

How will the new VPAG rebate regulations affect launch strategy in the UK?

Ally Robert, Michaela Lysakova Ivanova; Avalere Health, Knutsford, UK

Introduction

The UK has two regulatory schemes for pharmaceutical pricing: a statutory scheme and a voluntary scheme. The current Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) is a voluntary, non-contractual agreement between the Department of Health and Social Care (DHSC), National Health Service (NHS), and Association of the British Pharmaceutical Industry (ABPI) under which participating pharmaceutical manufacturers pay back a percentage of revenue from sales to the NHS over a certain amount, with the aim of containing NHS expenditure on branded medicines within an agreed limit between 2024 and 2028.^{1,2} VPAG is intended to promote patient outcomes by ensuring access to new cost-effective medicines and encouraging innovation, while striking a balance with supporting the UK economy and the sustainability of NHS finances.³ However, the extent to which the VPAG will achieve these aims remains to be seen, with the previous Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) scheme, which ended in December 2023, serving as a warning.

Methods

Objectives

- To understand and characterize the differences between the old VPAS and new VPAG.
- To assess the potential impact of VPAG on pharmaceutical manufacturers.
- To develop recommendations for a UK launch strategy.

Methodology

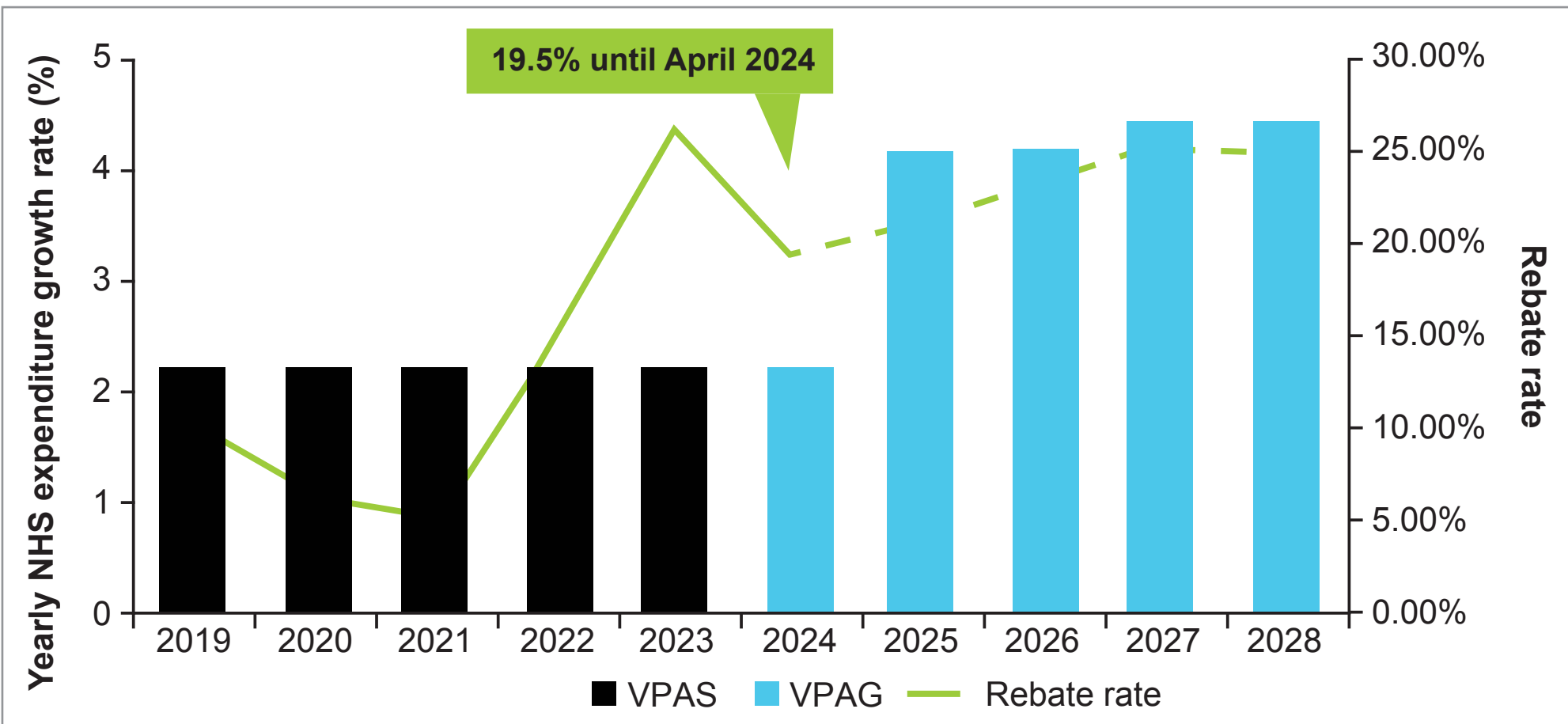
- Targeted literature search of relevant gray literature published between June 2023 and March 2024 to analyze the differences between the old VPAS and new VPAG schemes.
- Qualitative review to define the impact of VPAG on UK pricing and launch strategy.

