ABPI 2023 Statutory Scheme consultation

Executive summary

25 January 2023

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 to the 2023 statutory scheme to control the costs of branded health service medicines, launched on 16 December 2022.

Overview of the ABPI response

The Statutory Scheme has long existed as a ‘back-stop’ to the Voluntary Scheme (VPAS), with Government policy to seek ‘broad commercial equivalence’ between the two Schemes. In the past, when VPAS rates were under 10%, this approach was largely accepted by the industry. With a proposed Statutory Scheme payment now reaching the historically and internationally unprecedented rate of 27.5%, the industry can no longer accept this principle. Such rates, both in the Statutory Scheme and the Voluntary Scheme – where the payment rate for 2023 has been set at 26.5% - are having a demonstrably harmful impact on the ability to deliver the UK’s Life Sciences Vision. This, in turn, will impact the quality of health services, outcomes and research within the UK, which the Secretary of State has a duty to promote[1]. The ABPI’s response to the consultation sets out our concerns on the latest status of pricing regulation of branded medicines in the UK across both schemes.

National and international context

Between 2019 and 2023, there will have been a 12% decline in medicines spending at a time when Government has provided the NHS with an 8% real-term increase in funding. In effect, recent Government policy has led to a disinvestment in medicines through the cap on growth for a decade.

At the same time, the UK is slipping behind its global competitors in Life Sciences. The UK's share of global pharmaceutical R&D has been declining over the past decade, falling from 7.7 per cent in 2012 to 4.2 per cent in 2022; there has been a 44% decline in patient access to industry clinical trials vs. 2017/2018[2]; and whilst improvements in specific areas have been made, variation persists. Across the UK, use of medicines in the NHS two years after launch is typically 64% behind other nations[3].

The contribution required from industry through the ‘revenue tax’ of the Voluntary Scheme and Statutory Scheme needs to return to internationally competitive levels. The UK’s position as a global outlier is limiting the ability for the UK to become a global hub in Life Sciences, including R&D, manufacturing, the launch of new medicines and UK access to new medicines.

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[1] As per section 1 of the NHS Act 2006
[2] ABPI, ‘Rescuing patient access to industry clinical trials in the UK,’ October 2022
[3] Office for Life Sciences, ‘Life science competitiveness indicators 2022,’ 21 July 2022

Specific question response summaries:

The rationale for the proposal to update the payment percentage is flawed

Government policy has been to ensure the Statutory Scheme should be set to ensure commercial equivalence with a future voluntary settlement. Yet, as the existing Voluntary Scheme ends in December 2023, setting 'broad commercial equivalence' with the VPAS would no longer be relevant as the outcome of negotiations on a future Voluntary Scheme have not concluded. Furthermore, changing the Statutory Scheme rate now can have no material impact on future Voluntary Scheme membership.

Increasing the Statutory Scheme payment rate would only have a marginal financial impact to the NHS, yet doing so will send a strong disinvestment signal to companies that the UK intends to maintain its current unprecedented and uncompetitive rebate rates – potentially offsetting any benefit.

To reflect the shared intent by government and the industry to approach the future scheme with a 'clean slate', the industry proposes that any Statutory Scheme payment rate applied in 2023 should explicitly only apply until 31 December 2023, when the current VPAS ends.

A future consultation should be conducted towards the end of 2023 to ensure any new statutory rate is appropriate to the outcome of the negotiations for a new Voluntary Scheme.

The proposed Statutory Scheme payment percentages are unacceptable

The current proposals are to set payment levels to achieve an average growth rate of 1.1% annually. The Government has never given any economic rationale for this selection.

The average Statutory Scheme payment rate across the last four years has been 10.6%. Yet companies are now facing a proposed revenue tax of 27.5% in the 2023 Statutory Scheme.

Statutory Scheme members, by definition, have not consented to such terms. Imposing such levels of payment rates will put at risk the UK's reputation as a globally leading life sciences ecosystem and there is now a real risk that companies will not invest in or bring new innovations to the UK.

We propose that no further change to the statutory scheme is made until a replacement to the Voluntary Scheme is agreed, with the Statutory Scheme payment rate being held at the existing rate of 24.4% and not increased in 2023.

The government's impact assessment analysis is flawed

In our submission to the 2022 Statutory Consultation, the ABPI made clear our objections to the Government's impact assessment and have made similar arguments again. We believe the evidence submitted by the industry has been ignored, and we have seen further tangible examples of the negative impact in the UK due to increasing VPAS and Statutory Scheme payments.

The industry does not agree with the methodology used in the economic impact assessment to assess the benefit of the proposal, with many points requiring clarification and further consideration.

With key innovations coming down the Life Sciences pipeline, targeted to address the UK's key health missions such as dementia, cancer and cardiovascular, including obesity, any delay in access to medicines will have a detrimental impact on patient outcomes and loss of productivity in the economy.

Compared to other leading EU countries (Italy, Spain, Germany, France), the UK has experienced the largest decline in its global share of new medicine launches between 2016-2021[4]. And UK patient outcomes remain behind other countries. Data highlights how the UK ranks 17th out of 18 countries for life expectancy, worst for stroke and heart attack survival, and 16th out of 18 for five types of cancer[5].

Companies are making long-term decisions on the future of their UK ‘footprint’. In 2023, UK industry headcount is expected to fall by 6%. If rates of this rate of decline is maintained up to 2028, it could equate to a reduction in UK headcount of over a third. This translates to 27,000 jobs and a lost annual GVA of £2.6bn at a national level[6].

Due to company planning cycles, disinvestment decisions at a global level are difficult to reverse, and the long-term implications for the UK have yet to be seen. Immediate action from Government to reverse these trends is urgently needed.

Conclusion

One of the overarching aims of both the Statutory and Voluntary Schemes is to ensure payments made are reasonable and do not overly impact medicines supply or R&D.

ABPI research demonstrates that the UK has already fallen down the global rankings across all phases of industry clinical trial delivery between 2018-2020, and UK manufacturing production volumes have fallen by 29% since 2009. None of these trends support the Government’s impact assessment and assertion that increased payments from industry will benefit the UK overall.

Increasing the Statutory Scheme rate at this time sends the worst possible signal in advance of the current Voluntary Scheme ending in December 2023. As currently proposed, any Statutory Scheme rate update will endure beyond December 2023, having a material impact on long term investment, new medicine launch and supply decision-making. It also risks prejudicing the upcoming negotiations on a new Voluntary Scheme – acting as a Damocles sword over the industry – but one that also risks slicing off the UK’s life sciences sector.

We need a sustainable long-term voluntary settlement between industry, Government and the NHS that supports the ambition of the Life Sciences Vision, delivers world-class patient outcomes, NHS financial sustainability, and a sustainable industry that can continue to invest in tomorrow’s medicines and vaccines.

We strongly urge the government to reconsider these proposals. Doing so will send a strong public signal that the UK remains committed to its ambition to be a Life Sciences Superpower.

[4] Informa Pharma Projects 2022
[5] Organisation for Economic Co-operation and Development, Health Care Quality Indicators, Cancer Care
[6] Analysis from ABPI company survey, Q4 2022.