

## **BIA response: Proposed review of the 2023 scheme to control the cost of branded health service medicines**

### **Introduction and summary**

The BioIndustry Association (BIA) is supportive of a statutory scheme which improves patients' access to medicines while rewarding innovation and supporting the growth of the UK life sciences sector. However, we are concerned that the proposals set out of this consultation will fail to achieve these objectives. In particular, we are concerned that:

- The proposed 2% cap on the allowed growth rate is not sustainable and will reduce the attractiveness of the UK as a destination for investment and product launches.
- The proposed lifecycle adjustment (LCA) mechanism risks reducing the value of IP protections as an incentive for innovation, as well as harming certain types of products where there are unlikely to be high levels of competition, such as rare disease medicines.
- The proposals would place a significant administrative burden on both the Government and industry, which will be especially challenging for smaller companies with limited resources.
- The impact assessment is based on several unsubstantiated assumptions about industry investment decisions and fails to consider the wider impact of the proposals on the UK life sciences sector.

### **About the BIA**

The BIA is the trade association for innovative life sciences and biotech industry in the UK, counting over 500 companies including start-ups, biotechnology, universities, research centres, investors and lawyers among its members. Our mission is to be the voice of the industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

BIA represents the interests of its members to a broad section of stakeholders, from Government and regulators to patient groups and the media. We also work with organisations at an international level to ensure that UK biotech is represented on the global stage including EuropaBio, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Council of Biotechnology Associations (ICBA).

BIA is the key thought leader for the sector, operating across a wide range of areas such as policy, finance, science, regulatory, legal, skills and talent as well as genomics, engineering biology and techbio.

## Consultation questions

### Relationship with the voluntary scheme

- 1. Do you agree or disagree that in the event that a voluntary scheme is agreed, the statutory scheme should seek to maintain broad commercial equivalence as far as possible with the voluntary scheme? Agree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The BIA agrees that the voluntary scheme should seek to maintain broad commercial equivalence with the future voluntary scheme if it is agreed. However, we are concerned that no detail has been provided as to how this process will work in the event that a voluntary scheme is agreed towards the end of the year. The timelines for updating the statutory scheme will be very short, and it is unclear how this could be done in time for 1 January 2024. This is creating further uncertainty for companies, making difficult to them to make forecasts and decisions for the coming year.

The statutory scheme proposals should also be amended to include the Medium Sized Company exemption in the 2019 voluntary scheme, whereby companies with sales of between £5m and £25m will have their first £5m of sales exempt from the rebate. This will help to avoid companies earning just over £5m being severely disadvantaged in the scheme. The £5m allowance should also be increased to reflect the impact of inflation since 2019.

### Allowed growth rate

- 2. Do you agree or disagree with our proposals to increase the level of allowed growth in the scheme and to uprate the baseline from which allowed growth is controlled, which will change the payment percentages, as set out in our impact assessment of the changes? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The BIA believes that the proposed 2% cap on the allowed growth rate is too low and will restrict the growth of the UK life sciences sector and reduce access to medicines for patients in the NHS. The consultation fails to provide any rationale or assessment of how the proposed cap is suitable for the UK beyond an unexplained statement that allowing any growth rate over 2% would result in “unsustainable budget pressure on the NHS”.

The BIA believes that the proposed 2% cap is not sustainable for the following reasons:

- Since 2018, total NHS expenditure has consistently exceeded the allowed growth cap in the VPAS agreement, placing increasingly unsustainable financial pressure on the pharmaceutical industry to pay more in rebates each year. This is an unsustainable

position for the UK pharmaceutical industry and will result in the UK being deprioritised as a launch market.<sup>1</sup>

- The proposed 2% cap fails to account for the significant increases in inflation over the past few years, meaning that it will lead to a further decline in real terms medicines spending.
- UK medicines spend per capita is lower than other comparable countries, including France and Germany.<sup>2</sup>
- The cap has resulted in rebate percentages significantly higher than comparable European countries, where rates are between 7.5-12%. This is damaging UK competitiveness, impacting global investment and launch decisions.
- Global boardrooms are choosing to deprioritise the UK in favour of more ‘pro-innovation’ markets, which is reflected in recent data on levels of medicine launches, R&D investment and clinical trials.
  - The number of industry clinical trials initiated in the UK per year has fallen by 41% between 2017 and 2021.<sup>3</sup>
  - The UK’s share of global R&D spend has decreased from 4.9% to 3.6% between 2012-2020.<sup>4</sup>
  - Between 2016 and 2021, the UK experienced the highest rate of decline in new drug launches across EU4+UK as a percentage of global launches, at 6.7%.<sup>5</sup>

The BIA believes that the Government should adopt a more sustainable approach which allows the growth rate for both the statutory and voluntary schemes to increase in line with wider healthcare spending increases. Medicines are only approved by NICE/SMC for use in NHS if they are deemed to be cost-effective. They are also subject to budget impact test to control in year affordability. Therefore, removing the cap would not result in unsustainable budget pressure on the NHS.