Results

Old vs new: VPAS vs VPAG

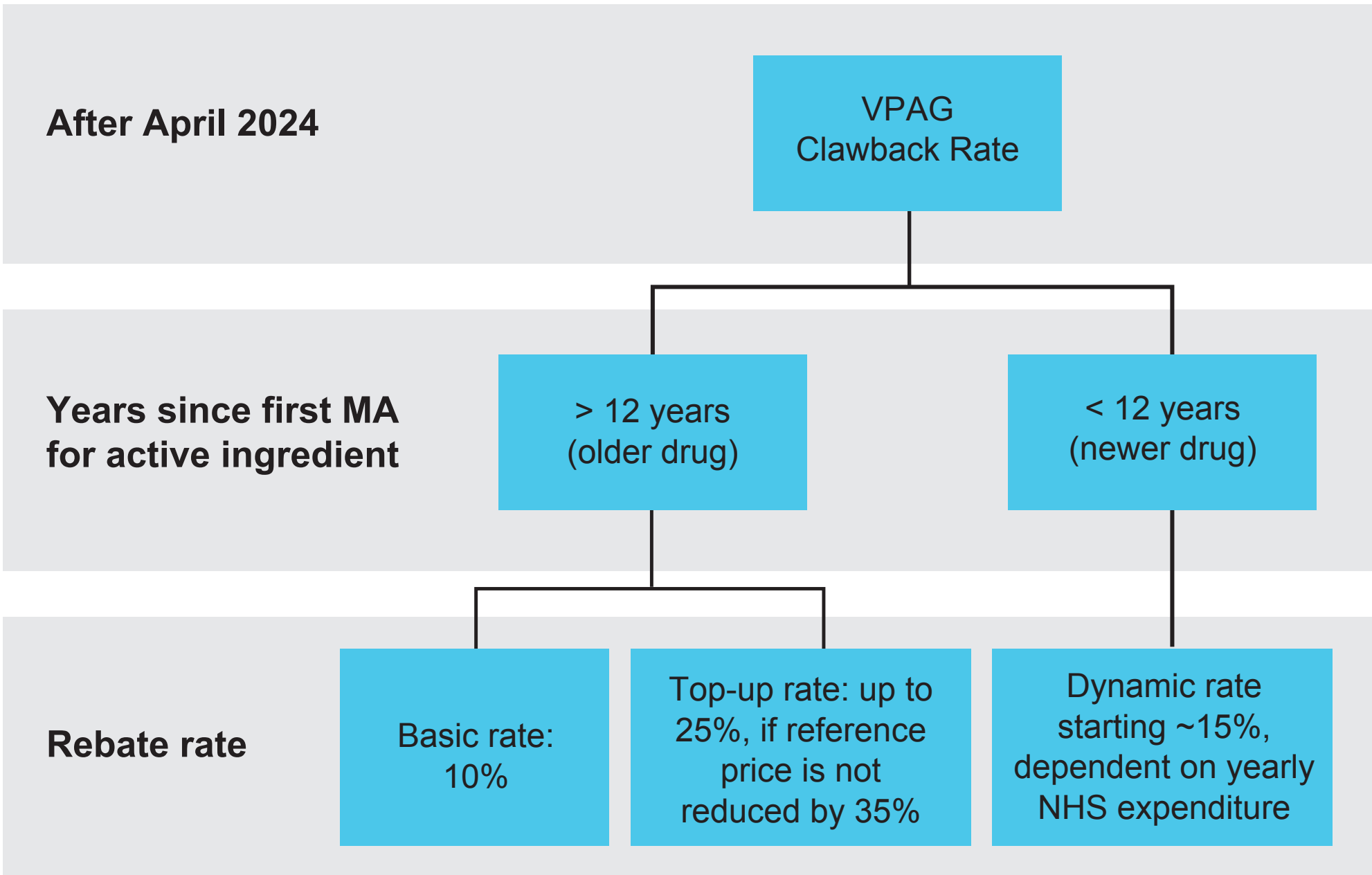
The previous voluntary scheme, VPAS, started in January 2019 and ended in December 2023, with a similar aim of controlling NHS expenditure and benefiting the UK economy, patient access, and innovation. Under VPAS, expenditure growth was capped at 2% per year, with the yearly claw-back rate based on the previous year's sales. VPAG will permit a spending growth rate of 2% in 2024, 3.75% in 2025 and 2026, and 4% in 2027 and 2028.⁴

Figure 1: NHS expenditure growth and rebate rates



The NHS spent £19.2 billion on medicines in 2022/2023, of which £14 billion was for patented medicines. The NHS received £2 billion in rebates that year⁵

The new VPAG scheme decides clawback rates depending on whether a drug is newer to the market (any product with the active ingredient received first marketing authorization less than 12 years ago) or an established treatment, favoring newer drugs to encourage development. Until April 2024, all medicines will be subject to a fixed rebate of 19.5%.⁶ After this, older medicines, including off-patent and branded generics, will face a basic rebate level of 10%, followed by a “top-up” rebate up to an additional 25% if the reference price has not been reduced by 35%. The DHSC will use the revenue to subsidize the lower payback of more innovative medicines. The rate for newer medicines will have a dynamic rate, expected to be about 15.1%.^{7,8} There will be exceptions to rebates for three groups: new active substances for three years after launch, centrally procured vaccines and exceptional procurements, and some small- and medium-sized manufacturers.⁴



