

Influencing and shaping our sector

January - April 2023

INTRODUCTION

The BioIndustry Association (BIA) continued to represent the innovative life science sector to Ministers and senior policymakers between January and April 2023. This quarterly report provides an overview of these engagements, including with new government stakeholders such as the Department of Science, Innovation and Technology, formed in February.

Nobody would say that 2023 got off to a slow start for the BIA's External Affairs team, with the Spring Budget, a ministerial reshuffle, and the run on Silicon Valley Bank all falling within the first three months of the year. These momentous events did nothing to stall the publication of groundbreaking new BIA reports, namely the first survey of diversity, equity and inclusion in UK biotech and our Rare Insights paper on public perceptions of rare disease treatments.

As ever, the hard work of the BIA's membership has been central to our influencing efforts. The Treasury Connect: Life Sciences Conference in March saw dozens of BIA members engaging in roundtables with the Chancellor and Health Secretary, among others.



5 consultation responses and briefings submitted



10 engagement meetings with 12 parliamentarians, incl. 5 ministers

The benefits to be gained from working with HM Treasury were illustrated by our success in securing an enhanced R&D tax relief rate for loss-making SMEs. Our community also came together at the Committee Summit to inform and align our influencing work for 2023.



6 letters to Ministers

The BIA's long-term stakeholder relationships have paid dividends this quarter. From the announcement of £277 million worth of grants via the Innovative Manufacturing Fund, to the MHRA's decision not to introduce new fees for the Innovative Licensing and Access Pathway (ILAP), it has been rewarding to see our influencing work bear fruit. The BIA has also engaged with the Labour Party's policy development by contributing to Lord O'Neill's 'Start-Up, Scale-Up' review, another important stakeholder to influence in the coming months.

Read on for further details of all of the BIA's influencing work.

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Engagement with the Government and Parliament on life sciences policy

In February there was a major reorganisation of government, with the creation of a new Department for Science, Innovation and Technology (DSIT) with Michelle Donelan MP as its first Secretary of State and George Freeman back once again as a science minister, working closely with Will Quince MP, who holds the life sciences portfolio at the Department for Health and Social Care (DHSC). DSIT is tasked with fulfilling the Prime Minister's ambition for the UK to become a science and technology superpower. Another major change was the restructuring of the Department for Business, Energy and Industrial Strategy (BEIS) and the Department for International Trade (DIT) into the new Department for Business and Trade (DBT). The BIA has had early meetings with the key new ministers.



Figure 1 - A meeting between the Chancellor, Jeremy Hunt MP, other Ministers, and life science leaders in February 2023. Visible from left to right are Nus Ghani MP, Health Secretary Steve Barclay MP, and Nerida Scott of J&J Innovation. (Photograph from HM Treasury).

After the political upheavals at the end of 2022, it had been hoped that this year would usher in calmer conditions and the opportunity to undo the damage caused by the market-spooking 'mini' Budget of short-lived Chancellor of the Exchequer, Kwasi Kwarteng MP. Taking over at Number 11, Jeremy Hunt MP managed to restore stability, but his first Autumn Statement with its announcement of a near-halving of the SME R&D tax relief rate, triggered a major influencing campaign by the BIA for whose SME members this is a vital source of cash.

In the middle of this effort, with regular high-level meetings with Ministers and Treasury officials, broke the news of the failure of Silicon Valley Bank (SVB). The consequences for SVB's UK

subsidiary were not initially regarded by the Bank of England as presenting a systemic risk. While this may have been true for the banking sector, it was very much not the case for life sciences. The BIA quickly mobilised the evidence of the importance of the UK branch to our sector, informing the Treasury's understanding of what was at stake. After an intense period of discussion there was a very positive outcome with [the acquisition of SVB UK by HSBC](#).

Attention then returned to the R&D tax campaign and the **Spring Budget** on 15 March at which the Chancellor, Jeremy Hunt MP, announced a special higher R&D tax relief rate for the UK's most innovative businesses. SMEs investing over 40% of their total operating costs in R&D and not yet making a profit will receive a cash payment of 27p for each £1 they have invested in R&D. A BIA webinar was held the following day to explain what the Budget meant for members.

