

Influencing and shaping our sector

April - July 2023

INTRODUCTION

The BioIndustry Association (BIA) continued to represent the innovative life science and biotech sector to ministers and senior policymakers between April and July 2023. This quarterly report provides an overview of these engagements.

In July, our twenty-third annual Parliament Day was the biggest yet, with the Science Secretary, Minister for Health, and Minister for Investment among those welcoming delegations of BIA members. Thirty stakeholder meetings with our members were held to hear about the importance of delivering growth, improving health outcomes, and innovating for the future.

The Chancellor's announcement of the Mansion House Compact saw the culmination of years of influencing by the BIA, unlocking pension funds to invest in innovative, AIM-listed companies that will be the life science leaders of the future.



4 consultation responses and briefings submitted



35 engagement meetings with 30 parliamentarians, incl. 7 ministers and 3 shadow ministers

Our influencing on skills also reached new heights with the launch of the #BIGIMPACT campaign, which aims to direct talent into our growing sector.

The BIA also published its vision for the next VPAS agreement, collaborated on a blueprint for the future of medicines manufacturing as part of MMIP, and welcomed the arrival of the O'Shaughnessy Review of clinical trials, helping to shape the environment for life sciences for years to come.



4 letters to Ministers

Read on for further details of all of the BIA's important influencing work across our key policy areas.

Contents

Engagement with the Government and Parliament on life sciences policy	3
Finance, tax and investment	7
Watershed moment reached in BIA’s quest to unlock pension funds	7
BIA brings together US investor delegation and member CEOs	8
HMRC consultation offers opportunity for modernisation of stamp taxes on shares	8
Strategic technologies and areas of scientific focus	10
Membership of the HDR Alliance opens opportunities for BIA to champion SMEs	10
BIA suggests amendments to Nagoya Regulation under REUL	10
BIA join ministerial roundtable on global mechanism for the governance of DSI	10
UK well-represented at Synbiobeta conference, with BIA leading the charge for UK biotechs	11
Innovative biotech sector’s requirements of AI regulation set out by BIA	12
BIA champions the unification of health data access	12
Submission to OLS on barriers to partnerships between academia and SMEs	12
People, skills, and talent	14
BIA launch #BIGIMPACT campaign to bridge UK biotech’s digital skills gap.....	14
BIA collaborate with government colleagues on flexible apprenticeships manual.....	15
Impact of landmark diversity and inclusion survey shines through.....	15
Intellectual property and technology transfer	17
BIA meet with Science Minister discuss IP’s importance to life sciences	17
BIA weighs in on EPO’s efforts towards patent law harmonisation	17
Government review of the UK’s university spin-out landscape supported by BIA.....	17
Pre-clinical and clinical research	19
BIA raises members’ concerns about new border inspections.....	19
Government support for Lord O’Shaughnessy Review	19
Letter co-signed by BIA urges Labour frontbench to fight misinformation on animal research	20
Manufacturing	21
BIA collaborate on new report with a vision for the future of medicines manufacturing.....	21
Medicines regulation	22
BIA members input into new recognition routes to facilitate access to innovative medicines.....	22
MHRA on track to improve clinical trial performance thanks to BIA contribution.....	22
BIA joins group overseeing the Implementation of the Windsor Framework for the supply of medicines into Northern Ireland	22
Access to medicines	24
BIA launches its vision for making VPAS fit for the future	24
BIA engages with NHS Innovation Ecosystem review	24

Engagement with the Government and Parliament on life sciences policy

A quarter of intense focus on investment in life sciences culminated with the Chancellor of the Exchequer, Jeremy Hunt MP's **Mansion House** speech on 10 July. Together with the Lord Mayor, he unveiled the Mansion House Compact, a voluntary agreement by the pensions industry to allocate 5% of investment to unlisted equities. Along with other reforms announced as part of the package, this is good news for scaling life science companies and goes a long way to fulfil the mission of the Scale-up Taskforce, which the BIA proposed as part of the Life Sciences Vision (LSV).

In April, Department for Science, Innovation and Technology (DSIT) Secretary Michelle Donelan MP went on maternity leave with Chloe Smith MP stepping up to the Cabinet in her absence.

Science Minister George Freeman MP had a high profile at BIO in Boston in June and the BIA was pleased to host a roundtable during the conference on 6 June at which the Minister spoke.



