



# **INFLUENCING AND SHAPING OUR SECTOR**

**October 2022 - January 2023**

**[bioindustry.org](https://bioindustry.org)**

# INTRODUCTION

The BioIndustry Association (BIA) continued to influence and engage with senior stakeholders on behalf of the UK life sciences sector across a range of policy areas from October 2022 to January 2023. This quarterly report provides a summary of these engagements and situates them in their political context.

Q4 saw further change in government in an already turbulent year. Rishi Sunak became Prime Minister in October, bringing with him a new cabinet and a revised agenda for the life science sector. Chancellor Jeremy Hunt's move to reduce R&D tax credit provision for SMEs has been a focus for BIA, launching a campaign which saw over 300 CEOs sign a letter explaining the detrimental impact this would have on innovative companies within our sector. The Chancellor's response offered some reassurance, but this is a live issue which BIA will monitor closely in the run up to the Spring Budget in March 2023.



**3 consultation responses and briefings submitted**



**10 engagement meetings with 16 parliamentarians, incl. 6 ministers**

Read on for further details of BIA's work in the finance, tax, and investment space.



**5 letters to Ministers**

With engagements including a workshop with the NHS Centre for Improving Data Collaboration, a consultation response on the UK's AMR action plans and the publication of a brochure on One Health with the Department for International Trade (DIT), BIA's work on strategic technologies also continued apace. Our party conference panels on life science apprenticeships and the return of the bioProcessUK conference provided great opportunities to include BIA member organisations in our influencing work.

Read on for further details of our meetings, consultation responses and ministerial letters this quarter.

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## Engagement with the Government and Parliament on life sciences policy

The political tumult of 2022 reached a crescendo in the final quarter, with the resignation of **Liz Truss** making her the shortest-serving Prime Minister in British history. Her 44 days in office were packed with incident, most notably the ‘mini-Budget’ with which Truss and her Chancellor, Kwasi Kwarteng, contrived to spook the markets and jack up the cost of government borrowing with its radical approach to unfunded tax cuts.

The Budget rapidly unravelled, with the abolition of the top 45p rate of income tax being reversed overnight during the Conservative Party conference. Kwarteng was then peremptorily recalled from the IMF meeting in New York to be sacked, with his replacement, Jeremy Hunt having been offered the job before his predecessor’s wheels had touched down. The new Chancellor steadied the ship by scrapping the rest of the ill-fated Budget, but it was not enough to save Truss and she was replaced by **Rishi Sunak** as PM on 25 October.



*Prime Minister Rishi Sunak makes his New Year speech in which he referred to his ambition to make the UK a ‘beacon of science’ on 4 January 2023 ([Image credit: Independent](#))*

The subsequent reshuffle meant a new team of Ministers for BIA to meet and brief, with key appointments including at the Department for Business, Energy & Industrial Strategy (BEIS) Grant Shapps as Secretary of State, the welcome return of George Freeman as Minister for Science, Research and Innovation and Nus Ghani as Minister for Industry and Investment Security (life sciences and vaccine production). At the Department of Health and Social Care, Steve Barclay returned as Secretary of State, with Will Quince as Minister of State (research, genomics, life sciences, medicines and medicines regulation, and VPAS) and junior Minister, Neil O’Brien

responsible for AMR and vaccines. Jeremy Hunt kept his place at Number 11. The **National Science and Technology Council** (NSTC) abolished by Truss, was also [re-established](#) by Rishi Sunak.

The new administration lost no time in setting out its stall with an **Autumn Statement** on 17 November. While there was much to welcome, the Chancellor's announcement of reforms to R&D tax reliefs for SMEs effectively halving the value of the scheme for a loss-making life sciences company, caused grave concern for the BIA and our members. We immediately launched a sustained lobbying campaign with government and in Parliament, mobilised more than 300 CEOs of biotech firms to sign a letter to the Chancellor (which Steve Bates presented in person to the Health Secretary and Business Secretary), and secured multiple meetings with Ministers and officials to press the case for support for R&D intensive SMEs.

