ABPI Briefing

10 October 2023

ABPI Statutory Scheme consultation response: Executive Summary

Background & overview of the ABPI's response

This document summarises the Association of the British Pharmaceutical Industry's (ABPI's) response to the Department of Health and Social Care (DHSC) consultation on updates to the 2023 Statutory Scheme to control the cost of branded health service medicines.

The Statutory Scheme is one of two Schemes in the UK - alongside the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (known the 'Voluntary Scheme') - which control the prices of branded medicines to the NHS.

The Schemes operate through rebate mechanisms, where companies pay a percentage of their net sales revenues back to Government. Historically, rates in both Schemes have averaged well below 10 per cent. However, in the last two years, rates rapidly escalated and as of 2023, the rebate stands at 26.5 per cent of sales in the Voluntary Scheme and 27.5 per cent in the Statutory Scheme. Most companies (96 per cent by value of sales) are members of the Voluntary Scheme, which offers marginally better commercial terms, but the current agreement is set to expire at the end of 2023. Negotiations for a successor are ongoing and there is a real risk that no new deal will be agreed. If this happens, all companies will by default fall under the Statutory Scheme.

Though there are elements of the consultation proposals with which the ABPI agrees, we are concerned that, as currently drafted, the overall Statutory Scheme update would have disastrous consequences for the life sciences sector, investment in the UK and patients' access to new and existing medicines. We also consider that the proposals lack clarity in key areas and the impact assessment is insufficient given the scale of their potential effect on the whole life sciences sector.

Proposed Changes

DHSC has set out three policy objectives for the consultation proposals:

1. "To limit the growth in costs of branded health service medicines to safeguard the financial position of the NHS,
2. To ensure that medicines are available on reasonable terms, accounting for the costs of research and development,
3. To deliver the above objectives in a way consistent with supporting both the life sciences sector and the broader economy."

To achieve this, DHSC has proposed a series of amendments and options that largely bring the Statutory Scheme into line with the existing Voluntary Scheme. This includes:

- Increasing the growth cap under the statutory scheme, which determines the payment percentage for pharmaceutical companies, from 1.1 per cent to 2 per cent (the current allowed growth rate under the Voluntary Scheme).

- Introducing exemptions to the Statutory Scheme that are already present in the Voluntary Scheme. **The ABPI supports these exemptions, which we believe will help to safeguard supply.**

DHSC has also considered in the consultation introducing a Life Cycle Adjustment (LCA) whereby the payment percentage would be lower for newer medicines or medicines facing more competition and higher for other medicines.

The exemptions and the LCA represent different options, but the cap on annual growth is common across all options considered.

Published alongside the consultation is an Impact Assessment, which evaluates the proposed options alongside a Business as Usual (BAU) scenario in which the statutory scheme payment percentage remains at its current level of 27.5 per cent for each year from 2024 to 2026.

The proposed changes to the cap on growth

- **DHSC has proposed to cap growth in the market to 2 per cent a year, with companies paying back any medicines spend above this limit as a percentage of their sales to the NHS.**
- A cap on growth in the market was first introduced in 2014, as a temporary 'austerity measure' to support the NHS. At the time it was anticipated to be a 'one off' but it has now lasted almost a decade with industry self-funding almost all growth in medicines spend.
- In practice this means that while the NHS budgets have increased by £1.9 billion, since 2014 there has been a 15 per cent real terms decline in medicines sales despite the increased use of medicines by the NHS.
- The ABPI objects to both the artificial cap on growth, and the decision to choose an allowed growth rate of 2 per cent. This is not only well below inflation (which currently stands at 6.3 per cent) but DHSC has never provided any economic rationale or analysis to support the 2 per cent rate.
- The UK already spends less on medicines than most equivalent countries - at only 9 per cent of its healthcare budget compared to an average of 15 per cent amongst developed countries – and this represents further disinvestment.
- Over the last two years we have repeatedly presented evidence to Government that this approach is unsustainable, damaging investment and access to medicines. Our global share of R&D has fallen by over one-third (2012 – 2020) and the UK has experienced. largest decline in its global share of new medicine launches compared to other G7 countries.
- In our consultation response we have further highlighted that:
  - **The cap is out of line with international competitors.** The UK's payment rate is significantly higher than other similar clawback mechanisms operated by other countries - none of which use a cap - for example, 12 per cent in Germany (and under review for future years), 7.5 per cent in Spain and 8.25 per cent in Ireland. This is contributing to our falling investment and R&D.
  - **The cap comes on top of the rigorous value assessments, pricing, and affordability controls in the system**. All new medicines and significant extensions to

their licences are evaluated by NICE and only reimbursed if they are a cost-effective use of NHS resources. To manage in year affordability concerns, medicines are also subject to the budget impact test. If they are likely to cost >£20m in any of their first three years of launch, they are subject to further price negotiations. Following this, they are then subject to regional and local level tendering and pricing negotiations, which in the UK are far beyond other high-income countries and often even low- and middle-income economies.

- As a result of the issues outlined above, an independent assessment by NERA Economics (funded by the ABPI), found that the proposals are likely to only meet of limiting growth in branded medicines to the detriment of the other two goals (namely ensuring that medicines are available on reasonable terms and supporting growth in the economy). NERA further suggested that alternative policy options may provide a better balance across DHSC's own objectives.
- If Government is to meet its objective of '*supporting the life sciences sector'*, a future Statutory Scheme cannot resemble a continuation of the existing cap and must return the UK back to a position of international competitiveness as soon as possible so that the sector is not committed to long term decline.
- The ABPI is further concerned that all the options considered in the consultation include the 2 per cent cap on growth. This contradicts the Treasury Green Book guidance that Government consultations should avoid "a predetermined or complete final option".[i] DHSC provides no information in its consultation or impact assessment which suggests that any alternate options were considered beyond those in the consultation. Nor does it explain how these options were chosen.

