



UK BioIndustry Association

INFLUENCING AND SHAPING OUR SECTOR

July – October 2022

bioindustry.org

INTRODUCTION

The BioIndustry Association (BIA) continues to represent our members' voices at the highest levels through our policy and influencing work. This quarterly update gives an overview of key policy developments and BIA's continued involvement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from July to October 2022.

The summer break usually means less politics-watching for the BIA team, but the change in Government kept us on our toes this year. We saw Boris Johnson leave Number 10 and Liz Truss take over as the new Conservative Party leader and form a new Government. This resulted in an intense few days of networking with newly appointed Ministers at the Conservative Party Conference in Birmingham, topped off by our own successful fringe event on growing innovative manufacturing through apprenticeships. We launched our Women in Biotech pilot mentoring programme to support and inspire women in our sector, published our Genomics Nation 2022 report, and our Expert Advisory Group,



4 consultation responses and briefings submitted



9 influence meetings with 10 MPs, Peers and MEPs, including 4 Ministers

which has advised and guided the Government's Vaccine Taskforce (VTF) since 2020, met for the last time following the formal winding-down of the VTF.



14 letters to Ministers

BIA has continued to represent members' and the sectors' interests in numerous government consultations, workshops, and meetings. We continued to work with the Office for Life Sciences to keep up momentum of the Life Sciences Scale-up Taskforce recommendations and meet with the Treasury to influence incoming R&D tax relief changes. We engaged on Net Zero and sustainability through the Life Sciences Council, joined government workshops on Genome UK and cell and gene therapies, and fed into government consultations on the future strategy for batch testing and proposals to increase MHRA's statutory fees.

Read on for all of BIA's influencing work this quarter.

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Engagement with the Government and Parliament on life sciences policy

As though the alarms and excursions of the second quarter of 2022, during which Boris Johnson was forced out of Number 10, were not enough, Q3 has seen a dizzying succession of political events. **Liz Truss** was announced as the victor in the Conservative Party leadership contest on Monday 5 September and became Prime Minister following an audience with the Queen at Balmoral. Two days later, in the middle of the energy crisis debate in Parliament, the news was broken of Her Majesty's imminent death and by the end of the week the new PM was having her first audience with King Charles III. The normal business of politics was then suspended for ten days before a State funeral which brought most of the world's leaders to London. This added to the two-month political hiatus of the leadership election campaign over the summer.

Although the new Cabinet was appointed quickly, it has taken longer for the junior ministerial ranks to be filled. BIA has written to all the new key ministers, including Kwasi Kwarteng, Chancellor of the Exchequer, Thérèse Coffey, Deputy Prime Minister and Secretary of State for Health and Social Care (DHSC), Jacob Rees-Mogg, Secretary of State for Business, Energy and Industrial Strategy (BEIS), Nusrat Ghani, Minister for Science and Investment Security, BEIS, Dean Russell, Minister for Enterprise and Markets, BEIS, Nadhim Zahawi, Chancellor of the Duchy of Lancaster, and Trade Secretary Kemi Badenoch. BIA had a meeting with Nus Ghani at the Conservative Party conference as her appointment was being announced, and is seeking early meetings with other ministers.

During the leadership campaign, Liz Truss tweeted her support for life sciences, which she committed to driving investment into the sector as part of making the UK a science and technology superpower. The BIA will continue to make the case that our industry is central to delivering the growth that is the Government's top priority.



Now Prime Minister Liz Truss tweets about Life Sciences during her leadership campaign in August 2022.

With the energy price shock and cost of living (and doing business) crisis demanding attention from day one, the new Chancellor announced a £100bn+ package of emergency support on energy prices which extended beyond domestic consumers to include businesses for a limited period. At the request of government officials, BIA gathered evidence of how our members, especially SMEs, were being impacted by increased costs.

The Chancellor set out his agenda in a 'mini-Budget' on 23 September. In the accompanying 'Plan for Growth', there were some positive announcements for life sciences, including: a new £500 million Long-

Term Investment for Technology & Science (LIFTS) competition to catalyse investment from pension funds into venture capital (VC) funds to support scaling businesses; accelerated changes to the charge cap for defined contribution pensions, which has been a barrier for pensions investing in VC funds; and continuation of the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) beyond 2025 and more generous terms for the Seed Enterprise Investment Scheme (SEIS) to support investment in start-ups.

