Delivering a financially sustainable VPAS that supports widened medicines access to patients:

The BGMA's position for the 2024-2028 VPAS negotiations

June 2023

BRITISH GENERIC MANUFACTURERS ASSOCIATION

The branded off-patent sector in numbers[1]

4/10

The proportion of branded medicine presentations that are either branded generic or biosimilar

18%

The average annual growth rate for on-patent medicine sales value from 2019-22

2%

The average annual growth rate for off-patent medicine sales value from 2019-22

2/3

The approximate average selling price discount from branded generics compared to the originator price

72%

The average biosimilar selling price discount from NHS maximum selling price

£7.8bn

The extra amount the NHS would pay in higher medicine prices, according to OHE and LSE analysis, if the VPAS levy stays at the current rate for branded generics and biosimilars from 2024-28

5

The average number of branded generic participants in a market

4

The average number of biosimilar participants in a market

20-50%

The increase in patients who got access to rheumatoid arthritis treatments because biosimilar competition widened access

[1] All numbers referred to and footnoted later in document.

What should the next VPAS look like?

1. Introduction

The British Generic Manufacturers Association (BGMA) represents the suppliers and manufacturers of generic and biosimilar medicines to the UK market. Our members supply two thirds of all the medicines that the NHS uses.

In addition to unbranded generics, most of our members supply branded generic or biosimilar medicines, which fall into the Voluntary Pricing and Access Scheme (VPAS).[2] VPAS requires companies selling branded medicines to the NHS of a value above £5m to pay a percentage of these sales back to the Department of Health and Social Care (DHSC) whenever the branded market sales grow at higher than the allowed rate.

The current VPAS places a 26.5% levy (Payment Percentage) on branded medicine sales. This threatens the sustainability of many off-patent medicines upon which the NHS relies, day in, day out. As such, it is crucial that the perspective and voice of the off-patent sector is heard in the negotiations for the next VPAS, to take effect on 1 January 2024 and be in place until 31 December 2028. This paper sets out the present operating environment for branded generic and biosimilar manufacturers and the BGMA's calls for how the next VPAS should be designed.

[2] Or the Statutory Scheme for Branded Medicines, the payment rate for which is pegged off VPAS.

2. Executive summary

We want to see the following objectives delivered through the agreement of the next VPAS:

1. Deliver access to an affordable and sustainable supply of medicines for patients and the NHS that improve population health, reduce health inequalities and boost UK economic productivity and investment,
2. Recognise the critical role played by branded generics and biosimilars in the context of patient access to these medicines, securing best value for the taxpayer pound and the development of the broader life sciences ecosystem,
3. Foster a competitive off-patent sector – where the next scheme complements the fluidity of competitive markets, with the VPAS levy taking into account the price of a medicine, the competition it is subject to and the NHS savings it generates,
4. Ensure that the UK is a leader in the use of biosimilars, providing essential NHS cost savings while delivering earlier and widened access for patients, and
5. Make the UK a globally attractive environment for companies investing in and launching off-patent medicines, where licences can be acquired promptly and the NHS receives the stock allocations it needs.

To deliver upon these objectives, the BGMA must first and foremost be given equal representation alongside the Association of the British Pharmaceutical Industry (ABPI) in the negotiations taking place from May 2023.

The BGMA represents the off-patent sector, with branded generics and biosimilars making up 4 in 10 of the branded medicines used in the NHS.[3] The health of this distinct part of the pharmaceuticals industry is of vital importance since the savings it generates provides the headroom to pay for widened patient access and for new medicines that meet unmet demand. As such, it drives and makes possible better patient outcomes.

The off-patent sector is at its most efficient and resilient when competitive markets are enabled. Every year, generic and biosimilar competition saves the NHS billions in lower medicine prices paid compared with the originator price.[4] Looking specifically at off-patent branded medicines, effective competition produces savings over a consistent period that are in advance of any clawback the Government has so far levied.[5]

Yet, over the past 10 years, VPAS has created a system which has treated on- and off-patent medicines in the same way, despite their supply being driven by different business models, cost pressures and market dynamics. Looking back at the four complete years of the current VPAS (2019-22), the value of on-patent medicine sales grew on average by 18% each year. The value of off-patent sales grew on average by 2% each year.[6]

[3] IQVIA data, September 2022.
[4] Prescription Cost Analysis - England 2021/22, June 2022.
[5] The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by the London School of Economics (LSE), commissioned by BGMA, October 2022.
[6] IQVIA data, March 2023.