## Exemptions

### 3. Do you agree or disagree that the statutory scheme should provide an exemption from payment for medicines containing a new active substance? **Agree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The BIA supports the exemption from payment for medicines containing a new active substance (NAS) to mirror the exemption in the 2019 voluntary scheme. While the

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<sup>1</sup> BIA report, Making VPAS fit for the future: the BIA vision (2023)

<sup>2</sup> Ibid

<sup>3</sup> ABPI, Rescuing patient access to industry clinical trials in the UK (2022)

<sup>4</sup> Evaluate pharma world preview (2021); ONS UK business enterprise expenditure on R&D

<sup>5</sup> <https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/voluntary-scheme-on-branded-medicines/variations-in-access-and-adoption-of-innovative-medicines-need-to-be-addressed/>

exemption will go some way to incentivise companies to launch their products quickly in the UK, the impact of the exemption is undermined by the fact that it can take many months for a product to be approved by NICE/SMC for use in the NHS after it has received marketing authorisation. This issue is particularly acute for innovative rare disease medicines given the challenges in securing timely NICE/SMC approval for these treatments. The BIA therefore recommends that the exemption begins at the point of reimbursement instead of marketing authorisation.

The BIA also believes that additional markers of innovation – such as participation in the Innovative Licensing and Access Pathway (ILAP) and/or Early Access to Medicines Scheme (EAMS) should also be recognised as equivalent to NAS. In addition to being a clear marker of innovation, the investment made by companies into these programmes should be recognised and supported, independent of NAS status.

If the non-LCA scenario is adopted, then the BIA would support an increase in the duration of the NAS exemption beyond 36 months as a way to strengthen support and incentives for innovation.

**4. Do you agree or disagree that the statutory scheme should provide an exemption for centrally procured vaccines (CPVs)?** Agree

**Please explain your answer and provide evidence to support further development of our analysis. Please include any comments you may have on whether the Secretary of State ought to have discretion to waive the exemption criterion for management by UKHSA or a successor where this is not possible due to exceptional circumstances.**

The BIA supports the exemption for centrally procured vaccines to provide consistency with the exemption in the current voluntary scheme. This will help to ensure that the procurement of vaccines is not impacted in the event that a future voluntary scheme is not agreed.

**5. Do you agree or disagree that the statutory scheme should provide an exemption for exceptional central procurements (ECPs)?** Agree

**Please explain your answer and provide evidence to support further development of our analysis. Please include any comments you may have on whether the Secretary of State ought to have discretion to waive the exemption criterion for management by UKHSA or a successor where this is not possible due to exceptional circumstances.**

The BIA supports the exemption for exceptional central procurements to provide consistency with the exemption in the current voluntary scheme. This will help to ensure that the procurement of vaccines is not impacted in the event that a future voluntary scheme is not agreed.

## **Lifecycle adjustment mechanism: background and rationale**

- 6. Do you agree or disagree with the principle that in relative terms payment percentages should be higher for older products when not subject to adequate competition, and lower for newer products and older products when subject to adequate competition? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The BIA is supportive of a statutory scheme which rewards innovation and supports the growth of the UK life sciences sector. However, the BIA is concerned that the proposals for the LCA mechanism will fail to achieve these aims. The BIA's concerns about the proposed LCA mechanism include:

- The proposed LCA mechanism sets arbitrary definitions for a 'older' products and 'competitive' markets which fail to recognise variation between different types of branded medicines and would unfairly penalise certain types of products.
- The proposal to define a product as older when it has been marketed in the UK for at least 12 years risks reducing the value of IP as the average period of exclusivity of products with a supplementary protection certificate (SPC) is 14.4 years post-market authorisation, and the maximum 15.5 years (including paediatric extension).<sup>6</sup> The UK has historically been a strong advocate of the value of IP protections in international discussions and this approach would undermine the UK's position.
- The proposal for an arbitrary definition of a competitive market will disadvantage certain types of products where there are unlikely to be high levels of competition. This includes many rare disease medicines, where there are limited incentives for companies to enter the market due to small patient populations.
- The proposals for quarterly data analysis to assess competition would place a significant administrative burden on both the Government and companies. This would be especially challenging for smaller companies with limited resources.
- While the proposed rates are lower for newer products and older products subject to competition, these rates are still comparatively high compared to other European countries and will therefore fail to provide a significant incentive for investment and product launches in the UK.

