BIA policy submission

17 January 2024

UK BioIndustry Association

BIA response to the DBT call for evidence on smarter regulation and the regulatory landscape

Introduction

The BioIndustry Association (BIA) welcomes the Government's commitment to ensuring the UK has an effective and proportionate regulatory landscape, which is essential to succeed in the global innovation-driven economy.

The BIA is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

We have over 600 members including:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, and IP consultants

The BIA advocates for the interests and advancement of biotechnology in healthcare and beyond, including but not limited to applications in food and the environment. Working closely with various stakeholders including government bodies, regulatory agencies, and our diverse member companies, we seek to foster an environment conducive to the growth and success of the biotech industry, underpinned by robust, proportionate and science-led regulatory frameworks.

By achieving these goals in a collective effort between the government, regulators and industry, the UK can enhance its role as a global innovation leader, driving growth, prosperity, and public trust.

As a trade association representing a broad membership, we have limited our responses to the overarching themes of each section of the call for evidence.

Section One: Questions on the Landscape of Regulation

The BIA welcomes the opportunity to engage in this consultation process. Active participation in discussions about regulatory frameworks is vital for ensuring that the perspectives and needs of the innovative life sciences and biotech sector are adequately represented and considered.

Despite the challenges described later in this consultation, there have been some undeniable successes within the UK regulatory landscape, particularly during the COVID-19 pandemic. There are continuing positive developments within UK regulators in the life science sector, such as the MHRA and NICE, who demonstrate a willingness to collaborate and engage with the industry, for example through the MHRA Regulatory conference[1] with SMEs and overall proactive engagement with industry events. This cooperative and open approach is a competitive advantage over other countries and should be further encouraged and exemplified.

Regulators BIA members engage with most frequently

As the majority of members work within the healthcare and life sciences sector, the main regulators they (and BIA itself) engage with are:

- MHRA, for clinical trials, as well as the authorization of medicines, medical devices, and applications of AI and data to healthcare
- NICE, for medicines price setting
- Human Tissue Authority, for biological samples and cell therapies
- Health Research Authority, for research ethics and patient data
- NHS Improvement, for data use and adoption and diffusion of innovation across the health service
- Information Commissioners Office, for data use, particularly patient data
- Animals in Science Regulatory Unit, for research involving animals

For members that work in the food industry:

- Food Standards Agency, for genetic technologies, and those developing alternative proteins

All companies may also interact with, at one time or another during their lifetime:

- Office for Product Safety and Standards, for compliance with the Nagoya Protocol and a range of regulatory frameworks
- Intellectual Property Office, for compliance with patent regimes
- National Security and Investment Unit (Cabinet Office), for national security concerns in AI, data and engineering biology
- Competition and Markets Authority, for takeovers
- Trade Remedies Authority, for international state aid and competition concerns

Although we recognize they are out of scope of this consultation, the following regulators have a strong direct or indirect impact on the growth and success of the sector:

- HMRC, for tax
- Financial Conduct Authority, for regulation of investors and corporate finance rules
- Prudential Regulation Authority and the Pensions Regulator, for corporate pensions and the ability of pension funds to invest into innovative sectors of the economy, primarily through venture capital

The above lists are not exhaustive and additional regulators will be engaged with depending on R&D activities and end users.

[1] https://www.bioindustry.org/event-listing/bia-regulatory-conference-2023.html

Section Two: Complexity and Ease of Understanding the Regulatory System

The cost and opportunities of regulatory divergence

Sovereign UK medicines regulation has become less pertinent compared to five years ago, especially in globalised sectors that continue to deliver products and services to US and European specifications, and therefore needing to adhere to US and European standards. Despite the sector's efforts to highlight workable solutions during the Brexit transition, the UK's regulatory landscape has become increasingly divergent, impacting the attractiveness of the UK market for life sciences R&D and manufacturing.

There is, therefore, a significant balancing act to be achieved regarding international regulatory alignment and divergence. In some areas, where our competitors are notably behind in pro-innovation regulation – such as the EU's approach to precision breeding for food and animal feed – divergence can bring economic and societal benefits (the EU is now following the UK's lead). In other areas, divergence can negatively impact investment, collaboration and supply chains, and overall create unnecessary burden on small companies trying to navigate multiple sets of complex regulations.

Impact of change and inconsistency within UK medicines regulation

The life sciences sector has also been burdened by constant changes in regulation, particularly regarding the Northern Ireland Protocol and inconsistencies in medicine regulation. These factors have contributed to the UK being perceived as an increasingly unreliable and costly business environment.

