

Influencing and shaping our sector

July - October 2023

INTRODUCTION

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

This quarter was dominated by speculation about the next General Election widely expected next year. The BIA ran two panels focused on engineering biology at the Labour and Conservative Party conferences, bringing BIA members and policymakers together to discuss how the UK can harness emerging technologies.

The BIA was a leading voice for the sector on multiple occasions, organising a stellar lineup for our Future of UK Regulation conference and publishing an mRNA explainer to chart a path for the UK to become a world leader in this field.



4 engagement meetings with 8 parliamentarians, incl. 2 Ministers and 6 Shadow Ministers

We also submitted to the Government's consultation on the statutory scheme for branded medicines, joined the inaugural meeting of the UK Biosecurity Leadership Council, and collaborated with our Canadian colleagues on boosting biomanufacturing skills.



5 letters to Ministers

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



10 consultation responses and briefings submitted

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Engagement with the Government and Parliament on life sciences policy

The change of the seasons signals it is time for another fiscal event, for which the BIA has prepared by writing to Chancellor of the Exchequer, Jeremy Hunt MP, ahead of his **Autumn Statement** on 22 November, urging him to build on his positive response to our concerns about SME R&D tax reliefs which arose from [last year's Autumn Statement](#) and go further to create a globally competitive tax relief regime for R&D-intensive SMEs. We have also urged the Chancellor to keep up the momentum on the Mansion House Compact and his associated reforms to increase investment in innovative life sciences and deep tech companies.



Keir Starmer, Leader of the Opposition, addresses Labour Party Conference in a [speech](#) referencing life sciences on 10 October. (Peter Byrn/PA)

With Parliament in recess for much of the period covered by this report, the focus of our engagement with politicians turned to the party conference season. As the next **General Election** is thought by many likely to be called in October 2024, this was a great opportunity to make the case for life sciences policy to feature prominently in the parties' thinking as they prepare to make their pitch to the electorate. First up was the [Liberal Democrat gathering in Bournemouth](#). Buoyed by recent by-election successes, the Lib Dems have high hopes of putting cracks in the 'blue wall' of Conservative seats and aim to hold the balance of power if neither of the main parties secures a decisive majority.

At the [Conservative Party conference in Manchester](#), the BIA hosted a panel discussion on 'Innovating for a sustainable future: can biotechnology save the world?' to which Science Minister, George Freeman MP, had no hesitation in answering in the affirmative. A similarly well-attended fringe event with the same title at Labour's conference in Liverpool returned an equally positive response. Both Prime Minister Rishi Sunak MP and Leader of the Opposition Keir Starmer MP acknowledged the importance of life sciences in their respective leader's speeches. Over the course

of the three conferences, the BIA has spoken to many Ministers, Shadow Ministers, MPs and key advisers about our policy concerns and hope to see these discussions reflected in the parties' manifestos and programmes for government.



Panellists at the BIA's Conservative Party Conference fringe event (L-R): Dr Virginia Corless (moa Technology), Science Minister George Freeman MP, Anna Dickinson (Onward), Insiya Jafferjee (Shellworks).

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. Preparations are well underway for the Autumn meeting of the Council in November.

Through the secretariat, we have been pushing for a replacement for the Life Sciences Vision Innovation, Research and Data Group (IRDG). A new LSC **health data sub-group** has now been formed and will shortly have its inaugural meeting at which the BIA will be well represented.

With the current Voluntary Pricing and Access Scheme (**VPAS**) due to expire on 31 December and negotiations on a new Scheme ongoing, the Government launched a [consultation on the Statutory Scheme](#) which will be the default mechanism if agreement on the next VPAS has not been reached by the year's end. Following on from our work with MPs and Minister Will Quince MP to highlight the importance of a positive commercial environment for firms of all sizes in the life sciences ecosystem and the publication of our report '[Making VPAS fit for the future: the BIA vision](#)', we have made a [submission to the consultation](#). We co-hosted a webinar with DHSC on the Statutory Scheme, at which members were able to quiz officials about technical issues, such as the proposed lifecycle adjustment (LCA) mechanism which many see as potentially reducing the value of IP protections as an incentive for innovation.