While the BIA welcomed these initiatives, they were somewhat overshadowed by the market reaction to the fiscal event overall. The combination of unfunded tax cuts, including the hastily reversed abolition of the 45p additional rate, the refusal to let the independent Office for Budget Responsibility (OBR) run the rule over the Chancellor's sums and the dismissal of HMT Permanent Secretary, Tom Scholar, as an earnest of the new administration's war on 'Treasury orthodoxy', spooked the markets and forced the publication date of the medium term fiscal plan (with accompanying OBR forecasts) to be brought forward to 31 October. To help members make sense of all this, we held a **new government webinar** on 22 September at which we discussed what these changes meant for innovative life sciences.

In the midst of the political turmoil, the BIA continued to work with government and opposition, meeting then-**Chancellor of the Exchequer, Nadhim Zahawi** in Downing Street on 25 August to discuss one of the key elements of the Life Sciences Vision, the **Life Sciences Scale-up Taskforce**, which recommended the launch of a UK Life Sciences Growth Scheme to secure capital commitments from institutional investors and stimulate growth fund creation in the UK, and the appointment of a 'Life Sciences Investment Envoy', with the remit and credibility to bring investors, companies, and government together. We met **Lord Kamall**, then-DHSC Innovation Minister, on 6 September to discuss BIA-government partnership working, including on access and pricing, international regulatory cooperation, clinical trials recovery and the importance of intellectual property in trade agreements.

We met Praful Nargund of the Labour Party's skills advisory council, which used the Advanced Therapies Apprenticeships Community (ATAC) as an exemplar in their skills report. Praful also joined the panel for our 'Growing innovative manufacturing through apprenticeships' fringe event at the Labour Party conference in Liverpool. We held a similar, equally very successful event at the Conservative Party conference where our panel was joined by Theresa Villiers MP and Aaron Bell MP. The undoubted stars of the show on both panels were the apprentices themselves who spoke compellingly about their experience. At both Party conferences, as well as running our own events, the BIA was represented at the Business Day events and met many Ministers, Shadow Ministers, MPs and other policy makers.

Life Sciences Council and other government/industry engagement

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.

After an 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 BIA was represented by Kit Erlebach, Chair of the BIA's Manufacturing Advisory Committee (MAC).

The LSC's **Business Environment Board** met on 28 July and heard an update on the MHRA's strategic priorities, as well as discussing the fiscal landscape for life sciences and the impact of the TRIPS waiver. The BIA's SME representative at this meeting was Melissa Strange, Vice-Chair of the BIA's Finance and Tax Advisory Committee (FTAC).

The **Accelerated Access Collaborative** (AAC) Steering Group met on 12 October to discuss the Medicines Pathway Programme and to receive an update and programme report from AAC CEO, Matt Whitty. This was the final meeting of the Steering Group, which will be replaced by five AAC Priority Coordination Groups to take a more project management approach to the five AAC priorities: embedding research; horizon scanning and demand signaling; uptake of proven innovations; building innovation capacity; and innovator support.

Finance, tax and investment

New Government's mini-Budget marks progress on key BIA campaign

Delivering his first statement as Chancellor of the Exchequer on 23 September, Kwasi Kwarteng said the UK enjoys an “unbound entrepreneurial culture” and “immense global presence in sectors like... life sciences”. He announced a raft of tax cuts and policy initiatives intended to boost economic growth.

A new £500 million Long-Term Investment for Technology & Science (LIFTS) competition will be established to catalyse investment from pension funds into venture capital (VC) funds to support scaling businesses. This will be complemented by accelerated changes to the charge cap for defined contribution pensions, which has been a barrier for pensions investing in VC funds. Both initiatives are the result of the BIA's work on the Life Sciences Scale-Up Taskforce, which Kwarteng chaired in 2021. BIA will now work with the British Business Bank, which has been tasked with developing the LIFTS competition.