The risk of the current approach is that the subsidy of on-patent single-source drugs by more affordable multi-sourced generic and biosimilar medicines becomes unsustainable and finite global manufacturing capacity is diverted elsewhere.

Differentiability

VPAS must therefore properly reflect both the on- and off-patent market sectors if it is to enable a consistent and predictable supply of medicines over the next five years. The Payment Percentage should not apply to off-patent medicines that are at least 30% less than the originator List Price.[7]

Equitability

Ultimately, VPAS must be equitable if it is to be seen as a credible scheme by the entire pharmaceutical industry. If it does not, it increases the likelihood that international company boards will take a commercial view that the UK is not a destination for additional investment, new product launches or prioritised medicines supply. This means it is essential to have a VPAS that seeks a fair and progressive contribution among suppliers based on the products they market and the NHS savings they generate.

Predictability

If recognising market differentiation and seeking an equitable contribution are vital elements for a successful VPAS, so is ensuring predictability for both the NHS and industry. This can only be achieved by enabling a VPAS growth rate (i.e., of medicine spend) that is aligned with projected healthcare needs and broader spending. If the Government wants to provide the NHS with financial certainty over the next five years as to what it will pay for branded medicines, then such alignment is the only way to achieve this.

Pushing for a year-on-year growth rate cap that is too low will inevitably lead to unsustainable Payment Percentages. And while the NHS may ultimately receive money as a result of the VPAS Payment Percentage revenue, our feedback from NHS finance directors is that this revenue does not feature in considerations, nor does it act as a counterbalance to higher prices paid by the NHS because of high VPAS clawback rates faced by manufacturers. Therefore, a high VPAS Payment Percentage could ultimately push Integrated Care Boards into having to ration medicines. It will also lead to ICBs having to deprioritise prevention strategies, which are vital for a healthier, more productive population and to move care away from more expensive hospital interventions.

None of us wants to see this transpire and we, as the BGMA, want to play a full role in ensuring that the next VPAS is equitable, affordable to the NHS and widens patient access to improve health outcomes.

[7] Compared to the originator List Price no less than one year prior to loss of exclusivity.

3. What is VPAS?

The current Voluntary Scheme is an agreement between the DHSC, NHS England and the ABPI intended to get best-value and most effective medicines into use more quickly.[8] [9]

It sets out a UK-wide affordability mechanism under which VPAS scheme members make a financial contribution to the DHSC for sales of branded medicines above the agreed allowable growth rate. Second, it provides for a range of measures to support innovation and better patient outcomes through improved access to the most transformative and cost-effective medicines.

VPAS requires companies selling branded medicines to the NHS of a value above £5m to pay a percentage of these sales back to the DHSC whenever the growth rate of branded market sales exceeds the allowed rate, set for the period of the current VPAS at 2% per annum. For companies with sales up to £25m, their first £5m of sales are excluded from their Payment Percentage calculation.

The Payment Percentage in 2023, the final year of the current scheme, is 26.5% of companies' sales of branded medicines to the NHS. The next VPAS is planned to cover from 2024 to 2028 inclusive.

A Statutory Scheme for Branded Health Service Medicines exists for companies who do not wish to join VPAS or who leave the Voluntary Scheme. The Statutory Scheme has an associated higher Payment Percentage to incentivise joining the VPAS, with its rate finalised when the annual VPAS rate for the coming year is known.

[8] The BGMA was not a negotiating party for the current scheme.
[9] The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by the London School of Economics (LSE), commissioned by BGMA, October 2022.

4. Why brand a generic or biosimilar?

A generic may be branded for two reasons.

The first is where it is required by the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), because it recommends that a patient should be maintained on a single manufacturer's brand. Prescribers can make their own decision as to whether to require a pharmacist to dispense a particular brand, or whether to enable the pharmacist to dispense a version of their choosing.

