Influencing and shaping our sector – BIA update January – April 2021

UK BioIndustry Association

Influence, connect, save

www.bioindustry.org

Introduction

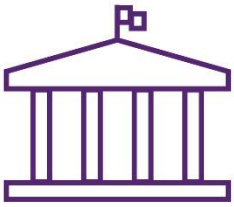
The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the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

As the COVID-19 vaccine rollout has continued at pace throughout the quarter, the BIA has worked with Ministers via the Life Sciences COVID-19 Response Group, and with the Government's Vaccine Taskforce via the BIA Expert Advisory Group, on the UK vaccine supply chains and future opportunities for UK manufacturing. As variants of the virus started to emerge, the BIA organised an Industry Forum on COVID-19 vaccine regulation, which led to the MHRA publishing new guidance on strain changes in authorised COVID-19 vaccines to fast-track approvals, without compromising on safety and efficacy. We also hosted a well-attended virtual briefing for MPs, where Kate Bingham and other experts spoke about the UK's COVID-19 response.

We have also published new finance data for the UK biotech sector which showed that 2020 was a record-breaking fundraising year and 2021 looks even more promising. Many members are concerned about the new National Security and Investment Bill, which will introduce increased government powers to intervene in investment deals, and as a result of our advocacy efforts the Government has scaled back the scope of the mandatory regime by changing the definitions of engineering biology and AI. The BIA has also responded to the second consultation on the NICE Methods Review and continues to engage actively with the process through formal working groups. Read about this and much more below.

This quarter in numbers:

15+ influence meetings with 24+ different MPs, Peers and MEPs, including 6 Ministers



9 consultation responses and briefings submitted

7 letters to Ministers

Contents

BIA engagement with the Government and Parliament on life sciences policy

The first quarter of 2021 saw the UK begin its new relationship with the EU, having completed Brexit with a last-minute Trade and Cooperation Agreement (TCA). Much remains to be resolved about how this will work in practice and the BIA has engaged with the Government, regulators and industry partners to find solutions as well as sustaining a strong focus on the COVID-19 pandemic.

The **Life Sciences COVID-19 Response Group (CRG)** continued 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. Following discussion at the January meeting, Minister Zahawi wrote to the industry-side members of the group to clarify the COVID-19 vaccination prioritisation of frontline healthcare staff. At a meeting on 8 February, the CRG discussed the vaccine rollout (and some of the issues that had arisen when the EU briefly invoked and then rescinded Article 16 of the Northern Ireland Protocol), the work of the Vaccine Taskforce and the Therapeutics Taskforce, and the Life Sciences Recovery Road Map.

At the 8 March meeting, the CRG considered the return to 'business as usual', including the roadmap out of lockdown, safer working guidance and endemic management. The BIA raised concerns about the impact of the proportionality of the definitions within the **National Security and Investment Bill** and the potential impact on the ability of UK life sciences to attract investment. Minister Zahawi agreed to follow this up with a bilateral meeting. Vaccine surveillance and the improved collection of real-world data to boost UK competitiveness was also discussed, with surveillance activity considered a key learning from the pandemic.

The CRG is supported by officials from the Office for Life Sciences (OLS) and industry representatives in a COVID-19 Industry Group which convenes between the ministerial meetings. There is a regular virtual meeting of the Testing Taskforce, convened by the DHSC's mass testing secretariat.

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

The **Life Sciences European Union Relationship Group** (EURG), an expert group of the LSC, met on 1 February to discuss with Ministers James Bethell and Ed Argar the impact of the TCA on regulation, continuity of supply and Northern Ireland. There was also a discussion about the future role of EURG, which led to the Group recently being reconstituted as the **Global Opportunities Board** (GOB) with a renewed focus on the global competitiveness of UK life sciences. At the first meeting of GOB on 16 March, the role of the refocused Board was discussed, along with the TCA and NI protocol implementation. The BIA takes part in the weekly government/industry meeting to take these agendas forward between EURG (GOB) meetings.

The **Life Sciences Industrial Strategy Implementation Board** (LSISIB) co-chaired by Nadhim Zahawi and Professor Sir John Bell met on 4 February to discuss skills, the Spending Review and the MHRA's Innovative Regulation programme. At the subsequent meeting of LSISIB scheduled for 15 April, Steve Bates was due to present the BIA's proposal for the creation of large-scale antibody biomanufacturing. The meeting was however postponed following the death of the Duke of Edinburgh.

The **Patient Access to Medicines Partnership (PAMP)** co-chaired by Lord Bethell and John Young, on which the BIA is represented by our Rare Disease Industry Group (RDIG) Chair, Charlie Galvin, met on 12

February to discuss uptake opportunities in the NHS, strategic category management, the NICE Methods Review consultation and the Innovative Medicines Fund.