The BIA attended the **Labour and Conservative Party conferences**, holding successful fringe events on '[Growing innovative manufacturing through apprenticeships](#)'. At both conferences, as well as running our own events, we took part in the Business Days where we met many Ministers, shadow Ministers, MPs, and other policymakers.

The BIA contributed to the Labour Party Shadow Chancellor Rachel Reeves' **start-up review**, focusing on need to unlock pension funds to invest in scaling companies and SME tax reliefs. The [report](#) was launched at the Labour Party Business Conference 8 December, a sold-out event in London at which BIA spoke to Keir Starmer and many of his shadow Ministers.



*A meeting of the APPG for Life Sciences in the House of Lords. Attendees included Chi Onwurah MP, Lord Patel, and Lord Bethell, with Daniel Zeichner MP chairing.*

In Parliament, the **All-Party Parliamentary Group** (APPG) for Life Sciences, for which the BIA jointly provides the secretariat, held a roundtable discussion on ‘Implementing the Life Sciences Vision: One Year On’ on 25 October chaired by Daniel Zeichner MP, with Roz Campion, Director of the Office for Life Sciences speaking.

In November, BIA met with Theresa Villers MP in Parliament to discuss skills and the R&D tax credit campaign and Colin Hailey of our Finance and Tax Advisory Committee ([FTAC](#)) [gave evidence](#) to the House of Lords Finance Bill sub-Committee (14 November). Colin was quizzed on fraud in the R&D tax credit regime and gave a robust response, identifying solutions to the problems of abuse that would protect genuinely knowledge-intensive industries.

### **Life Sciences Council and other government/industry engagement**

The **Life Sciences Council (LSC)** met on **28 November** at 10 Downing Street, for the first in-person meeting since before the pandemic. **Prime Minister Rishi Sunak** opened the meeting and Health Secretary Steve Barclay and Business Secretary Grant Shapps co-chaired with Ministers Will Quince and Nus Ghani in support. The main item of business was the implementation of the [Life Sciences Vision](#).

Representing the BIA and speaking on the investment landscape and the global ecosystem, Steve Bates welcomed the Scale-up Taskforce set up as part of the Vision with the aim of driving institutional investment into the UK’s innovative life sciences. He also celebrated the [appointment](#) of Dan Mahony as the UK Life Science Investment Envoy and the inaugural investor roadshow as tangible outputs from this part of the Vision, creating the preconditions for the Vision’s success; investment in science and research, and access to finance. He highlighted the reduction in the SME R&D tax credit rate announced in the Autumn Statement, which goes against the grain of the ambition to make the UK the most attractive place to establish, grow and invest in innovative life sciences. He also called for the MHRA to be properly resourced to enable innovation.

Also representing the BIA, **Angela Osborne** spoke of the importance of biotech SMEs to the UK’s life sciences ecosystem and stressed that the competitiveness and attractiveness of the UK depends on the ability of these companies to scale-up. She further explained how R&D tax credits enabled her firm to leave profits in the business, enabling manufacturing facility expansion, part of anchoring CGT companies to the UK.

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. After the additional meeting of the LSC to discuss **Net Zero and sustainability**, a third follow-up meeting was held on 11 October in the form of a deep-dive working group on regulatory barriers to Net Zero at which the BIA was represented by **Kit Erlebach**.

Finally, the **Accelerated Access Collaborative** (AAC) Board met on 23 November. Dan Mahony represented the BIA.

## Finance, tax and investment

### **BIA secures further support for life science SMEs after R&D tax relief is cut**

The Chancellor [has written](#) to BIA and our members saying that he sees ‘merit’ in further support for life science SMEs that will see their R&D tax credits almost halved from April 2023 if the cut announced in the Autumn Statement goes ahead as planned.

Following the announcement of the cut on 17 November, the BIA led an intense effort to raise the sector’s concerns with policymakers. BIA CEO Steve Bates raised it in person with Cabinet ministers including the Prime Minister, held two roundtables with the Financial Secretary to the Treasury, met officials from No 10 to explain our concerns, and had several meetings with Treasury officials to discuss the policy detail. Over 300 BIA members and sector leaders signed [our open letter to the Chancellor](#), many members wrote to their own MPs about it, and the MP for South Cambridgeshire, Anthony Browne MP, raised the sector’s concerns in several debates in Parliament, as did the Labour front bench following briefing from BIA.