Steve Bates joined the Chancellor's roundtable on **university spinouts** in 11 Downing Street on 8 February. Jeremy Hunt convened a group of sector leaders, investors and experts to discuss the integral role of universities in supporting economic growth and fuelling innovation across the UK and to explore a particular aspect of the role of universities in UK prosperity and growth – commercialisation and spinouts.

Following an invitation from then Health Minister, Syed Kamall, for a broad range of views to be heard on the next **Voluntary Pricing and Access Scheme (VPAS)**, the BIA convened a group of members to bring the perspective of biotech and especially SME firms to the fore. A reflection paper on VPAS will be published soon. The group met with the responsible minister, Will Quince, on 14 March to discuss the impact of the Scheme on the attractiveness of the UK for SMEs developing innovative medicines. The BIA has also taken part in the series of 'Voluntary Scheme 2024 pre-negotiation engagement workshops', which have seen detailed discussion between government, industry, patient groups, and regulators.

The BIA proposed and briefed a number of members for the **Treasury Connect: Life Sciences Conference** which took place on 29 March. The Chancellor was joined at the event by the Secretaries of State from DSIT (Michelle Donelan) and DHSC (Steve Barclay) as well as Ministers Will Quince from DHSC and Nus Ghani from DBT. Discussion groups focused on: the independent review of commercial clinical trials; regulation; MedTech and adoption; infrastructure and manufacturing; and access to finance. These conferences are organized by the Treasury to give ministers and officials an opportunity to hear directly from businesses on key policy issues in their sector.



Figure 2 - The Chancellor addressing attendees at the Treasury Connect: Life Sciences Conference on 29 March 2023. Also on the panel were Nus Ghani MP (Department of Business and Trade), Will Quince MP (Department of Health and Social Care), Sir John Bell, and Sir John Symonds. (Photograph from HM Treasury).

In **Parliament**, the BIA's concerns about SME R&D tax reliefs were taken up by MPs we had briefed who brought them to the attention of the Financial Secretary to the Treasury, Victoria Atkins MP. During the Commons debate on the Finance Bill (following the Budget) the minister spoke about the importance of supporting SMEs in life sciences. She referenced the changes to R&D tax reliefs made in the Budget, quoting the BIA's view that 'modernising R&D tax reliefs to include data and cloud computing is essential for life science firms discovering and developing life-changing therapies for patients'.

At the **Committee Summit** on 23 February, Daniel Zeichner MP, Chair of the All-Party Parliamentary Group (APPG) for Life Sciences, took part in a fireside conversation about what a Labour Government would mean for our industry and how life sciences can work effectively to



Figure 3 - Daniel Zeichner MP and Nicky Edwards, BIA's Director of External Affairs, addressing attendees at BIA's Committee Summit on 23 February 2023.

influence Parliament. All of the BIA's Advisory Committees held their quarterly meetings at the day-long event, being held in person for the first time since the pandemic.

Life Sciences Council and other government/industry engagement

The BIA continues to support government-industry engagement through its membership of the **Life Sciences Council (LSC)** and the joint government-industry secretariat that coordinates the work of the Council and its sub-Councils and expert groups.

The **Business Engagement Board (BEB)** met on 23 January with the main item of interest being the fiscal environment in which the BIA's engagement with HM Treasury on the SME R&D tax relief regime was discussed.

The **Patient Access to Medicines Partnership (PAMP)** met on 1 March to discuss early access pathways with an update on the progress on ILAP 2.0 and in particular the enhanced information sharing between MHRA, NICE and NHSE. There was also an update on NICE process and methods changes and proportionate approach to technology appraisals. The BIA was represented by Charlie Galvin, and it was the first PAMP meeting for the new DHSC Minister, Will Quince.

