

**Influencing and shaping our
sector – BIA update
July – October 2021**



Introduction

The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from July to October 2021.

There's no such thing as a quiet summer for the BIA. In Q3, seminal reports on the UK's genomics sector and the public's attitude to rare disease medicines were published, as was the latest investment update, showing the sector continues to attract record sums. We also launched a report highlighting the importance of continuing government fiscal support for the sector ahead of the Spending Review due on 27 October.

The Life Sciences Scale-Up Taskforce, announced as part of the Life Sciences Vision in Q2, was established to increase UK investors' participation in the sector and had its first meeting with the Secretary of State for Business. The team delivered a triumphant Parliament Day, in which over 30 BIA members participated in 24 influencing meetings, including with two ministers and 13 MPs. Rounding off the summer, Steve Bates appeared on the main stage at the Conservative Party Conference in Manchester to talk about the success of scaling-up COVID-19 vaccine manufacturing in the UK. Read on for more details on these activities and much more that the BIA delivered in Q3.

This quarter in numbers:



28+ influence meetings with 14+ different MPs, Peers and MEPs, including 3 Ministers



6 consultation responses and briefings submitted



7 letters to Ministers

Contents

BIA engagement with the Government and Parliament on life sciences policy	4
Finance, tax and investment	6
UK biotech sector enjoys record year of investment	6
Sector celebrated at the London Stock Exchange	6
Strategic technologies and areas of scientific focus	7
BIA calls on Government to improve implementation of the Nagoya Protocol and not extend it to DSI	8
People, skills and talent	9
BIA outlines strengths and weaknesses in current visa routes	9
BIA co-founds group to promote equality, diversity & inclusion for the medicines manufacturing sector	9
New skills proposals championed by cross-industry coalition	9
Intellectual property and technology transfer	10
The UK moves a step closer to greater IP protections for AI inventions following BIA input	10
Pre-clinical and clinical research	11
BIA input to Clinical Trials Legislation Expert Working Group	11
Manufacturing	12
BIA manufacturing community celebrates vaccine success	12
Medicines regulation	13
BIA responds to the Early Access to Medicines Scheme consultation	13
BIA ILAP Working Group established	13
BIA continues engagement with government on Northern Ireland Protocol implementation	13
Access to medicines	15
BIA engages in final phase of the NICE Methods Review	15
Chair of NICE meets RDIG members	15

BIA engagement with the Government and Parliament on life sciences policy

The Government's [Life Sciences Vision](#) was published in July with the endorsement of the Prime Minister, the Secretaries of State for Health and Business, the NHS and industry. The Vision, which is the first of five sectoral visions to be completed is the product of an intensive and productive collaboration by government, industry and the health service. Delivery plans to achieve the Vision have been fed into the forthcoming Comprehensive Spending Review.

One of the key deliverables for the from the Vision for our members will be the report of the **Life Sciences Scale-up Taskforce** which has been established by BEIS Secretary of State, Kwasi Kwarteng, following a proposal by the BIA. The taskforce will follow the model of the Life Sciences Vision External Advisory Group, with a high-level group of UK-based financial institutions (including Legal & General and BC&E, which runs The People's Pension), Government and life sciences organisations coming together with an ambitious goal of producing a plan by the end of 2021 to unlock capital from institutional investors, such as pension funds.

The first meeting of the Scale-up Taskforce, which is chaired by Kwasi Kwarteng, was held on 15 September and agreed to establish a number of work streams. Steve Bates, jointly with Miles Celic of TheCityUK and Nigel Wilson of Legal & General, is leading a work programme tackling the barriers to institutional investors and the UK's scale up risk capital gap. The Taskforce will have two further meetings in Q4 before reporting to the Secretary of State in December.