Strategic changes within regulators and their consequences

Strategic alterations within the MHRA have led to a loss of expertise, a decline in global standing, and increased operational costs and delays. The initial successes, particularly during the COVID-19 pandemic, masked underlying challenges, resulting in unmet expectations based on the resources allocated.

Because of the accelerating pace of innovation, there is a risk that regulators will lag behind the latest technological developments. The existing pace of competition-driven development and the volume of capital committed by industry means that these issues will have significant consequences in the very near future. Ensuring that regulatory bodies can attract sufficient skilled talent and have continual proactive engagement with communities, industry and innovators will be a key factor for success.

Section Five: Process and Governance

Underestimating the impact of regulation on innovation

The BIA's previous experience indicates a disconcerting trend whereby key regulatory policy consultations for our sector appear to be overlooked by government departments as a result of a poor understanding about the effect of regulatory policies within innovative sectors of the economy.

A recent example involves the Department of Health's consultation on the statutory scheme for the pricing of medicines. This consultation seemed to ignore the fundamental principles of the regulation agenda, particularly in its assumption that the regulation only impacts companies selling to the NHS.

The statutory pricing and access consultation erroneously or deliberately assumed that "The regulation under consideration in this impact assessment only impacts companies which choose to sell to the NHS." (Paragraph 26 page 11). This enabled the DHSC on page 24 of the impact assessment to inappropriately state: "As such, the Statutory exclusion "Procurement 22(4)(b)" applies to the proposals, and they are deemed to be exempt from the Better Regulation Framework." This view failed to recognize the broader impact on early-stage, innovative companies aspiring to introduce medicinal products in the future.

Such oversight raises serious concerns about the efficacy and comprehensiveness of the Better Regulation Framework in future regulatory considerations for our sector. BIA wrote to Deputy Prime Minister Dowden (included as an annex to this submission) but did not get a reply.

Another example involves the regulation of the commercialisation of genetic resources and digital sequence information (DSI) of those resources (i.e. genetic code). Under the Nagoya Protocol of the Convention on Biological Diversity, the Office for Product Safety and Standards applies EU-derived regulation of genetic resources that is inconstant with the international treaty and not refined enough to be applied to innovative sectors of the economy. This current problem is the result of international negotiations that unfolded over decades, but the same mistakes are now being committed as multiple new international treaties are developed to cover the DSI of genetic resources. Different government departments are engaging in these negotiations with insufficient coordination and without appreciating the impact on innovation (or even workability) that downstream regulations will have.

Cooperation within the UK landscape in emerging strategic technology areas

Novel technologies tend to be disruptive across sectors, rather than impacting single industries. In Strategic technologies, such as artificial intelligence and engineering biology, regulators will need to be more agile and work together across each application.

Moreover, as a technology with potential impacts across many UK sectors, many regulators are faced with understanding and correctly supporting engineering biology approaches and products. Innovative start-ups and SMEs are faced with regulatory uncertainty and a lack of guidance due to

the novelty of their products. We therefore welcome the establishment of the Engineering Biology Regulatory Network (EBRN) and sandboxes. Regulation should be pro-innovation and industry-led, with regulators working closely with existing engineering biology companies.

Section Seven: Concluding Questions

Relevance of Deregulatory Legislation

The Access to Medical Treatments (Innovation) Act 2016, aimed at deregulating innovative medicine rules, appears to have had minimal impact on promoting innovation or improving access to medical treatments. This raises questions about the effectiveness of such legislative efforts and the value of dedicating parliamentary time to them.

The regulatory review team may wish to use this as a case study to see how effective this has been in driving innovation and the adoption of innovation in access to medical treatments in the decade that has followed. On an initial review it seems to have been largely irrelevant and consideration of the value of parliamentary time to such initiatives should be considered with this historical precedent.

Section Eight: Closing Questions

Fees

The regulatory changes have led to increased fees from both MHRA and NICE for SMEs. In contrast, competitor regimes, like the EMA, offer fee waivers to attract innovative SMEs, highlighting a disparity in support for small businesses within our sector.

For any further information on the contents of this submission, please contact the BIA policy team at policy@bioindustry.org.