During the summer, the BIA was in constant dialogue with the **MHRA** as the Agency grappled with the backlog of clinical trials approvals. We had a bilateral meeting with CEO Dr June Raine and her senior team on 1 August and we were pleased hear from June and other domestic and international regulators at our 'Future of UK regulation: driving innovation in the life sciences conference' on 5 October.



Dr June Raine DBE, CEO of the MHRA, addresses the BIA's 'Future of UK Regulation' conference on 5 October.

The BIA was represented by Steve Bates and BIA SME member RQ Bio on the International Council of Biotechnology Associations (**ICBA**) delegation to the World Health Organisation (WHO) in Geneva 4-5 October. The delegation made representations on the WHO's Pandemic Preparedness Accord and the proposed expanded TRIPS waivers for therapeutics.

Finance, tax and investment

Draft Finance Bill confirms enhanced tax relief for R&D-intensive SMEs

The BIA's [submission](#) to a consultation on [draft legislation](#) for R&D tax reliefs and a potential merged scheme, published by the Government in July, has welcomed confirmation that an enhanced rate will continue to be available to qualifying SMEs. This follows BIA engagement with HMT and HMRC, building on the support for R&D-intensive SMEs secured by the BIA in the [2023 Spring Budget](#).

The BIA also welcomed the confirmation that sub-contracted R&D would be claimable in the new merged scheme based on the existing R&D Expenditure Credit ([RDEC](#)) scheme. Our submission called for detailed guidance and clear boundaries for the implementation of Qualifying Overseas Expenditure rules, clarification of the position for R&D service providers established in the UK, and further detail on the intended qualification requirements for the R&D Intensive Scheme. The BIA is also calling for the adoption of a concept of 'exceptional circumstances' to mitigate the risk of extraordinary expenditure in a given year affecting qualification for R&D-intensive SMEs. [Read the BIA's blog](#) for further background.

BIA brings together venture capital leaders to prepare for pension funds deployment

The BIA supported Dr Dan Mahony, BIA Chair and [UK Government Life Science Investment Envoy](#), in convening a lunch briefing for life sciences VC investors in London on 27 September.

The event continued the BIA's work to help our sector prepare for the implications of the [Mansion House Compact](#). This was an agreement by pension providers to allocate a minimum 5% to unlisted equities through defined contribution (DC) pension funds, potentially unlocking over £50 billion to support growing companies, whilst also benefiting pension savers and the wider economy. The compact was itself a key outcome of many years of campaigning by the BIA and detailed thinking by the Life Sciences Scale-Up Taskforce, led by the BIA and the Office for Life Sciences (OLS).

The lunch briefing updated attendees on the progress on the [LIFTS initiative](#) and the Mansion House agenda and facilitated the sharing of views on how VC can best work with pension funds on the effective deployment of capital. The BIA will continue to engage closely with the investment community to help them realise the life sciences opportunity on their doorstep.

Government removes stamp duty on Nasdaq financings following BIA outcry

In September the Government [announced](#) that it would not introduce a stamp duty on financings by UK companies on foreign stock markets like Nasdaq as a result of leaving the EU. The announcement followed a letter sent by the BIA to Treasury Minister Andrew Griffiths MP that said such a levy would become a tax on companies raising foreign capital to invest in UK R&D.

Griffiths acknowledged the BIA's concerns in a letter on 6 September and then [made a statement](#) to the House of Commons on 14 September. The Minister said the Government would legislate to ensure that the existing 0% charge, under Stamp Duty and Stamp Duty Reserve Tax, will be brought permanently into UK law following the changes in the Retained EU Law (Revocation and Reform)

Act 2023 taking effect. Without BIA and government action, the Act would have automatically resulted in a 1.5% stamp duty on capital raised on foreign exchanges.

BIA data shows steady improvement in financing environment

The second quarter of 2023 saw steady growth in financing activity for the UK's life sciences sector, [data released](#) by BIA and Clarivate in August showed.

Despite the prevailing global market downturn, UK-headquartered life science and biotech companies secured a total of £382 million in venture and public financing, up 29% from the previous quarter's £295 million. The growth was largely driven by venture capital investment. There were 26 private deals totalling £338 million, with an average size of £13 million.

