPAS at 25% would discourage UK entry.
- We would not consider at these rates and with the unpredictability.
- Diabetes - yes would consider entering but again the ROI would be critical to our decision.
- Multiple therapy areas and would not consider entering if VPAS was 25%, this will limit any new molecules entering the market.
- Oncology & respiratory. No, we wouldn't enter.
- Markets where the originator is brand prescribed and where we can offer the NHS meaningful savings, clinician and patient support. We would not consider this if VPAS was 25% as the list price discount + 25% rebate would make most products unviable.
- Wouldn’t launch any branded generics.

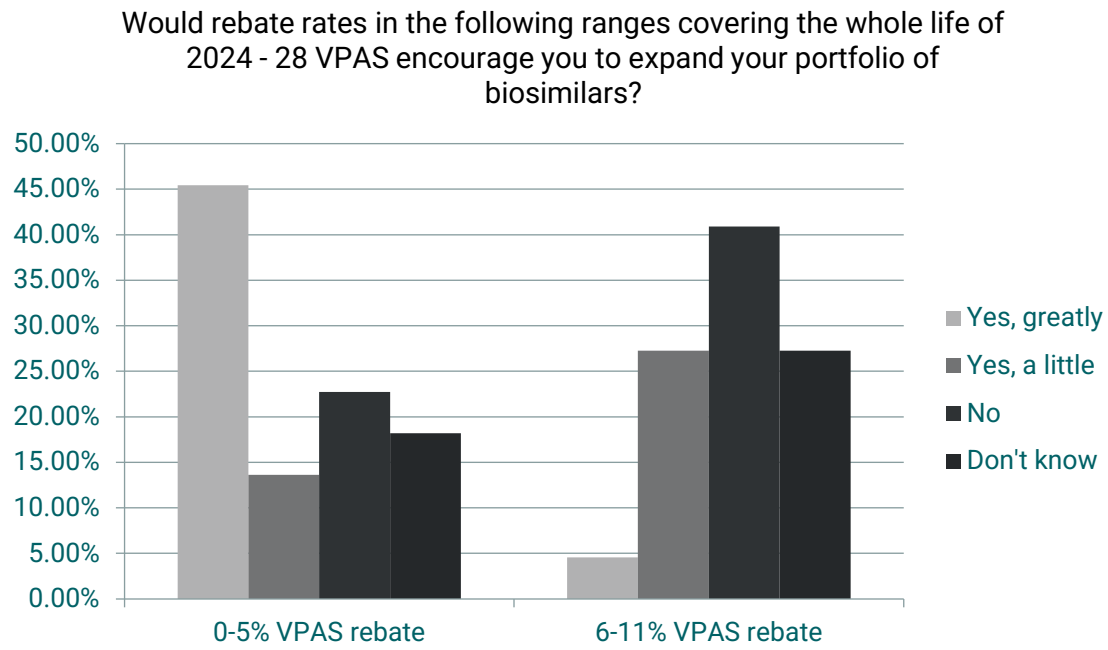
A VPAS rebate between 0%-5% would encourage 82% of the respondents to expand their portfolio of branded generics.

A VPAS rebate between 6%-11% would discourage 50% of the respondents to expand their portfolio of branded generics.



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

A VPAS rebate between 6%-11% would discourage 41% of the respondents to expand their portfolio of biosimilars.



The decision to apply for a price increase in at least one product varies across companies.

Has your company applied for a price increase in at least one product in your portfolio?

- Yes [50%], No[50%].
- We have not yet applied for a List Price increase, however we are reviewing our level of commercial discounts and secondary care tender pricing. The biosimilar and branded generic tender model (volume uptake criteria is largely lowest price) encourages competition and generates significant savings for the NHS.
- Yes, we applied for and had granted 6 price increases.

Almost all respondents agree that commercial viability is critical in applying for a price increase.

What were the reasons for applying for this price increase, or if you have applied for multiple increases, what were the reasons for applying for your last price increase?

- Because at the previous price (with increasing costs) it would have been unviable to continue to supply.
- Reduction and negative margins.
- The increase in VPAS percentage has a direct impact on the commercial viability of a product that is already significantly discounted in a competitive typically tendered market.
- Increase in manufacturing costs.
- N/A.