FShadow Science Minister, Chi Onwurah MP, speaks to BIA members during our Parliament Day lunch reception in July.

Department for Environment, Food and Rural Affairs (Defra) Minister, Lord Benyon invited the BIA to a roundtable on 'multilateral benefit-sharing mechanism for the use of digital sequence information (DSI) on genetic resources', on 3 July, following on from the DSI stakeholder event held in December 2022 to help the Minister prepare for the Montreal meeting of the Convention on Biological Diversity.

Lord Harrington has been asked by the Chancellor of the Exchequer and the Business & Trade Secretary to conduct a review into the UK Government's approach to attracting Foreign Direct

Investment (FDI). As part of the review, he held a life sciences roundtable at the Treasury on 29 June at which the BIA was represented by Steve Bates.

In **Parliament** there was a Westminster Hall debate on the **Voluntary Pricing and Access Scheme (VPAS)** on 3 May. The BIA, which has published a report '[Making VPAS fit for the future](#)' and met Will Quince MP, the Minister leading negotiations for the Government briefed MPs ahead of the debate. Daniel Zeichner MP spoke about the importance of a positive commercial environment for life sciences research and innovation and thanked the BIA for the briefing. Responding for the Government, Will Quince acknowledged the challenge for UK General Managers making the case for medicines launching here to global boards in the face of the current high rebate rate and recognised the importance of the whole ecosystem, from SMEs to global pharma firms, two of the key points from the BIA meeting with the Minister.

The negotiations continue, unfortunately with no prospect of agreeing heads of terms before the summer recess.

The pinnacle of the BIA's year in Parliament came with the **23rd Parliament Day** on 5 July which saw 35 members in 30 meetings with stakeholders around Whitehall and Westminster, with a lunchtime reception in the House of Commons hosted by Shadow Minister for Science, Research and Innovation, Chi Onwurah MP.



Two trips to 10 Downing Street for the BIA: Steve Bates, Dan Mahony, and Nerida Scott (left) visited for the Life Sciences Council in May and a BIA delegation met with Science Secretary Chloe Smith (right) at our Parliament Day in July

Life Sciences Council and other government/industry engagement

The spring meeting of the **Life Sciences Council (LSC)** held at 10 Downing Street on 25 May was synchronised with the launch of a [package of government announcements](#) in support of life

sciences. These included proposals for the Long-Term Investment in Technology and Science (LIFTS) programme, the O’Shaughnessy review of clinical trials (see below) and Vallance review of life sciences regulation, as well as investments in medicines manufacturing.

The Chancellor of the Exchequer signalled his support for the sector by attending the Life Sciences Council, along with Secretary of State Chloe Smith MP and Science Minister George Freeman from DSIT, Health Minister, Will Quince MP and Department for Business and Trade (DBT) Minister, Lord Johnson.

Speaking at the LSC about the raft of life science announcements, Steve Bates welcomed the great partnership working with HM Treasury that had produced such positive results on R&D tax credits and the Silicon Valley Bank UK rescue. He noted that the Chancellor’s presence at the LSC, and the fact that Treasury Connect event put life sciences as the first of five key industry sectors was a welcome signal of the Government’s commitment to our industry. He welcomed the Vallance and O’Shaughnessy reviews, saying that getting the regulatory framework and clinical trials regime right is essential to UK competitiveness.

The LSC also heard from the Government’s Life Sciences Investment Envoy, BIA Chair Dan Mahony, in the discussion of the implementation of the Life Sciences Vision. He described the ambition for his role as Envoy and what has already been done (including the first investor roundtable). He welcomed the call for proposals to use £250 million through the British Business Bank (BBB) to attract pension funds into Venture Capital (VC) and the work that has been ongoing with the Treasury to reform the way pension funds invest in life sciences. He stressed the importance of rebuilding the investment infrastructure to support scaling life sciences businesses with growth capital.

Also representing the BIA at LSC, Board member Lisa Anson said that the UK is home to fantastic science which needs capital to scale up and deliver for patients and the economy. With 60% of UK drugs originating in biotech SMEs, these firms as a vital part of the life sciences ecosystem and can only thrive if the UK is a first-launch market of choice. Global players are needed to support the life sciences ecosystem - to attract them the UK must provide an attractive commercial environment. The success of the next VPAS is therefore vital both to big pharma companies and biotech SMEs.