The **Life Sciences COVID-19 Response Group** (CRG) began its collaborative work as a Ministerial virtual meeting with industry, led jointly by Department of Health and Social Care (DHSC) Life Sciences Minister, Lord Bethell and Department for Business, Energy and Industrial Strategy (BEIS)/DHSC Vaccines Minister, Nadhim Zahawi meeting weekly at the outset of the pandemic before moving to monthly meetings. With both the Ministers having moved on from their roles and the initial critical phase having passed, the CRG will no longer meet regularly but will be convened on an ad hoc basis in future. In the year and a half of its existence, the CRG has been an invaluable forum. The final meeting in the old format was held on 21 July.

Following 2020's fully virtual **Parliament Day** this year's event on 8 September saw us return to the Palace of Westminster for a lunch reception in the House of Commons hosted by Anthony Browne the MP for South Cambridgeshire at which [the BIA's report](#) ahead of the 2021 **Comprehensive Spending Review** was launched. The day was a hybrid of in-person and virtual meetings with 35 members in 24 meetings with two Ministers, 13 MPs and 21 officials.

In the Government **reshuffle** in September there were changes at two of our key departments, with Lord Bethell being replaced as Minister for Innovation at DHSC by former MEP Lord Kamall. Also at Health, Maggie Throup Minister for Prevention, Public Health and Primary Care was given responsibility for overseeing vaccine deployment, with Gillian Keegan Minister of State for Care overseeing the COVID-19 test and trace programme in the newly established Joint Biosecurity Centre.

Nadhim Zahawi, the Vaccines Minister, received a well-earned promotion to the Cabinet as Secretary of State for Education. There was no direct replacement for his role, across BEIS and DHSC, which was appropriate to the earlier stage of COVID-19, providing useful join-up and acknowledging the importance of industry in the pandemic response. Lee Rowley has become BEIS Minister for Business and Industry, with responsibility for the Vaccines Task Force and Life Sciences. Amanda Solloway has been replaced by George Freeman as Minister for Science, Research and Innovation. Freeman is experienced in this sector having previously acted as Parliamentary Under-Secretary of State for Life Sciences (2014-2016). The BIA

had an introductory meeting with Lord Kamall on 6 October and George Freeman will speak at the Bioscience Forum on 14 October.

Steve Bates spoke on the main stage at the **Conservative Party Conference** in Manchester during a panel discussion of the Vaccines Taskforce, joined by Nadhim Zahawi MP, Maggie Throup MP and Professor Anthony Harnden of the University of Oxford.

The **Global Opportunities Board** (GOB) (formerly the EU Relationship Group – EURG) met on 22 July for an update from Health Minister Ed Argar on the Northern Ireland Protocol Command Paper and on 20 September, when there was an opportunity for Cabinet Office Minister Lord Frost (who leads the UK’s negotiations with the European Commission) to hear the concerns of the life sciences industry about the future relationship with the EU and in particular the operation of the Northern Ireland Protocol. The meeting also heard from the Department for International Trade about the role of international trade in delivery of the Life Sciences Vision.

The **Innovation Research and Data Expert Group** (IRDG) met on 22 July to discuss the data, genomics and innovation elements of the Life Sciences Vision and the data landscape for research in the UK. Following the meeting, Chris Molloy who represents the BIA on IRDG wrote to Catherine Pollard, Director of Centre for Improving Data Collaboration, NHSX with further industry input on the Life Science Vision (Health Data).

The **Accelerated Access Collaborative (AAC) Steering Group** met on 6 September to discuss Rapid Uptake Products and early stage support for ATMPs as well as receiving programme updates.

The BIA has continued to support our representatives from the Rare Disease Industry Group (RDIG) on the **NICE Methods Review** Working Group and task and finish groups and has responded to the latest consultation, with a call to rediscover the ambition of the original Case for Change.

Finance, tax and investment

Becoming a life sciences superpower: BIA launches report ahead of 2021 Spending Review

With the Chancellor having announced that he is conducting a three-year Spending Review, which will conclude on 27 October alongside the Budget, the BIA has launched a report with key recommendations for HM Treasury to support and bolster the life sciences sector. [*Becoming a life sciences superpower*](#) was launched by Anthony Browne MP at Parliament Day and focuses on four key recommendations: increasing the budget of Innovate UK; refilling the Biomedical Catalyst on a long-term basis; expanding research and development (R&D) tax credits; and supporting the British Business Bank to address the scale-up challenge in the sector and deliver cross-government support for the Life Sciences Scale-Up Taskforce. The report was also discussed with ministers, MPs and representatives from HM Treasury at Parliament Day.