Processes can act as barriers when seeking price increases.

When seeking price increases, what have you found to be the barriers and bottlenecks in this process?

- No clear guidance, the uncertainty of the outcome.
- Process / Lack of visibility of the process by the DHSC.
- Restricted and unrealistic ROI.
- Timelines.

The response from the DHSC regarding a price increase varies across companies.

What was the response from the DHSC regarding the last request for a price increase, and was your company able to reach a successful outcome?

- Declined and no successful outcome.
- Still in discussions.
- We have not yet applied for a DH price increase.
- Yes, with some negotiation.

Survey Questionnaire

OFFICE OF HEALTH ECONOMICS

VPAS and Statutory Scheme investigative survey

Thank you for agreeing to take part in this survey. OHE Consulting is conducting a study to investigate the operation of the NHS primary and secondary care market for branded generic and biosimilar medicines and the impact of competition on prices and expenditure.
The qualitative information gained through this questionnaire will support quantitative analyses of price and volume data across a large number of products.
The following questions have been designed to facilitate and strengthen the modelling activities. All responses will be deleted upon the completion of the project. No comments or responses will be attributed directly to you or your company in any write-up of the survey results.

1. Please provide your name

2. Please state the company you currently work for

3. Which type of products does your company sell?

- ◯ Branded Generics
- ◯ Biosimilars
- ◯ Both
- ◯ Other (please specify)

4. Please indicate which description fits your department best

- ☐ Pricing
- ☐ Market Access
- ☐ Health Economics and Outcomes Research
- ☐ Sales
- ☐ Marketing
- ☐ Governmental Affairs
- ☐ Other (please specify)

5. Please provide information regarding the scope of your work responsibilities

- ◯ National level (single country)
- ◯ Regional level (selection of multiple countries)
- ◯ Global level (all relevant countries)
- ◯ Other (please specify)

6. What are the therapeutic areas in which your company operates?

- ☐ Cardiovascular
- ☐ Dermatological
- ☐ Obstetrics
- ☐ Gynaecology and Urinary-Tract
- ☐ Central Nervous System
- ☐ Endocrine System
- ☐ Respiratory System
- ☐ Malignant Disease and Immunosuppression
- ☐ Other (please specify)

7. Approximately how many branded generics or biosimilar SKUs do you currently market?

- ◯ 0
- ◯ 1-10
- ◯ 11-30
- ◯ 31-60
- ◯ 61-99
- ◯ 100+

Next

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OFFICE OF HEALTH ECONOMICS

VPAS and Statutory Scheme investigative survey

Questions around market costs

8. Thinking broadly, what percentage of your revenue for a typical branded generic medicine currently goes towards marketing costs where you brand by choice?

- ◯ 0%
- ◯ 1-5%
- ◯ 5-10%
- ◯ 10-15%
- ◯ 15%+
- ◯ Exact figure

9. Thinking broadly, What percentage of your revenue for a typical branded generic medicine currently goes towards marketing costs where you brand because it is a regulatory requirement?

- ◯ 0%
- ◯ 1-5%
- ◯ 5-10%
- ◯ 10-15%
- ◯ 15%+
- ◯ Exact figure

10. Thinking broadly, what percentage of your revenue from the typical biosimilar medicine currently goes towards marketing costs?

- ◯ 0%
- ◯ 1-5%
- ◯ 5-10%
- ◯ 10-15
- ◯ 15%+
- ◯ Exact figure

11. How would you describe the change (if any) in marketing costs as a percentage of revenue over the past ten years? Please, specify an approximate figure or range in %

- ◯ Halve
- ◯ The same
- ◯ Double
- ◯ Triple
- ◯ Other (please specify)

12. How much do you expect market costs to increase over the next five years? Please, specify an approximate figure or range in %

13. What do you see as the key factors that drive your company's marketing costs?

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Survey Questionnaire

OFFICE OF HEALTH ECONOMICS

VPAS and Statutory Scheme investigative survey

Questions about local CCG discounts

14. For how many products in your portfolio have you reached commercial agreements with local CCGs to discount your products?