The Innovation, Research and Data Expert Group **(IRDG)** co-chaired by Lord Bethell and Mene Pangalos, on which the BIA is represented by Chris Molloy, met on 23 February to receive updates on the OLS Spending Review Bids, and from UKRI with a discussion of the R&D roadmap. The future of UK clinical research was also discussed.

The **Accelerated Access Collaborative (AAC) Board** on which the BIA is represented by our Chair, Ruth McKernan, met on 24 February with a programme and strategy update from its new CEO Matt Whitty, as well as a discussion of the Innovation Manifesto, the Medicines and Medical Devices Bill and the NICE Methods review. The BIA's work with the AAC is supported by our membership of the **AAC Steering Group** which met on 28 January with the Innovation Manifesto as the main item of business. The **NICE Methods Review** (in which the BIA has been represented on the Steering Group and Task and Finish Groups) continues its work, more details below.

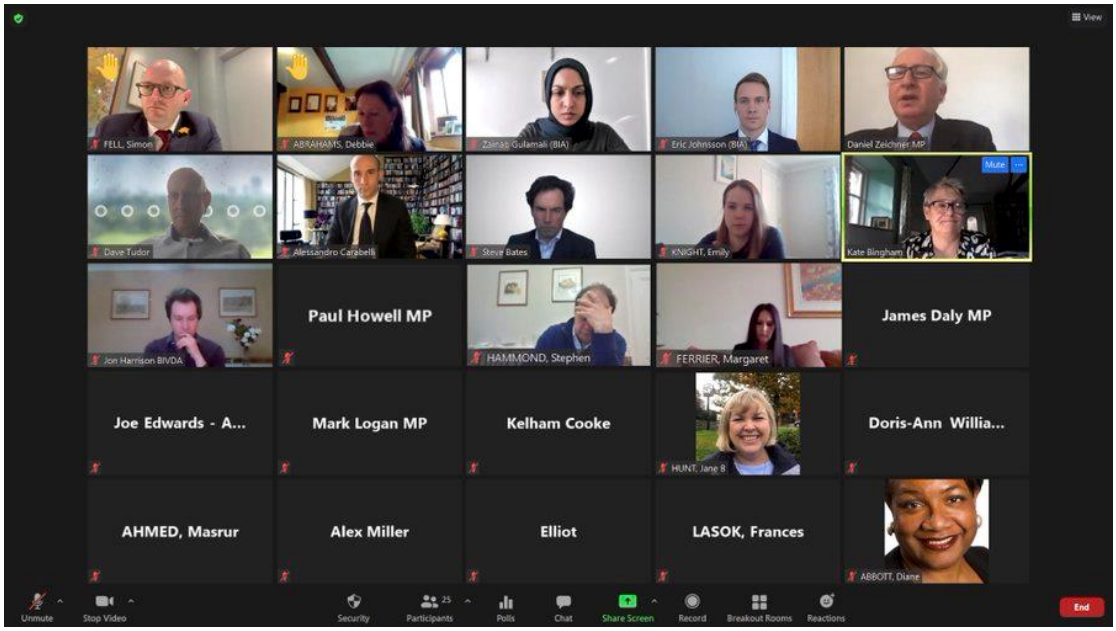
The BIA attended a meeting of the Government's Taskforce for Innovation, Growth and Regulatory Reform **(TIGGR)** chaired by George Freeman MP on 19 February and raised State Aid, the National Security and Investment Bill, financial regulation, innovative medicines regulation and gene editing.

BIA CEO Steve Bates appearing at Sky News to talk about the financing of the UK biotech sector.

The BIA has continued to be a strong voice for the sector with national and international media. Steve Bates was interviewed by the Times, the Telegraph and CNN to explain the work of UK life sciences companies and the Government's Vaccine Taskforce in procuring and deploying COVID-19 vaccines to patients. The BIA continues to be the leading sector voice on the financing of the UK biotech sector with the BIA appearing in Sky News, Bloomberg, the Financial Times and the London Evening Standard commenting on recent high-profile IPOs by UK biotech companies. As tensions increased on the supply of COVID-19 vaccines to Europe, Steve Bates called for a continued focus on collaboration and preserving international supply chains on the BBC's Newsnight programme and Radio 5 live.