The **Business Environment Board** (BEB) met on 18 May and discussed the fiscal environment. Nicky Edwards, representing the BIA, thanked colleagues from HM Treasury for the close collaborative approach they took with industry in the run-up to Spring Budget to develop the enhanced rate of R&D tax relief for SMEs. Many biotech start-ups and scale-ups had been facing serious financial difficulty as a result of the threat of the Autumn Statement cut. Work continues on the new single scheme in which start-ups and scale-ups must continue to receive an enhanced rate in the new regime and this should be internationally competitive. The 27p rate announced in the Spring Budget is very welcome but the original 33p rate was more competitive and crucial in businesses’ decisions on where to start and grow. It is also essential SMEs are able to claim for sub-contracted R&D in the new regime.

In June the **Medicines Manufacturing Industry Partnership** (MMIP) published ‘[Follow the green, high-tech road](#)’: A path to UK growth, net zero and health resilience from innovation in medicines

manufacturing' arguing that if the UK is to be a global life sciences superpower, it must not only discover and develop the medicines of the future in the UK, but must also manufacture a significant share of them here too.

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

Finance, tax and investment

Watershed moment reached in BIA's quest to unlock pension funds

At the Lord Mayor of London's annual Mansion House Dinner on 10 July, the Chancellor [announced](#) a package of reforms to the pensions and wider financial services industry to deliver better returns for savers, improve the functioning of public markets, and increase investment in innovative sectors of the UK economy, including life sciences and biotech. The development marks a major milestone in the BIA's multi-year campaign to unlock pension funds, which is expected to be worth more than £75 billion for growing firms.

A prominent feature of the package is the Mansion House Compact, an agreement by pension providers to allocate a minimum 5% to unlisted equities through defined contribution (DC) pension funds, and other sources of long-term savings, by 2030. Unlisted equities include venture capital backed companies and those quoted on London's growth market, AIM.

Steve Bates OBE, CEO of the BIA, said: 'History has handed the UK two world-leading industries: financial services and life sciences. This Compact marks the beginning of a new era in which they are brought together to accelerate the delivery of innovative new medicines for patients, jobs and economic growth, and greater financial returns for pension savers.'

'This significant step forward comes after many years of campaigning by the BIA and critical detailed thinking by the Life Sciences Scale-Up Taskforce, led by the BIA and the Office for Life Sciences. We will continue to engage closely with the signatories of the Compact to help them explore the life sciences opportunity on their doorstep. As Nasdaq sleeps, the City of London is waking up.'

For a full breakdown of the reforms, read the [BIA blog](#) and [press release](#).



The Chancellor announces his plans to unlock pension funds in his Mansion House speech on 10 July (c) [CNN](#)

BIA brings together US investor delegation and member CEOs

The BIA convened a mixer reception at its new Holborn offices on 28 June, bringing together member CEOs with a delegation of US venture investors as part of a UK tour arranged by the Department of Business and Trade (DBT).

As part of a week-long programme for a group of over 30 US life sciences venture capital firms visiting the UK, the BIA was asked by the Government to help showcase the strength of the UK ecosystem. It was a huge pleasure to host the event at our offices in Victoria House, where BIA member CEOs and UK-based investors met and mingled with the delegation, and to showcase some of the most exciting science and business opportunities the UK has to offer.

Feedback from members has been overwhelmingly positive, with one noting that:

‘The greatest challenges when raising capital are finding the right ‘fit’ for your investment and finding the right person to champion your cause. The reception in London provided that opportunity for both needs. Identifying those who were interested in therapeutics, at what stage and at what level of investment, was invaluable. It allowed all of us to focus.’



A delegation of US VCs gathered at the BIA's offices in Victoria House, meeting BIA members, BIA staff, and civil servants.

HMRC consultation offers opportunity for modernisation of stamp taxes on shares

A BIA [submission](#) to the [Stamp Taxes on Shares modernisation consultation](#) has welcomed the opportunity to address a long-standing difficulty for the life sciences sector.

The BIA highlighted a significant problem with the current Stamp Taxes on Shares framework, under which a sale of shares triggers a stamp duty liability at 0.5% of the deal value, even if milestone payments mean that value will only be realised in the future, if at all.