The BIA has formally responded to HM Treasury's Spending Review consultation with these recommendations and others to best support the life sciences sector, encourage innovation and boost R&D investment. On 1 October, the BIA met with the Director of Growth Strategy at HM Treasury to discuss the submission.

UK biotech sector enjoys record year of investment

A record £3 billion has been raised by the UK biotech and life science sector in the first three quarters of 2021, according to new data released on 11 October by the BIA and Clarivate.

With £576m raised between June and the end of August, fundraising in 2021 has already surpassed the previous record year of 2020, when £2.8 billion was raised, with another three months of the year left to go. The figures received coverage in the Financial Times and the trade press.

The breakdown of investments from June to August 2021 was:

- £ 429m was raised in venture capital by UK biotech and life science companies
- £70m was raised through market launches, including a £20m listing of Arecor on AIM
- £78m was raised in follow-on financing

Sector celebrated at the London Stock Exchange

The BIA once again supported the London Stock Exchange's flagship life sciences event, *The Future of Healthcare Investor Forum*, on 12 October.

Generalist and specialist investors, and life science companies, heard keynote speeches from the Secretary of State for Business, Kwasi Kwarteng MP, and the former Chair of the UK Vaccines Taskforce, Dame Kate Bingham, who praised the BIA's work during the pandemic. Panel discussions also gave insight into the next generation of healthcare technologies, lessons learned from the pandemic and what the future holds for the sector.

Strategic technologies and areas of scientific focus

BIA publishes report on the UK's thriving genomics sector

On the 30 July, the BIA, Wellcome Sanger Institute and the Medicines Discovery Catapult published [Genomics Nation](#), a report showcasing the strengths and opportunities in the UK's genomics sector for investors, patients and the UK economy. The report describes a thriving genomics ecosystem, underpinned by world-leading institutes and a healthy investor base. Strong growth is predicted in the sector, and the report provides a useful reference for investors in both the private and public sectors, as well as policy makers.

The BIA will be presenting findings from the report to the Government's National Genomics Board on 13 October and will continue to work with ministers and officials to make the UK the most attractive location for genomic start-ups and SMEs.

Definition of Synthetic Biology published as part of the National Security and Investment Act

Ahead of the National Security and Investment Act coming into force on 4 January 2022, the Government has [now published the sector definition of Synthetic Biology in secondary legislation](#). The BIA had discussed the wording of this version of the definition with civil servants, raising concerns about the exemption included and the impact this would have on biotechs. While civil servants have indicated they understand the concerns of the sector, the Government is proceeding with this approach. The BIA is continuing to press the Department for Business, Energy and Industrial Strategy (BEIS) to clarify the issues with the definition and provide more advice in the guidance it is developing to accompany the sector definition.

BEIS also held a consultation on the draft statement on the Secretary of State's use of the call-in powers, to which the BIA responded with feedback from members and advisory committees. The BIA used this consultation as an opportunity to put on record the concerns associated with the Synthetic Biology sector definition. Further guidance to complement the legislation has also been published by BEIS, on which the BIA was consulted through the Expert Panel set up for the NSI regime. The BIA is also hosting a webinar for members on 18 October to help them understand the regime and how it applies to life sciences.

Building the BIA's Health data, Digital and AI policy presence

The BIA has begun mapping the policy landscape for health data, digital and AI, all of which are becoming increasingly prevalent throughout the life sciences sector, and the BIA is exploring and showcasing these as a sub-sector in its own right. Through a series of meetings with external stakeholders, including Health Data Research UK (HDRUK), the Health Research Authority (HRA), Association of Medical Research Charities (AMRC) and NHSX, the BIA is linking with an already influential network. This effort builds on existing work to compile our new paper *Tech Bio: How data driven life science companies are transforming drug discovery and patient care* which will be published on 14 October.