Finally, the BIA marked the end of an era as we wished Professor Sir Patrick Vallance farewell as he stepped down as **Government Chief Scientific Adviser (GCSA)** in April 2023. BIA CEO Steve Bates bid Vallance farewell at a leaving party, handing him a framed cartoon from *The Times*

commemorating his many appearances on TV during the pandemic, signed by leading figures from our sector. The BIA has written to Professor Dame Angela McLean, offering congratulations on her appointment as the new GCSA and noting the opportunity to work together to promote science across government departments, rising to the ambition of an innovation-led economy set out by the Prime Minister.

Finance, tax and investment

BIA helps rescue Silicon Valley Bank UK

Over the weekend of 10 March, the BIA was at the heart of a rapid response to the collapse of Silicon Valley Bank UK (SVB), securing recognition within government of the bank's strategic value and helping to facilitate its subsequent rescue by HSBC.

Following the Bank Of England [statement](#) on the Friday placing the bank into insolvency proceedings, the BIA made urgent representations to HM Treasury, Ministers, and other relevant government bodies in order to avert a major financial crisis for our members. With over 40% of UK SME biotech and life sciences companies customers of SVB UK, such swift action was essential to protect the entire innovative life sciences and biotech sector.

The BIA team engaged throughout the weekend, with Steve Bates, CEO, and Chair Dan Mahony presenting a plan for urgent action to government, following co-ordination of member experts and collection of data in collaboration with the British Venture Capital Association (BVCA). This resulted in a change of posture by the Bank of England and the Government, facilitating the sale of the UK SVB entity to HSBC.

Steve Bates OBE [said](#): 'The UK life science sector wants to thank and congratulate the UK Government, the Bank of England and HSBC for listening and moving at pace to find a great solution to the SVB UK issue.'

BIA welcomes enhanced relief for innovative SMEs in Spring Budget

In March, the BIA welcomed the announcement of a new R&D tax relief rate for 'R&D intensive SMEs' and delayed restrictions for claims on overseas activity in a [Spring Budget](#) packed full of announcements for the life sciences sector, including a funding boost for the medicines regulator and plans for investment zones around the UK.

The creation of a new enhanced rate for loss-making SMEs that are investing 40% or more of their total operating costs on R&D is a highly effective way to incentivise truly innovative businesses. Eligible companies will receive 27p for every £1 of their own R&D spending. By targeting UK taxpayer support, the relief will enable life science entrepreneurs to crowd in further private investment, allowing them to grow and accelerate innovation in the UK.

The new enhanced rate followed an intense four months of lobbying by BIA initiated by a severe cut to the relief rate for SMEs in the Autumn Statement, covered in [the previous edition of this report](#). For example, a BIA [submission](#) to the Treasury ahead of the Budget highlighted the impact of instability caused by successive changes to R&D tax relief for innovative start-ups and scale-ups. The one-year delay to new restrictions for overseas activity claims will therefore significantly help companies struggling with the turbulent policy landscape.

A full analysis of the Spring Budget can be found [on the BIA blog](#). If you have any further questions about tax reliefs for life science companies, please contact Head of Policy and Public Affairs, [Dr Martin Turner](#).

Treasury consultation on a single R&D tax relief scheme influenced by BIA

The BIA's [submission](#) to HM Treasury's R&D Tax Reliefs Review [consultation](#) on creating a new single scheme highlighted the importance of long-term support from successive governments, most crucially via the R&D tax relief scheme.

In welcoming the intention to create a simplified scheme to ensure taxpayers' money is spent as effectively as possible to support innovation, while reducing fraud and misuse of public funds, our submission set out four key requirements for the merged scheme, which should:

- provide an additional rate of credit for R&D-intensive SMEs
- exclude soft innovation
- include sub-contract R&D as eligible expenditure, and
- support specialist R&D service providers

An additional rate of credit for R&D-intensive SMEs was included in the subsequent [Spring Budget](#) announcement in the form of the new 'R&D-intensive company category'. The BIA will continue to work closely with members and HM Treasury officials as the new scheme is developed throughout 2023. It is expected to be in place by Spring 2024.

BIA's tax experts feed into HMRC guidance on overseas restrictions

New R&D tax relief rules will restrict the types of overseas activity for which companies can claim. In response to draft HMRC guidance on the restrictions published before the Spring Budget, the BIA advocated for grandfathering of existing contracted R&D and a delay to implementation, which was delivered in the Spring Budget. The BIA also flagged uncertainty over the evidence companies will be required to provide, and concern about the ability of companies to source such evidence.