BIA raises concerns about changes to EIS and VCT rules with Treasury Minister

In September, the BIA wrote to Treasury Minister Victoria Atkins MP about amendments to HMRC guidance on eligibility for the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) to include an EU definition of "Undertakings in Difficulty". These rules are inappropriate for the R&D-intensive companies the Government is seeking to support with EIS and VCT due to the way they look at accumulated losses, which can lead to companies being wrongly classed as at risk of bankruptcy and thus ineligible for government support.

The Minister wrote back to the BIA to say that government policy was unchanged and that flexibility would be used when applying the definition. The BIA met Treasury and HMRC officials on 12 October and was reassured that HMRC inspectors would look at the individual circumstances of each company and the wording in the manual would be kept under review to ensure that there are no unintended consequences. Please get in touch with Head of Policy and Public Affairs, [Dr Martin Turner](#), for further information.

BIA supports Life Science Investment Envoy response to DWP call for evidence

The BIA assisted Dr Dan Mahony, BIA Chair and UK Government Life Science Investment Envoy, in responding to a call for evidence from the Department for Work and Pensions (DWP) on pension trustee skills, capability, and culture. This was supported by a letter to the Minister for Pensions, Laura Trott MP, outlining the Envoy's role and priorities, and contextualising the opportunity for UK pension savers and the wider economy presented by the Mansion House Compact.

After decades of investing in liquid and fixed income assets, many institutional investors are less experienced in allocating capital to illiquid investments in the UK, especially venture capital. Pension Trustees, along with many others working in the pensions industry, are wary of the fees associated with investing in this 'high risk, high reward' asset class.

In support of the Government's ambition to establish a globally competitive life sciences investment ecosystem, the letter addresses barriers to the deployment of institutional capital into growth equities. It calls on the Government to provide reassurance to trustees and their advisors that investing in venture capital is an acceptable level of risk for pension funds, as well as proposing an information and awareness campaign highlighting the opportunities for pension savers in venture

capital, so that they can invest with confidence in assets that will deliver real financial returns for their scheme members, whilst supporting the growth of innovative UK companies and the wider economy. Dan also spoke about these issues in a podcast with the [People's Pensions in June](#).

Dan and the BIA team will be meeting with DWP officials in November to discuss the submission and the Government's wider approach to pensions.

Strategic technologies and areas of scientific focus

Growing UK engineering biology sector trumpeted by the BIA

The BIA has flown the flag for UK engineering biology this quarter with a meeting with the Secretary of State for Science, Innovation and Technology and a detailed submission to a t consultation on how to accelerate the development and uptake of the technology.

On 19 July, the BIA joined a [meeting in No 10](#) with Chloe Smith MP, interim Secretary of State for Science, Innovation and Technology, alongside leading UK SMEs to discuss how to unleash the full potential of the UK's engineering biology sector, [identified as a critical technology](#) by DSIT.

The meeting further served to launch a [call for evidence](#) on engineering biology, to which the BIA has made a submission, calling for more cooperation between government, academia, industry, investors, and other stakeholders to create a coherent narrative around engineering biology in the UK and to drive its commercial uptake. A key part of this will be public perception. Our response stressed the importance of leading with the benefits to consumers arising from engineering biology rather than the innovative science behind them. We would like to see a coordinated effort to promote engineering biology as a solution to global sustainability and health challenges.

The BIA's submission also highlighted the challenges that engineering biology companies face when starting and scaling up in the UK, noting that the commercialisation of our world-class research could be better supported with long term public funding, increased private investment, and a strategic approach to attracting talent and skills. For more information, please get in touch with Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA joins launch of UK Biosecurity Leadership Council

On 14 September, the BIA joined the inaugural meeting of the [UK Biosecurity Leadership Council](#) chaired by Science Minister George Freeman MP. The Council will help shape the way advances in engineering biology are governed, guarding against potential risks whilst ensuring the UK's world-leading life science innovators are supported to explore, invent, and continue to thrive. Engineering biology could help tackle the world's greatest challenges beyond health, from climate change to environmental degradation and food security.

The BIA has championed the UK's health engineering biology industry for many years and continues to work closely with our Engineering Biology Advisory Committee ([EBAC](#)) representing industry views across government and the new Council. The BIA is also expanding its work to support engineering biology companies which apply engineering biology to areas beyond health. To learn more, please get in touch with Policy & Public Affairs Manager, [Linda Bedenik](#).