The BIA is now in detailed talks with Treasury officials and ministers about what support could be made available. This work is likely to continue up until the Spring Budget on 15 March, when details of the support will be made public. For further information on R&D tax credits, get in touch with [Dr Martin Turner](#).

### **Autumn Statement confirms that commitment to R&D budget remains**

Elsewhere in the [Autumn Statement](#), the Government recommitted to raising its own investment in R&D to £20 billion per year by 2024/25. Chancellor Jeremy Hunt said he wanted to ‘combine our technology and science brilliance with our formidable financial services to turn Britain into the world’s next Silicon Valley’.

Funding for the UK’s nine Catapults will increase by 35% compared to the last five-year funding cycle. Investment Zones will now be more focused, catalysing a limited number of the highest potential knowledge-intensive growth clusters, including through leveraging local research strengths.

The Autumn Statement also confirmed that the Seed Enterprise Investment Scheme (SEIS) will [still be made more generous](#) and that Government remains committed to continuing the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs), also seeing value in ‘extending them in the future’. It is not yet clear whether that means making them more generous or extending them beyond 2025, which is when they are due to end.

### **BIA Chair announced as government’s first Life Sciences Investment Envoy**

The Government has created a new dedicated Life Sciences Investment Envoy, with the Business Secretary appointing Dan Mahony, Chair of the BIA and Entrepreneur in Residence at Evotec, to the role on 17 November. The new envoy will champion access to finance for the UK life sciences sector by bridging the gap between the UK’s financial and life science industries.

The envoy role was created following the recommendations of the Life Sciences Scale-Up Taskforce, part of the Life Sciences Vision, which was led by the BIA in partnership with the Office for Life Sciences.

### **First Investor Roadshow convenes over 90 world-leading investors**

The BIA, the Office for Life Sciences, and the Department for International Trade co-hosted an Investor Roadshow event in London on 17 November. Over 90 investors from across the UK and abroad had the opportunity to meet some of the UK's most exciting scaling companies and to learn how the UK life sciences ecosystem is supporting medical innovation.

The all-day conference was opened by Business Secretary Grant Shapps MP and also featured Sir John Bell and the leaders of key institutions such as the MHRA and NHS Transformation. An exclusive dinner was held in the evening with a keynote address from the Government's Chief Scientific Adviser, Sir Patrick Vallance.

Further roadshows are expected to be held in 2023 across the country to promote the strengths of UK life sciences to investors.

### **Labour Party review on supporting innovative companies adopts BIA recommendations**

The BIA has contributed to a report that will inform the Labour Party's manifesto for the next general election which calls for the continuation of venture tax reliefs and the unlocking of pension fund capital to support innovative companies.

[Start-Up, Scale-up](#) is the product of a review led by Lord Jim O'Neil, to which the BIA [submitted evidence and made recommendations](#) and attended contributory roundtable discussions. Key BIA recommendations have been adopted by the review, including: exploring a UK version of the French Tibi Scheme, a policy developed by the Life Sciences Scale-Up Taskforce; reviewing the mandate of the British Business Bank to better support cutting-edge businesses; and continuing but reviewing the Enterprise Investment Scheme and Venture Capital Trust tax reliefs to ensure they are appropriately targeted. The BIA will continue to engage with Labour's policy development in the runup to the next general election and beyond.

### **BIA urges government to be more ambitious in reform of pension funds**

In response to the [latest public consultation](#) on changes to pension fund rules to encourage greater investment in productive finance, such as venture capital, the [BIA has said](#) that new transparency rules do not go far enough. The BIA called for further transparency to give consumers the information they need to choose pension schemes that invest in innovative industries of the future.

The BIA welcomed new rules that would permit pension schemes to invest in venture capital funds despite high performance-related fees but warned that merely giving pension trustees the option to do this would not drive a change in behaviour, calling for the Government to champion investment in venture capital and monitor progress carefully to ensure behaviour change spreads across the pensions industry.