The second reason is where a manufacturer may brand by choice as the company wants to differentiate its product. This can be to draw attention to and promote certain features of the product.[10]

Biosimilars are prescribed by brand name.

Biosimilar medicines are biological medicines made or derived from living cells or organisms and consist of large, highly complex molecular entities. Like generics, biosimilar medicines are also marketed once the originator biologic medicinal exclusivity provisions have expired.

Biosimilar medicines are approved to the same standards of safety, quality and efficacy as originator or reference products, but due to the variability of the biological system and the manufacturing process, biological medicines may show a certain degree of variation, even between batches of the same product. As such, while the MHRA has now ruled that biosimilars (and the originator biologic version) are interchangeable, biosimilars are prescribed by brand name.

[10] The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by the London School of Economics (LSE), commissioned by BGMA, October 2022.

5. The current operating environment

5.1 The value created by generic and biosimilar competition

The UK generic and biosimilar environment is very competitive. This has helped the UK consistently benefit from the lowest average manufacturer selling prices in Europe.[11]

Independent analysis[12] found that in unbranded markets, generic selling prices are typically 80-90% less than the originator version, pre-loss of the originator version's exclusivity. Across a basket of branded generics that the BGMA analysed, the actual selling price was 63% less than the originator product before loss of exclusivity.[13] The actual selling price of one third of these branded generics was over 80% less than the originator product before competition formed. Across a basket of biosimilars, actual selling prices were on average 72% less than the NHS maximum selling price that all companies agree with the DHSC, likely bringing the price erosion levels of many biosimilars in line with, or near to, those of unbranded generics.[14]

As a result of these levels of price erosion, 4 in 5 of all medicines[15] prescribed and dispensed on the NHS are generic or biosimilar. Generic and biosimilar medicines roughly account for less than one third of the NHS's drugs spend.[16] In terms of volume, this equates to several million packs a day, 2.2m in primary care alone.[17]

This is the result of competitive off-patent markets. Lower prices also provide wider access and improved health outcomes for large patient populations. For example, rheumatoid arthritis patients in England had a higher threshold to gain access to treatments than those in other European countries, until biosimilar entry of Infliximab and Adalimumab brought costs down and allowed NHS patients to be treated earlier, improving health outcomes. The number of rheumatoid arthritis patients treated has since expanded by 20-50%.[18]

5.2 The branded off-patent market

Branded generic and biosimilar medicines represent 39% of the volume of all branded medicines sold to the NHS.[19] They account for 17%[20] of the overall cost, probably less if one assumes that discounts from List Price, upon which the measurement is based, will be greatest where competition exists.

Despite these products having a brand name, competition exists. It exists at prescriber level, as well as at dispenser level where the prescriber prescribes by the generic name, as is the case for many branded generics which are supplied. Branded generics then compete in much the same way as their unbranded counterparts. At secondary care level, the NHS conducts

[11] The supply of generic medicines in the UK, Oxera, June 2019.
[12] The supply of generic medicines in the UK, Oxera, June 2019.
[13] A BGMA analysis of 90 branded generic products undertaken, 2021.
[14] A BGMA analysis of 20 biosimilar products undertaken, 2022.
[15] Based on data from Prescription Cost Analysis – England – 2021/22, June 2022; and IQVIA data covering sales in 2021/22.
[16] Prescribing Costs in Hospitals and the Community – England 2021/22, NHS BSA, November 2022.
[17] Prescription Cost Analysis – England – 2021/22, June 2022.
[18] Numbers based on member market feedback.
[19] IQVIA, November 2022.
[20] IQVIA, November 2022.

competitive tenders for off-patent medicines, and the brand name in such cases is irrelevant to the award. Most biosimilars are currently secondary care-supplied.

The BGMA's analysis from a basket of members' branded generic products shows that the average number of generic competitors operating in the market is five.[21] In only 7% of cases was the member providing the information the only generic supplier on the market. These figures are on a par with the levels of competition in unbranded generic markets, based on the BGMA's analysis of Scheme M returns.[22] In a similar exercise covering biosimilars, it was found that competition existed in all cases, with an average of four biosimilar competitors active in supplying each presentation.[23]

The impact of competition can be seen when comparing the growth of the value of on-patent medicines with that for off-patent drugs over the lifetime of the current VPAS so far. IQVIA analysis shows that from 2019-22, the value of on-patent sales grew at an average rate of 18% per annum, while the value of off-patent medicines grew at an average rate of only 2%.