The submission noted that life science companies already have a need to determine the present value of future contingent payments for commercial purposes, by means of discounted cashflow calculations, and proposes that the value of the consideration for stamp duty purposes be determined on the same basis, at the time of sale.

BIA's Finance and Tax Committee ([FTAC](#)) will monitor progress and engage with any future stages.

Strategic technologies and areas of scientific focus

Membership of the HDR Alliance opens opportunities for BIA to champion SMEs

The BIA has joined the [Health Research Data Alliance](#). This decision reflects the BIA's ongoing commitment to advancing health R&D and our belief in the power of data to change lives for the better.

Joining the HRDA means being part of a network which aims to build interoperability and promote responsible data sharing practices. This will enable the BIA to contribute to the HRDA's mission to revolutionise healthcare through the power of data while representing SMEs. Through our membership, the BIA will ensure that SMEs can access and use health research data in an ethical, secure, and efficient manner to accelerate medical breakthroughs.

BIA suggests amendments to Nagoya Regulation under REUL

On 12 May, the BIA wrote to the Department for Environment, Food and Rural Affairs (Defra) to suggest targeted amendments to the retained EU law (REUL) that regulates compliance with the [Nagoya Protocol](#) in the UK.

The BIA has engaged with Defra on the [regulation](#) and associated [UK Access and Benefit Sharing \(ABS\) Guidance](#) for a number of years, highlighting our concerns that aspects of the regulation have harmful effects on innovation, including innovation relating to public health and the environment, without any counter-balancing positive effects on achieving the biodiversity goals of the Convention on Biological Diversity ([CBD](#)).

The [Retained EU Law \(Revocation and Reform\) Act](#) introduced to Parliament at the end of last year, and passed into law on 29 June 2023, enables government to amend, repeal, or replace regulations that were retained in the UK after leaving the EU.

In our letter, we outlined amendments to the EU Nagoya regulation retained under the Bill, including aspects of the obligations of users, user compliance measures in emergency situations, and clarifications around the monitoring of user compliance. For more information, please get in touch with Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA join ministerial roundtable on global mechanism for the governance of DSI

On 3 July, the BIA was invited to a ministerial roundtable discussion with Lord Benyon, Minister for Biosecurity, Marine and Rural Affairs, concerning a multilateral benefit sharing mechanism for the use of digital sequence information (DSI) on genetic resources. The invitation followed the BIA's contribution to an industry roundtable that took place in November last year, ahead of COP15, where the [decision](#) was made to adopt a multilateral benefit sharing mechanism for DSI.

July's roundtable brought together key industry stakeholders to discuss the development of this mechanism, particularly concerning its calls for the creation of a Global Biodiversity Fund. The BIA

commented on each of the options presented, emphasising that the new mechanism must not hinder or disincentivise innovation.

Our views will feed into the UK's official negotiation position on the mechanism, the details of which will be developed in the lead up to COP16, to be held at the end of 2024. If you use DSI in your R&D activities and are concerned about the impacts of the new mechanism, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

UK well-represented at Synbiobeta conference, with BIA leading the charge for UK biotechs

This year, the BIA joined Synbiobeta 2023, a flagship global synthetic biology conference taking place in Oakland, California. With the UK the second-best represented country at the conference, multiple talks, panels and breakout sessions featured UK speakers, including a keynote by UK Shadow Science Minister, Chi Onwurah MP, highlighting the strength of the UK's synthetic biology ecosystem.

The BIA joined a panel alongside UK-based Systemiq Capital, Evonetix, and DSIT, discussing the UK's roadmap towards becoming a synthetic biology superpower. Synthetic biology, or engineering biology, is a key area of growth for the BIA and please email Policy and Public Affairs Manager, [Linda Bedenik](#), to get involved.



Linda Bedenik, Policy and Public Affairs Manager at the BIA, appearing on a panel on 'The UK's Roadmap to SynBio Superpower' at SynBioBeta in Oakland, CA.