### **'Capital hungry' companies supported by stock market rules following BIA recommendation**

Life science companies will be able to raise money faster and more efficiently following new guidance. The Financial Reporting Council (FRC) has issued a [new Statement of Principles](#) on behalf of the Pre-Emption Group that will allow certain companies, including those in life sciences, to secure agreement at Annual General Meetings to raise larger sums of money without needing to offer shares to existing shareholders through what are known as pre-emption rights. The new

principles [implement the recommendations](#) of the Secondary Capital Raising Review led by Mark Austin, which the BIA heavily influenced.

## Strategic technologies and areas of scientific focus

### **BIA publishes landmark paper on Secure Data Environments for SMEs**

On 12 December, the BIA published '[Driving growth and patient benefit through SDEs](#)', a paper outlining life science SMEs' requirements for new Secure Data Environments (SDEs). The paper highlights important industry requirements under the four themes: discovery; access; usability; and interconnectivity. Improving the data access process and the user technical specification are important areas for innovators in the life science sector. The paper was developed by the BIA SDE working group.

The primary aim of the paper is to influence the development of national and subnational NHS data environments, which will become the default route for accessing NHS data for research and development. The paper will also be of interest to other SDE developers in academia and the charity sector. This new SDE ecosystem is arising as a result of the Government's [Data Saves Lives](#) strategy to improve the public confidence in data sharing.

You can find out more about the paper in our blog, '[Why we all need data environments to unlock the potential of data](#)'. To get involved, please contact Senior Policy and Public Affairs Manager, [Dr Emma Lawrence](#).

### **BIA hosts workshop with the NHS Centre for Improving Data Collaboration**

The BIA hosted a workshop with the NHS [Centre for Improving Data Collaboration](#) on 17 January. The workshop was attended by members of the BIA's [TechBio](#) community and covered the [NHS Data for R&D programme](#), which seeks to improve NHS infrastructure in order to foster R&D. Topics included the development of national and subnational [Secure Data Environments](#) (SDEs) and commercial principles for data sharing.

BIA members were able to share their feedback with the NHS representatives and we will continue to engage with them throughout their programme of work.

### **England's Genome UK implementation plan adopts BIA recommendations**

The Government published England's 3-year [Genome UK implementation plan](#) in December. Genome UK was published in 2020 and sets out the ambition of making the UK the best place globally to start and scale new genomics companies. This is the first full three-year implementation plan since the publication of the strategy.

Following calls from BIA, the plan features a commitment to review the process through which SMEs apply for access to genomic resources. The Government has also committed to 'simplify[ing] the application process for small businesses which want to supply to government'. This is a great achievement for the BIA, which has been calling for SME recognition in the plan. The plan also showcases the work of BIA from [Genomics Nation](#), to [MAC Leap](#) (Manufacturing Advisory Committee Leadership Programme) and the Life Sciences Scale-Up Task Force.

Throughout 2022, the BIA has been engaging with government on the development of the implementation plan for the '[Genome UK: the future of healthcare](#)' strategy. We will continue to work with stakeholders, including NHS England and Genomics England, on this in 2023.

### **BIA responds to inquiry on the governance of artificial intelligence**

In November, the BIA responded to the Science and Technology Committee's [inquiry on the governance of AI](#). The [response](#) covered the different applications of AI in the life sciences, from basic research planning through to medical diagnostics. BIA members' feedback on the advantages and disadvantages of the current system, developed with input from our TechBio community, was included in the response.

The BIA recommended a sector- and application-based approach to regulation as this would best support innovation. Our response also called for more guidance to make it clear which technologies fall under the existing MHRA regulation and highlights the need for appropriate in-house expertise and resources within sector-level regulators. For further information, or to get involved in future BIA work on AI, contact [Dr Emma Lawrence](#).

### **BIA meets with Defra ahead of COP15**

On 24 November, the BIA's Nagoya subcommittee to our Intellectual Property Advisory Committee ([IPAC](#)) took part in a small roundtable with Defra's Minister of State for Biosecurity, Marine and Rural Affairs, Lord Benyon, ahead of the UN's [COP15](#) in Montreal. Attendees discussed industry views on the introduction of a Nagoya-like international benefit sharing mechanism for the use of Digital Sequence Information (DSI) of genetic resources. The BIA has opposed the introduction of such a mechanism for DSI for many years and highlighted the detrimental impact it could have on R&D and innovation taking place in UK companies.