BIA working to increase access to health data for research

The BIA has submitted its response to the [Government's data access policy update](#), which stated that secure data environments (SDEs) will become the default route for accessing NHS data for research and external uses.

The BIA reaffirmed its support for moving to transparent, efficient SDEs as discussed in its recent publication on [Driving Growth and Patient Benefit through Secure Data Environments](#). We also emphasised the need for holistic, comprehensive datasets that SMEs can access in an efficient manner, such as a national platform providing access to regional SDEs.

We argued that this national platform should prioritise interconnectivity, by implementing a system that allows for single-point access, standard data models, interoperability, and the ability to search across all SDEs. This kind of unified system would greatly enhance user experience and data accessibility, ultimately accelerating healthcare innovation, improvements, and positive health outcomes for patients.

Stakeholder groups including NHSE, the ABPI, the ABHI, and HDRUK have come together to form a strategic implementation group to oversee the SDE programme. The BIA will make sure that the specific requirements of SMEs are met so that the UK can establish itself as a world leader in making large datasets available to industry in a way that is effective, efficient, and respectful of patient concerns. For further information, please contact Policy and Public Affairs Manager [Olivier Roth](#).

Expansion of BIA's work on artificial intelligence

The BIA expanded its influencing work on artificial intelligence (AI) this quarter.

On 26 September, the BIA attended a workshop organised by the Office for Life Sciences (OLS) to discuss how the Government can best support the development of AI in the life science sector. We argued that the genomics SME sector is a massive driver of innovation in AI and highlighted the importance of ensuring that AI and life science skills were nurtured in the UK as well as imported from abroad. We also argued that funding should be specifically targeted towards SMEs in the life science sector, for example by ringfencing some of the funding from the British Business Bank.

The BIA was also invited to join the Life Sciences Council (LSC) Data Sub-Group, which will be a forum for government/industry discussion of the use of data and AI in the life sciences. BIA representatives on the group will include Danuta Jeziorska and Manish Patel.

BIA feeds into Office of Life Science review of Genome UK metrics

The BIA held a meeting with the Office of Life Sciences to discuss the metrics of the [Genome UK implementation plan](#) on 4 November.

The aim of the meeting was to measure the activity of the genomic industry, and its impact on the NHS, patients, and health outcomes in general. The BIA and its members gave an in-depth presentation on the genomic sector, highlighting use cases and key metrics when trying to measure its impact. Members also fed into discussions on funding for functional genomics. The BIA will continue to oversee the implementation of Genome UK, which runs until 2025.

People, skills, and talent

New BIA campaign highlights career opportunities in the cell and gene therapy sector

The BIA has launched a [new campaign](#) showcasing some of the inspiring people working the UK cell and gene therapy sector and highlighting the variety of different roles and career paths available. The campaign features a series of video interviews which were developed with support from LifeArc and filmed at the Cell and Gene Therapy Catapult's [Skills Training Labs](#) in Stevenage.

The campaign aims to attract more people to careers in the cell and gene therapy sector, helping to support the growth of the sector. The videos include people working in a range of roles, from lab-based roles in manufacturing and process development, to office-based roles in technology transfer and investment. In the interviews, the participants shared their motivations for working in the sector and advice for those starting out. They also highlighted the many different routes into a cell and gene therapy career, including apprenticeships and PhD programmes. If you would like to find out more about the campaign, please contact Policy and Public Affairs Manager [Rosie Lindup](#).

Collaboration with Canada on biomanufacturing skills

On 24 August, the BIA met with the Office for Life Sciences and Biomanufacturing Readiness Canada (OLSBR) to share learnings from the availability of skills and talent in scaling vaccine manufacturing.

This meeting followed on from a June 2023 [announcement](#) by Science Minister George Freeman MP of a package of science and research agreements, including an expected partnership on building a robust talent pipeline. This partnership aims to provide the skilled workforce needed to grow the sector in the future, providing funding for UK and Canadian businesses and research organisations to work together on joint projects.