Innovative biotech sector's requirements of AI regulation set out by BIA

The BIA has responded to the UK Government's [consultation](#) on Artificial Intelligence (AI) regulation. Our submission supported the creation of an effective AI regulatory framework through adaptive, sector-specific regulation tailored to the unique AI applications in biotech. It proposed using regulatory sandboxes and a cyclical regulatory approach to stay apace with AI advancements. It also recommended additional tools such as ethical guidelines and data standards to promote responsible AI use.

The BIA offered industry input on the development of best practice guidelines for AI in health, highlighting the need for community and industry engagement in crafting effective regulation. The submission also called for international alignment and interoperability with global partners in establishing high-quality global AI standards, with the goal of affirming the UK's role as a global AI leader. If you have any questions about the BIA's work on AI, please contact Policy and Public Affairs Manager [Olivier Roth](#).

BIA champions the unification of health data access

The BIA has responded to two reviews on unifying health data in the UK, focusing on the current challenges and potential solutions to unifying health data in the UK.

National health data is currently divided into subscale datasets and organisations; most data is held by sub-national organisations without the resources to provide secure, efficient data access to SMEs. Government initiatives supporting the continuation of subscale, regional and disease-specific datasets, have produced a fragmented landscape of numerous Secure Data Environments (SDEs) which use different formats and standards for data storage and exchange, leading to compatibility issues.

In our submission to the [Sudlow Review](#) led by Prof. Sudlow of Health Data Research UK (HDR UK), the BIA [recommended](#) moving to a single national platform focused on interconnectivity, with government supporting this transition from subscale SDEs. This would comprise a unified system with a single access point, standard data models, interoperability, and data search across all SDEs.

The Government also recently published a [SDE Policy Update](#), which stated that secure data environments (SDEs) will become the default route for accessing NHS data for research. The BIA is engaging in this process and welcomes the creation of transparent, efficient SDEs as discussed in our recent publication on '[Driving Growth and Patient Benefit through Secure Data Environments](#)'.

Submission to OLS on barriers to partnerships between academia and SMEs

The BIA has provided evidence to the Office for Life Sciences on the barriers to partnerships between academia and SMEs.

Our response set out the potential for collaboration between academia and SMEs within the TechBio and genomics sectors, which is vast and largely untapped. The mutual benefits are

significant, with academia providing cutting-edge research and expertise in specific domains, and SMEs offering their own innovations, practical applications and commercialisation pathways alongside academic findings.

The BIA's submission calls for OLS to re-evaluate the framework of partnership agreements, rethink the structure of grants, enforce requirements to share grant funded datasets using a pre-agreed template, improve the capacity of Technology Transfer Offices (TTOs), and develop standards for data quality and standardisation.

People, skills, and talent

BIA launch #BIGIMPACT campaign to bridge UK biotech's digital skills gap

The BIA's [TechBio](#) community has an ever-growing demand for the application of AI/ML and data analytic skills within life sciences. In response, the BIA has [launched](#) the #BIGIMPACT campaign, complete with a [website](#) which has been developed as a platform for talent to discover new career opportunities and connect with job opportunities. #BIGIMPACT aims to attract the next generation of talent with these incredible digital skills to join the biotech sector by showcasing the difference companies are making.



Example of the branding used for BIA's #BIGIMPACT campaign.

#BIGIMPACT also uses new social media channels for the BIA, collaborating with influencers to get the message to a target audience which had previously not considered applying their skills to our sector. The campaign is gaining traction more widely and was been picked up by Royal Society of Biology in their members' newsletter and featured in an [article](#) in Business Weekly.

BIA collaborate with government colleagues on flexible apprenticeships manual

Co-developed by the BIA, the Office for Life Sciences, and the Department for Education, a new manual sets out how flexible apprenticeships can be used and delivered in the life sciences to meet skill gaps. The '[Flexible Apprenticeships in the Life Sciences Sector](#)' manual outlines different ways that apprenticeships can be used, including:

- Flexible models for training such as weekly delivery, front-loading, or block training, so off-the-job training can be delivered to best suit the needs of employers.
- Accelerated apprenticeships, which can significantly reduce the duration of an apprenticeship to reflect prior learning within the role.
- Piloting Portable Flexi-Job Apprenticeships and Flexi-Job Apprenticeship Agencies to support learners to move between shorter-term employment with different employers.

SMEs receive 95% funding for the training and assessment of apprentices and can access additional incentive payments. Innovative biotech companies are already using flexible apprenticeships and the aim is to support more biotech organisations in attracting and developing talent through these well-funded, flexible routes.