The work also includes exploring the sector's interests in key government consultations: [Data: A new direction](#), The MHRA's [Software and AI as a Medical Device](#) and the NHSX [National Strategy for AI in Health and Social Care](#).

BIA calls on Government to improve implementation of the Nagoya Protocol and not extend it to DSI

The BIA has continued to engage with the Department for Environment, Food and Rural Affairs (Defra) to call for improved guidance for how the [Access and Benefit Sharing \(ABS\) Regulation](#) and [Nagoya Protocol](#) apply in the UK. The BIA has also been in discussions with the Office of Product Safety and Standards (OPSS), which enforces the Nagoya Protocol, on how they are currently interpreting and implementing the Regulation. The BIA is concerned about inconsistencies and encourages members to get in touch if they have any interactions with the OPSS.

The BIA's ABS and Nagoya sub-committee also attended a Defra workshop on 11 August, in which officials shared details of the Government's approach to the potential inclusion of Digital Sequence Information (DSI) in an international Access and Benefit Sharing mechanism, such as the Nagoya Protocol. It was clear to the sub-committee that the Defra was proceeding on the basis that DSI should fall into the Convention on Biological Diversity (CBD), and on 23 August the UK delegation to the CBD made a statement that 'the UK recognises that where benefits arise, they should be shared fairly and equitably'. In light of the statement, the BIA will be engaging with senior officials to understand the Government's intentions and to express the strong concern of the industry.

People, skills and talent

BIA outlines strengths and weaknesses in current visa routes

The BIA has continued to expand its work championing the importance the UKs immigration system to allow the free flow of highly skilled talent globally. In meetings and a follow-up letter submitted to UK Research and Innovation (UKRI), the BIA and its members have provided evidence to UKRI and the Office for Life Sciences (OLS) on the functioning of current visa routes. This included benefits seen to changes in the salary threshold and qualification level required for the [Skilled Worker visa](#) enabling sponsorship of research and manufacturing talent in short supply within the UK. However, the BIA also said that the shortage occupation list is outdated and inflexible and industry barriers include considerable cost and time taken to gain company sponsors licences and individual visas. Industry engagement with the Highly Skilled Worker Route is minimal, with almost no member companies using [Global Talent visa](#), [Innovator visa](#) or [Start-up visa](#). The Global Talent Visa is currently targeted at academic researchers and must focus on an efficient and effective route of highly skilled industry talent to increase attractiveness of the UK to international talent. Feedback from BIA members is that this should include clearly articulated highly skilled talent visa routes for PhD students and post-doctoral researchers transferring from academia to industry increasing the porosity of skills across the industry academic interface. The BIA has also raised concerns with OLS on the criteria for a new Scale-Up Visa, announced in the Innovation Strategy.

BIA co-founds group to promote equality, diversity & inclusion for the medicines manufacturing sector

In Q1 2021 BIA contributed to the APPG inquiry into [Equity in the STEM Workforce](#), the final report of which was [published](#) in July, highlighting widespread inequity, with barriers for every minoritized group along career pathways. The BIA is now a founding member of the Equality, Diversity & Inclusion (EDI) for the Medicines Manufacturing sector, which launched this quarter as a small group of subject matter experts and representatives from the pharmaceutical and digital health sectors reviewing the common challenges within EDI, and to identify initiatives for collective action and collaboration. The current focus is addressing the absence of data for an EDI evidence base across the biotech sector which impacts the direction of future actions and learning from experts from outside our sector.

New skills proposals championed by cross-industry coalition

The BIA has worked with industry and government partners to support funding for education and skills programmes to attract new talent, as well as upskill those within the sector, as the UK does not have enough trained and skilled people to fill the roles anticipated and there are structural problems that need to be addressed. The [Life Sciences Future Skills](#) group, of which BIA is a key member, forecasted the potential to create 133,000 new jobs by 2030 covering informatics, translational, genomics and specialised manufacturing skills and the [Advanced Therapies](#) manufacturing sector forecasted skills demand within their industry to at least double by 2024. The BIA supported spending review and funding proposals across the sector which centre on addressing the skills challenges by developing and delivering key targeted talent solutions including Advanced Therapies Manufacturing Skills programmes, Life Sciences Emerging Skills Demand proposal and a focus on supporting Apprenticeships for SMEs.