The BIA has been engaged through roundtable discussions with Canadian training providers such as Mitacs, BioTalent Canada, Canadian Advanced Therapies Training Institute (CATTI), and Canadian Alliance for Skills and Training in Life Sciences (CASTL) on potential shared opportunities to upskill within biomanufacturing globally.

BIA leads diversity and inclusion workshop

Following the successful launch of our pioneering [Diversity and Inclusion in UK Biotech](#) report, the BIA held an engaging member-focussed workshop on inclusive hiring and recruitment practices on 28 September. The workshop provided a forum to share best practices for member organisations across the sector and was well attended by a range of people leaders and human resource professionals. The event included:

- Coulter Partners sharing their DEI journey, explaining what they have learnt so far working with clients and why diversity is important to their organisation.
- A panel session attended by representatives from OMass Therapeutics, Cell and Gene Therapy Catapult and Sitryx discussing current practices and challenges.
- Interactive workshop discussions where attendees shared recruitment policies, exploring what is working well and identifying future workforce needs.



Fiona Irvine (Sitryx), Hsin Loke (OMass Tx), and Steve Stewart (CGTC) on a panel chaired by the BIA's Skills Strategy Consultant, Kate Barclay

One takeaway from the discussion was the need not only for diverse and inclusive recruitment practices but also a forum for broader discussion around DEI. The workshop is the first in a series planned to address some of the challenges raised in the DEI report. To find out more, please contact [Dr Kate Barclay](#), Skills Strategy Consultant at the BIA.

Intellectual property and technology transfer

BIA gives voice to SMEs during WHO pandemic accord development

The Government is currently involved in the negotiation of an international treaty on pandemic preparedness, prevention, and response at the World Health Organization (WHO). The BIA has submitted a [position statement](#) to the Department for Health and Social Care (DHSC), sharing concerns emerging from the [zero draft](#) of the accord from the SME perspective.

We urged the Government to consider the significance of IP in the life sciences while negotiating. Our statement asked that the Government carefully considers the role of strong intellectual property (IP) rights in enabling technology transfer and the sharing of know-how, and be aware of the pitfalls of access and benefit sharing (ABS) mechanisms for genetic resources and their impact on innovation. This is a topic on which the BIA has engaged for many years in relation to the Convention of Biological Diversity (CBD)'s Nagoya Protocol on ABS of genetic resources.

The BIA was also represented by Steve Bates and SME member RQ Bio in the International Council of Biotechnology Associations (ICBA) delegation to the WHO, 4-5 October to discuss the accord and the proposed expanded TRIPS waivers for therapeutics.

Defra Business Advisory Group on Digital Sequence Information (DSI) joined by BIA

Following on from a ministerial roundtable discussion with Lord Benyon, Minister for Biosecurity, Marine and Rural Affairs in early July, the BIA joined a new DSI Business Advisory Group to support the Department for Environment, Food and Rural Affairs (Defra) in positioning towards an international, [multilateral benefit sharing mechanism](#) for the use of digital sequence information (DSI) of genetic resources. The advisory group brings together key industry stakeholders from across and beyond the life sciences, to discuss the details of this mechanism and ensure it works for UK businesses.

The BIA's views will inform the UK's negotiation position on the mechanism, the details of which will be developed in the lead up to the next Conference of the Parties signatory to the UN Convention on Biological Diversity (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](#).

BIA meet with Defra to discuss changes to UK Access and Benefit Sharing Guidance

On 19 July, the BIA's Nagoya subcommittee of our Intellectual Property Advisory Committee ([IPAC](#)) met with the Defra to discuss amendments to the UK's Access and Benefit Sharing (ABS) [Guidance](#). The guidance helps guide UK users of non-human genetic resources on how to comply with the Nagoya Protocol in the UK. The BIA previously made recommendations on the development of the guidance in 2021 which were largely taken on board. However, aspects of the guidance fail to adequately reflect the scope of the UK regulations, while others need further clarification.

During the meeting, the BIA highlighted some aspects of the guidance that need further

development, including the definition of ‘research and development’, the scope for inclusion of the human microbiome, and where ‘utilisation’ starts and ends, specifically in a commercial setting.

BIA and members respond to DBT survey on ‘Triplets’

The Department for Business and Trade (DBT) consulted the BIA, our member companies, and other life sciences industry representatives to support the UK’s position on the ‘Triplets’. The Triplets are three policy items regularly discussed at the World Trade Organisation’s Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council), including patentable subject matter, the protection of genetic resources, and the relationship between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD).