Experts from the BIA's Finance and Tax Advisory Committee (FTAC) also met HMRC officials and provided detailed suggestions for guidance that would ensure companies in our sector could implement the new rules. Addressing a lack of sector-specific guidance, the BIA invited HMRC to work with industry, or to adopt BIA's suggested text.

Putting on record the gratitude of the BIA and members for the engagement of HMRC and HM Treasury officials throughout the R&D tax relief review, the BIA's submission welcomed the opportunity to provide comment on the draft guidance, and the inclusion of data and cloud computing costs within the regime.

Support scaling businesses, BIA tells Labour

The BIA's [submission](#) to The Labour Party's National Policy Forum on Delivering Growth, which will develop the party's next manifesto, strongly encouraged any future Labour Government to adopt the recommendations of Lord Jim O'Neill's '[Start-Up, Scale-Up](#)' review in full, including unlocking institutional investment.

Noting support for all of the review's recommendations, our submission suggested unlocking institutional investment and patient capital by implementing a UK version of the successful [French Tibi scheme](#), transforming the British Business Bank, and incentivising investment and entrepreneurship. The BIA recommended that a Labour government should commit to increasing the budget of Innovate UK, and specifically the Biomedical Catalyst, to support both mission-led and business-led innovation within start-ups.

Lord O'Neill's review was [commissioned by the Shadow Chancellor](#) last year to look at how best to support start-ups and scale-ups, and to which the BIA submitted evidence and made recommendations, almost all of which were adopted.

Strategic technologies and areas of scientific focus

BIA submits views on governance of Digital Sequence Information to the CBD

In February, the BIA responded to a call for views from the Convention on Biological Diversity (CBD) following on from [COP15](#).

The [decision](#) was made at COP15 to establish a multilateral benefit sharing mechanism for the use of Digital Sequence Information (DSI) on non-human genetic resources, but it remains unclear what the new mechanism for DSI may look like. The details are to be developed by COP16, scheduled for 2024 in Turkey.

In advance of COP16, the Convention on Biological Diversity (CBD) [called for views](#) on some of the 'issues for further consideration' that were identified in December. The BIA [responded](#) to the call, highlighting that we support a multilateral benefit sharing mechanism that promotes both the conservation objectives of the CBD *and* innovation. The BIA also reiterated that the innovative work of life sciences companies should not be undermined and that the definition of 'DSI' needs to be clarified.

Over the coming months, the BIA will engage closely with government on the development of the new mechanism for DSI. If you are working with non-human DSI and have concerns about the ongoing international discussions, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA supports Government Office for Science work on engineering biology

In August 2022, BIA members took part in a Government Office for Science (GO-Science) workshop to understand the opportunities for the UK's non-human-health life sciences and biotechnology sectors. The workshop brought together industry, key government stakeholders, and academic experts to gather insights around policy, financial and regulatory aspects affecting the future success of the biotechnology-based industry in the UK.

The insights gathered through the workshop were published as part of the '[Life sciences beyond human health](#)' report in March 2023 which will inform the work of the Government Chief Scientific Advisor. The report is part of wider ongoing work at GO-Science around biotechnology and engineering biology that the BIA is feeding into.

The BIA has begun scoping new activities to promote biotechnology solutions beyond human health. To get involved with the BIA's work in this area, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA joins Business Select Committee conference on economic growth

On 27 March, the BIA joined a half-day conference of the [Business, Energy and Industrial Strategy \(BEIS\) Select Committee](#) on 'Moving the dial on economic growth in the UK' in Parliament, led by committee chair Darren Jones MP. The conference explored four avenues to stimulate economic growth in the UK: innovation-led, investment-led, labour-led and industrial strategy-led.

In attendance were stakeholders from across different industries and government departments as well as MPs from both the Conservative and Labour parties that make up the committee. While there is cross-party consensus on the necessity for growth, there are several levers through which this can be achieved. The BIA highlighted the role of innovative SMEs as economic drivers and the importance of long-term implementation of sector-specific strategies such as the [Life Sciences Vision](#).