Year	Overall growth in on-patent sales (%)	Overall growth in off-patent sales (%)
2019	**24**	**4**
2020	**24**	**1**
2021	**28**	**5**
2022	**16**	**3**

5.3 The effect of the VPAS Payment Percentage

The Payment Percentage is a justifiable tool where markets are not competitive. Yet for those that are, and where selling prices have already been very significantly discounted as a result, it will have a detrimental impact on supply over time. This will lead to a rise in the cost of medicines to the NHS, with competition less than what it might be if no Payment Percentage is applied.

Generic and biosimilar portfolios are much larger than that of originators. The BGMA's membership collectively holds around 4,500 licences.[24] To retain overall portfolio profitability, suppliers have to be flexible and must make clear-minded judgements around where market withdrawals or volume reductions are necessary. UK management teams have to bid for international manufacturing capacity, regardless of whether production is in-house or contracted.

[21] A BGMA analysis of 90 branded generic products undertaken, 2021.
[22] Which ceased in 2019.
[23] A BGMA analysis of 20 biosimilar products undertaken, 2022.
[24] BGMA research on licences held, 2020.

Such decisions will directly result from a high, unpredictable VPAS rate which cannot be easily passed on by suppliers, particularly in competitive markets, to reflect in their pricing. NHS and community pharmacy buyers do not commonly know what VPAS is, and therefore may not recognise it as an additional cost. Moreover, in a competitive market, seeking a commensurate rise will result in a loss of market share. For secondary care-supplied medicines, securing price increases in hospital tenders to take account of a higher rate is very difficult. Even if an application is granted, because there is no obligation for an NHS trust to buy from the supplier awarded that region's usage, it again risks a significant loss in business.

5.4 Less competition will raise NHS prices and create greater supply instability

If competition is reduced, there will ultimately be less downward pressure on selling prices. The Office of Health Economics (OHE), supported by Professor Alistair McGuire of the London School of Economics (LSE), calculated that applying the current Payment Percentage (26.5%) to branded generics and biosimilars would actually lead to the NHS paying £7.8bn more than the revenue brought in over the lifetime of the next VPAS.

Europe Economics has calculated that the impact of one and two fewer biosimilar competitors in biologic markets where patents will expire between 2023 and 2028 would potentially mean annual losses in expected NHS savings from biosimilar competition of 13% and 28% respectively by 2028.

Rather, the next VPAS must encourage effective competition. This is particularly necessary for biosimilars where investment is significant. Biosimilar development takes 6-9 years, and $100-300m of investment is required to bring a product to market.[25] Research is complex and inherently high risk with a 53% probability of success in preclinical phases.[26] Consequently, there is a smaller pool of active players. Yet the opportunity for NHS savings that far outweigh any VPAS Government revenue is clear. According to the OHE, the sales forecast of new biosimilars launched between 2024 and 2028 is £8.1bn, during which time the sales of existing biosimilars are projected to be £13.6bn.[27]

The true impacts of the high VPAS rate are currently being masked as companies are reluctant to take decisions before seeing what the next five years will bring. But even so, we have seen recent confirmations of product withdrawals and volume reductions in the media.

Furthermore, the impact on supply is also evident. The BGMA analyses the Specialist Pharmacy Service's medicine supply tool on a regular basis. Of the 72 supply issues currently affecting off-patent medicines,[28] 37 are for branded generics and biosimilars and 35 are for unbranded medicines; a further 12 are faced by originator-supplied on-patent treatments. The high number of supply issues affecting branded generic and biosimilar lines is disproportionate to the relatively small number of these medicines compared with unbranded drugs.

