ABPI Submission

April 2025

ABPI 2025 statutory scheme consultation
Executive summary of submission

Introduction

This document provides a summary of the Association of the British Pharmaceutical Industry (ABPI) response to the Department of Health and Social Care (DHSC) consultation on proposals to update the statutory scheme to control the costs of branded health service medicines, launched on 14 March 2025. ABPI does not publish full consultation submissions; additional evidence and information about this submission is available on request on a case-by-case basis.

Overview of the ABPI response

- **The ABPI is deeply concerned about the proposals set out in this consultation and the signal this sends to global boardrooms.** The repayment rates the government is proposing – 32.2% in the second half of 2025, 24.7% in 2026, and 26.4% in 2027 – are not viable, and demonstrate the increasing unsustainability of the rate-setting mechanism used in the Voluntary and Statutory Schemes. Rate increases at this level, implemented in-year, will force companies to make very severe choices about headcount, about the scale of their operations in the UK, and about the viability of the UK as a significant destination for current and future pharmaceutical activity.
- **UK medicine payment rates are increasingly far from internationally competitive rates.** Similar clawback mechanisms in France and Germany are set at 5.7% and 7% respectively, making the existing and proposed high UK rates harmful to the UK life sciences sector, the UK economy, and to patients, if they are imposed. The proposals the government is consulting on will therefore harm the UK's competitiveness, and undermine the objectives of its forthcoming Life Sciences Sector Plan, and broader industrial strategy.
- **The proposals run counter to the government's stated objectives.** The government has recognised that the existing VPAG repayment rates need to be addressed to allow the government and industry to work together to further the country's objectives on science and technology, and most importantly, to improve patient care and health outcomes.[1] Publishing rates at this level with respect to the statutory scheme clearly run counter to the government's expressed intentions and other actions, such as pursuing an expedited June Review of the VPAG.
- **The impact assessment that the government uses to appraise its options needs significant updating and reform**. The consultation impact assessment does not take into account how rates of this level will impact wider economic investment or activity. The ABPI have noted several areas where we believe the impact assessment falls short, in its unreasonable assumptions, its failure to incorporate new evidence, and its interpretation of the evidence that it does cite. The government should aim to be more transparent about changes it makes to impact assessments to take account of new evidence in future years.

[1] Wes Streeting's keynote address from the ABPI conference 3 June, transcript available upon request.

Additional details on specific consultation questions

1. Do you agree or disagree with our proposal to maintain the level of allowed growth in the scheme to 2% each year, with baseline adjustments of £50 million in 2025, £430 million in 2026 and £380 million in 2027?

ABPI response: Disagree

- We believe the overall effect of imposing rates of this level on industry will be acutely harmful to the UK life sciences ecosystem, whether in a Statutory Scheme or Voluntary Scheme, and want to make clear that industry could never agree to rates at this level.
- Rate increases at this level, implemented in-year, will force companies to make very severe choices about headcount, about the scale of their operations here and about the viability of the UK as a significant destination for current and future pharmaceutical activity.
- The current model needs significant reform: a hard cap on the medicines market with no risk sharing between government and industry has driven the escalation of rates over time. Since this mechanism was imposed in 2014, rates have increased from 3.73% to 23.8% today.[2]
- Ultimately, the voluntary scheme and the statutory scheme both need to move away from setting allowed sales through adjustments to a hard cap, towards a market that shares risk and value fairly across government and industry.

2. Do you agree or disagree with the levels at which we propose to set the statutory scheme payment percentages, and the rationale provided for this?

ABPI response: Disagree

- The ABPI strongly disagrees with the government's proposal to set statutory scheme rates at these levels. As stated in answer to the previous question, codifying rates of this level in legislation and imposing them on companies will be acutely harmful to the UK life sciences industry.
- The proposed payment rates represent successive breaches of the highest real rates imposed on industry, and in 2025 more than doubles in the second half of the year, with companies' operating plans already set. That the government is proposing to more-than double rates in-year, with barely 3 months' notice, crystallises the acute fiscal and regulatory uncertainty that stems from the current method of setting rates.
- This is clearly not compatible with the government's stated objective of procuring medicines 'in a way consistent with supporting both the life sciences sector and broader economy'.
- The government's rationale for setting rates at this level does not follow any rational process for pursuing its policy objectives related to health care or driving the economy, but rather mechanically follows the unsustainable path that VPAG is currently on.
- Baseline changes being deferred detracts from planned growth; imposing rates of this level codifies the fact that industry is the sole owner of risk related to growth in the market; and sets rates between three and four times as high as the UK's closest competitors.