- None
- Very few
- Some
- A lot
- Almost all
- All

15. Does the impact of competition and discounting on local CCGs change across therapeutic areas, and if so, how?

16. What is the average CCG discount or rebate, as an approximate percentage of the final selling price of the branded generic or biosimilar?

17. To what extent does your company seek formularies at the CCG level?

18. What has been the cost of these negotiations, and how have the local CCGs benefited? Has this resulted in those CCGs buying at a discount?

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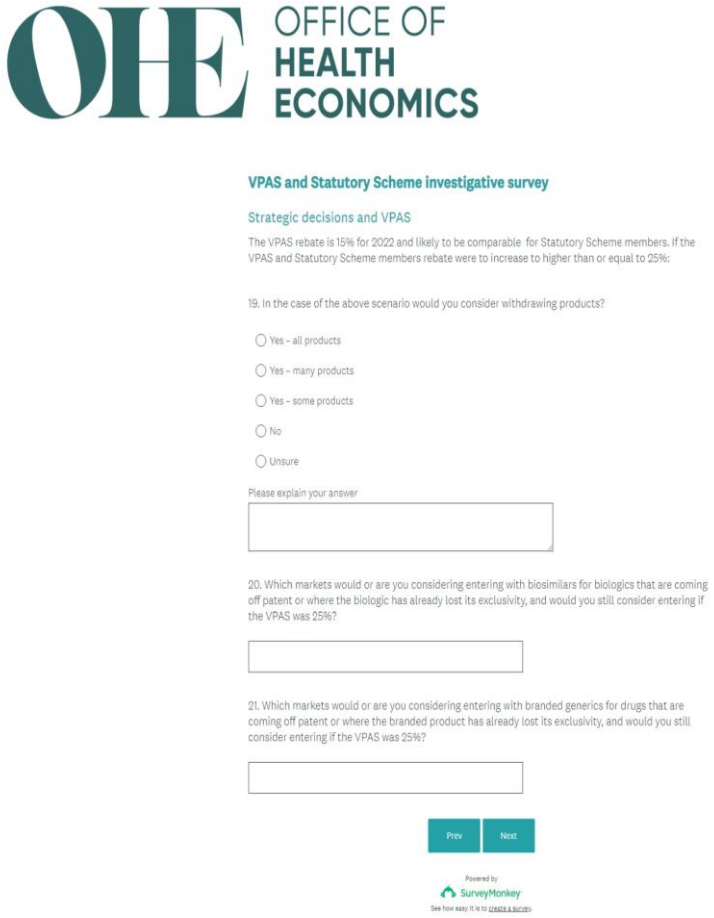

OFFICE OF HEALTH ECONOMICS

VPAS and Statutory Scheme investigative survey

Strategic decisions and VPAS

The VPAS rebate is 15% for 2022 and likely to be comparable for Statutory Scheme members. If the VPAS and Statutory Scheme members rebate were to increase to higher than or equal to 25%:

19. In the case of the above scenario would you consider withdrawing products?

- Yes - all products
- Yes - many products
- Yes - some products
- No
- Unsure

Please explain your answer

20. Which markets would or are you considering entering with biosimilars for biologics that are coming off patent or where the biologic has already lost its exclusivity, and would you still consider entering if the VPAS was 25%?

21. Which markets would or are you considering entering with branded generics for drugs that are coming off patent or where the branded product has already lost its exclusivity, and would you still consider entering if the VPAS was 25%?

