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UK Generics Body Opens Rift With Government And Originators Over Rebate Scheme

BGMA Says It Felt Forced To Seek Judicial Review After Exclusion From VPAS Negotiations

by David Wallace

By launching a bid for judicial review of its exclusion from UK negotiations over the VPAS rebate scheme, the BGMA has thrust itself into conflict with the country's government as well as local brand industry association the ABPI.

UK off-patent industry body the British Generic Manufacturers Association has opened up a fresh battle over the country's Voluntary Scheme for Branded Medicines Pricing and Access rebate mechanism, by lodging a bid for judicial review of a government decision to exclude the BGMA from fresh negotiations over the VPAS scheme.

As well as positioning the BGMA in opposition to the UK government, the legal challenge also puts the association in conflict with brand industry body the Association of the British Pharmaceutical Industry, with the generics group claiming that the ABPI – the only party with whom the government currently negotiates – cannot adequately represent the interests of the off-patent industry.

The VPAS scheme has been contentious for some time among off-patent industry stakeholders, given that it applies a rebate designed for branded originator products to branded generics and biosimilars.

VPAS aims to balance innovation and patient access, as well as ensure predictability on National Health Service spending for branded medicines, by limiting spending growth to no more than 2%

in any of the five years of its existence.

If the total branded medicines spend exceeds the 2% cap, a rebate is charged to all manufacturers on the sales of their branded medicines to the NHS, with the scale of the rebate varying depending on the size of the overspend.

Previously, the BGMA has called for branded generics and biosimilars to be exempted from the scheme altogether, cautioning that their inclusion could jeopardize UK launches and force withdrawals, putting at risk the savings that would stem from competition to originator medicines. (Also see "*UK Rebate Mechanism Could Force Market Withdrawals, Warns BGMA*" - Generics Bulletin, 24 Oct, 2022.)

Latest UK Rebate Rate Pushes Profit Out Of Portfolios

By David Wallace

16 Dec 2022
The UK government's announcement of a 26.5% VPAS rate for 2023 "will make some products lossmaking," the BGMA has cautioned, expressing serious concerns for the branded generics and biosimilars sector as it points to the risk of shortages, higher prices and fewer launches in the UK.

Read the full article here

And more recently, the BGMA has hit back against the latest VPAS rate hike, pointing out that in the space of just a few years, the rate has risen from around 5% in 2021 up to 26.5% for 2023 (*see sidebar*).

'No Choice But To Take Legal Action'

Announcing the legal challenge, the BGMA said that given the UK government's "continued refusal to allow us to participate fully" in the process, it had "begun a judicial review process to challenge the decision to exclude us as a full partner in the forthcoming VPAS negotiations."

Despite generics and biosimilars representing four out of five drugs used by the NHS – or 2.2 million medicines a day – "the government has decided not to involve the trade body representing these medicine suppliers in its negotiations on VPAS," underlined BGMA chief executive Mark Samuels. "We are deeply concerned by this decision. It has left us no choice but to take legal action."

While acknowledging that not all generics fall within VPAS, "four out of ten products in the current scheme are branded generics or biosimilars," Samuels observed. Therefore, he insisted, "as the representative trade body for both generic and biosimilar UK manufacturers, we must play a full part in the VPAS negotiations for the next period of the scheme from 2024 to 2028."

> *"Our sector currently has no input into the negotiations on future schemes or rates; this is untenable as any decisions made on VPAS could significantly define the future of our sector in the UK and its ability to supply the NHS."*

The generics and biosimilars industry was particularly sensitive to the impact of VPAS, Samuels explained, noting that "the industry subsists on thin margins because these medicines do not benefit from patent-protected prices."

"Off-patent medicine manufacturers operate in a highly competitive market – it keeps prices low, and the NHS's drug bill would be unaffordable without them," he emphasized. "Generic and biosimilar medicines are often over 80% cheaper than the originator's product."

Yet "despite delivering the lowest generic medicine prices in Europe," he said, "our manufacturers currently have to pay an additional 26.5% VPAS tax on their revenues as a result of VPAS."