The annual **Committee Summit** was held virtually on 10 February with over 200 attendees. The day started with a well-attended meeting for members of the Board with Advisory Committee Chairs and Vice-Chairs. During the day, meetings of the Advisory Committees were held as well as meetings of the People, Skills and Talent working group, Communications Network and the Manufacturing Advisory Committee Leadership Programme. The Summit heard about **the impact of Brexit and COVID-19 on UK politics in**

2021 from Sebastian Payne of the Financial Times, followed by a plenary session with a panel discussion on the future for UK biotech and life sciences. The second plenary session focused on how skills needed for a thriving biotech sector can be developed.



The APPG for Life Sciences hosted an event with Kate Bingham and other expert speakers on the UK's response to the pandemic.

In March, the BIA organised an All-Party Parliamentary Group (APPG) for Life Sciences event together with BIVDA and ABPI on the UK's COVID-19 response. We were delighted to hear from Kate Bingham, Dave Tudor from CPI and Alessandro Carabelli from COG-UK on how our sector has collaborated with the Government, regulators and the NHS to achieve the successful vaccine rollout we see today. They also explored how to build on this positive momentum to enable UK life sciences to grow further. The meeting had a record number of MPs in attendance – a strong signal that Parliamentarians are keen to support and hear more from our sector.

EU and international relationships

BIA works with members and stakeholders on the impact of the Brexit deal

The BIA started the year by hosting a Brexit Webinar on 7 January to set out the headlines, emerging analysis of the Brexit deal and to hear BIA member perspectives. The webinar focused on the areas included in the deal, such as changes to the movement of people and movement of data. We also discussed what was not included the deal, such as mutual recognition of batch testing.

Later in January, the BIA jointly held a member-only Brexit Lead Network meeting with the ABPI. This saw Jonathan Mogford from the MHRA join Matt Harpur and David Simmons from the Department for Health and Social Care (DHSC) to talk about regulatory change, the EU-UK trade agreement, Northern Ireland and issues around the continuity of supply. Following these presentations and a Q&A, there was an industry-only discussion to agree priorities now that the UK has left the EU. These priorities agreed included batch testing, the UK State Aid regime and Northern Ireland.

The BIA has also continued to work with the Brexit Health Alliance, a group of UK health organisations including professional bodies and charities, to share intelligence and develop joint objectives. We have also been working closely with EuropaBio to explore the impact of Brexit on EU Member States and how national associations can influence the EU Commission for better outcomes for patients and industry.

UK proposes temporary arrangements for medicines in Northern Ireland following BIA advocacy

Under current arrangements, batch testing conducted in the UK will no longer be accepted in Northern Ireland after 1 January 2022. Along with the wider life sciences sector, the BIA has been emphasising to Ministers and officials that this is not enough time to redesign supply chains to continue to supply medicines to Northern Ireland. These advocacy efforts led to the inclusion of a paragraph in a letter from Michael Gove to the EU Commission on 3 February, which called for the temporary arrangements for medicines in Northern Ireland to be extended to 1 January 2023. The BIA welcomed the proposed extension, which would allow time for a long-term solution to be explored. The proposal has not yet been agreed by the EU Commission, but we understand negotiations are ongoing. We hope that a political solution can be reached soon.

BIA continues to work with the Government to ensure the supply of medicines to the UK

This quarter, the BIA has been working closely with the DHSC and the wider life sciences sector to ensure continuity of supply of medicines to Great Britain and Northern Ireland. Several BIA members have highlighted issues with the supply of medicines and medicinal products to the UK or exports from the UK. Many of these issues are due to 'teething troubles' or individual EU Member States' different interpretations of guidance. However, some relate to systemic issues, particularly in the regulatory space, which we are highlighting to the Government and currently exploring solutions.

BIA sets its initial priorities for future UK trade deals

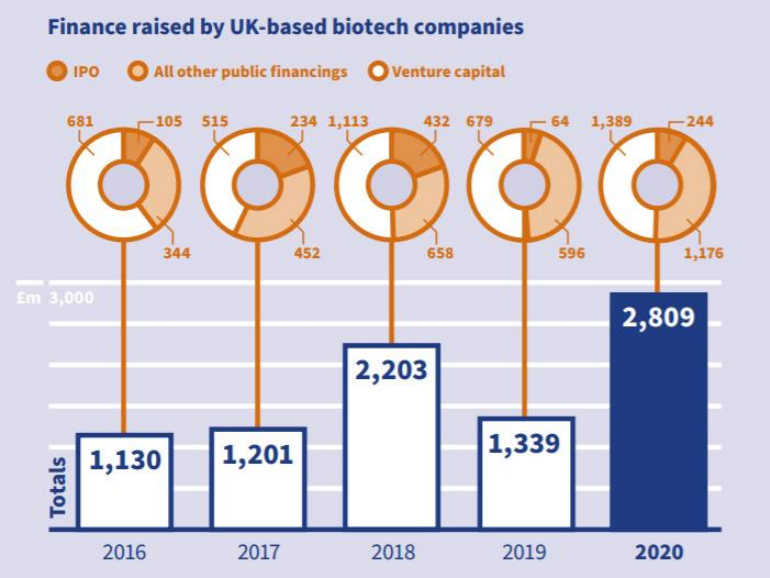
This quarter, the BIA began to set out its priorities for the UK's future trade deals. These priorities focus on IP and recognise potential issues in a future deal between the UK and the US, in particular potential conflict between the UK's aspiration to membership of Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) as well as the European Patent Convention. Beyond IP, our priorities include greater regulatory cooperation with countries around the world, the ease of movement of people and enabling foreign investment.