[25] Three imperatives for R&D in biosimilars, McKinsey, August 2022.
[26] Three imperatives for R&D in biosimilars, McKinsey, August 2022.
[27] The impact on the NHS of the VPAS levy on branded generics and biosimilars. A report by the Office of Health Economics (OHE), supported by the London School of Economics (LSE), commissioned by BGMA, October 2022.
[28] BGMA analysis undertaken on 4 May 2023.

Supply issues are exacerbated by less competition and often result in the NHS paying more; in addition, they are a huge drain on limited NHS and pharmacy capacity, with staff focused on mitigating shortages.

VPAS in its current form, particularly at the current 26.5% Payment Percentage, serves to undermine the effective functioning of competitive off-patent markets. It is crucial that the next VPAS reflects the differences in on- and off-patent supply. The next section sets out how we recommend doing this.

6. Principles and scheme design

We propose our ideas for how the next VPAS should be designed on the basis of three guiding principles:

Differentiability: Recognition that off-patent, competitive markets behave differently to on-patent, single-source supply, with the BGMA afforded equal status in representing the off-patent sector in the negotiations.

- One VPAS, two segments; with different provisions applying to the branded on- and off-patent sectors.
- For branded off-patent medicines,[29] an exemption from VPAS where the selling price of off-patent medicines to the NHS has been discounted 30% or more compared with the originator List Price pre-loss of exclusivity; or where off-patent medicines have been supplied to the NHS through hospital tenders.
- A more reasonable process of agreeing an NHS maximum price increase: one that does not disincentivise those firms with larger portfolios where the applicant must claim an individual price increase is warranted as a result of diminished profitability across its portfolio. The DHSC should clarify that profitability can be measured on an individual product basis. Since off-patent medicines operate in more dynamic markets, price application decisions should also be made in a more expedited timeframe.
- The next VPAS should promote uptake of the best-value biologic through 'NHS system' incentives that recognise the administrative cost of switching patients. This will support biosimilar competition and lead to more NHS savings by providing for larger, more predictable patient usage levels.

Equitability: Designing a system that seeks a fair and progressive contribution among suppliers based on the products they market and the NHS savings they generate.

- The low-value sales exemption, which has been set at £2 (NHS Maximum Price) for at least 10 years, should be increased to £10 to protect the supply and viability of the lowest-cost branded medicines.
- There should be greater transparency for what the NHS is paying for a medicine. Like other on- and off-patent presentations, medicines purchased by the NHS under special commercial arrangements should still have a Drug Tariff price listed, and their presentation level sales data should be shown in the Prescription Cost Analysis.
- Multi-year funding and access arrangements, which promote innovative preventative treatments, should also be made available in the NHS regardless of whether those treatments are patented.
- We must be mindful of the relationship between companies which supply UK-licensed branded medicines and make a VPAS contribution, and those which bring medicines into the UK under a Parallel Import (PI) licence that do not. A high VPAS rate will promote further growth in PIs[30] and create supply volatility by actively discouraging the holding of

[29] Exemption to include off-patent legacy originator brands.
[30] Although PI branded sales do not count towards the measured sales under VPAS, they totalled £913m in 2022: https://www.gov.uk/government/publications/voluntary-scheme-aggregate-net-sales-and-payment-information-february-2023/aggregate-net-sales-and-payment-information-february-2023

UK licences and a UK life sciences base built around them; the exact opposite of what VPAS is designed to nurture.

Predictability: This is vital for both the NHS and industry in planning the NHS budget and providing stability for UK company product decisions. The BGMA is calling for:

- A controlled expenditure scheme similar to the current VPAS.
- Allowed year-on-year VPAS growth in line with the previous five (non-Covid) years of healthcare spending or pegged against future projections.[31]
- A Payment Percentage review clause if official UK inflation reaches a certain pre-agreed figure, or if required by a health emergency.

If you would like to know more about the BGMA and its position on VPAS, please contact bgma_internal@britishgenerics.co.uk.

[31] Looking at Spring Budget 2023, NHS England expenditure levels will average year-on-year growth of 7.62% between 2021-25, albeit with a 16.23% jump from 2021-22 to 2022-23. Spanning part of the next VPAS period, smaller year-on-year rises of 3.21% and 3.43% are planned to take place from 2022-23 to 2023-24 and from 2023-24 to 2024-25 respectively.


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