The conference also served to launch the [UK plc report](#) which features recommendations on what role Government and regulation can play in increasing UK productivity.

Letter in support of innovation in the sustainable protein sector signed by BIA

On 13 March, the BIA co-signed a letter to Secretary of State for Environment, Food and Rural Affairs, Thérèse Coffey MP, in support of innovation in the sustainable protein sector. The letter was signed by 23 organisations in the sector, including the Good Food Institute (GFI) Europe and BIA members.

The letter urged the UK Government to allocate at least £120 million in R&D funding to sustainable proteins by the end of 2024, and to explicitly include funding for plant-based, fermentation-made, and cultivated meat. These technologies can play an instrumental role in bolstering food security, improving public health, and creating sustainable economic opportunities in agriculture, biotechnology, and food manufacturing.

As the BIA's membership in non-human biotech continues to grow, so do our influencing activities in this space. To learn more about our work on biotech beyond human health, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

People, skills, and talent

BIA launches landmark report on diversity and inclusion in UK biotech

March 2023 saw the BIA launch the first baseline survey of diversity, equity and inclusion for our sector. Over 1,200 individuals took part in data collection, representing 30 BIA member companies, providing a broad dataset reflecting companies large and small from across the life science ecosystem. Over 20,000 data points were analysed in total, reflecting how the diversity of talent working within UK biotech feel about their workplace flexibility, fair management, and career development.

Overall, the results show that UK biotech is a diverse and inclusive sector in which to work. The report also offers key recommendations for the UK life sciences and biotech sector to improve diversity and inclusion. It also offers guidance to support individual organisations on attracting diverse talent, accessing investment, and retaining the skills needed to start, grow, and deliver world-changing innovation.

To learn more about the BIA's work on skills, please contact Skills Strategy Consultant, [Dr Kate Barclay](#).



Figure 4 - Simon Simpkins and Ksenia Sitara of Oxford Biomedica (OXB) holding the Richard Wilson Impact Award, awarded to OXB for their work on the Advanced Therapies Apprenticeship Community (ATAC) programme.

BIA on the road for National Apprenticeship Week

The BIA has been working hard to promote apprenticeships in the innovative life sciences, a key vocational training tool for attracting new talent and upskilling existing employees. During National Apprenticeship Week (6-12 February) and Scottish Apprenticeship Week (6-10 March), the BIA

supported the Advanced Therapies Apprenticeship Community (ATAC) in showcasing the incredible range of talent accessing apprenticeships, from laboratory scientists to senior leaders.

The ATAC Roadshow took place in four locations across the UK, bringing together current and future employers as well as celebrating the apprentices themselves. Each day featured an incredible apprentice panel, employer and apprentice award ceremonies, facility tours, and all manner of networking opportunities. Employer feedback reaffirmed the value of the face-to-face roadshow of events in showcasing the range of apprenticeships available.

Intellectual property and technology transfer

BIA asks for continuity and predictability in UK IP law under Retained EU Law Bill

The [retained EU Law \(REUL\) Bill](#) is progressing through Parliament, with Royal Assent expected by June. Over [3,745 pieces](#) of retained EU legislation have been identified across all government departments, over a thousand more than initially counted. Working closely with stakeholders including the BIA, the Intellectual Property Office (IPO) identified around [80 pieces of retained IP law](#) that fall within the Bill's scope.

In March, the BIA wrote a letter to new Secretary of State for Science, Innovation and Technology Michelle Donelan MP and new Minister for AI and IP, Viscount Camrose, on IP law under REUL. We stated that while we are not opposed to precisely targeted, pro-innovation changes that assure the high quality and competitiveness of the UK's IP system, certainty and predictability in the UK's world-class system need to be maintained, and any changes to IP law under the Bill carefully considered and consulted on. This stance is aligned with the IPO's approach, and no substantial policy changes are expected.