Other welcome news for life sciences, following BIA calls, was the continuation of the Enterprise Investment Scheme (EIS) and Venture Capital Trusts (VCTs) beyond 2025, and more generous terms for the Seed Enterprise Investment Scheme (SEIS) to support investment in start-ups.

[BIA's blog contains a full analysis](#) and reaction to the announcement.

BIA secures key exemptions to protect sector in R&D tax relief changes

The BIA's Finance and Tax Advisory Committee ([FTAC](#)) has been working over the summer to influence new rules being introduced by HM Treasury and HMRC that are intended to “refocus R&D tax reliefs on innovation in the UK” by restricting claims on activity done overseas.

This resulted in [draft legislation](#) being published that included exemptions to the new rules where companies can prove that they could not conduct the R&D in the UK because the conditions were not present here. We have submitted a [detailed response](#) to the draft legislation, which we believe goes a long way to protect life sciences companies' claims, and had a further meeting with HMRC to discuss some of our key questions.

We are continuing to speak to HMRC and provide evidence collected from our members. FTAC member Richard Turner has [written a full update for BIA members on our blog](#).

BIA meets with Treasury officials to discuss including capex in R&D tax relief

In August, BIA met with Treasury officials to discuss [our submission](#) to the review of the UK's capital allowances regime, including providing R&D tax relief on capital expenditure so that loss-making companies can receive an incentive for capital investments. BIA's arguments were well received, and the Government is considering the policy as part of its wider R&D tax reliefs review, which is expected to conclude at the next fiscal event. It is not yet known when this will take place.

However, at the ‘mini-Budget’ on 23 September, the Government did announce that the Annual Investment Allowance will remain at £1 million permanently. This means businesses can deduct 100% of the costs of

qualifying plant and machinery up to £1 million in the first year, which is even more generous than the £500,000 [recommended by BIA](#).

Labour Party looks to boost UK start-ups

Labour's Shadow Chancellor Rachel Reeves [launched a review](#) to develop the Party's new strategy to support start-ups in the UK to reach their full potential.

The review is looking at issues such as access to patient capital, the incentives for growing businesses in the UK, the role of universities, and how to boost diversity among British founders and entrepreneurs.

BIA's [submission](#) commented on all of these areas but pushed for a radical approach to unlocking pension funds to invest in innovative sectors of the economy, including life sciences, and the maintenance and expansion of tax reliefs that benefit SMEs. BIA has also spoken to members of Labour's shadow business front bench team including Jonathan Reynolds MP, Lord McNicol and Seema Malhotra MP, as well as Leader of the Opposition in the Lords, Baroness Smith and Shadow Health Secretary Wes Streeting MP and Shadow Chancellor Rachel Reeves MP about how life sciences start-ups and scale-ups can be better supported.

BIA co-hosts 7th annual Future of Healthcare Investor Forum

Along with the London Stock Exchange, MedCity, Numis, Consilium and JP Morgan, BIA co-hosted the 7th annual Future of Healthcare Investor Forum on 4 October.

A mix of generalist and specialist investors and life sciences company representatives heard from leading figures of the industry about how the use of data, digital and AI are transforming drug discovery and healthcare delivery.

Sir Jonathan Symonds, Chairman of GSK and co-author of the Government's [Life Sciences Vision](#), delivered a keynote to open the conference and Stephen Lightfoot, Chair of the MHRA, delivered the end speech on how the regulator is accelerating patients' access to data and AI-led innovations.

Ahead of the conference, BIA CEO Steve Bates [spoke to the Stock Exchange's Head of Primary Markets about investment in the sector](#).

On 13 October, BIA hosted its own [TechBio UK 2022](#) conference focusing on data-driven discovery in life sciences.

Strategic technologies and areas of scientific focus

BIA publishes Genomics Nation 2022, showcasing a thriving UK genomics sector

On 27 July, BIA, Wellcome Sanger Institute and the Medicines Discovery Catapult published [Genomics Nation 2022](#), following on from last year's successful report, to showcase the strengths of the UK's genomics sector. The report describes a thriving genomics ecosystem made of young innovative companies who are particularly strong at attracting investment. Strong growth is predicted for the sector, and the report provides a useful reference for investors in both the private and public sectors, as well as for policy makers.