Finance, tax and investment

BIA data shows 2020 was a record-breaking fundraising year and 2021 looks even more promising

A record £2.8 billion was raised by UK biotech companies in 2020, according to data published by BIA and Clarivate on 2 February. Further data published on 29 March revealed this positive activity accelerated in the first quarter of 2021, with £830m raised, almost topping the amount raised by the half-way point of 2020.

The annual 2020 report, *The science of success: biotech financing in 2020*, showed strong investor appetite for both public and private UK biotech companies. Venture capital financings secured £1,389m, with five companies each raising over £50m in the year. Initial Public Offerings (IPOs) netted £244m, including two £100m+ launches on NASDAQ, and all other public financings raised £1,176m, with both London's AIM and New York's NASDAQ being equally buoyant in the year.



UK-based biotech companies raised a total of £2.8 billion in 2020, marking the best ever year for the sector,

However, the report showed the pandemic had impacted company creation and there was also a drop in grant funding support for UK biotech companies, although this was partly because the 2020 Biomedical Catalyst winners had not been announced when the report went to print.

The Q1 finance update included £336m raised in venture capital between December 2020 and February 2021, up from £123m in the same period a year ago. In addition, it reported that Immunocore achieved a £215m IPO on NASDAQ and £279m was raised through follow-on financings, up from £186m a year ago.

Responding to the news, BIA CEO Steve Bates said: "This strong start to 2021, with investments outpacing the record setting year of 2020, shows the incredible appetite amongst international and some domestic investors for the UK's world leading biotech and life sciences companies. This has been reinforced by the recent announcement that £1 billion will be invested in the sector through a UAE-UK Sovereign Investment Partnership. This quarter has also seen significant private sector investments into UK medicine manufacturing capability and clinical development pipelines, which has fuelled increased confidence in the sectors outlook for 2021."

A new Government fund to invest in biotechs and an R&D tax credits review announced at Budget

With the economy still suppressed by the pandemic, the Chancellor used his Budget on 3 March to extend many of the business support measures, such as furlough, and he also announced a series of measures to help drive economic recovery through investment in science and innovation. Noting the success of the Future Fund, the Chancellor announced a new 'Future Fund: Breakthrough' programme to be run by British Patient Capital, part of the British Business Bank. This additional capital for the Bank will be used to invest directly in R&D intensive companies seeking a minimum of £20m and will crowd in private sector investment to support their growth. The BIA's Finance and Tax Advisory Committee (FTAC) has already met with Bank officials to discuss the design of the programme, which is expected to launch in the summer.

Two important reviews for BIA members were also launched. The first on R&D tax credits is to assess the value, functionality and opportunity for improvements of both the SME and large company R&D tax credit schemes. This includes looking at the inclusion of data and cloud computing spend, and capital expenditure, within the eligible costs, for which the BIA has campaigned over the last few years. However, the review also raises the potential for negative changes, which the BIA will seek to address. The second review is of the Enterprise Management Incentive (EMI) employee share option scheme, which is seeking to determine if any changes are required to allow more companies to benefit. FTAC is responding to both consultations.

For full details of the Budget, see the BIA blog.

Life Sciences Investment Programme launched alongside £800m commitment from Abu Dhabi

In the run up to the Budget, the BIA urged the Chancellor to confirm and launch the £200m Life Sciences Investment Programme (LSIP), a previously-promised new fund run by British Patient Capital to support later-stage life science VC funds. The Budget passed without mention of the programme, but on 24 March the Government announced that LSIP was to launch shortly and that it had leveraged in an £800m commitment from Abu Dhabi's sovereign wealth fund, Mubadala. The details are yet to be worked out, but the BIA has already built a relationship with the Government's new Office for Investment, which will manage the relationship with Mubadala.