Following the meeting, the BIA wrote to the Minister setting out the importance of access to DSI, asserting that all [options for benefit sharing](#) currently on the table need to be fully analysed to ensure they don't inhibit innovation, and made clear that the lack of evidence and detail on each of the options means that the BIA cannot endorse any of them at this stage.

While the [decision](#) was taken at COP15 to go ahead with developing a multilateral benefit sharing mechanism for the use of DSI, the form the mechanism itself will take is yet to be conceptualised. The BIA continues to engage closely with government and members on this issue.

If you are working with DSI and have concerns about the ongoing international discussions, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

### **UK One Health brochure published by DIT in collaboration with BIA**

The BIA has partnered with the Department for International Trade (DIT) and other UK stakeholders to produce a brochure on One Health. '[UK Global innovations: Adopting a One Health approach to promote future sustainability](#)' was launched by DIT at the 7th World One Health Congress in November 2022 in Singapore.

It is the product of the UK DIT One Health Think Tank that the BIA is part of and includes an extensive directory of UK companies in the space, featuring many BIA members.

The BIA will continue to represent the life sciences industry in the DIT think tank in 2023 in support of a holistic approach to sustainability in health.

### **BIA support call for Government action on animal activism**

In October, the BIA co-signed an Understanding Animal Research (UAR) letter to BEIS and the Home Office to highlight the continued animal rights protests disturbing the research beagle breeding facility at MBR Acres, Wyton. In the letter, BIA, along with seven other organisations, asked for immediate government action to protect this critically important facility so that bioscientific research in the UK can continue.

The letter highlighted that for the UK to continue as a major global player in life sciences, access to the animals needed to satisfy regulatory requirements is essential, as later stage research cannot proceed without animal testing.

The BIA also supported a UK Biosciences Sector Coalition (UKBSC) letter on the same matter. The BIA is a member of UKBSC and UAR and is a [signatory of the Concordat on Openness on the Use of Animals in Research](#), an agreement supported by a range of organisations to commit to being open about the use of animals in research in the UK.

### **BIA supports BEIS business consultation on Horizon Europe alternatives programme**

The BIA took part in a BEIS workshop on 5 December called to gather industry views on the Government's alternative programme to Horizon Europe. The programme is being developed while the UK's association to Horizon Europe continues to be delayed.

During the meeting, BIA highlighted the importance of collaboration in the life sciences sector and pointed to how existing funding and support structures, such as those offered by Innovate UK, should be built upon. BIA was pleased to see health and life sciences highlighted as priority areas as well as a strong commitment to embedding SMEs within the alternatives programme.

While the BIA supports the UK's full association to Horizon Europe, it is essential that any alternative programme provides the support life sciences SMEs need in case of non-association.

### **BIA responds to DHSC consultation on the next national action plan to tackle AMR**

On 20 January, the BIA responded to DHSC's [call for evidence](#) on the UK's next five-year national action plan to tackle antimicrobial resistance (AMR). The action plan covers 2024 to 2029, and will support the delivery of the Government's [20-year vision for AMR](#), published in 2019. The UK's [first national action plan](#) in support of the vision was published in 2019 and will run until 2024.

The BIA's response was developed with input from a range of members working in the AMR space. The response highlighted the areas in which the UK has demonstrated leadership in tackling AMR, including the [launch](#) of NICE and NHS England's pilot project for a subscription-style payment

model for antimicrobial drugs. The BIA emphasised the importance of sharing lessons learned from the project and of championing the principle of a subscription-style model across the world.

It is important that the next national action plan recognises the areas which require more development in the UK, including incentivising the development of innovative diagnostics for antimicrobial infections, and ensuring that new diagnostic technologies are utilised in healthcare settings in the UK and globally. Improvements could also be made to data sharing and accessibility in the UK to ensure that stakeholders have accurate and timely information to inform their decision making.

