April 2024

ABPI Statutory Scheme consultation response 2024

Executive summary

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes which invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world.

In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs. www.abpi.org.uk

Background

This document summarises the ABPI's full response to the Department of Health and Social Care (DHSC) consultation to update the Statutory Scheme for branded medicine, published on 18 March 2024. Further detailed arguments and industry evidence are provided in the ABPI's complete submission to the consultation.

The statutory scheme is set out in legislation in The Branded Health Service Medicines (Costs) Regulations 2018. It is one of two schemes, alongside the 2024 voluntary scheme for branded medicines pricing, access and growth (VPAG), that control the costs of branded medicines to the NHS. VPAG was agreed upon in late 2023 and replaced the 2019 voluntary scheme for branded medicines pricing and access on 1 January 2024.

The government proposes to update the statutory scheme to maintain broad commercial equivalence with VPAG. In its consultation, the DHSC set out its proposals as a series of questions, with respondents asked to indicate agreement, disagreement or neither to each question. In this summary, for both the sake of brevity and clarity, we do not follow this formulation. Instead, we seek to clearly articulate the industry's position in as few words as possible.

General principles

The ABPI acknowledges the government's policy of the schemes being commercially equivalent and broadly supports measures to do so.

However, support for alignment between the two schemes does not necessarily indicate that the ABPI supports any single policy measure within either scheme, particularly when considered independently from the whole.

The VPAG is a broad and complex agreement which recognises the value to both industry and government in continuing to partner through successive Voluntary Schemes. Importantly, this allows both parties to enter dialogue on matters affecting the scheme to ensure it achieves its intended objectives. It is on this basis industry agreed to the terms in the VPAG. There are many details within the VPAG which industry shared concerns about with government during negotiations, but agreed to on the basis that the impact would be assessed. There are no such means for dialogue and monitoring in the Statutory Scheme.

The ABPI consultation response on the Statutory Scheme reflects this. Some proposals to change the Statutory Scheme remain novel and untested despite featuring in the 2024 VPAG. Further monitoring and dialogue are therefore required to ensure unintended consequences of either scheme are recognised and rapidly addressed.

ABPI views on specific proposals in the consultation

Maintain the allowed growth rate at 2% and make baseline adjustments in line with the Voluntary Scheme.
The ABPI supports the proposals to introduce baseline adjustments to the Statutory Scheme in line with the 2024 VPAG.

The ABPI disagrees with proposals to retain allowed growth at 2%, as this rate does not reflect the real-world growth of NHS use of branded medicines, or the current or historic inflationary pressures on the UK economy. The ABPI has, on many occasions, presented very clear evidence and rationale that such a cap and resulting escalation of payment rates is unsustainable, damaging investment and risking the future availability of medicines.

Set payment percentages for Q3 and Q4 of 2024 to control growth in Q3 and Q4 only
The ABPI agrees with this proposal. When introducing a different approach, simplicity should always be a consideration. Companies must also have as much time as possible to prepare and plan for the revised affordability mechanism to minimise unpredictability.

The proposed definitions for newer and older medicines
The definitions for older and newer medicines should be the same across the voluntary and Statutory schemes. However, the ABPI is concerned that the current older medicine approach could undermine the value of Intellectual Property and discourage future investment in innovation. The rules in place pose a risk to the viability of older medicines and the launch of medicines defined as ‘older’. Across both schemes, the ABPI would support a definition of older medicines that supports all the innovations protected from replicator entry under our current IP framework and extend beyond the Supplementary Protection Certificate (SPC).

The proposed payment percentage for newer medicines
The ABPI disagrees with the proposed rates and the underlying financial mechanism used to calculate these rates. They do not bring the UK rebate back to a position of international competitiveness and represent an increase in payment rates year on year due to retaining the 2% allowable growth rate.

The proposed basic payment percentage for older medicines
The ABPI agrees that the basic rate should align with the VPAG. A fixed rate brings

predictability and supports competition for these products. However, fixed payments of 10% remain higher than the UK average in PPRS and VPAS schemes over the past ten years and are also higher than rates seen in international comparators.

The proposed system for top-up payment system for older medicines
The ABPI agrees that this system should align with VPAG. However, we disagree with the proposed thresholds currently proposed. Introducing top-up payments for products unless they have seen a price decline of less than 35% compared to the reference price is an untested mechanism. The impact of introducing payment percentages of this magnitude risks negative unintended consequences such as jeopardising the commercial viability or supply of certain medicines.

Companies in both schemes must be able to seek exemptions if rates at this level will negatively impact a product's viability, which could lead to an unwarranted impact on patients or the NHS. It will be essential to monitor and address any issues arising from this in the Statutory and Voluntary Schemes.

Proposed exemptions for plasma-derived medicinal products (PDMPs), products with sales under £1.5 million, smaller companies.
The ABPI agrees with these proposals based on the principle of maintaining commercial equivalence between the VPAG and the Statutory Scheme. However, we believe DHSC should also extend the broader exemptions in VPAG to the Statutory Scheme.

Operational requirements for implementing the proposals
The additional burden on companies to track their prices at a Virtual Medicinal Product (VMP) presentation or Stock Keeping Unit (SKP) level across the year and accrue for payments will substantially increase the time and resources required to operate the differentiated affordability mechanism compared to previous schemes. The ABPI would like the DHSC to streamline reporting when it is not essential to the scheme's operation and simplify the detail required.

The analysis in the impact assessment
The ABPI has previously expressed serious concerns about the quality and appropriateness of the government approach to Statutory Scheme consultations and accompanying cost-benefit analysis, and this is examined in detail by NERA in their Review of DHSC's Proposal for the Statutory Scheme from 2024.