Impact of landmark diversity and inclusion survey

The BIA has been working hard to follow up on the [our first baseline survey measuring diversity and inclusion across UK biotech](#) launched in March. This included an interactive panel session at our Life Sciences Leadership Summit ([LSLS](#)) in June on Investors' Perspective on Diversity and an invitation to discuss findings and follow-on recommendations with the Life Sciences HR Directors' Forum.



A panel on 'Investors' perspective on diversity' at the BIA's Life Sciences Leadership Summit in June.

Both sessions endorsed the overall conclusion that UK biotech is a diverse and inclusive sector in which to work and validated the evidence for further targeted change. There has been wide support for the BIA's key recommendations and a new, rapidly growing working group within our skills community is dedicated to championing improvement across the sector.

Please contact our Skills Strategy Consultant, [Dr Kate Barclay](#), for further information on the BIA's work in this space.

Intellectual property and technology transfer

BIA meet with Science Minister to discuss IP's importance to life sciences

On 6 July, the BIA met with Viscount Camrose, Minister for AI and Intellectual Property at DSIT, in a focused industry roundtable. Attendees discussed the importance of patent protection in AI drug discovery, the EU patent package and its implications for the UK, plus Supplementary Protection Certificates.

BIA CEO Steve Bates OBE was joined by Jodie Albutt, Vice-Chair of the BIA's Intellectual Property Advisory Committee ([IPAC](#)), in the meeting. The BIA was pleased to see the Minister's recognition of the value of the UK life sciences and the important role of IP rights to innovation in our sector. The BIA continues to engage closely with the Intellectual Property Office (IPO) on IP policy relevant to our sector.

BIA weighs in on EPO's efforts towards patent law harmonisation

In May, the European Symposium on Substantive Patent Law Harmonisation (SPLH), coordinated by the European Patent Office (EPO), asked stakeholder associations such as the BIA to find points of consensus on contentious items of patent law harmonisation in order to hone a common European position. These include grace periods, conflicting applications, and prior user rights. The BIA's Intellectual Property Advisory Committee ([IPAC](#)) lead the BIA's response.

The Symposium follows on from an EPO consultation on SPLH in 2022 and the discussions will inform patent law harmonisation efforts at a global stage, led by the [Group B+](#). Whilst the BIA supports global patent law harmonisation, we continue to insist that all users of the patent system are considered when agreeing on a harmonisation package, particularly smaller companies that have limited capability to navigate complex systems.

With the UK negotiating numerous Free Trade Agreements (FTAs), it becomes ever more important to ensure that changes to the UK's IP framework, such as the potential introduction of grace periods, are affected by the competent authorities, including the EPO, who are in close consultation with the BIA and other industry bodies.

Please get in touch with Policy and Public Affairs Manager [Linda Bedenik](#) if you have any questions about IPAC or the BIA's wider work on intellectual property.

Government review of the UK's university spin-out landscape supported by BIA

In June, the BIA met the team conducting an independent review of university spin-out companies that will ensure the right incentives are in place for the UK to continue to seed and grow the innovative companies of the future. Supported by the Department for Science, Innovation and Technology (DSIT) and HM Treasury (HMT), the review includes a survey of UK spin-out founders' experiences and a study of the distribution of performance across universities to identify best practice in university spin-outs and licencing deals.

The Government's survey comes just a few weeks after TenU, an independent group of university technology transfer offices in the UK and US, launched the University Spinout Investment Terms ([USIT](#)) Guide in April. The USIT Guide was created to facilitate faster spin-out negotiations, to identify a landing zone for what a positive deal should look like, and to demonstrate that there is a shared commitment across Technology Transfer Offices (TTOs) and VC communities to work together to build new businesses. The BIA provided feedback on both the draft USIT Guide and independent review to ensure both are fit for purpose for our sector.

Pre-clinical and clinical research

BIA raises members' concerns about new border inspections

The UK is planning to implement a new post-Brexit border control regime for imports, leading to fears in the life sciences sector that research animals and products for use in laboratories and medicine manufacture will face unnecessary and burdensome inspections and delays as they enter the country.