Intellectual property and technology transfer

The UK moves a step closer to greater IP protections for AI inventions following BIA input

On 23 March, the Government published its response to its [call for views on artificial intelligence and intellectual property](#). This was an important consultation looking at a range of issues, but most significantly for the life sciences sector, it asked if inventions derived from artificial intelligence (AI) machines should be afforded the same protections as human inventions. In [the BIA's submission to the consultation](#), we outlined the growing importance of AI in life sciences and the need to offer the same protection to inventions generated through the use of AI as is offered to human-generated inventions.

Overall, the BIA welcomed the outcome of the consultation. Many of the views submitted by other respondents were aligned with those of the BIA, and some common themes are starting to emerge. This has enabled the Government to make some constructive follow-up plans to delve deeper into specific aspects of the UK's IP laws and their operation in the context of AI, paving the way for positive change. As part of this, the BIA's AI and IP sub-committee attended a roundtable organised by the Intellectual Property Office to discuss how some of the proposals in the Government's response could be implemented in practice. For more information, please [read the BIA blog](#).

Pre-clinical and clinical research

BIA input to Clinical Trials Legislation Expert Working Group

The BIA is participating by invitation in an Expert Working Group to provide the MHRA with advice and input on potential changes to the legislation for clinical trials (The Medicines for Human Use (Clinical Trials) Regulations 2004) before the public consultation is launched later this year.

The current UK clinical trials legislation will be reviewed to:

- remove obstacles to innovation
- streamline requirements
- identify areas where alignment with EU legislation is in the UK's best interest
- ensure legislation builds international interoperability, and
- promote public health and ensure protection of trial participants.

The legislative proposals will be in line with the [Government's vision for clinical research](#). The Working Group will also discuss where guidance is more appropriate and where cultural/behavioural change may be needed to support implementation of the proposals.

Manufacturing

BIA manufacturing community celebrates vaccine success

In September, several members of the BIA's manufacturing community were proud to join a dinner at Exeter College, Oxford University, hosted by Dr Sandy Douglas, to celebrate the work done to develop, scale & manufacture the Oxford-AstraZeneca COVID-19 vaccine.

In February last year, the BIA convened a COVID-19 Vaccine Manufacturing Taskforce, chaired by Ian McCubbin CBE, which supported the Oxford vaccine, working alongside Dr Sandy Douglas and Professor Cath Green OBE of Oxford.

Pall Biotech, Fujifilm Diosynth Biotechnologies, Cobra Biologics, Cell and Gene Therapy Catapult, the Vaccines Manufacturing Innovation Centre (VMIC), Oxford Biomedica and others rallied together to develop rapid scale up of Oxford's vaccine, which critically gave AstraZeneca a head start when they partnered with Oxford. The dinner recognised the importance of this early, collaborative work by the BIA community in the rapid deployment of the vaccine once it was approved, saving many lives.



Members of the BIA's manufacturing community join a dinner at Exeter College, Oxford University, to celebrate the successful scale-up of the Oxford-AstraZeneca COVID-19 vaccine.

Medicines regulation

BIA responds to the Early Access to Medicines Scheme consultation

In September, the BIA responded to the [consultation on The UK Early Access to Medicines Scheme \(EAMS\)](#). The legislative proposals are designed to ensure that EAMS remains relevant and attractive following the UK's exit from the EU, and that patients in the UK can access cutting-edge therapies in advance of licensing decisions where there is an unmet clinical need.

The BIA supported the proposed legislative changes as they will provide a clearer legal basis and improve regulatory certainty for companies as regards the status of the scheme, which was originally launched in April 2014. Reducing the burden for EAMS medicines supply and simplifying the requirements for data collection would be welcome. To incentivise industry's participation in the EAMS, the BIA recommended that consideration be given to developing a coherent framework for innovative methods of treatment to be made available and reimbursed for effective adoption in the NHS. The BIA's response is available via [this link](#).