Prev Next

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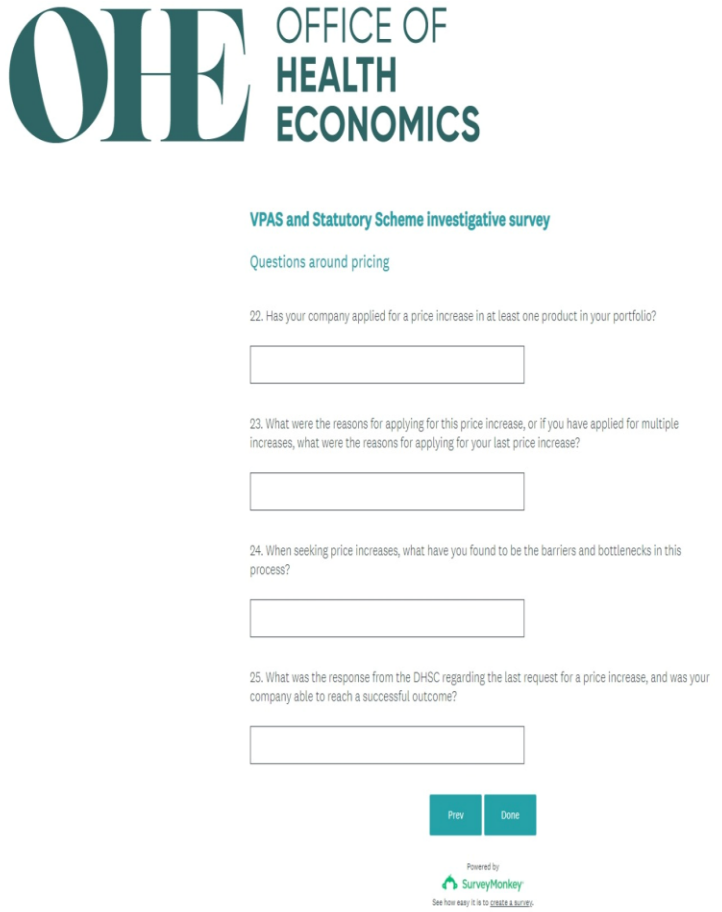

OFFICE OF HEALTH ECONOMICS

VPAS and Statutory Scheme investigative survey

Questions around pricing

22. Has your company applied for a price increase in at least one product in your portfolio?

23. What were the reasons for applying for this price increase, or if you have applied for multiple increases, what were the reasons for applying for your last price increase?

24. When seeking price increases, what have you found to be the barriers and bottlenecks in this process?

25. What was the response from the DHSC regarding the last request for a price increase, and was your company able to reach a successful outcome?

Prev Done

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Survey Questionnaire (additional survey)

OHE Study Survey

* 1. What company are you responding on behalf of?

2. Roughly how many branded generic presentations do you currently supply? (Please select the most appropriate answer)

- ◯ Between 0 - 10
- ◯ Between 11 - 30
- ◯ Between 31 - 60
- ◯ Between 61 - 100
- ◯ Over 100

3. Do you market biosimilars or have any plans to? (Please select the most appropriate answer)

- ◯ Yes
- ◯ No
- ◯ Don't Know

4. Based on your company's current portfolio, roughly how many products would you withdraw if there was a rebate covering the whole life of 2024 - 28 VPAS? (Please answer in the table below)

	5% VPAS rebate	10% VPAS rebate	15% VPAS rebate	20% VPAS rebate
% of branded generics you market that you would withdraw where it is a regulatory requirement				
% of branded generics you market that you would withdraw where you brand by choice				
% of the biosimilars you market that you would withdraw				

5. Would rebate rates in the following ranges covering the whole life of 2024 - 28 VPAS encourage you to expand your portfolio of branded generics? (Please tick the most appropriate answer)

	Yes, greatly	Yes, a little	No	Don't know
0-5% VPAS rebate	◯	◯	◯	◯
6-11% VPAS rebate	◯	◯	◯	◯

6. Would rebate rates in the following ranges covering the whole life of 2024 - 28 VPAS encourage you to expand your portfolio of biosimilars? (Please tick the most appropriate answer)

	Yes, greatly	Yes, a little	No	Don't know
0-5% VPAS rebate	◯	◯	◯	◯
6-11% VPAS rebate	◯	◯	◯	◯

7. On average, how much in rough percentage terms has total inflation in energy, materials, transport and staff increased your cost of supply in 2022, compared to 2021? (Please specify percentage)

DONE

APPENDIX 3

Market Tracking Tool and Simulations

Market Tool and Simulations – Data Management.

- For the analyses, the OHE team utilised the members' survey, IQVIA, and firm-specific proprietary data, and publicly available data.
- This slide-deck is supplemented with an excel file, which contains the dataset and the market tracking tool and simulations.

To enquire about additional information and analyses, please contact:

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