MPs calls for the Biomedical Catalyst to be refilled following BIA briefings

In March, Daniel Zeichner MP, Chair of the All-Party Parliamentary Group (APPG) for Life Sciences, led a Westminster Hall debate on the future of R&D funding. Following briefings by the BIA, both Zeichner and his Cambridge neighbour Anthony Browne MP highlighted that the life sciences sector is consistently the largest R&D investor in the UK and commented on the sector's key role in providing solutions to the pandemic. They both called on the Government as a matter of urgency to relaunch the Biomedical Catalyst with a significant budget to ensure that this successful funding programme continues to support early-stage biotech companies and SMEs.

Throughout the quarter, the BIA has also continued to emphasise the importance of the Biomedical Catalyst to Ministers and ask in meetings and letters that the funding programme is refilled. A potential Biomedical Catalyst competition in 2021 is subject to the outcome of the ongoing UKRI Spending Review allocation process. The potential long-term budget of the funding programme will be decided by the Comprehensive Spending Review 2021, which is expected to be launched over the summer and concluded in the autumn.

Dominic Cummings echoes BIA views on ARIA at Parliamentary hearing

In March, the Government published its plans for the new Advanced Research and Invention Agency (ARIA) and laid the Bill introducing the new agency to Parliament. Also in March, Boris Johnson's former Chief of Staff, Dominic Cummings, gave evidence on ARIA to the Science and Technology Select Committee. Cummings highlighted the UK's strength in life sciences and that genomics in particular could be a key focus of ARIA. He also said that the Vaccine Taskforce and the VC industry offer prime examples of how ARIA should operate, which echoes the BIA's own views on the new agency.

BIA continues works to limit the scope of the National Security and Investment Bill

With the National Security and Investment (NSI) Bill nearing the end of its Parliamentary passage, the BIA has been working with Parliamentarians scrutinising the Bill, Ministers and civil servants implementing the new regime, and potentially affected members to address the undue burden this could place on the UK life sciences sector.

Ahead of the Bill's debate in the House of Lords, the BIA briefed Parliamentarians on the impact the Bill could have on investment in life sciences companies and supported members of the House of Lords in drafting amendments. The Department for Business, Energy and Industrial Strategy (BEIS) also published its response to its consultation on sector definitions and national security, in which it narrowed the definition of Artificial Intelligence and significantly changed the definition of Engineering Biology (now called Synthetic Biology). The BEIS' response cited feedback from the BIA as one of the reasons for this change (paragraph 433). The BIA has continued to work with BEIS officials and Ministers Nadhim Zahawi and Paul Scully to feed back the views of members on these definitions and push for the Synthetic Biology definition to be narrowed further.

Supporting members with this new regime, the BIA hosted a webinar with expert lawyers from Covington & Burling LLP and the Deputy Director of National Security and Investment in BEIS, to discuss the impact of the Bill on the life sciences sector and hear from members. The BIA will continue to push for changes to the new regime to ensure it does not place an unnecessary burden on UK life sciences companies and investors, and work to support members in understanding how the regime may impact them as the Bill completes its Parliamentary passage and comes into force later in the year.

BIA calls for 'Undertaking in Difficulty' rules to be scrapped in new UK subsidy control regime

Following the signing of the EU-UK Trade and Cooperation Agreement, the UK is free to set its own State Aid/subsidy control rules. A consultation was launched on 3 February to explore the design of a new regime, to which the BIA responded. Since 2018, the BIA has raised concerns across government regarding the Undertaking in Difficulty definition within EU State Aid rules, which is not appropriate for identifying ailing or insolvent enterprises in the R&D-intensive industries. Due to its formulaic approach, the definition has prevented BIA members from accessing government R&D grants. The Government's consultation document acknowledged this problem and said the UK was no longer required to follow the EU rules. In our consultation response, we recommended that the new regime uses the 'going concern test already used for some UK subsidies; it allows for a subjective assessment to be made by an expert, who is able to apply their understanding of the particular characteristics of different sectors to determine the viability of a company.

Strategic technologies and areas of scientific focus

BIA urges the Government to take a science-based approach to regulation of gene editing and GMOs

In March, the BIA urged the Government to adopt a science-based and innovation-friendly regulatory framework for gene editing and genetically modified organisms (GMOs). The BIA made the comments in a submission to the Department for Environment, Food and Rural Affairs (Defra), which has been consulting on the regulation of genetic technologies. A key focus of the consultation was on the Court of Justice of the European Union (CJEU)'s judgement to regulate gene edited products as GMOs. The BIA called on the Government to diverge from the judgement.