The BIA reiterated its opposition to the introduction of a mandatory disclosure requirement for the source of genetic resources in patent applications, stating that UK ‘users’ of genetic resources already exercise due diligence to ascertain that the genetic resources which they utilise have been accessed in accordance with the relevant regulatory requirements, such as those under UK Nagoya Regulations, which ensure that benefits are fairly and equitably shared.

The BIA continues to engage with the Government and internationally on the ‘Triplets’.

EuropaBio and BIA collaborate on response to EC’s compulsory licensing proposal

The BIA has worked closely with EuropaBio to inform its [position](#) on the European Commission’s (EC’s) proposal for a new EU-wide [regulation](#) on compulsory licensing for crisis management. The proposal would allow a compulsory licence to be issued by a government during a health crisis, which would authorise a party other than the patent holder to use the patented invention without the consent of the patent holder, with the aim of more rapidly scaling up the manufacturing of medicines or medical supplies that help combat the health crisis.

Submitted on 28 July, the EuropaBio response warns that the EC’s proposal undermines intellectual property protection and innovation in the life sciences, setting a dangerous precedent about the stability and value of IP rights in Europe. It reiterates that the experience of the COVID-19 pandemic has shown that IP is not a barrier to access, arguing that compulsory licensing must remain a last resort option.

The EC’s proposal is part of a raft of proposed reforms that impact life sciences companies and their IP, including in the UK. If you are concerned about the reforms’ impacts, please get in touch with Policy and Public Affairs Manager, [Linda Bedenik](#).

Pre-clinical and clinical research

Threat of animal rights activism raised with Labour

The BIA, alongside Understanding Animal Research (UAR) and ABPI, met with Daniel Zeichner, Labour MP for Cambridge and Chair of the APPG for Life Sciences, on 5 August to provide a briefing about the complex issues at play in animal activism and to reiterate the importance of animal research to the life sciences sector.

In recent months, active campaigns have united campaign groups, media outlets, celebrities, and others with front-line campaigners who engage in factually incorrect narratives with damaging consequences. Disinformation among the public and Parliamentarians has increased in the past two years, harming medical progress. UAR is working 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](#), an agreement to commit to being transparent about the use of animals in research in the UK.

BIA contributes to new report on the rare disease research landscape

In September, the National Institute for Health and Care Research (NIHR) published a [new report](#) which mapped the UK rare disease landscape for the first time. The report was developed in collaboration with the Medical Research Council (MRC), industry, charities, and the devolved administrations. The report provides an overview of rare disease research being sponsored by the Government, charities, and industry in the UK. The BIA is a member of the Steering Group for the project and worked with the ABPI to contribute data and case studies on industry-sponsored research.

The report covers a five-year period from 2016-2021. The data identified 254 rare disease research projects supported by industry in this period, with the most researched conditions being cystic fibrosis (11%), idiopathic pulmonary fibrosis (7%), uveitis (5%), retinitis pigmentosa (5%) and motor neuron disease (4%). The report also highlighted the role of the wider life sciences sector in improving the lives of people with rare diseases, including a case study on [Mendelian](#), a UK-based digital health company using an AI-powered platform to accelerate diagnosis of rare diseases.

The report is the result of a commitment made in the [England Rare Diseases Action Plan](#), as part of the [UK Rare Diseases Framework](#). The BIA looks forward to continuing to engage with system partners on the next phase of the project, which will involve identifying priorities for future research.

Manufacturing

BIA publishes mRNA explainer heralding a new generation of medicines

The BIA has [published](#) an mRNA explainer in partnership with CPI and supported by Cytiva. It demonstrates how the UK is poised to become a global leader in mRNA medicine, an emerging technology that rose to prominence during the COVID-19 pandemic but has myriad other applications.



BIA CEO Steve Bates speaking on a panel at the inaugural RNA Vaccines and Therapeutics Conference held in early October.

This new report explores the technology and its potential before highlighting the UK's leading position in the development of mRNA technology, citing its strong foundation in research and development and the presence of several companies developing mRNA-based products. At the same time, the UK has proven itself to be the fastest regulator, payer, and adopter of the first new vaccines produced from this technology and is an exciting hub for innovation.