Annex 1: BIA letter to the Deputy Prime Minister

The voice of the innovative life sciences and biotech industry in the UK

UK BioIndustry Association

The Rt Hon Oliver Dowden CBE MP
Deputy Prime Minister and Chancellor of the Duchy of Lancaster, and Secretary of State in the Cabinet Office
The Cabinet Office
70 Whitehall
London
SW1A 2AS

17 October 2023

Dear Deputy Prime Minister,

Statutory scheme economic impact argument not consistent with government economic policy to put UK life science at the centre of UK growth in the 2020s

We have been encouraged by Department of Health and Social Care (DHSC) officials to comment on the proposed review of the statutory scheme to control the cost of branded health service medicines (SPAS).[1] This letter, making a broader argument, accompanies our formal response to the specific questions asked by the consultation.[2]

The BIA has major concerns that the economic analysis used to underpin the impact assessment[3] is extremely narrowly drawn, avoids engagement with key government policies designed to ensure effective regulation, and has not had the broad discussion across government at Ministerial level that such an important intervention into a key growth sector of the economy deserves.

It is clear from recent public statements that the Prime Minister, the Chancellor of the Exchequer, the Secretary of State for Science and Innovation, the Secretary of State for Business and Trade and you yourself all have a keen interest in the competitiveness of the UK life science ecosystem, and it is key that the economic benefits and risks proposed in the review by DHSC are given full Ministerial discussion.

Because of this, we ask that the economic impact assessment of this policy (and the associated state of negotiations for the Voluntary Pricing and Access Scheme's successor) be discussed by Cabinet, or Ministers at the relevant Cabinet committee before being tabled in Parliament.

Our core contention is that the medicines pricing environment (and certainly a statutory scheme) sends a very important signal to investors and companies considering whether the UK is a country to invest or even launch medicine in. Life science product development is a lengthy multi-year development process – and market expectations are a core part of global development thinking.

---

[1] https://www.gov.uk/government/consultations/review-of-the-scheme-to-control-the-cost-of-branded-health-service-medicines
[2] https://www.bioindustry.org/resource-listing/bia-response-to-dhsc-statutory-scheme-consultation-pdf.html
[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1179564/impact-assessment-review-scheme-cost-branded-medicines-updated-21-august-2023.pdf

UK BioIndustry Association I Victoria House, Bloomsbury Way, London, WC1B 4DA
T: 020 7630 2180 I E: info@bioindustry.org I www.bioindustry.org

Registered in England No. 1889626
Company Limited by guarantee

The voice of the innovative life sciences and biotech industry in the UK

UK BioIndustry Association

We have already seen global companies such as Bayer and AbbVie withdraw from the UK as a result of the unreasonable downward pressure on medicines pricing. It is well accepted that large "anchor businesses" are critical to developing world-leading science and technology clusters. The loss of major R&D investors and employers from the UK is felt across our ecosystem, impacting the circulation of talent and R&D collaboration opportunities for smaller companies developing new medicines but not yet selling to the NHS.

The detail

The core problem with the SPAS consultation and the proposed scheme is that it has not engaged sufficiently with broader government policies for economic growth.

At the heart of this is the stated assumption that "The regulation under consideration in this impact assessment **only impacts companies which choose to sell to the NHS**." (Paragraph 26 page 11). As described above, this is not the case.

This assumption is used by DHSC on page 24 of the impact assessment to inappropriately state: "As such, the Statutory exclusion "Procurement 22(4)(b)" applies to the proposals, and they are **deemed to be exempt from the Better Regulation Framework**."

The fact that there has not been Ministerial discussion on this point is made clear by the fact that the impact assessment argues that "This position has been **confirmed previously by the Economic and Domestic Affairs Secretariat at Cabinet Office**", opening the possibility that this position has not in fact been checked recently and the DHSC impact assessment relies on a historic position from Cabinet Office civil service colleagues.

If it is the case that this regulation will only impact companies that sell to the NHS, why has DHSC sought the views – via the BIA – of early stage innovative companies that do not – but hope to have products that may in the years ahead? Why seek to engage broadly with the life science industry and the investment community that support it?

Equally, we contend that DHSC is entirely wrong not to have micro and small business in scope for the impact assessment of this regulatory development. The life sciences sector is highly interconnected and changes which directly impact large and medium-size companies will also impact the sector and ecosystem as a whole.

I hope you can see the value of convening a cross-departmental group of ministers to discuss this, to enable all views to be considered and we would be happy to provide further evidence as appropriate.

Yours sincerely,

Steve Bates OBE
Chief Executive, BioIndustry Association

UK BioIndustry Association I Victoria House, Bloomsbury Way, London, WC1B 4DA
T: 020 7630 2180 I E: info@bioindustry.org I www.bioindustry.org

Registered in England No. 1889626
Company Limited by guarantee