Government Medicines Levy Could Cost the NHS Billions in Lost Savings

- Scheme designed to encourage new treatments is critically impacting generic and biosimilar medicines market, forcing manufacturers to withdraw products
- Billions of pounds being lost to the NHS through reduction in competition
- Rising rebate rate is forcing manufacturers to shun the UK market further reducing price competition
- BGMA calls for branded generics and biosimilars to be exempt from VPAS

A Government levy on medicines designed to increase access to new treatments and promote affordability could actually be denying the NHS billions of pounds of annual savings due to the impact it is having on branded generics and biosimilars, according to a new economic study.

The Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) is an agreement between the UK Government, NHS England, and the pharmaceutical industry. The purpose of the scheme - which came into being in 2019 - is to strike a balance between supporting innovation and patient access as well as ensuring complete predictability on spend for the entire branded medicines bill for the NHS. As a result of VPAS, the branded medicines bill cannot grow by more than 2% in any of the five years of its existence.

It contains a UK-wide affordability mechanism under which Scheme members make a financial contribution to the Department of Health and Social Care (DHSC) for NHS sales of branded medicines if the overall drugs budget for branded products exceeds the 2% cap. This includes the manufacturers of branded generics and biosimilars[1].

However, analysis conducted by the Office of Health Economics (OHE) reviewed and supported by Prof. Alistair McGuire of the London School of Economics (LSE), showed that rather than controlling costs for the NHS, the scheme could be set to cost billions of pounds in forfeited savings every year.

The repayment percentage for each year of VPAS depends on the difference between the allowed growth of 2% and forecast growth in sales to the NHS of the branded medicines. In 2019, the first calendar year of VPAS, the repayment percentage was 9.6%, in line with the anticipated increase in spending on branded medicines, and in total pharmaceutical companies repaid DHSC just under £850 million.

However, the rate was most recently raised from 5.1% to 15% in January to recognise the exceptional levels of spend on medicines during the pandemic. Next year it is expected to rise to 23.7% and could reach as high as 30% before the current agreement renews. The scale of the levy is exacerbated by manufacturers of new blockbuster patented medicines being exempted for three years, the costs of which other VPAS member companies have to bear.

[1] Those that don't sign up automatically become members of the Statutory Scheme for Branded Medicines, which applies a similar levy.

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Branded medicines which fall under the remit of the scheme make up about 30% of all prescription medicines in England. Of those about a third are branded generics and biosimilars. These are products which by being genericised already mean they face competition which drives down prices. For example, the research shows that the average branded generic is a third of the price of the originator pre-loss of exclusivity, with around one third of those branded generics being sold at a price that is 80% less than the originator version.

However, due to the rising rate of VPAS on top of existing competition, manufacturers are finding the additional levy economically unviable given their already low prices. According to research done by OHE and Professor Alistair McGuire (LSE) this will see manufacturers pull out of the market meaning prices will rise due to a lack of competition and critical savings to the NHS will be lost.

OHE's forecast analysis looks ahead to the next five-year VPAS period between 2024 and 2028 and shows that at a VPAS rebate rate of 5%, the NHS will lose out on £3.071bn of branded generics and biosimilars savings between 2024 and 2028, compared to exempting branded generics and biosimilars from the VPAS levy. This includes offsetting the losses to the NHS with the income the Government receives from the VPAS levy being applied to branded generics and biosimilars.

Similarly, this rises to £3.068bn at 20%, £7.852bn at 25% and £7.811bn at 30%.

These lost savings are the consolidation of three costs borne by the NHS: higher reimbursement prices paid for medicines; a reduction in the level of discounts received by local NHS trusts; and higher prices paid for biosimilars in hospital tenders.

Based on the first year of the new VPAS period in 2024 being at predicted rate of around 25%, the NHS is set to lose out by more than £800m over and above the projected levy income in the first 12 months alone.

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	

Professor Alistair McGuire from LSE, said: "Our simulation analysis shows a clear link that the VPAS mechanism, which is aimed at capping costs to the Government by increasing the rates of rebates, could actually reduce generic and biosimilar competition to such an extent that prices rise for the NHS. Our model predicts that the detrimental impact over the next five-year period could cost the NHS billions of pounds far outweighing any income the levy brings in.

"The VPAS volatility - moving from 5% of revenue in 2021 to 15% this year and potentially higher - means that the central Government revenue increases but the NHS pays more for its medicines."

Separate data from IQVIA shows that growth in spend on originator medicines in 2021 and in 2022 (to date) is 15% and 18% respectively, whilst off-patent medicines spend contracted by 2% in 2021 and grew 3% in 2022. This further reinforces the point that branded generics and biosimilars are supporting the growth in spend on on-patent medicines.

Mark Samuels, Chief Executive of the British Generic Manufacturers Association (BGMA), the trade body for generic medicine manufacturers, said: "Generics and biosimilars represent 4 out of 5 medicines used by the NHS. They provide crucial competition when an originator product patent expires, and this saves the NHS approximately £15billion annually and means the UK has the lowest medicine prices in Europe.

"However, this is being put in jeopardy by this penalising rebate, which is effectively an additional tax on branded generic medicines. We have argued for a long time that branded generic and biosimilar medicines should be exempt as it is in effect a double taxation on products already delivering massive savings via competition.

"This study shows the very harmful effect on the market from VPAS and ultimately it will be the NHS and patients which are most impacted."

Manufacturers can seek to raise their prices in response to the VPAS rate, but if they want to go beyond their submitted NHS list price or the hospital tender price, they must enter negotiations which requires the sharing of commercial pricing information. In many instances these applications are unsuccessful and very time-consuming which is an off-putting factor for a company that markets tens or even hundreds of presentations.

Biosimilar medicines and many branded generics are branded because it is a requirement of the regulator in patients' interests. However, doctors prescribe generically to enable competition, or they are procured through competitive tenders, so the brand does not offer any particular value.

Mark Samuels, added: "I have heard from companies directly that they are having to withdraw products as the operating environment is simply unfeasible. The VPAS payment was one of the factors connected to the recent shortage of HRT products. One company in particular is considering closing its UK operations completely as a result of the VPAS scheme. The rocketing levy also comes at a time when medicines production, transportation and distribution costs are also increasing.

"The system is just not sustainable. It is high time the Government reviewed their approach to make it fairer and encourage more competition, which has been independently shown[2] to be most effective at regulating the prices of medicines paid by the NHS."

The study also examined the rebate rise across various scenarios for biosimilar products. Although a reduction in competition was much less in relation to rebate rises, it was evident that new product launches would be greatly reduced as a result meaning again potential savings to the NHS would disappear.

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About the British Generic Manufacturers Association (BGMA)

The BGMA is made up of members of the generic manufacturing supply industry, who between them account for approximately 85% of the total UK generic market by volume. A key feature of the strong generics industry in the UK is that it introduces competition to the supply of prescription medicines making them more affordable to the NHS and enhancing their availability to patients.

According to NHS figures (NHS Digital), more than a billion items are prescribed generically every year. The competition provided by generic medicines saves the NHS around £15billion annually.

Notes to editors

- OHE's methodology in this report is based on extensive simulation modelling. This has been undertaken on 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. Central to this modelling has been extensive surveying of BGMA members.