The publication was launched at the inaugural RNA Vaccines and Therapeutics Conference organised by CPI and Imperial College London and held at the Royal Academy of Engineering on 4-5 October 2023, bringing together experts focusing on the rapidly evolving science of encoded RNA medicines.

By working together, we can make the UK a leading centre for mRNA research, development and manufacturing, ensuring that the UK remains at the forefront of this rapidly growing field and that patients globally have access to the latest mRNA-based treatments. If you would like to join the BIA's growing mRNA community, please contact [Netty England](#).

Visit to UCL East for BIA Manufacturing Advisory Committee Leadership Programme (LeaP)

The BIA Manufacturing Advisory Committee Leadership Programme ([BIA MAC LeaP](#)) has engaged almost 120 next generation leaders from 42 organisations since 2017. In September, one of its newest cohorts visited the recently opened UCL East Manufacturing Futures Lab (MFL), on the Marshgate site at the Olympic Park in East London.

Professor Gary Lye, Director of the MFL, impressed LeaPers with UCL East's focus on sustainability, innovation, enterprise, and commercialisation, with all teaching programme leads stressing the importance of good industrial contacts and collaborations. Opportunities for collaboration and input to the programmes, through project design, project sponsorship and through industrial advisory boards, was discussed over lunch. The group also visited the MFL research spaces and met the academic leads whose research groups span industrial biocatalysts, scale-up and intensified bioprocessing, continuous and flow processes, and biobased materials.

This popular LeaP programme, which is free to join and suitable for BIA members who have a biomanufacturing footprint in the UK, is now opening registration for the next cohort, starting in January 2024. If you feel your organisation is eligible to join and would like to benefit from this leadership development programme, please contact [Netty England](#) for further details.

Post-Brexit border checks delayed as BIA feeds into new regime

The introduction of post-Brexit border inspections on food, plant and animal products, which includes laboratory animals and many reagents and ingredients used in drug development and manufacture, was delayed for the fifth time, the Government confirmed in August. The measures were due to start in October but will now not begin until the end of January 2024.

The BIA has been feeding in sector concerns about the start of inspections despite the rules and guidance not being finalised or shared with businesses which need to bring in products. Of particular concern was the lack of specific identification codes for life science products and unnecessary inspections on high-value degradable biological samples. We therefore welcomed the delay but are continuing to ensure the new regime will work for our sector.

Medicines regulation

BIA Future of UK Regulation Conference 2023 an outstanding success

On 5 October, the BIA brought together over 200 regulatory experts, industry leaders, and international stakeholders with the senior leadership of the UK's Medicines and Healthcare products Regulatory Agency (MHRA) at our flagship [Conference on the Future of UK Regulation](#) in London. Delegates heard directly from a stellar line up of speakers on the latest developments, tackling insightful topics, at a time of significant change, challenge, and opportunity around three themed sessions:

- Getting UK clinical trials back on track
- International recognition framework for medicines – enabling access to innovation and supporting a UK USP
- Regulation of novel technologies.

The event was a fantastic showcase of the BIA's leading role in setting the regulatory agenda for innovative medicines. Dr June Raine, Chief Executive of the MHRA, gave the keynote address, noting that regulators in the UK are innovating hard through new pathways and support systems to enable patients access to safe and effective products. Lord O'Shaughnessy presented the recommendations from the [review into the UK commercial clinical trials landscape](#). We would like to pay tribute to the session chairs as well as thank expert speakers and delegates for a highly engaging event with some great discussions.



BIA CEO Steve Bates at the BIA's Future of UK Regulation Conference alongside (L-R): Dr June Raine DBE (MHRA), Jorg Schlapfer (Swiss Agency for Therapeutic Products), Shannon Thor (Food & Drug Administration), and Julian Beach (MHRA).

Consultation on end to the European Commission decision reliance procedure responded to by BIA

On 27 September, the BIA responded to an MHRA [consultation](#) on its proposal to amend the Human Medicines Regulations 2012 to remove the power for the agency to rely on the decision of the European Commission to approve a medicine for the Great Britain market. The European Commission Decision Reliance Procedure (ECDRP), which was introduced when the UK left the EU in 2021, will be replaced with the [new international recognition framework](#) from January 2024 (see below).