The BIA has raised these concerns with the supply chain resilience directorate of the Department for Health and Social Care (DHSC) and [responded](#) to a Cabinet Office consultation on the proposed regime. We have called for greater clarity and certainty about the new rules, many of which have not yet been published, and more time for companies to prepare for their implementation (currently scheduled for October). We have also asked that life science products receive special categorisation and risk classification and are currently seeking to work with the Department for the Environment, Food and Rural Affairs (Defra) to determine these.

Government support for Lord O'Shaughnessy Review

On 25 May, the report of the [Independent Review of Commercial Clinical Trials](#) led by Lord O'Shaughnessy was published, together with the Government's [response](#), reflecting contributions made by the BIA.

Lord O'Shaughnessy's independent review was commissioned by the Government in February to offer recommendations on how commercial clinical trials can help the life sciences sector to unlock UK health, growth, and further investment opportunities. During the review, Lord O'Shaughnessy consulted with industry, including the BIA, with a high degree of consensus on action needed to increase the UK's competitiveness.

The review sets out 27 recommendations, including both priority actions to progress in 2023 and longer-term ambitions for UK commercial clinical trials. The recommendations seek to improve workforce and patient engagement, set-up times, approvals processes, and data access. These recommendations were welcomed by the Government, which has [committed](#) £121 million to support their implementation, an update on which will be published in the autumn. Although the focus of the review is on Phase II/III commercial trials, it should be noted that any proposals that improve commercially led research will also benefit all clinical trials including early phase trials and academic studies.

Lord O'Shaughnessy will present the recommendations from the review into the UK commercial clinical trials landscape at the [BIA Conference on the Future of UK Regulation](#) as a driver for Innovation in Life Sciences, taking place on Thursday 5 October 2023 in London.

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

Letter co-signed by BIA urges Labour frontbench to fight misinformation on animal research

The BIA co-signed a letter sent to Daniel Zeichner, MP for Cambridge and Chair of the APPG for Life Sciences, on 19 June to highlight the importance of animal research and testing for the life sciences sector. Disinformation among the public and parliamentarians has increased in the past two years, harming medical progress.

In recent months, active campaigns have united campaign groups, media outlets, celebrities and political assets with front-line campaigners who engage in pseudoscientific claims and factually incorrect narratives with damaging consequences.

In the letter sent by Understanding Animal Research (UAR), BIA, ABPI, and AMRC offer a briefing to key Labour policy makers to help with their understanding of the complex issues involved and to provide evidence-based information when the time comes to formulate policy.

The BIA is a [signatory](#) to the [Concordat on Openness on the Use of Animals in Research](#), and agreement to commit to being transparent about the use of animals in research in the UK.

Manufacturing

BIA collaborate on new report with a vision for the future of medicines manufacturing

The Medicines Manufacturing Industry Partnership (MMIP), of which the BIA is a founding partner, published a report in June entitled '[Follow the green, high-tech road: A path to UK growth, net zero and health resilience from innovation in medicines manufacturing](#)'. The report calls for focused action for medicines manufacturing in key areas that build on the work of recent successes, such as the [Advanced Therapies Manufacturing Action Plan](#) which has resulted in early UK leadership in the manufacture of cell and gene therapies.

The report highlights that the first tranche of the Government's existing [Life Sciences Innovative Manufacturing Fund \(LSIMF\)](#), worth £17m in government funding, unlocked a further £260 million in private sector investment, creating 320 jobs and safeguarding 199 jobs. Increasing that Government investment, alongside other policy changes, could release a further £15bn in company investment over ten years, based on the views of industry experts. In the paper, MMIP welcomes recent government announcements to create a [Biomanufacturing Fund](#) to incentivise new investment and additional funding for innovation projects via Innovate UK's [Transforming Medicines Manufacturing Programme](#).

The report's recommendations and progress on delivery will be presented at [bioProcessUK](#), taking place in Brighton from 28-30 November 2023.

Medicines regulation

BIA members input into new recognition routes to facilitate access to innovative medicines

On 26 May, the MHRA [announced](#) new recognition routes to facilitate access to new, innovative medicines with seven international partners, using approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States. BIA members participated in an online focus group in June, providing industry insight based on experience of using existing reliance and recognition routes for medicines.