To stay up to date on developments, members can sign up to the BIA's IP bulletin by emailing Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA meets with IPO to discuss Genetic Resources in patent applications

The World Intellectual Property Organisation ([WIPO Intergovernmental Committee on IP and Genetic Resources](#)) (GRs) are considering the introduction of a mandatory requirement for patent applicants to disclose the source of GRs that are utilised in their applications. The disclosure requirement would be a defensive measure intended to prevent the misappropriation of GRs from their country of origin.

On 23 February, the BIA's Nagoya subcommittee to the Intellectual Property Advisory Committee ([IPAC](#)) took part in a UKIPO workshop that sought stakeholder views on the [WIPO draft text](#) of the mandatory disclosure requirement. The subcommittee stated that there should be no mandatory disclosure obligation in patent applications on the basis that this would not lead to a reduction in 'bad' patents or an increase in transparency, as hoped for by WIPO.

In its current form, the requirement would extend to human genetic resources used in an invention, implicating most of the BIA's membership. A [diplomatic conference](#) is scheduled to take place no later than 2024, from which an international treaty will likely transpire.

Clinical research

Lord O'Shaughnessy independent review of clinical trials

The BIA has fed into [Lord O'Shaughnessy's review](#) of the UK commercial clinical trials landscape. Lord O'Shaughnessy was appointed to prepare independent advice for Ministers on the subject following a meeting of the Life Sciences Council in November 2022. This piece of work will acknowledge the wealth of pre-existing and ongoing work to improve UK clinical research, aiming to build on these through engagement with expert stakeholders.

The BIA contributed to the review at workshops with Lord O'Shaughnessy hosted in January and March 2023. The review's recommendations will be finalised and published towards end of April, followed by a government response soon after. The review will include priority actions to be taken rapidly in 2023, as well as longer-term actions informed by horizon scanning for future growth opportunities. It is important to note that the recommendations will not include any legislative measures and rather focus on approval times, resources, patient recruitment, and access to innovative medicines.

For further information on the BIA's work in this space, please contact Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

Manufacturing

BIA's Manufacturing Leadership Programme reaches 100 future leaders

Following the January intake (see photograph below), the BIA Manufacturing Advisory Committee (MAC) Leadership Programme (LeaP) has now engaged over 100 next generation leaders from nearly 50 BIA member companies.



Figure 5 - The most recent MAC LeaP cohort, bringing the overall number of LeaPers to over 100 #LeaP100

Established in 2017 to support the development and training of these future leaders in the vaccine, biopharmaceutical and cell & gene therapy industries through cross-sector learning, site visits and peer networks, LeaP has continued to evolve through the development of a member directory and further establishment of an alumni network. The inaugural chair of the alumni group, Will Milligan, CEO of Extracellular, has now stepped down to become Co-Vice-Chair of MAC. The BIA would like to formally thank Will for his drive and enthusiasm in helping set up this community, and to welcome the incumbent Chair, Chris Sadler of Pharmaron, to the role.

To find out more about this popular programme, which is free to join and suitable for BIA members who have a biomanufacturing footprint in the UK, please take a look at this short [video](#), visit the [webpage](#), or reach out to Bioprocessing Consultant [Netty England](#).

BIA's work on Innovative Manufacturing Fund pays dividends for member companies

The BIA's ongoing work to support the [Life Sciences Innovative Manufacturing Fund \(LSIMF\)](#) grants has borne fruit, with multiple BIA member companies receiving money from the first tranche of grants.

As [announced](#) by the Government in March, £17 million in public funding will be matched by £260 million of private sector investment, creating 320 jobs and safeguarding 199 jobs. Successful BIA member companies include:

- Ipsen - £75 million investment to grow the manufacture of innovative medicines for neurological conditions, creating 39 new jobs and safeguarding a further 37 at their Wrexham facility
- Pharmaron - £151 million investment in capital and people will substantially grow operations in Liverpool, increasing production capacity four-fold for critical gene therapy and vaccine components and creating 174 jobs, while also safeguarding a further 156
- Touchlight – £14 million investment will create 17 jobs and protect a further 6, boosting UK health resilience by establishing the commercial scale manufacture of DNA at their Hampton, London base.