While we supported this proposal, we noted in our response that BIA member companies used the ECDRP many times and indicated their satisfaction with the timelines and the speedy review to authorise medicines in GB. This has ensured timely patients access to new, innovative medicines.

BIA gives feedback on the International Recognition Procedure Guidance

On 11 August, the BIA provided our members' feedback on the MHRA draft International Recognition Guidance to help improve this guidance with greater clarity and certainty. The MHRA developed a new international recognition framework for medicines utilising pre-existing approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore, and the United States, which will sit alongside the MHRA's current national procedures from 1 January 2024.

Our members expressed concern about the timelines for Recognition B which will replace the ECDRP. This is because most of their products which contain a first-in-class new active substance or incorporates novel technologies, as well as ATMPs and orphan medicines, would fall into this recognition route.

Following consultation with the Trade Associations, the MHRA published on 30 August the guidance on [International Recognition Procedure](#), including how to use this new procedure for medicines licensing applications. For further information, contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

BIA commented on MHRA guidance for UK-wide licensing under the Windsor Framework

The BIA continues to engage with the MHRA and DHSC on the implementation of the Windsor Framework, considering the process of packaging changes, the impact on medicines licencing, and interim arrangements until commencement from 1 January 2025.

In August, the BIA provided comments from our Regulatory Affairs Advisory Committee ([RAAC](#)) on a first draft of the proposed guidance on changes to the licensing of medicines in the UK. The MHRA guidance on [UK-wide licensing for human medicines](#) was published on 29 September, after consultation with the Trade Associations.

For further information, contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#)

Access to medicines

Consultation on antimicrobial subscription model responded to by BIA

In October, the [BIA submitted its response](#) to an NHS England [consultation](#) on proposals for the antimicrobial products subscription model. The consultation followed the success of the pilot project, which saw NHS England and NICE work together to determine a fixed annual fee for two antimicrobial drugs. The subscription-style model aims to stimulate greater investment into novel antimicrobials to tackle the urgent challenge of antimicrobial resistance (AMR). Under the proposed new model, this approach will be extended to more antimicrobial products and across the four nations of the UK. The UK is the first country in the world to implement a subscription-based payment model for antimicrobials, a significant step forward in developing the necessary global pull incentive to stimulate R&D investment in this space.

In our consultation response, we expressed strong support for the subscription model, while also setting out number of recommendations to make sure that it is as effective as possible in stimulating investment into antimicrobial R&D across the life sciences sector. These recommendations included revisions to the proposed eligibility criteria and scoring system to ensure that smaller, innovative companies are not disadvantaged in the process.

We look forward to continuing to engage with NHS England, NICE and other stakeholders as the subscription model is introduced. To find out more about the BIA's work on AMR, please contact Policy and Public Affairs Manager [Rosie Lindup](#).

BIA engages with DHSC proposals to revise the statutory scheme

The BIA has been engaging with DHSC on its [proposals](#) to revise the statutory scheme to control the cost of branded health service medicines. A key element of the proposals is the introduction of a 'lifecycle adjustment' (LCA) approach, whereby older products in 'uncompetitive' markets would be subject to a higher rebate rate. In September, the BIA hosted a webinar with DHSC officials to give members the opportunity to ask questions about the proposed changes to the scheme and the potential impact on the sector.

The BIA has submitted a [response](#) to the [consultation](#) on the proposals, which closed on 10 October. In our response, we outlined our concerns that the proposed changes would risk limiting patient access to medicines and discouraging investment into the life sciences sector. In particular, we are concerned that the proposed LCA mechanism risks reducing the value of IP protections as an incentive for innovation, as well as harming certain types of products where there are unlikely to be high levels of competition, such as rare disease medicines. We also outlined concerns about the administrative burden of the proposals on both government and industry and called for a more comprehensive assessment of the potential impact of the proposals on the UK life sciences sector.

The BIA will be writing to the Minister Will Quince MP to share our concerns on the proposals and the limited impact assessment. If you have any questions about the BIA's engagement on the statutory scheme, please get in touch with Policy and Public Affairs Manager [Rosie Lindup](#).

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

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