The 2022 report shows that 82% of genomics companies surveyed struggle to recruit the appropriate skills for their business. Computational science, data science, machine learning and artificial intelligence (AI) skills are the most difficult to recruit for. Respondents highlighted difficulties in recruiting international talent and breadth of experience. BIA is engaging with the Office for Life Sciences on skills and talent to address these skills challenges.

BIA hosts Genome UK workshop with the Office for Life Sciences and ABPI

In September, BIA co-hosted a workshop with the Office for Life Sciences (OLS) and the ABPI to seek industry feedback on the Government's '[Genome UK: the future of healthcare](#)' strategy implementation plan. 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 will be the first full three-year implementation plan since publication of the strategy.

The workshop was attended by six BIA members who discussed the skills needs of the sector. The feedback gathered in the workshop will be instrumental in forming an implementation plan that works for industry. A representative from the Medical Research Council also presented a new functional genomics initiative which the BIA provided feedback to in April.

The implementation plan is due to be published in the coming month. To find out more, please contact Senior Policy and Public Affairs Manager, [Dr Emma Lawrence](#).

TechBio Trusted Research Environment working group established

The BIA has convened a new working group to draw on expertise from its TechBio community. The group is sharing experience associated with accessing data in Trusted Research Environments (TRE), also known as Secure Data Environments (SDE).

The aim of the new group is to produce a paper setting out industry's position on the new TRE ecosystem that is arising as a result of the Government's [Data Saves Lives](#) strategy and to improve the public confidence in data sharing. BIA will be engaging with DHSC, the NHS and other data custodians to ensure that any new TREs are fit for purpose for innovators in the life sciences sector.

If you are interested in or would like to contribute to the group's activities, please contact Senior Policy and Public Affairs Manager, [Dr Emma Lawrence](#).

BIA hosts workshop with HRA on supporting data-driven innovation

In September, the BIA hosted a workshop with the Health Research Authority (HRA) to find out more about the work they are doing to support data-driven innovation. The workshop was attended by members of the BIA's TechBio community. Topics included the purpose of Research Ethics Committees (REC), Confidentiality Advisory Groups (CAG), and combined review.

The HRA introduced novel regulatory platforms to expedite AI or data-driven research, including the 'multi-agency advisory service', the 'innovation service' and the 'data decision tool'.

BIA members were able to share their feedback with the HRA representatives and we will continue to engage with them throughout their programme of work. To find out more, please contact Senior Policy and Public Affairs Manager, [Dr Emma Lawrence](#).

BIA joins Government workshop to explore opportunities for the UK's biotech-based industry

On 4 August, the Government Office of Science (GOS) organised a workshop to understand the opportunities for the UK's non-human-health life sciences and biotechnology sectors. Several BIA members attended the workshop to explore the opportunities and barriers for life sciences beyond human health within the UK.

The workshop brought industry together with key government stakeholders and academic experts to provide insights around policy, economic and regulatory aspects affecting the future success of the biotechnology-based industry in the UK. Discussions will feed into a final report which will inform policy recommendations to government in this area.

To get involved in the BIA's activities in biotechnology beyond human health, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA supports UAR to ensure access to animals for life sciences R&D

In October, the BIA co-signed a letter sent from Understanding Animal Research (UAR) to new Minister for Science and Investment Security, Nus Ghani MP, new Minister for Crime, Policing and Fire, Jeremy Quin MP, and new Parliamentary Under-Secretary for the Home Office, Lord Sharpe of Epsom.

In the letter, we reiterated that for the UK to continue as a major global player in life sciences, companies conducting R&D need to be able to access the animals needed to satisfy the strict regulatory requirements necessary to develop new medicines and treatments. The letter calls on the Government to support the protection of critically important research animal breeding facilities in the UK, so that life sciences R&D can continue to take place in line with regulatory requirements.

The BIA is a signatory of the [Concordat on Openness on the Use of Animals in Research](#), an agreement supported by a range of organisations that commits to being open about the use of animals in research in the UK. The BIA is also part of the [UK Bioscience Sector Coalition](#), which aims to represent the collective views of the bioscience sector with an interest in the use of animals in research, recognising that good science and good animal welfare go hand-in-hand. [Visit our website to learn more](#).