In our response, we also said that the Government should put in place an exemption scheme for medicines containing or consisting of GMOs undergoing clinical trials. This would ensure that the UK remains a globally competitive location for clinical development and allow rapid patient access to these potentially curative medicines. Significant experience with gene delivery systems in the manufacture of medicines provides demonstrable evidence of the lack of increased risk of harm to human health or the environment posed by organisms produced by gene editing. Our full response to the consultation is available on our website.

Dr David Atkins joins the National Genomics Board as the BIA SME representative

Dr David Atkins, Chief Executive Officer of Congenica and BIA Board member, has joined the National Genomics Board as the BIA's SME representative. The Board brings together senior decision makers from government, the NHS, academia and industry to advise the Government on its national genomics strategy, Genome UK. Dr Atkins' appointment to the Board follows BIA lobbying and means that the voice of genomic start-ups and SMEs will be heard at the highest levels of government.

BIA CEO Steve Bates OBE said: "The UK is a world-leader in genomics as demonstrated by the great work in sequencing genetic variants of SARS-CoV-2. The role of SMEs in driving genomic innovation cannot be overstated and I am delighted that David is joining the National Genomics Board. As the Chief Executive of a successful UK-grown genomic SME, a BIA Board Member and an active member of the BIA's Genomics Advisory Committee, David is uniquely qualified to represent the BIA's genomics community to the Board. We look forward to working with David and the rest of the Board to build a thriving genomics industry to benefit NHS patients and as we rebuild our economy from COVID-19."

BIA continues to build our strong working relationship with the ATTC network

The BIA continued its representation on the Advanced Therapy Treatment Centre (ATTC) Network Industry Advisory Groups on Adoption and Standardisation. The Adoption group, in particular, is becoming increasingly important to our work on reimbursement of cell and gene therapies.

The group met twice this quarter and discussed learnings from the launch of CAR-Ts in the UK and the potential opportunities in the NICE Methods Review for cell and gene therapies.

People, skills and talent

BIA hosts fourth annual training programme for next generation entrepreneurs

In early March, the BIA and the Francis Crick Institute collaborated for the fourth year in a row to deliver the Programme for Up and coming Life Sciences Entrepreneurs (PULSE) training programme. The programme brought together 29 entrepreneurs for three days of practical advice, support and feedback from seasoned entrepreneurs, renowned professionals and experienced CEOs. The event culminated in a practice pitch to a panel of investors, who provided feedback on how the pitches could be improved.

This year, PULSE moved to a virtual setting, but still delivered exceptionally valuable advice, training and networking opportunities to those who joined. The online format allowed more entrepreneurs to join this cohort than ever before and created opportunities to meet with an even wider variety of experts one-to-one.

BIA highlights lack of diversity in the life sciences sector

In January, the All-Party Parliamentary Group (APPG) on Diversity and Inclusion in STEM called for evidence for their enquiry into equity in the STEM workforce. The BIA worked in partnership through the Futures 2030 Skills Group, with the ABPI and the Science Industry Partnership, to submit a comprehensive response which included data from across the life sciences sector and specific case studies from the BIA. The submission built on recommendations in the Life Sciences Future Skills 2030 Action Plan and included examples of employee data collection and best practice across the industry.

Data was presented on the demographics of the life sciences workforce, which is estimated to be around 350,000 employees in total. The data showed that women hold fewer leadership and Board positions compared to men, that fewer than 1% of employees are Black/African/Caribbean/Black British, that just 9% of professionals are from a working-class background and that 11% of the workforce is classed as having a disability, compared with16% in the wider economy. Our submission also highlighted programmes such as the BIA's Women in Biotech and the Advanced Therapies Apprenticeship Community as examples of best practice.

As a follow-up to the APPG submission, the BIA chaired an interactive Equality, Diversity and Inclusion panel session at the Medicines Manufacturing Community event to engage the wider community in addressing inequality across the sector.

BIA celebrates apprenticeships in life sciences sector with Ministers

In early February, the BIA supported the National Apprenticeship Week with numerous events engaging a wide range of stakeholders discussing vocation routes into the life sciences sector. Kate Bingham opened an evening of celebration to recognise the achievements of apprentices and employers across the Advanced Therapies Apprenticeship Community and participated in a Q&A session.

In addition, apprentice and employer panel sessions throughout the week showcased the opportunities of apprenticeships to bring a diverse and innovative workforce into the sector, to upskill those already employed and retain exciting talent. The BIA participated on a panel with Bim Afolami MP and Gillian Keegan MP, Parliamentary Under-Secretary of State for Apprenticeships and Skills.

The BIA also supported the Scottish Apprenticeship Week in early March, with events attended by Scottish Minister for Trade, Innovation and Public Finance, Ivan Mckee.