[2] https://assets.publishing.service.gov.uk/media/5a8203f440f0b6230269a61b/The_pharmaceutical_price_regulation_scheme_2014.pdf

- For example, none of the US, Canada, or Japan have a similar clawback mechanism. Those who do maintain such a scheme almost universally keep rates below 10%, for example France's equates to 5.7%, Italy's to 6.8%, and Germany's at 7%.[3]

3. Do you agree or disagree with the proposal to introduce some form of additional assurance requirement on presentation level sales reports (PLRs)?

ABPI response: Agree

- The ABPI agrees with the government's proposal to increase assurance on PLRs, given the importance of these to delivering timely and reliable data to companies.

4. If you have any comments on the proposed methodology used in determining the payment percentages (as set out in the accompanying impact assessment), please set them out here. Please give reasons and provide any evidence or analysis that would support any refinement you think the department should make.

ABPI response:

- There are serious and substantial issues with the methodology that the government uses in determining its favoured option as set out by the impact assessment. The ABPI has submitted detailed evidence to this effect in response to previous consultations, and it is not clear whether the government has made changes to its methodology to reflect these comments.
- In summary, the methodology used in the impact assessment could never find that a rate the government was proposing is too high, other than if it is higher than proportionate to align with the voluntary scheme, and is clearly an inadequate framework for assessing the costs to the government's core objectives, of ensuring patients get access to the best medicines through the NHS, and of growing the UK life sciences industry together with the broader economy.
- The government should in future conduct a detailed macroeconomic assessment of each of its proposed options, and should also seek to quantify the impacts to patients given the above evidence, which sets out that there are large impacts already to access to new medicines. These will increase over time as they are compounded by the loss of R&D and clinical trials activity.

5. Do you agree or disagree with the analysis in the impact assessment of our proposals, including impacts on those areas where the NHS Act 2006 requires that we consult?

ABPI response: disagree

- The analysis in the impact assessment systematically underestimates the costs of the government's proposals, and biases its analysis towards transfers of funding from industry to the NHS.
- The NHS Act 2006 requires that the government consult on the economic consequences for the life sciences industry in the UK, the economy of the UK, and for patients.
- With respect to the health of the life sciences sector in the UK, and the consequences to the UK economy, we have set out the links between the domestic market and global

[3] Analysis undertaken for the ABPI by Neil Grubert Consulting, available upon request.

companies' willingness to invest in the UK. It is also worth noting that for the government's specific proposals, which involve more-than doubling the rate payable under the statutory scheme with fewer than 3 months notice in-year, will inevitably result in cuts to companies' UK operating plans.

- With respect to impacts on patients, our work with members show that the likely impact of these changes will be to reduce the number of treatments that are available to patients in the future, and decrease companies' prioritisation of the UK market for launching new medicines. As our VPAG report detailed in company case studies, given rates of this level, companies will in some cases be forced to make reductions to NHS value added services, and reduce or cancel planned NHS partnership programmes.[4]

6. Do you agree or disagree with our initial conclusions about the impact that the proposed updates to the statutory scheme will have when taking into account the statutory duties of the Secretary of State?

ABPI response: <u>disagree</u>

- Companies who are members of the ABPI have reported that payment rates of this level will undermine the life sciences industry in the UK, as well as its broader economic growth, and will very likely have consequences for patients of the NHS.
- This proposal is therefore in conflict with the Secretary of State's (SofS) duties under the 2006 NHS Act.
- While the evidence cited by the government its impact is outdated, having been conducted before the current period of rates above 20 percent, its assessment still shows that payment rates are one factor in determining companies' investment and medicines launch decisions.

[4] abpi-vpag-report-20-march-2025.pdf