The scheme came into being as a result of work the BIA did some years ago to develop the [Life Science Vision](#) with the government, and was significantly oversubscribed, demonstrating the potential for future significant economic growth through further government investment.

BIA writes letter to the Chancellor in support of funding for cell and gene skills training

Ahead of the Spring Budget, the BIA wrote to the Chancellor in support of further funding of the advanced medicine manufacturing skills training programmes being coordinated by the Cell & Gene Therapy Catapult (CGTC).

Led by the BIA's Manufacturing Advisory Committee (MAC) and co-signed by representatives from more than 30 key bioprocessing organisations, plus the Medicines Manufacturing Industry Partnership ([MMIP](#)), the letter highlighted the continued importance of the provision of advanced medicine manufacturing skills. The letter cited the leading contribution being made by the Advanced Therapy Apprenticeship Community ([ATAC](#)) and the Advanced Therapy Skills Training Network ([ATSTN](#)) in the establishment of a sustainable UK skills development ecosystem.

While recognising that funding cannot last forever, the BIA's letter strongly recommended that ATAC and ATSTN receive further tapered funding to build the diverse bioprocessing talent pools and pipelines necessary to secure world-beating biomanufacturing growth across the UK.

Medicines regulation

BIA engages with MHRA regarding its operational performance

The BIA has continued engagement with the MHRA, including through membership of the Established Medicines Task and Finish Group, to address delays in the processing of applications for clinical trials, marketing authorisations, and variations to existing approvals. MHRA senior officials have acknowledged our member companies' concerns about delays and lack of predictability on regulatory decisions, combined with a general lack of communication from the Agency and barriers to checking the progress of applications in the regulatory process.

MHRA are now taking a number of actions to remedy the situation. These include recruiting and training new assessors to reduce the backlog of delayed applications and improving communication. The MHRA is committed to providing a timely and reliable service and will publish metrics going forward on their performance in clinical trial applications and licence lifecycle management to support companies' planning. On 14 April, the MHRA [published information on current performance](#) in the assessment of clinical trials and established medicines.

MHRA will make regulatory decisions in accordance with statutory timeframes for all new fully compliant clinical trial applications received from 1 September 2023, and applications for new national marketing authorisations received from 1 January 2024.

The BIA will continue to engage closely with MHRA, but should members have any questions or concerns, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

MHRA follows BIA advice on statutory fees

On 31 January, the MHRA published the [outcome](#) from its consultation on proposals to increase statutory fees, which came into effect on 1 April 2023. The MHRA listened to our concerns provided in the BIA's [consultation response](#) and as a result will not introduce new fees for the Innovative Licensing and Access Pathway (ILAP) and complex amendments to clinical trials. The holding of the ILAP fee is particularly important for small companies as the MHRA and its partners are still working on improving this pathway which aims to accelerate patient access to medicines.

The BIA looks forward to continuing engagement with the MHRA on the development of their new fees and charges plan and to ensuring the Agency's long-term financial sustainability, as well as its capacity to foster innovation. It is vital that the UK's offer to SMEs remains globally attractive and does not put the country at a disadvantage for conducting clinical trials and launching new products.

BIA influences the future of clinical trials regulation in the UK

On 21 March, the UK Government published the long-awaited [response](#) to the consultation on proposals to improve UK clinical trials legislation, with a foreword by life science champions Sir John Bell and Sir Jonathan Symonds.

These reforms represent the biggest overhaul of UK clinical trials regulation in over 20 years and could make the UK one of the best countries to conduct clinical research for the benefit of patients, powered by the life science sector. We are pleased that the MHRA have taken on board our comments provided in the [BIA's submission](#), with input from our Regulatory Affairs Advisory Committee ([RAAC](#)).

It is important that the introduction of a more streamlined and flexible regulatory regime for clinical trial approvals is accompanied by improved efficiency in setting up NHS sites. These legislative changes are aligned with the [review of clinical trials led by Lord O'Shaughnessy](#) to which the BIA has contributed (see above), and come after the government announced [£10 million funding](#) to the MHRA in the Budget to accelerate the delivery of cutting-edge treatments including cancer vaccines.