BIA ILAP Working Group established

The BIA has brought together member companies from its Regulatory Affairs Advisory Committee and Rare Disease Industry Group to form a working group on the Innovative Licensing and Access Pathway (ILAP). These companies have either been awarded, or are applying for, an innovation passport designation – the entry point to the ILAP.

Innovation Passport holders, the MHRA and partner organisations NICE, the Scottish Medicines Consortium (SMC) and the All Wales Therapeutics and Toxicology Centre (AWTTC) will then work together to create a product-specific Target Development Profile which will define key regulatory and development features and create a roadmap for delivering early patient access to innovative medicines. Supporting partners include NHS England and NHS Improvement, Health Research Authority (HRA) and the National Institute for Health Research (NIHR). Guidance on the [Innovative Licensing and Access Pathway](#) is available on the MHRA website.

In October, the BIA and member company representatives are meeting with the MHRA and partner organisations to give feedback on experiences of the ILAP process and ensure the success of this UK flagship initiative to make the UK attractive to R&D companies post-Brexit by making the regulatory process as attractive and innovation-embracing as possible.

BIA continues engagement with government on Northern Ireland Protocol implementation

The BIA has continued to engage with the Government to address ongoing challenges for medicines regulation and supply of medicines from Great Britain to Northern Ireland. A sustainable and long-term solution is required for Northern Ireland's Brexit issues to ensure patients get access to the medicines they need.

The Government set out its position in the July [Northern Ireland Protocol Command Paper](#), stating that its preferred option is to take medicines outside the scope of the Protocol. The Health Department and the MHRA recognise the importance of maintaining supply to Northern Ireland and are working jointly to find a way forward. Subsequently the Government announced in its 6 September [Written Ministerial Statement](#) that it would continue to operate the Protocol on its current basis, with the existing arrangements to

continue and giving reasonable notice if any of these arrangements were to change. This means the grace periods and easements for medicines were extended.

We understand that the European Commission would present “comprehensive proposals” to UK Government to solve the outstanding issues.

Access to medicines

BIA engages in final phase of the NICE Methods Review

In August, the NICE Methods Review advanced into its final phase with the launch of the [final consultation](#) of the Review. This consultation focuses on the proposals for change to NICE's methods, processes and topic selection for health technology evaluation. Along with papers describing the key proposals for change, NICE has also made available a draft of the full updated manual to allow for a clear picture of how the proposals fit together.

Having responded to the [two previous consultations](#) on the case for change to NICE's health technology evaluation methods and on NICE's processes, the BIA is working with the BIA Rare Disease Industry Group (RDIG) and other members to develop a response to this final consultation.

The response will welcome some of the positive proposals whilst emphasising that the proposals do not go far enough to meet the level ambition set out at the start of the Review, nor that promised in the Life Sciences Vision. In particular, it will focus on the limited effect that the current proposals will have in addressing the barriers faced by treatments for rare and ultra-rare disease treatments in the evaluation process.

This consultation will be the last opportunity to influence the final outputs of the Review and represents the culmination of two years of hard work by NICE and stakeholders, including members, who have represented the BIA on the Working Group and two Task and Finish Groups.

The BIA has been working closely with the ABPI and EMIG to ensure aligned messaging in our respective responses and we will seek continued engagement with NICE through the implementation process and during forthcoming modular updates.

Chair of NICE meets RDIG members

In September, the General Managers of the BIA's RDIG held a roundtable with the Chair of NICE, Sharmila Nebhrajani. The event provided a valuable opportunity for members to hear how NICE is evolving to ensure access to medicines for people with rare diseases. Members were eager to discuss the extent to which the NICE Methods Review will secure improved access and to understand how access challenges that lie beyond the scope of the Review will be addressed by NICE. Attendees also discussed NICE's relationship with the MHRA as well as NICE's role in delivering the Life Sciences Vision.

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.

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 0207 630 2194 or mmcgivern@bioindustry.org

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