Intellectual property and technology transfer

BIA briefs MPs on importance of IP for COVID-19 vaccines

In response to claims that waiving IP rights for COVID-19 vaccines would increase developing countries' access to COVID-19 vaccines, the BIA produced a briefing for MPs to explain the need to protect IP to ensure equitable global access to safe and effective vaccines. In the paper, the BIA explained the role IP plays in biomedical innovation, how being able to develop vaccines at speed is a direct result of having strong IP rights, and how simply sharing the methodology for producing vaccines is not a safe or efficient way to increase vaccine production. The paper also highlighted key collaborations in the last year to support equitable global access, including AstraZeneca undertaking technology transfers and training to increase capacity to support sustainable and equitable logistics for vaccine distribution, Gilead entering into long-term voluntary licencing agreements with generic drug makers to supply remdesivir to treat COVID-19 and Johnson & Johnson committing to providing 500 million vaccine doses to developing countries, among other examples.

Pre-clinical and clinical research

New vision for the future of UK clinical research delivery

On 23 March, the Government published an ambitious vision for the future of clinical research delivery, which was developed by the four UK nations as part of the UK cross-sector Recovery, Resilience and Growth Programme, including NHS England and NHS Improvement, the MHRA, the HRA, the NIHR, industry, charities, academia and patient representatives. *Saving and improving lives: the future of UK clinical research delivery* sets out to create a more efficient, pro-innovation and digitally-enabled clinical research environment, which supports research into all treatments and technologies.

Plans to recover the NIHR Clinical Research Network (CRN)'s research portfolio are now being developed, taking account of feedback from stakeholders and lessons learnt from efforts to restart non-COVID research during 2020.

In addition, on the same day, the MHRA launched a pilot project seeking evidence from companies of patient involvement in medicine development for applications for new active substances and new indications. For more information, see the MHRA's press release.

Manufacturing

Steve Bagshaw replaces Ian McCubbin as Chair of the Vaccine Taskforce's Expert Advisory Group

The BIA continues to support the Government's Vaccine Taskforce through the Expert Advisory Group (EAG) by assisting with the manufacture of emerging vaccines and antibodies against COVID-19, as well as developing future manufacturing and formulation strategy.

Ian McCubbin OBE, who has been Chair of the EAG since its inception, recently stepped down as Chair but remains as an integral member of the group. The BIA is grateful to Ian for his inspirational leadership over the last year and his instrumental role in expediting the manufacture of the COVID-19 vaccine frontrunners to quickly deliver vaccines to patients and save lives.

Steve Bagshaw CBE, former CEO and current Chair of FUJIFILM Diosynth Biotechnologies, has replaced Ian as Chair of the EAG. Steve has been a key member of the EAG since its formation and, as well as taking over as Chair of the group, has formally joined the Vaccine Taskforce. As the economy starts to recover from the pandemic, Steve will lead the team making the case to policymakers that investment in manufacturing will be fundamental to deliver economic growth, highly skilled jobs and enhance the UK's world leading capability to tackle future pandemics.

Medicines regulation

BIA welcomes updated guidance from the MHRA on approved countries for batch testing

On 16 March, the MHRA updated its guidance on the list of approved countries for authorised human medicines – the approved countries for batch testing and importation of medicines – stating that the UK's acceptance of batch testing done in EU/EEA countries will not end on 1 January 2023. This will provide certainty to industry and time for appropriate reflection on the way forward, while focusing on the COVID-19 pandemic response and protecting the supply of medicines to UK patients.

There will be a two-year notice period of any changes to the current position of continued recognition of EU/EEA batch testing after the Government has conducted a comprehensive review of the future batch testing strategy for the UK.

This change in guidance follows continued advocacy by the BIA in collaboration with the broader life sciences sector. We look forward to continuing to work with the Government and member companies to shape this review.

New UK/ACCESS Consortium guidance to speed up variant vaccine approvals

On 4 March, the MHRA published new guidance on strain changes in authorised COVID-19 vaccines to fast-track approvals, without compromising on safety and efficacy. The guidance, which was developed in collaboration with the Agency's international partners in the ACCESS consortium, a coalition of regulatory authorities from the UK, Australia, Canada, Singapore and Switzerland, sets out the information that regulators would need in order to approve any modifications to authorised COVID-19 vaccines, should virus mutations make them less effective at preventing the disease. It is important to note that the UK/ACCESS Consortium guidance provides scientific flexibility and is aligned with what the EMA and the FDA have proposed.

The vaccine manufacturer would be expected to provide evidence showing that the modified vaccine is safe and is of the expected quality, together with data on the immune response. In addition, data from the original robust clinical trials and the ongoing studies on real-world use in millions of people could be used to support any decision by the regulators. This approach is based on the tried and tested regulatory process used for seasonal flu vaccines.