The BIA looks forward to the implementation of the new clinical trial legislative measures and working with the MHRA and the Health Research Authority (HRA) on the development of guidance to help with the interpretation of the requirements. The Statutory Instrument is expected to be laid before Parliament in the autumn.

BIA welcomes the Windsor Framework for Northern Ireland

On 27 February the UK Government and the European Commission [announced](#) a political agreement on the [Windsor Framework](#), following months of negotiations to address the challenges arising from the post-Brexit Northern Ireland Protocol. The new deal for Northern Ireland was formally adopted by the UK and EU on 24 March and the legislation sets out a date of application of 1 January 2025.



Figure 6 - Prime Minister Rishi Sunak and European Commission President Ursula von der Leyen following the agreement of the Windsor Framework in February (PA Media).

The Windsor Framework restores the smooth flow of trade within the UK internal market by removing unnecessary red tape for goods moving but remaining within the UK market. This agreement includes significant changes to medicine regulatory arrangements, specifically:

- Replacement of the European Medicines Agency (EMA) by the MHRA as Northern Ireland’s regulator for all novel medicines, making the MHRA the sole medicines regulator for Northern Ireland
- Patients in Northern Ireland will be able to access the same medicines in the same packs, with the same ‘UK ONLY’ labels as the rest of the UK, permanently protecting the supply of medicines for Northern Ireland
- Disapplication of the Falsified Medicines Directive requirements on packaging, labelling and barcode for medicines in the UK
- Medicines and medical products sent from Great Britain to Northern Ireland going through the new Green Lane with only ordinary commercial information required

This is an important agreement, which is welcome as it provides a permanent solution and much-needed certainty to UK patients and the life sciences industry. There are no changes that industry needs to make immediately, and the BIA is looking forward to working with DHSC and MHRA on the framework’s implementation.



Access to medicines

BIA calls on NICE to refresh evidence informing how rare disease medicines are evaluated

In April, the BIA launched a new report, '[Rare insights: examining the social values of treating rare diseases](#)', which presented the findings of primary research into public opinion on how treatments for rare diseases should be evaluated and funded within the NHS. The purpose of the research, which was supported by the BIA's Rare Disease Industry Group ([RDIG](#)), was to provide the National Institute for Health and Care Excellence (NICE) with robust evidence on the social value associated with treating rare diseases.

Through a series of focus groups and an online survey of 1,000 people, the research found that the public believes that a distinctive and alternative approach should be adopted for making funding decisions about treatments for rare diseases, including the methods and processes in place to make these decisions.

The report recommends that NICE utilises its '[NICE Listens](#)' programme to undertake fresh research on the social value associated with treating rare diseases that underpin its methods and processes. It also recommends that NICE prioritise rarity as a priority topic for future [modular updates to its methods and processes](#).

The BIA will continue to engage with NICE as it implements its new approach for modular updates, as well as with other relevant stakeholders to communicate the research findings.

For further information on BIA's work on access to medicines, contact Policy and Public Affairs Manager, [Rosie Lindup](#).

BIA submits response to Labour's 2023 National Policy Forum consultation

In March, the BIA submitted a response on access to medicines to the Labour Party's [2023 National Policy Forum \(NPF\) consultation](#), which will inform Labour's policy development ahead of the next general election.

In our [submission](#), we highlighted that innovative new medicines, such as cell and gene therapies, have the potential to transform patient care in the UK by treating the root cause of previously incurable diseases. They could also generate significant cost savings for the NHS, as fewer patients would require long-term or lifelong treatment and care for their condition. As more innovative medicines become available in the next few years, Labour should work alongside the life sciences industry to ensure that NHS patients can access the best available treatments on an equitable basis.

The BIA looks forward to continuing to engage with Labour and other parties in the run-up to the next general election.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Martin Turner, Head of Policy and Public Affairs, at mturner@bioindustry.org.



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If you want to have a say on policy areas key to the life science sector, contact Michael McGivern, Head of Membership and Business Development, on 079 2029 3171 or mmcgivern@bioindustry.org

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