VPAG impact on the industry

VPAG is a unique mechanism with no direct equivalent in other countries, requiring innovative approaches to market access in the UK. Rebate rates are significantly higher than those in other developed countries: Germany has the next highest rates at 12%, followed by Spain at 7.5%.⁹ Faster overall growth in the pharmaceuticals market is expected despite manufacturers paying back more over the next five years than in the last five years; the Chief Executive of the ABPI stated: “The new voluntary scheme ... will allow the sector to grow faster than it has for a decade.”^{2,10}

However, VPAG may introduce uncertainty into financial planning due to the variable annual payback rates, which are set at a level that will keep NHS spending within the allowed growth cap.^{4,8} This could push medium-sized manufacturers, who have dubbed the rebates “punitive”, to scale back investment in research and development, de-brand, or move their efforts to other markets.⁶

Concerns about medicine shortages have been voiced, as the price erosion mechanism appears to damage competition through the method for calculating reference prices, which could create additional hurdles for generics and biosimilars.⁵ Further, global generic companies may be deterred from investing in the UK, considering the VPAG to make “some medicines loss-making.”¹¹

The increased predictability of VPAG compared with VPAS may prevent pharmaceutical companies from jumping between the voluntary and statutory schemes, as was seen previously. Although the details of the statutory scheme are not yet known, clawback rates will reportedly be up to 21.9% (with VPAG rates starting at 19.5%).⁹ The NHS has pledged to deliver two innovative payment models to explore outcomes-based agreements to support the introduction of advanced therapy medicinal products (ATMPs) into the NHS.⁴

Impacts on the NHS and economy

The Department of Health has estimated the clawback deal will save the NHS £14 billion by 2028, while giving patients access to more lifesaving treatments.¹⁰ VPAG is intended to strengthen the competitiveness of health and life sciences in the UK, and is expected to provide £400 million of additional funding (from the industry) to strengthen clinical trials, manufacturing, and health technology assessment.⁷ Funding from the rebates will also be allocated to support the Medicines and Healthcare products Regulatory Agency and the NHS horizon scanning efforts.⁴

Discussion

Key recommendations for manufacturer’s UK launch strategy

Be informed:

- Early dialog with NHS England should be sought to determine optimal access and eligibility for innovative payment mechanisms.
- Monitor the development of the statutory scheme, which is expected in late 2024.

Be flexible:

- Pipeline planning and launch strategy: new molecules will be prioritized to launch in the UK over new indications of older medicines, which are subject to high clawback rates.

Be proactive:

- Use innovative tools, including generative artificial intelligence, to track and predict rebate rates with the help of calculation references provided by the DHSC.

Conclusions

Companies will need to evaluate their portfolios to understand what aggregated rebate rate their unique product mix will result in. For companies with complex portfolios (eg, a mix of ATMPs and generics), it is advisable to seek early dialog with NHS England through the newly established single contact pathway to optimize UK pricing strategies under the new rebate measures.

References

- ABPI. <https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/voluntary-scheme-on-branded-medicines/> [accessed March 25, 2024].
- Reuters. <https://www.reuters.com/world/uk/drugmakers-agree-with-uk-govt-renewed-pharma-revenue-clawback-scheme-2023-11-20/> [accessed March 26, 2024].
- UK Government. <https://assets.publishing.service.gov.uk/media/657b2977095987001295e139/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth.pdf> [accessed March 21, 2024].
- UK Government. <https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth-summary-of-the-heads-of-agreement> [accessed March 21, 2024].
- The Pharmacist. <https://www.thepharmacist.co.uk/news/vpag-rebate-calculations-risk-nhs-drug-shortages-warns-bgma/> [accessed March 25, 2024].
- Pharmacy Magazine. <https://www.pharmacymagazine.co.uk/opinion/opinion-vpag-can-only-lead-to-further-medicines-shortages> [accessed March 21, 2024].
- VWV. <https://www.vwv.co.uk/news-and-events/blog/pharma-life-sciences-law/pharma-uk-vpag-pricing-scheme> [accessed March 25, 2024].
- Pharmaceutical Technology. <https://www.pharmaceutical-technology.com/analyst-comment/vpas-is-dead-long-live-vpag/?cf-view> [accessed March 25, 2024].
- ABPI. <https://www.abpi.org.uk/media/news/2023/december/latest-economic-data-underlines-risk-of-disincentivising-uk-life-sciences-growth/> [accessed March 21, 2024].
- ABPI. <https://www.abpi.org.uk/media/news/2023/december/2024-voluntary-scheme-agreement-published/> [accessed March 21, 2024].
- EMJ Reviews. <https://www.emjreviews.com/emj-gold/article/vpag-the-uks-ticket-to-pharma-superpower-status/> [accessed March 25, 2024].