

Statutory scheme to control costs of branded health service medicines – BIA's response

September 2018



Introduction

The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives. Our membership includes large, multinational pharmaceutical and biotech companies as well as SMEs. Collectively, BIA members are responsible for over 90% of biotech medicines currently in clinical development in the UK.

The BIA welcomes the opportunity to respond to this consultation. We have limited our comments to the broader implications of the proposals rather than the technical details concerning the methods and models used for forecasting.

Key points

- The BIA is concerned about the message this consultation, and other proposed changes affecting UK life sciences, are sending to the international life science community about the UK as a location to research, develop and launch innovative medicines.
- The BIA welcomes the funding settlement for the NHS but calls on government to ensure that allowable growth in medicine spend reflects the increase in NHS funding.
- Brexit is creating a great deal of uncertainty for UK life science companies and depending on the outcome of the negotiations, the UK's exit from the EU could pose a number of risks for the success and sustainability of the UK's life science sector.
- In addition, the sector is yet to see the full impact of changes made to NICE processes last year and earlier this year and, simultaneously to this consultation, industry is being consulted on the introduction of charges for NICE Technology Appraisals. The BIA believes that the potential negative impacts of the proposals set out in this consultation will be compounded by broader developments affecting the sector and it calls on the government to take this into consideration when deciding next steps.
- Following the EU referendum, the government has consistently stressed the strategic importance of the UK biopharmaceutical sector to the UK's future prosperity. The changes proposed in this consultation, and broader developments affecting UK life science companies, go against this. Government needs to be consistent and transparent about its ambitions for the sector.

Impact on Investment and the Future Success of the UK Life Science Sector

The BIA is concerned about the message this consultation, and other proposed changes affecting UK life sciences, are sending to the international life science community about the UK as a location to research, develop and launch innovative medicines. With the UK's exit from the EU on the horizon, now is a critical time for demonstrating to global markets and companies that the UK remains an excellent location to invest and develop medicines. Bioscience companies, even if they are based in the UK, make their commercial decisions from a global perspective. Rather than showcasing the UK as a good place to do business, the proposals set out in this consultation have caused alarm among industry and have sent a negative signal to global-looking boardrooms.

The NHS is an integral part of the UK's thriving life science ecosystem. As a single, national purchaser and provider of healthcare, the NHS could be a significant draw for life sciences companies considering whether to invest in the UK post-Brexit. Subsequently, the BIA welcomes the new funding settlement for the NHS however, in light of this increase in funding (3-4% in real terms) the proposed payment rates set out in this consultation equate to a 10-year disinvestment in medicines. This sends a strong signal to companies deciding where to invest and launch their product that the UK is not willing to invest in innovation and the best available healthcare for patients. The government should ensure that allowable growth in medicine spend reflects the increase in NHS funding.

In addition, Brexit is creating a great deal of uncertainty for UK life science companies and depending on the outcome of the negotiations, the UK's exit from the EU could pose a number of risks for the success and sustainability of the UK's life science sector. For instance, recently published government guidance has now made it clear that a 'no deal' Brexit would mean a significant increase in replicative bureaucratic red tape for developers of innovative medicines who choose to sell their products in the UK. Even if the UK negotiates a deal with the EU, operating costs for UK companies will potentially increase. Additional regulatory processes and costs for a market worth less than 3% of the world's value will most likely diminish the UK's attractiveness for life science businesses and may mean that NHS patients get access to new therapies later than other countries in Europe.

On top of this, there have been various changes to NICE's Technology Appraisal processes over the last 18 months, including the introduction of the Budget Impact Test, the use of a QALY threshold for Highly Specialised Technologies and changes to increase capacity, all of which we are yet to see the full impact of. Furthermore, industry is currently being consulted on the introduction of charges for NICE Technology Appraisals. The BIA believes that the potential negative impacts of the proposals set out in this consultation will be compounded by these broader developments, which are also affecting the sector.

Following the EU referendum, the government has consistently stressed the strategic importance of the UK biopharmaceutical sector to the UK's future prosperity however, the changes proposed in this consultation, and broader developments affecting UK life science companies, go against this. In fact, the impact assessment accompanying this consultation suggests government believes there is no link between an internationally-competitive medicines access environment and investment in the UK. This is in direct contrast to sentiments expressed in the Life Sciences Industrial Strategy and the Accelerated Access Review, both of which the government has committed to implementing in full.

The BIA believes that in conjunction with broader developments, the proposals set out in this consultation are likely to result in a poor commercial environment which, when further exacerbated by the complications of Brexit, will reduce the attractiveness of the UK as a place for bioscience companies to do business. The government should consider the collective impact of broader developments, including Brexit, on the UK's life science ecosystem when deciding how to take the proposals set out in this consultation forward and ensure it is consistent and transparent about its ambitions for the sector.

For additional information or clarification on any of the points raised please contact Rachael Stewart, Policy and Public Affairs Manager at rstewart@bioindustry.org or on 02076302187