"We supply nearly half the products in the pricing scheme yet are hit twice," he explained. "This double-whammy makes some products lossmaking; hence we must play a full part in the VPAS negotiations to find ways to avoid damaging one of the UK's most critical industries."

With the VPAS rate having risen five-fold in less than two years – an "unprecedented tax increase," according to the BGMA – Samuels complained that "our sector currently has no input into the negotiations on future schemes or rates; this is untenable as any decisions made on VPAS could significantly define the future of our sector in the UK and its ability to supply the NHS."

Having first raised the issue of the BGMA's full participation in the VPAS negotiations with the UK government last November, the association said it was initially offered observer status in relation to the negotiations. However, this was "not sufficient," Samuels said, "given the existential impact the rate is, and will have, on branded generic and biosimilar manufacturers."

Essentially, he summarized, "if not changed, [VPAS] will mean the NHS paying substantially more and the supply chain becoming significantly less resilient."

ABPI Cannot Represent Off-Patent Sector Interests

As it announced the bid for judicial review of its exclusion from the VPAS negotiations, the BGMA also made clear its belief that brand industry body the ABPI would be unable to make the case to government on behalf of generics and biosimilars suppliers.

"We also do not believe the ABPI – who are the only party with whom the government currently negotiates – can adequately represent or balance the interests of the off-patent sector in these negotiations," the association stated.

Responding to the BGMA's announcement of its legal challenge, ABPI chief executive Richard Torbett said the association was "disappointed that the BGMA has decided to take this action," but said "we recognize that it has been perpetuated by the extreme challenge placed on all parts of the industry from the surge in the branded medicine payment rates."

Mixed Support For ABPI's UK Price Scheme Proposals

By Leela Barham

21 Mar 2023

The UK pharma industry body has set out bold proposals for a new drug pricing agreement from 2024, but not everyone is convinced. Generics companies are pressing for more of a say in the negotiations, while patient groups want to know more about how the deal would help improve access to medicines.

Read the full article here

"The ABPI takes our responsibility to represent the entire branded medicine market extremely seriously," Torbett said, having for more than 60 years acted as the representative industry body for VPAS negotiations and with the ABPI "consistently engaging and involving the wider life sciences industry and trade associations as we approach the start of formal negotiations."

"Working with the whole industry," he outlined, "we have developed and published a positive and pragmatic vision for a new voluntary scheme that supports value for the NHS, medicines access for patients, and economic growth" (*see sidebar*).

"We now look forward to starting detailed discussions with the government as soon as possible to ensure timely agreement of a new Voluntary Scheme."

VPAS Criticized By Industry Leaders

The VPAS scheme has drawn increasing criticism from off-patent industry leaders in recent months.

Sandoz CEO Richard Saynor recently told *Generics Bulletin* that the mechanism was "a complete anathema and makes zero sense," expressing "frustration" in particular over the way that the scheme applied to biosimilars.

“Decide what we are,” Saynor urged. “If biosimilars are interchangeable, treat them as generic, then fine – which is basically how they’re reimbursed in the UK anyway. If they’re a brand, and then we get the benefit of a brand and stable pricing, then treat them as a brand.”

But in a sense, he said, “what we’ve ended up with is the worst of both worlds: we get taxed as though it’s an originator, and then we get hammered as though it’s a generic.” (Also see "*Sandoz’s Saynor Reflects On Industry Challenges*" - Generics Bulletin, 3 Mar, 2023.)

Meanwhile, Biogen’s head of biosimilars in the UK & Ireland, Jim Porter, told *Generics Bulletin* that “if we’re talking about generating a sustainable market, which I think is in the interest of everybody, then we need to balance VPAS, tendering and the various access capacities that we need, to drive the full and broad impact of biosimilars in the UK market.” (Also see "*Biogen: Patients Must Be At Center Of UK Biosimilar Decision Making*" - Generics Bulletin, 3 Jan, 2023.)