BIA meets with OPSS to discuss implementation of Nagoya Protocol in the UK

On 15 September, the BIA's Nagoya subcommittee to our Intellectual Property Advisory Committee ([IPAC](#)) met with the Office for Product Safety and Standards (OPSS) to discuss their approach to enforcing the [Nagoya Protocol \(Compliance\) Regulations 2015](#) in our sector. The meeting was the result of many months of effort to meet with OPSS to discuss our concerns over the scope of their enforcement activities after they wrote to many of our members.

As a result of the meeting, the BIA will continue to engage with members to collate evidence on the impacts of the Nagoya Protocol on our sector, and provide further information on how members can best engage with OPSS to ensure compliance with the regulations.

Also present at the meeting were representatives from the Department for Environment, Food and Rural Affairs (Defra) with whom we discussed our concerns over the likely inclusion of Digital Sequence Information (DSI) in an Access and Benefits Sharing (ABS) mechanism under the Nagoya Protocol. The BIA has been [opposing the inclusion of DSI under the Nagoya Protocol](#), but international discussions at the Convention on Biological Diversity (CBD) over the details of a multilateral ABS mechanism for DSI are progressing.

If you are impacted by the Nagoya Protocol or would like to learn more, please contact Policy and Public Affairs Manager, [Linda Bedenik](#).

People, skills and talent

BIA launches Women in Biotech mentoring programme for 2023

On 29 September, the BIA announced the launch of our pilot [Women in Biotech mentoring programme](#) at our sold-out Women in Biotech event held in Milton Park, Oxford. After an inclusive membership survey conducted earlier this year, followed by several focus groups, [the mentoring programme is now open](#) for expressions of interest from both mentors with experience across the sector, and mentees who may be in the early stages of their careers or at **C-suite level**.



BIA's new Women in Biotech mentoring programme was launched at the Women in Biotech regional event in Oxford.

With mentoring partnerships launching in early 2023, BIA are aiming to support and inspire incredible women in our sector by connecting them to the huge pool of experienced women in biotech leaders.

BIA showcases life science apprenticeships at the political party conferences

The BIA team attended both the Labour Party conference in Liverpool and the Conservative conference in Birmingham, delivering two exciting panels on life science apprenticeships and meeting with new ministers and other policy makers.

Our panels on 'Growing innovative manufacturing through apprenticeships' put apprentices themselves in the limelight as we heard about their own experiences and what more can be done to support this vital pathway into a rewarding job in the life science sector. By bringing in politicians, policymakers, and employers, we were able to have a wide-ranging discussion with BIA members and stakeholders who have the power to make a difference.

Increasing access to apprenticeships and ensuring SME participation was an issue with clear cross-party support. Praful Nargund, member of Keir Starmer's Council of Skills Advisors, celebrated the BIA's work on the [Advanced Therapies Apprenticeship Community \(ATAC\)](#) and called for further support to de-risk taking on apprentices for SMEs. In Birmingham, we heard Theresa Villiers MP speak about the contribution apprenticeships can make to levelling up and Aaron Bell MP on the importance of maintaining a skills pipeline into this high-growth industry.

A full write up of the events and BIA presence at the party conferences is available on the [BIA blog](#).

BIA link next generation healthcare leaders with industry experts

In September, University College London (UCL) launched the world's first business school dedicated to delivering the next generation of healthcare leaders and biotech entrepreneurs. The BIA collaborated with academics to link curriculum design to sector skills gaps, include industry speakers in curriculum content, and provide students with access to experienced mentors and healthcare leaders.



UCL launched its new Global Business School for Health in September 2022.

With innovative new postgraduate programmes, such as MSc's in Biotech & Pharma Management or Digital Health & Entrepreneurship, the new [UCL Global Business School for Health](#) was launched with an inaugural lecture delivered by Jeremy Hunt MP at the new UCL East Campus and was attended by new students, industry leaders, appointed Health Executives in residence, and external board members.