This work was complemented by a webinar on AMR held by BIA in November 2022 to mark World Antimicrobial Awareness Week. The [webinar](#) brought together speakers from NICE, Innovate UK, IFPMA and the Cystic Fibrosis Trust to discuss UK leadership on AMR. For more information on the BIA's work on AMR, contact Policy and Public Affairs Manager, [Rosie Lindup](#).

## People, skills, and talent

### BIA puts life science apprenticeships on the agenda at party conferences

The BIA had a strong presence at the Labour and Conservative Party conferences, with two panel events on '[Growing Innovative Manufacturing Through Apprenticeships](#)'. Politicians, policymakers, and local BIA members attended engaging and informative panel discussions focusing on the value vocational routes bring to UK biotech.



*Top image: BIA panel at Conservative Party conference in Birmingham. From left to right: Theresa Villiers MP, Emilia Reyes Pabon (Oxford University Clinical Biomanufacturing Facility), Aaron Bell MP, Aweek Bhattacharya (Social Market Foundation), Imann Bashorun (Oxford Biomedica) Simon Simpkins (Oxford Biomedica).*

*Bottom image: BIA panel at Labour Party conference in Liverpool. From left to right: David Hunt CBE (Astrazeneca), Michael Devey (Pharmaron), Lauren Howe (NHSBT), Christ Thomas (Institute for Public Policy Research), Praful Nargund (Member of Keir Starmer's Council of Skills Advisors), Izzy Sloan (GSK)*

Both panels included representatives from BIA member organisations, giving apprentices and their employers the opportunity to speak alongside MPs and policymakers. Each session showcased the incredible talent entering our sector through the apprenticeship route and the benefits to employers whilst highlighting the challenges current apprenticeship policy poses for our sector.

Measurable impact has been seen following the events. Praful Nargund, member of Keir Starmer's Council of Skills Advisors, has published a report on '[Learning and skills for economic recovery, social cohesion and a more equal Britain](#)'. The Advanced Therapies Apprenticeship Community (ATAC) is featured as a case study of how life science SMEs can be supported on skills. The BIA held a follow up meeting with Theresa Villiers MP, vice-chair of the All Party Parliamentary Group (APPG) on Apprenticeships, discussing policy changes that could reduce the barriers to biotech SMEs taking on apprentices. Theresa Villiers has since [raised](#) these issues in Parliament, referencing the work of BIA and ATAC.

The BIA continues to consult on how SMEs can make the most of the apprenticeship levy and other tax incentives, following on from our 2022 proposal on '[Driving quality apprenticeships across the life sciences](#)'. For more information, contact [Dr Kate Barclay](#), BIA's Skills and Talent Consultant.

### **Developing the next generation of UK biotech leadership talent**

The BIA has been working alongside UK Research and Innovation (UKRI) on their Future Leaders Fellowships (FLFs) programme, which looks to develop the next generation of leadership talent that is critical for UK biotech industry to start, scale, and grow.

Now in [Round 7](#), the fellowships are available to early career researchers and innovators from across academia and business. Working in partnership with universities, research organisations, businesses, charities, and government, the FLFs create the best possible environment for research and innovation to flourish. The BIA has been engaged in promoting the application process to businesses and publishing case studies of successful previous applications from BIA members [Sixfold Bioscience](#) and [MicrofluidX](#).

Round 7 applications closed at the start of December 2022, but BIA continues to engage with UKRI FLFs and Innovate UK Talent & Skills leads to ensure access to funding for researchers, innovators, and next generation leaders within business.

## Intellectual property and technology transfer

### **BIA engage closely with Government on the review of retained EU law**

The BIA has been closely engaging with the Intellectual Property Office (IPO) which identified 70 pieces of IP law that will be subject to the review of retained EU law introduced to Parliament by Jacob Rees-Mogg in September 2022 as the [Retained EU Law \(Revocation and Reform\) Bill](#). The Bill affects [over 2400 pieces of legislation](#) derived from EU law retained as UK law after Brexit. Once the Bill passes through Parliament, it will enable government to amend, repeal, or replace retained EU law.

The BIA's Intellectual Property Advisory Committee ([IPAC](#)) has also met with the Competition and Markets Authority (CMA) to discuss the Technology Transfer Block Exemption Regulation (TTBER) subject to the review. BIA had submitted to a government consultation on a draft TTBER in 2013 to highlight sector concerns and outline the essential role of licensing in supporting innovation, collaboration and growth across the biotechnology sector.