## **Lifecycle adjustment: defining older and newer products**

- 7. Do you agree or disagree with the definition of an older product as being any product where the active substance has been marketed in the UK for at least 12 years? Disagree**

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<sup>6</sup> <https://www.iqvia.com/insights/the-iqvia-institute/reports/protection-expiry-and-journey-into-the-market>

**Please explain your answer and provide evidence to support further development of our analysis.**

The rationale DHSC has provided for selecting 12 years is that is in an “easy to operationalise proxy for the time in a product lifecycle where we would ordinarily expect to see average selling prices start to fall.” However, patents can extend to up to 15.5 years, including through SPCs and paediatric extensions and subsequent innovation patents. By charging a higher rate for these products the value of these patents is severely undermined, reducing the incentives for follow-on innovation throughout the product life cycle, including new indications, combinations, formulations and modes of administration. This incremental innovation can offer significant benefits to health systems and patients and is essential to maintain incentives for companies to invest into this R&D beyond it receiving its first marketing authorisation. The UK has historically been a strong advocate of IP and its role in encouraging investment into innovation, however these proposals risk severely undermining this.

The BIA proposes that if a product is protected by an SPC or other exclusivity protections which would prevent the marketing of a product which replicates the innovator product beyond 12 years after marketing authorisation, then it should not be considered an ‘older product’ until it is no longer protected by a such exclusivity protections.

**Lifecycle adjustment: details of proposal**

**8. Do you agree or disagree with payment percentages proposed for the supplementary rate?** Disagree

**9. Do you agree or disagree with payment percentages proposed for the lower rate?** Don't know

**Please explain your answers and provide evidence to support further development of our analysis.**

The proposed payment percentages for the supplementary rate are far higher than those seen in comparable countries and risk severely impacting the viability of medicines in the UK. The consultation states that companies can request a price increase from DHSC if the increased rate makes it uneconomical for them to supply medicines to the NHS. However, this is a burdensome process that is not always viable for companies. Furthermore, if price increases are granted then this will increase the medicines bill, undermining the purpose of the scheme. Furthermore, higher medicines spend result in higher rebates for other medicines, penalising other products which have not increased in price.

The proposals create a risk that a high number of companies will be forced to ‘debrand’, meaning that less revenue will be generated from the supplementary than anticipated. There is also risk that uneconomical medicines will be withdrawn from the market if they cannot debrand or increase their price. The potential impact of this has not been fully considered in the impact assessment.

The proposed payment percentages for the lower rate are still higher than European comparators, including Ireland, France and Spain. Therefore, while the proposed lower rate is closer to internationally competitive rates, it will not provide significant incentives for companies to prioritise launching their products in the UK.

**10. Do you agree or disagree with how we propose to define the competitiveness of markets for older medicines? Disagree**

**Do you have any further comments on how we propose to define the competitiveness of markets for older medicines?**

The BIA is concerned that the proposed definition of a competitive market is arbitrary, oversimplistic and fails to consider variations between different types of products. The proposed definition will disadvantage certain types of products where there are unlikely to be high levels of competition. This includes many rare disease medicines, where there are limited incentives for companies to enter the market due to small patient populations. There is a danger that the high payment rate could impact the supply of these treatments to the NHS if it becomes uneconomical for companies. The BIA therefore proposes an exception for rare disease medicines, defined as those granted orphan designation, whereby they are subject to the lower payment percentage regardless of the level of competition in the market.

The proposal to measure competition at the virtual medicinal product (VMP) level is flawed as this is not where actual competition takes place. For example, many biosimilars experience a highly competitive marketplace in practice, but low competition at the VMP level. Therefore, the proposals risk penalising products in markets which are subject to high levels of competition in practice.

Furthermore, markets may experience fluctuations in the level of VMP competition, often due to factors outside of a company's control, such as the withdrawal of a competitor products and changes in NHS procurement. This would create significant administrative burdens for companies and high levels of uncertainty, making financial planning difficult.

**11. Do you agree or disagree with the proposal to collect supplier's quarterly sales data at individual presentation level? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The proposal for quarterly data collection will place a significant administrative burden on companies, which would be particularly challenging for smaller companies. The proposal would also place a significant administrative burden on DHSC and the BIA is concerned that no assessment has been provided as to the additional DHSC resources required to make the scheme operational. This is particularly concerning given the short timelines for implementation, with the new scheme proposed to begin on 1 January 2024.