Life Sciences Future Skills Group recognised as key forum to address sector skills challenges

As a founding member of the Life Sciences Future Skills Group, the BIA has worked in partnership with the Office for Life Sciences, the Science Industry Partnership and ABPI to deliver key skills and talent themes detailed in the [Life Sciences Future Skills 2030 Strategy](#). Due to the excellent work carried out by member organisations across the themes of Global Operating Environment, Apprenticeship & Technical Education, Integrated Skills, and Attraction & Perception of the sector, the Future Skills Group has now been recognised as the place for industry and government to come together to address skills challenges, chaired by Jacqui Hall, AstraZeneca, and with formal governance through the Life Sciences Vision.

Intellectual property and technology transfer

BIA opposes proposed extension of COVID-19 TRIPS waiver

Over the summer, the BIA met with the Department for International Trade (DIT) on the proposed extension of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver to COVID-19 therapeutics and diagnostics. The proposal for extension was part of the [agreement of a waiver for COVID-19 vaccines](#) at the 12th WTO Ministerial Conference in July.

The proposed extension has caused great concern in the UK and global life sciences and biotech sectors, as it would discourage critical private sector investment, innovative efforts, and collaboration, particularly in smaller companies.

In a meeting with DIT and further submission of written evidence, the BIA reiterated how waiving Intellectual Property (IP) rights would inhibit the development of COVID-19 therapeutics and diagnostics and those for future pandemics. Moreover, with the majority of COVID-19 therapeutics being repurposed, an IP waiver could impact the development and manufacture of therapeutics intended for many other disease areas and would go far beyond waiving IP rights for COVID-19 products only.

The BIA continues to advocate for the crucial role of intellectual property in our sector. To stay up to date with the BIA's IP activities, members can [sign up to the BIA's IP Policy Newsletter](#).

BIA meets UKIPO in second bilateral to discuss AI & IP

On 15 July, the BIA held its second bilateral meeting of the year with the UK Intellectual Property Office (IPO) to discuss ongoing [international talks towards substantial patent law harmonisation](#) and the [Government's response to the AI & IP consultation](#) to which the BIA [responded to earlier in the year](#). On the latter, attendees discussed the details of a new Text and Data Mining exception to be introduced which will allow lawful users to text/data mine copyright works and databases, as well as the Government's decision to seek close international collaboration before making any legal changes to AI patentability in the UK.

The meeting also touched upon ongoing talks at the World Intellectual Property Organisation (WIPO) Intergovernmental Conference (IGC) on the potential inclusion of a mandatory disclosure requirement for the source of genetic resources in patent applications. While these talks have been ongoing for many years, they have now gained momentum. The BIA will continue to engage with the IPO to advocate the vital role of intellectual property rights in the sector.

BIA meets with FCDO to discuss draft benefits sharing agreement for marine genetic resources

In August, the Nagoya subcommittee of our Intellectual Property Advisory Committee ([IPAC](#)) met with the Foreign, Commonwealth and Development Office (FCDO) to discuss the draft text of a legally binding international instrument under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction. Similar to the international discussions ongoing at the Convention of Biological Diversity (CBD), the draft text suggested the introduction of a type of access and benefits sharing agreement for marine genetic resources beyond national jurisdiction and Digital Sequence Information (DSI) thereof.

While the BIA fully supports the need to protect biodiversity and understand that there is an international desire for access and benefits sharing on marine genetic resources, we raised concerns over the current draft of the agreement, which could create significant barriers to commercial R&D into marine genetic resources in areas beyond national jurisdiction, and runs the risk that lessons have not been learned from the practical experience of access and benefits sharing agreements over genetic resources under the Nagoya Protocol.

As international negotiations resume in the coming months, the BIA will continue to work with the FCDO to represent industry views. If you have any concerns about this agreement, please get in touch with Policy and Public Affairs Manager, [Linda Bedenik](#).

Manufacturing

BIA Manufacturing Advisory Committee leadership programme grows

The BIA Manufacturing Advisory Committee Leadership Programme ([BIA MAC LeaP](#)) has engaged almost 100 next generation leaders from 36 organisations since 2017. It has continued to evolve through restarting site visits, the recent development of a member directory, and further establishment of an alumni network chaired by ex-LeaPer Will Milligan, CEO of Extracellular. The alumni network will support the development and training of future leaders in the vaccine, biopharmaceutical and cell & gene therapy industries through cross-sector learning, site visits and peer networks.