With the passing of the Bill, the BIA continues to work closely with the IPO and other government departments to ensure strong IP protection for member companies. If there are any regulations you are particularly concerned about in the context of the review of retained EU law, contact Policy and Public Affairs Manager, [Linda Bedenik](#).

## Manufacturing

### BIA gathers the UK bioprocessing community at bioProcessUK Conference

The nineteenth annual [bioProcessUK \(BPUK\) conference](#) took place in Edinburgh between 15-17 November and proved to be the most popular yet, with sponsorship and exhibition packages all purchased by May and delegate tickets completely sold out by August.

As always when the close-knit bioprocessing community get together, the atmosphere was buzzing at both the pre-party at the Royal College of Physicians and the conference dinner at The National Museum of Scotland.



*Attendees were piped into bioProcess UK, held in Edinburgh.*

During the conference, delegates enjoyed presentations from FUJIFILM Diosynth Biotechnologies, RoslinCT, Catalent and UCL, celebrating their recent investment news to help grow the UK biomanufacturing footprint. There was a New Frontiers session on the translation of scientific advances into new treatment modalities, including mRNA (CPI), exosomes (EvOx Therapeutics) and microbiome therapeutics (Microbiotica).

Day one saw delegates attend parallel workshops. One entitled 'Boom or Bust?' focused on the current environment for R&D and manufacturing investment. The second on 'Kidney Disease' featured a moving testimony from Janet Downie, ex-CEO of RoslinCT, telling her story of donating a kidney to her husband in 2010, who was living with renal failure at the time.

Day two kicked off with a Medicines Manufacturing Industry Partnership ([MMIP](#)) update, followed by a sustainable biotechnology themed Dragon's Den style technology showcase that saw Leaf Expression Systems receive the most votes and win tickets to BIA's Summer Party. The conference

finale, looking at digitalisation in the medicines development and manufacturing arenas, saw speakers from Oxford Biomedica, Cytiva and AMRC sharing their innovative digital solutions.

The event was also an opportunity to celebrate outstanding achievements; congratulations to Peter Levison, recently retired from Pall Corporation, and the Advanced Therapies Apprenticeship Community (ATAC), who were awarded the prestigious Peter Dunnill award and Richard Wilson Impact awards respectively. These worthy recipients have been recognised for their work and contributions to the bioprocessing and biologics manufacturing sector.



*Peter Levison (R) being awarded the Peter Dunnill by Stephen Ward (L), last year's recipient, at bioProcess UK.*

BPUK will be moving to a larger venue in Brighton for 2023 in order to accommodate the growth of the conference. For more information, contact BIA's Bioprocessing Consultant [Netty England](#).

## Medicines regulation

### **BIA influences government decision on the future strategy for batch testing of medicinal products in Great Britain**

On 15 December, the Government [announced](#) its decision to make permanent the approach favoured by the BIA and the life sciences sector: no import testing or UK Qualified Person certification for medicines imported from approved countries, including EU/EEA countries.

Government has taken the option of making permanent the post-Brexit transitional arrangements. The BIA has lobbied for this outcome, which ensures continuity of supply and patient access to medicines, while avoiding duplication of testing and cost increases for industry and the NHS.

The UK's future batch testing regime has taken into consideration the submissions to the public consultation including the BIA [response to the DHSC consultation](#), stakeholder engagement, and views of the MHRA. The [formal government response and conclusion of the batch testing review](#) includes detailed analysis of the public consultation.

### **BIA responds to MHRA consultation on statutory fees**

On 22 November, the BIA [responded](#) to the MHRA [consultation](#) on proposals to increase statutory fees. The BIA provided our members' feedback on the proposed changes and the implications of the proposed fee increases for SMEs in the innovative life sciences, which would apply from 1 April 2023.

The main concern for BIA member organisations is to ensure that the MHRA is adequately resourced with experienced staff and that it is financially sustainable in the long-term, benefiting both industry and UK patients while protecting public health. It is of paramount importance that a world-leading regulatory agency can fulfil its regulatory functions and deliver responsive and efficient services, if the ambition of the Government's [Life Sciences Vision](#) to make the UK the leading global hub for life sciences is to be realised.