This new international recognition framework will be in place by the first quarter of 2024, replacing the European Commission Decision Reliance Procedure (EC DRP) which was extended until 31 December 2023. It will sit alongside the MHRA's [Innovative Licensing and Access Pathway \(ILAP\)](#), establishing an additional avenue for accelerated access to life-saving new medicines. This new recognition framework will be supported by £10m funding from HM Treasury [announced](#) earlier this year.

The BIA look forward to continuing the positive dialogue and engagement with MHRA on the future of medicine regulation for the benefit of patients and UK life sciences. For more information, please contact BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

MHRA on track to improve clinical trial performance thanks to BIA contribution

The BIA has continued to engage closely with MHRA, including through membership of the Clinical Trials Task and Finish Group, to address delays in the processing of applications for clinical trial authorisation (CTA). The BIA provided comments from our Regulatory Affairs Advisory Committee ([RAAC](#)) on the draft 'initial CTA application triage form' for applicants, which is intended to help MHRA prioritise applications and improve the efficiency of assessment.

The Agency has taken a number of actions to remedy the situation, including increasing capacity to handle applications and reduce the backlog of delayed applications by recruiting and training new assessors, and improving communications and customer contact support. The MHRA informed stakeholder associations that it is aiming to make regulatory decisions within statutory timeframes for all new fully compliant clinical trial applications received from 1 September 2023. The BIA will continue to assess MHRA's performance metrics, [last updated](#) on 14 July, and will keep members updated.

BIA joins group overseeing the Implementation of the Windsor Framework for the supply of medicines into Northern Ireland

On 9 June, the Government issued a [statement](#) relating to the Windsor Framework which provides industry with information on new measures commencing on 1 January 2025. This includes guidance on the Centrally Authorised Products (CAPs) [Bridging Mechanism](#) to allow companies to supply Northern Ireland with innovative medicines that are within the scope of the EU Centralised

Procedure for up to 6 months when the MHRA licenses a product before the European Medicines Agency (EMA).

DHSC and MHRA have been working closely on the Windsor Framework implementation, considering the process of packaging changes, the impact of the Windsor Framework on licencing arrangements, as well as interim arrangements until commencement.

The BIA will form part of a group of trusted stakeholders who will meet monthly to discuss implementation plans, timelines and development of relevant guidance. In this regard, the BIA provided comments from our Regulatory Affairs Advisory Committee ([RAAC](#)) on a first draft of the proposed guidance on labelling and packaging requirements.

For more information, please contact BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

Access to medicines

BIA launches its vision for making VPAS fit for the future

In June, the BIA published a new report, '[Making VPAS fit for the future: the BIA vision](#)' which presented an analysis of the 2019 Voluntary Pricing and Access Scheme (VPAS) and recommendations for future schemes. The report, developed with Oxygen Strategy, identifies the risk of the UK losing its status as a first launch market for new medicines following a period of post-Brexit political uncertainty and the unprecedented rebate rate for pharmaceutical companies in the current voluntary scheme. In setting out its vision for making VPAS fit for the future, the BIA is calling for a reset between government and industry to deliver both taxpayer value and a fair return for innovators.

The publication of the report followed a [Westminster Hall debate on VPAS](#) in on 3 May, tabled by Conservative MP Anne-Marie Morris. The BIA briefed MPs on its position ahead of the debate, which was attended by Health Minister Will Quince and health spokespeople from Labour and SNP. During the debate, Labour MP Daniel Zeichner quoted BIA CEO Steve Bates' [comment](#) that the increased rebate rate has 'gone down like a lead balloon in key global pharma boardrooms'. Negotiations for the 2024 VPAS are currently underway.

BIA engages with NHS Innovation Ecosystem review

The BIA has been engaging with a new review of the NHS Innovation Ecosystem, which is being led by Roland Sinker, CEO of the Cambridge University Hospitals Foundation Trust. The review is seeking to address ongoing challenges in the adoption and spread of innovation and drive improvements in the health innovation ecosystem. It is considering both immediate actions to improve the ecosystem, and more long-term actions to build the NHS of the future.

An advisory group has been established to oversee the workstreams, of which the BIA is a member. As the review progresses, the BIA will use its voice on the advisory group to ensure that our members' interests are represented.

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.



BIA Supporters



Not a BIA member?

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

bioindustry.org