MAC LeaP cohorts 5a and 5b at their September meetings, visiting the Oxford Biomedica and ThermoFisher Scientific sites respectively.

This popular 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 2023. If you feel your organisation is eligible to join and would benefit from this leadership development programme, please contact Bioprocessing Consultant, [Netty England](#) for further details.

Thank you and good night – BIA’s Expert Advisory Group formally closes

Following the formal closure of the UK government’s COVID-19 Vaccine Taskforce (VTF) at the end of September with its responsibilities, team and budget now split between the Office for Life Sciences in BEIS and the UK Health Security Agency, the BIA’s Expert Advisory Group that advised and guided the VTF also met for the last time after over two and a half years of working in various formats.

The group first mobilised back in February 2020 as the BIA Vaccine Manufacturing Taskforce, led by Ian McCubbin CBE, to support potential vaccine and antibody candidates, assess supply chains, and understand what was required to scale and rapidly deploy vaccines. This work expedited the manufacture of the COVID-19 frontrunners to quickly deliver vaccines to patients and save lives.

As these projects moved from advice to multi-million-pound contracts, there was a natural stepping-off point for the BIA from the point of delivery to coordination. In July 2020, we handed over the delivery baton to the Government’s VTF, under the leadership of Dame Kate Bingham, who successfully delivered an approved vaccine and UK immunisation programme ahead of any other country in the world.

The VTF continued seamlessly to utilise industry expertise through the newly formed and streamlined BIA Expert Advisory Group, chaired initially again by Ian McCubbin CBE and then followed by Steve Bagshaw CBE. This group continued to assist with the manufacture of emerging vaccines and antibodies against COVID-19, as well as helping to develop a strategy for a national capability for manufacturing and vaccine formulation and delivery and supporting manufacturing onshoring. The group made the case to policy makers that investment in manufacturing will be fundamental in delivering economic growth, highly skilled and well-paid jobs and, most crucially, enhancing our world leading capability here in the UK to tackle future pandemics.

Industry, academia and government from all corners of the UK have contributed their expertise and resources over the years, with unreserved readiness to collaborate, often with competitors, and the BIA would like to thank each and every one of them for undoubtedly saving many lives.

Medicines regulation

BIA responds to DHSC consultation on the future strategy for batch testing in Great Britain

On 26 July, the BIA [responded to the DHSC consultation](#) on the long-term future for batch testing of medicines, the result of which will be announced by the Government by the end of 2022.

The consolidated BIA response was developed with input from our Regulatory Affairs Advisory Committee ([RAAC](#)). We provided BIA members' feedback on the four [policy options proposed in the consultation](#) with regards to medicines imported from a third country with which the UK does not have a mutual recognition agreement on batch testing. The BIA's preferred policy option was for there to be no import testing or UK Qualified Person certification or release for medicines imported from countries on the approved list because this option will have a favourable impact on the continued supply of, and patient access to, medicines.

It is important that the consultation outcome supports the ambitions of the [Life Sciences Vision](#) and ensures that the UK retains and grows its reputation as a world-leading base for innovation and investment in R&D, while protecting patient safety and access to medicines and maintaining globally harmonised standards.

BIA welcomes the European Commission Decision Reliance Procedure extension by MHRA

The BIA welcomes the one-year extension of the European Commission Decision Reliance Procedure (EC DRP) until 31 December 2023, which was announced by the Medicines and Healthcare products Regulatory Agency (MHRA) on 30 September. This regulatory route, which was introduced for two years in January 2021 after the UK left the European Union, allows biopharmaceutical companies to apply for Great Britain marketing authorisation of medicines granted an EU marketing authorisation via the centralised procedure.

The removal of the cliff edge in December 2022 will benefit both UK patients and life sciences companies and allow continued timely access to new, innovative medicines.