This guidance was issued following consultation with relevant companies at an Industry Forum on COVID-19 vaccine regulation, organised by the BIA as part of our ongoing engagement with the MHRA.

BIA contributes to MHRA COVID-19 review

The BIA and member company representatives participated in workshops reflecting on their experiences and sharing insights as part of the independent review carried out by MHRA on how the Agency was performing during the COVID-19 pandemic. The complexity of the continuously evolving situation required the MHRA to provide effective leadership and collaborate effectively at pace, while adapting alongside industry, to new ways of working digitally and from home. The outcome of this review will allow the MHRA to continue to improve its services to industry and to respond appropriately to any future pandemics.

First medicines receive innovation passport under new Innovative Licensing and Access Pathway

The BIA is pleased to report that some of our members were among the first companies to receive the Innovation Passport designation for their cutting-edge medicines from the MHRA, NICE and the Scottish Medicines Consortium under the new Innovative Licensing and Access Pathway (ILAP). Launched in January 2021, ILAP combines the MHRA's globally-recognised high standards of quality and safety with improved flexibility to accelerate through the approval process so that NHS patients can benefit sooner from innovative treatments. ILAP is a key initiative to make the UK attractive to R&D companies post-Brexit by making the regulatory process as attractive and innovation-embracing as possible.

The Innovation Passport is the first step in ILAP and is awarded to medicines in the early stages of development, including advanced therapy medicinal products, medicines for rare diseases, new indications and repurposed medicines. Innovation Passport holders, the MHRA and partner organisations will then work together to create a product-specific Target Development Profile which will define key regulatory and development features, identify potential pitfalls and create a roadmap for delivering early patient access to the new medicine. Guidance on the Innovative Licensing and Access Pathway is available on MHRA website.

Access to medicines

BIA highlights the value of medicines for patients at Rare Disease Day 2021

To mark this year's Rare Disease Day, the BIA distributed our *Rare Chance for Reform* report to all MPs. The feedback from MPs was positive and we secured engagement with Anne-Marie Morris, Chair of the APPG for Access to Medicines and Medical Devices and Dr Lisa Cameron, Chair of the APPG for Health. We hope to build on this engagement to secure meetings and new advocates in Parliament for changing the way rare disease medicines are evaluated.

In addition, we published a new blog reflecting on how the now widespread lived experience of COVID-19 casts new light on the value of medicines for rare diseases.

BIA engages in the second phase of the NICE Methods Review

The second phase of the NICE Methods Review began in January 2021, with the launch of new Task and Finish Groups to support the review of the responses to the first consultation and to contribute to the development of the new Programme Manual. In addition to continued representation on the overarching Working Group, the BIA is represented on two of the groups; one is focused on drafting the Programme Manual and the other on 'Benefits Realisation'. The latter group will focus on some of the challenging emerging technologies, such as advanced therapies.

In addition, NICE launched the second of three consultations planned during this process, which focuses on the details of the Programme Manual. It is broken down into four themes: alignment of current processes; opportunities for new process improvements and ways of working (adapting to the changing healthcare environment and addressing key challenges); commercial and Managed Access processes; and objectives and vision of the Highly Specialised Technologies (HST) programme.

The BIA has responded to the consultation and our response is available on our website. While we have responded in full to the consultation, including welcoming some of the positive changes proposed, our focus has been on NICE's proposals with regard the HST programme, which present significant concern in their current form.

We have been working with the ABPI and EMIG to develop a coherent industry response and will continue to seek additional opportunities to highlight these concerns.

BIA responds to the opportunity of the Rare Disease Framework

The Government published the UK Rare Disease Framework in January 2021. This is the successor to the UK Strategy for Rare Diseases published 2014.

The framework is based on four key priorities: faster diagnosis; increasing awareness of rare diseases among healthcare professionals; better coordination of care; and improving access to specialist care, treatments and drugs. These priorities are based on a 'national conversation survey' of patients, carers, families, patient organisations, healthcare professionals, and industry professionals. Each of the four nations in the UK will develop an action plan setting out how they will achieve those priorities.

The BIA welcomed the launch and we are seeking opportunities to engage with the ongoing development process of the Action Plan in England, and also those in the devolved nations. We submitted our *A Rare Chance for Reform* report to a review of evidence and briefed MPs as held a Westminster Hall Debate on the Framework and related access to medicines issues.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Eric Johnsson, Policy and Public Affairs Manager, on 0207 630 2197 or ejohnsson@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, Senior Membership and Business Development Manager, on 0207 630 2194 or mmcgivern@bioindustry.org

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