The proposed LCA Mechanism

- **DHSC has proposed the introduction of a Life Cycle Adjustment (LCA) mechanism, which aims to maintain the total revenue raised through sales clawbacks, but reduce rates paid by newer medicines, by imposing very high clawback rates of up to 40 per cent on certain medicines older than 12 years.**
- At present, DHSC's Statutory Scheme applies a "one-size-fits-all" approach, whereby companies face the same payment percentage on all branded medicine sales. The LCA proposes varying the payment percentages based on the age of the product and the degree to which it faces market competition.
- The LCA defines:
  - Competition as where no single company (or group of companies with the same parent company) controls greater than 80 per cent of sales quantity in the market (that is, units as opposed to packs).
  - Market as being the individual generic presentation level (also known as virtual medicinal product or VMP) when measured UK wide i.e., strength and formulation.
- While industry is open to measures that support innovation and competition, we believe that the proposed Life Cycle Adjustment will introduce even more instability to the UK market. As they stand, the proposals relating to LCA lack sufficient evidence, are inconsistent with Competition and Market's Authority guidance, and have the potential to jeopardise supply and place a considerable additional regulatory burden on companies.

- In particular:
  - **12 years is a blunt and arbitrary cut-off and would cover several products still under IP protection**.
  - **The definition of a 'market' at the individual generic presentation level is very narrow and highly problematic.** Many medicines come in different strength levels and formulations, often for valid clinical reasons (e.g., different dosages for different patient populations). This definition will classify each different strength level of one medicine as a whole market'. As a result, a company could very easily have the entire 'market' while still competing against other different products with a slightly different administration route or strength level.
  - **Defining the presentation level as the market contradicts the existing practice of NHS England, NICE and the CMA.** In competitive market shaping (e.g. tendering) processes and NICE guidelines competition is often considered at levels beyond VMP, such as the molecule, class or even therapy area level.
  - **Proposals could lead to requests for price increases in certain medicines.** This might cost the NHS more in net terms and contradicts the stated objectives of the Scheme. Member companies report that ~27 per cent of the sales in the 'supplementary' category might require a price increase to remain viable.
  - **Medicines could be withdrawn from the market if de-branding or price increases are not viable options.** This could lead to a switch towards unbranded and potentially more expensive products for the NHS in net terms. For example, generics may in turn raise their prices if there is less competition in the market. If this occurs in areas where there are no alternative treatment options, it will also significantly impact patient care.
  - **The 'headline' rate paid by younger medicines is subject to change** to meet the payments required under a 2 per cent cap. This will create highly volatile and unpredictable payments for medicines launching, worsening the UK's position as a launch market relative to other countries.
  - **The proposed definition would act as a strong disincentive to the development of new routes of administration for existing products,** where material R&D may be needed and would also disincentivise repurposing of older medicines for similar reasons, even where such repurposing is undertaken by unrelated companies – despite repurposing being a priority of the NHS and DHSC.
- Our analysis further suggests that DHSC has substantially overestimated the rebate payments the LCA could deliver. As a result, there is significant uncertainty about whether the associated rebate rates will need to change next year. This uncertainty will further undermine investment sentiment.

The impact assessment

- **DHSC has published an impact assessment (IA) alongside the consultation that sets out the benefits of each scenario.**
- There are profound questions about the assumptions and impact assessment used to justify these proposals. A full assessment by NERA Economic is available on the ABPI's website, but to summarise:

- **The Impact Assessment uses the 27.5 per cent rebate rate as the 'Business as Usual' (BaU) scenario, despite the fact Government's own analysis finds this rate to be inflated**. The 27.5 per cent rebate was selected to match the VPAS, however, current predictions suggest that in the VPAS end of Scheme Reconciliation, government will owe Scheme Members a sizeable refund due to 2023 rates being set too high. Government itself estimate the real rate to be around 18.6 per cent. It is therefore inaccurate to use 27.5 per cent as BaU.
- **The Impact Assessment is oversimplified and lacks transparency**. As the NERA report finds**,** DHSC does not quantify the benefits of reducing payment rates, making it impossible to critically assess the value of the proposals, does not account for the health benefits of R&D investment, is inconsistent with the LCA proposals and systematically biases the IA towards policy options that involve transfers to the NHS.
- **The consultation and Impact Assessment do not follow Treasury Green Book guidance**. The IA contains no evidence that DHSC considered any other options than those presented, which are essentially all variations on a 2 per cent cap on growth. This contradicts HMT guidance, which requires departments to avoid pre-determined outcomes in policy formulation. It also uses only a 3-year time frame, rather than the recommended 10 years, which therefore excludes the likely benefits of investment which will be lost because of the policy.

- These issues are of profound significance as, in the event of a Voluntary Scheme not being agreed, then updated Statutory Scheme terms would govern the entire branded medicines market. The proposals must therefore stand up to scrutiny and provide an accurate assessment of the risks and benefits. **As such, we ask Government to refer the Impact Assessment to the Regulatory Policy Committee for review.**

Closing remarks

An overarching concern across the consultation is that the proposals' outlines are unclear and/or lack sufficient analysis to inform policy. The proposals do not give legislative certainty. The computation of consultation feedback to questions which only ask "agree" or "disagree" may give misleading results. The ABPI requests that this lack of clarity on proposals be factored into the assessment of responses ahead of the publication of a final consultation outcome.

[i] The Green Book (2022) - GOV.UK (www.gov.uk)