We look forward to continuing the positive dialogue and engagement with MHRA to develop proposals for a new international reliance framework which will replace the EC DRP from January 2024. Reliance-based regulatory procedures can be utilised across all stages of the product lifecycle. The COVID-19 pandemic has stressed the importance of reliance to address the significant workloads of regulators as well as the urgent need to deliver new and established treatments for patients globally.

The BIA's [Reflection Paper on the role and value of reliance in the UK medicines regulatory framework](#), published in June 2022, will make a useful contribution to our discussions. For more information, please contact Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

MHRA consults on proposals to increase statutory fees

On 31 August, the MHRA launched a [consultation on proposals for changes to its statutory fees](#). The proposals fall into three categories: a 10% indexation uplift across statutory fees; a further uplift for 61

significantly under-recovering fees to achieve cost recovery, including daily inspection rates, variations, and medical devices; and the introduction of 22 new fees for services that require cost recovery since the last fee changes for medicines and medical devices, which includes new fees for ILAP, specifically for scientific advice for the Innovation Passport and the Target Development Profile, among other.

We are working with [RAAC](#) and [other BIA committees](#) to provide a consolidated BIA response to the consultation. If members would like to contribute to the BIA submission, please contact Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

Retained EU Law (Revocation and Reform) Bill introduced to Parliament

On 22 September, the [Retained EU Law \(Revocation and Reform\) Bill](#) was published and introduced to Parliament, together with a [written statement from the Secretary of State for BEIS](#), Jacob Rees-Mogg. Retained EU law is the category of domestic law created at the end of the transition period of the UK leaving the EU, and consists of EU-derived legislation that was preserved in the UK domestic legal framework by the European Union (Withdrawal) Act 2018 to ensure continuity as the UK left the EU.

The DHSC is reviewing all retained EU law relevant to our sector to identify opportunities for reform so that legislation is no longer retained EU law, or where it should be preserved in the UK's domestic legal system. Any retained EU law that the Government does not wish to preserve will expire on 31 December 2023.

The DHSC has advised that industry does not need to make any changes as a result of the Bill's publication, however, the BIA will track the passing of the Bill through Parliament and keep members updated on the changes ahead.

Access to medicines

BIA engages with NICE on their subscription-style model for antimicrobial drugs

Following the [launch](#) of the National Institute for Health and Care Excellence (NICE)'s [pilot project for a subscription-style payment model for antimicrobials](#) in April, BIA has engaged with NICE as it develops routine arrangements for the evaluation and purchase of antimicrobials. The pilot project was developed to try to address the lack of new antimicrobials being developed and the growing threat posed by antimicrobial resistance (AMR). During the pilot, NICE tested a new evaluation process and payment model for two antimicrobial drugs. Under this model, the payments made to companies are based on the value of their product to the NHS and are not linked to the volumes sold.

NICE and its partners are now working with stakeholders to review the approach taken in the pilot project and develop routine arrangements. In August, BIA attended a workshop to discuss lessons learned from the project and consider how the model could work on a larger scale. BIA highlighted the work of UK-based innovative biotech companies in developing novel antimicrobials and the need for ongoing horizon scanning of the pipeline.

BIA looks forward to continuing to engage with NICE as it develops draft evaluation and commercial frameworks. For more information, please contact Policy and Public Affairs Manager, [Rosie Lindup](#).

BIA supports efforts to improve the route to adoption of cell and gene therapies in the UK

Following the launch of the Cell and Gene Therapy Catapult's [National Cell and Gene Therapy Vision for the UK](#) in March, the BIA has been supporting the Catapult in its efforts to maintain the UK's position as a leader in the development and adoption of cell and gene therapies. The Catapult's vision document provided an overview of potential barriers to the approval and delivery of cell and gene therapies and the UK, and recommended a series of actions to address them, including around health technology assessment, innovative payment models, and improved collection of data.

In September, the BIA attended a roundtable organised by the Catapult which brought together senior representatives from industry to discuss how to further improve the UK's position on cell and gene therapies. Attendees discussed how stakeholders can work together to ensure that patients can access these transformative treatments.

The BIA will continue to support the Catapult in calling on the Government to take action to ensure that the UK can retain its leading role in the development of cell and gene therapies and deliver these life-changing therapies to patients. To learn more, please contact 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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