Fee reductions and waivers for the Innovative Licensing and Access Pathway ([ILAP](#)), the UK flagship initiative post-Brexit, and the Early Access to Medicines Scheme ([EAMS](#)) for SMEs that are developing innovative therapies are needed to avoid stifling innovation in the UK. Moreover, the proposals could have a negative impact on the development and access to medicines for rare conditions. The increasing costs for scientific advice mechanisms and medical device assessment may discourage companies developing products for smaller patient populations from making marketing authorisation applications or device submissions in Great Britain.

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

### **BIA meets with DHSC to discuss impact of the Retained EU Law Bill**

On 6 January, the BIA met officials from the DHSC, the Government department leading on the review of retained EU law relevant to our sector. Ministers confirmed that they are keen to preserve the legislation on medicines, medical devices and clinical trials, and any reform will follow normal policy process involving stakeholders. Implementation of the clinical trials and medical devices legislative reforms are outside the scope of the Bill; these issues will be taken forward under the Medicines and Medical Devices Act.

The BIA's work on retained EU law in Q4 has also been bolstered by a meeting with the Intellectual Property Office (IPO) and Competition and Markets Authority (CMA) to discuss this pressing issue.

The Retained EU Law (Revocation and Reform) Bill was introduced to Parliament on 22 September. The Bill will make it easier to amend, repeal, or replace EU-derived legislation that was preserved in the UK legal framework by the European Union (Withdrawal) Act to ensure continuity as the UK left the EU.

If members have any concerns about the impact of the Bill on their R&D activities, contact BIA Head of Regulatory Affairs, [Dr Christiane Abouzeid](#), or Policy and Public Affairs Manager, [Linda Bedenik](#).

## Access to medicines

### **BIA hosts cross-stakeholder roundtable on real-world evidence in rare diseases**

On 10 November 2022, BIA's Rare Disease Industry Group ([RDIG](#)) hosted an in-person roundtable to discuss the challenges and required steps for realising the potential of real-world evidence (RWE) in rare diseases. The roundtable brought together a range of experts and stakeholders including representatives from industry, DHSC, patient groups, clinicians, and other members of the UK rare diseases community.

The roundtable discussion provided an opportunity for attendees to hear from an expert speaker about how RWE is being used by industry members to develop tools for tackling the diagnostic odyssey. Attendees also heard from patient group representatives about the importance of clear communication when explaining how patient data will be used, as well as the need to ensure that data collection fits around patients' lives.

The BIA has since published a blog, '[Real-world evidence: the panacea for rare diseases?](#)', which investigates the value of RWE in the treatment of rare disease in more detail.

RDIG will continue to act as a facilitator in the ongoing discussion around the collection and use of real-world evidence to improve the lives of people with rare diseases. For further information, contact Senior Policy and Public Affairs Executive, [Joe Smale](#).

### **BIA engages with DHSC on 2023 England Rare Diseases Action Plan**

Following the publication of the first [England Rare Diseases Action Plan in 2022](#), the BIA has engaged with the DHSC in the development of their 2023 Action Plan.

As one of the core members of the [UK Rare Diseases Forum](#), BIA's feedback on the contents of the Action Plan will be considered and incorporated by the England Rare Diseases Delivery Group ahead of the Action Plan's publication in February.

The Action Plan will set out twelve new actions intended to deliver progress against each of the [Rare Disease Framework](#)'s four priorities. BIA feedback on the draft actions highlighted the importance of including actions that can deliver meaningful improvements to people living with rare diseases by February 2024. The BIA was encouraged to see these comments recognised by DHSC.

In addition to introducing a set of new actions, the plan will also include a progress report on the measures included in the 2022 plan. BIA comments on the draft progress report emphasised the need to ensure that delivery partners continue to provide progress reports throughout 2023 where actions are ongoing.

The BIA looks forward to the publication of the 2023 England Action Plan and to working with DHSC and other partners on its delivery.

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](mailto: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](mailto:mmcgivern@bioindustry.org)

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