This proposal also creates further uncertainty for companies as the payment rate for ‘older’ medicines could vary on a quarterly basis as the level of VMP competition fluctuates. A stable and predictable rate is required to enable companies to make financial plans. Further detail is required as to how DHSC will communicate any changes in payment rates and how much notice companies will be given.

**12. Do you agree or disagree with our proposed approach to small molecule medicines that are branded by choice? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The proposed approach to small molecule medicines that are “branded by choice” is oversimplistic as it does not consider the different reasons why a small molecule medicine would be branded if there is no regulatory requirement.

**13. Do you agree or disagree with the proposed exception for products launching into an existing market for the first time for up to 12 months? Don't know**

**14. Do you agree or disagree with the proposed exception for blood and plasma derived products? Agree**

**Do you have any further comments on our proposed approach to exceptions for products launching into an existing market, and for blood and plasma derived products?**

No evidence has been provided to confirm the impact of the proposed exception for products launching into an existing market for the first time for up to 12 months. If the proposed terms of the LCA model were not implemented, then no exception would be needed.

The BIA supports the exception for blood and plasma derived products and welcomes the recognition of these products as “strategically important”. For the reasons set out the proposal, the exception should be applicable in both the LCA and non-LCA scenario.

The BIA recommends that exceptions are also made for other strategically important products that could be disadvantaged in the scheme, including rare disease medicines and advanced therapy medicinal products (ATMPs).

**Proposed payment percentages**

**15. Do you agree or disagree with the payment percentages proposed in the non-LCA scenario? Disagree**



**16. Do you agree or disagree with the headline payment percentages proposed in the LCA scenario? Disagree**

**Please explain your answers and provide evidence to support further development of our analysis.**

The proposed payment rates in both the LCA and non-LCA scenarios are considerably higher than those in comparable European countries and are therefore highly uncompetitive. The proposed rates are impacting the decisions of global boardrooms which are now choosing to deprioritise the UK in favour of more 'pro-innovation' markets. This is damaging the UK's attractiveness as an early launch market and a destination for investment.

The BIA is also concerned that the payment rates could increase even further if the statutory scheme fails to keep medicines spending within the proposed 2% allowed growth rate.

**17. Do you have any comments on the proposed methodology used in determining the payment percentages (as set out in the impact assessment)?**

**Please give reasons and provide any evidence or analysis that would support any refinement you think the government should make.**

The proposed methodology is based on a 2% cap on the allowed growth rate which the BIA believes is too low and will restrict the growth of the UK life sciences sector and reduce access to medicines for patients in the NHS. The reasons for this position are set out in previous answers.

### **Unbranded biological products**

**18. Do you agree or disagree that the government should apply the statutory scheme to both branded and non-branded biological medicines from 1 January 2024? Agree**

**Please explain your answer and provide evidence to support further development of our analysis.**

BIA agrees with the rationale provided by DHSC as to the inclusion of both branded and non-branded biological medicines. However, as set out in other answers, we are concerned about the proposed timeline for implementation from 1 January 2024.

### **Impact of the proposal**

**19. 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? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The BIA has a number of concerns with the analysis provided in the impact assessment of the proposals. The impact assessment is based on several unsubstantiated assumptions, including that the proposals would “protect from a potential deterioration in industry sentiment” and “support innovation and access to novel treatments”. Counter to these assumptions, BIA member companies have reported to us that the proposals have led to global boardrooms becoming increasingly apathetic to the UK as a launch market and destination for investment. Companies are concerned not only about the uncompetitive rebate rates proposed, but also by the uncertainty and administrative burden the LCA approach would create.

The analysis in the impact assessment also fails to consider the impact that the proposals will have on smaller companies as businesses with NHS sales of less than £5m per annum are excluded from the scheme. This fails to recognise that the life sciences sector is highly interconnected and therefore changes which impact larger companies will also impact the sector as a whole.

It is essential that the Government fully considers the potential impact of these proposals and is transparent in these considerations. Ultimately, the proposed timelines for the introduction of the scheme do not give enough time for sufficient stakeholder engagement to develop an accurate assessment of the impact.

### **Statutory duties**

**20. 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? Disagree**

**Please explain your answer and provide evidence to support further development of our analysis.**

The Secretary of State’s statutory duties include promoting a comprehensive health service, the continuous improvement in the quality of services, and promoting research. For reasons set out in previous answers, the BIA is concerned that the proposals will negatively impact on these duties as they will reduce access to medicines for NHS patients, impact the supply of medicines, and reduce investment into R&D in the UK.