Influencing and shaping our sector – BIA update October 2021 – January 2022

UK BioIndustry Association

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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 October 2021 to January 2022.

This quarter has seen the long-awaited Spending Review and Budget announcements, which put the sector into a strong position going into 2022. In Q4, we launched a report on the benefits of cell and gene therapies, exploring the challenges companies face in the UK's evaluation and reimbursement system. We responded to consultations on Artificial Intelligence (AI) in the context of inventorship and IP, and to proposals for the new Innovative Medicines Fund (IMF) announced last summer.

The Life Sciences Scale-Up Taskforce, established in Q3 to increase UK investors' participation in the sector, had its third meeting with Secretary of State Kwasi Kwarteng and produced its first work package with tangible recommendations on how to attract the right investment into the sector. We brought together the UK's bioprocessing community at our annual bioprocessUK Conference in Cardiff and, together with the MHRA, the team delivered its annual Regulatory Innovation Conference virtually, with the keynote address delivered by Lord Kamall. Starting off the new year, Steve Bates attended the virtual annual J.P. Morgan healthcare conference, where the Prime Minister together with Lord Prior as Chair of the NHS sold the UK life science opportunity to the globe. Read on for more details on these activities and much more that the BIA delivered in Q4.

This quarter in numbers:

10+ influence meetings with 15 different MPs, Peers and MEPs, including 3 Ministers

8 consultation responses and briefings submitted

7 letters to Ministers

Contents

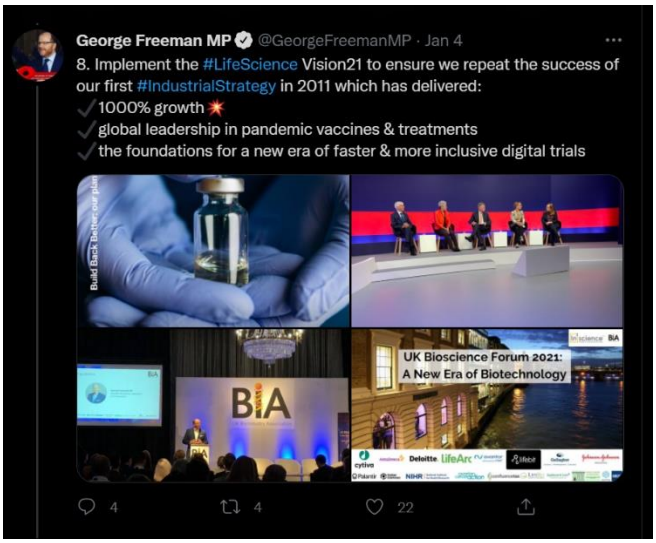
Engagement with the Government and Parliament on life sciences policy

One of the key deliverables from the Government's Life Science Vision for our members is the **Life Sciences Scale-up Taskforce** (SUTF) which was established and chaired by Secretary of State for Business, Kwasi Kwarteng, following a proposal by the BIA. The taskforce, on which the Secretary of State is supported by Vice Chairs Sir John Bell and Sir Jon Symonds, has looked at ways to unlock capital from institutional investors, such as pension funds. Jointly with Miles Celic of TheCityUK and Nigel Wilson of Legal & General, Steve Bates has led a work stream on tackling the barriers to institutional investors and the UK's scale up risk capital gap. The work was greatly assisted by PwC, interviewing stakeholders and experts from the life sciences and financial services industries from UK and internationally to produce a report on unlocking UK-based institutional investment.

The third and final meeting of the Taskforce was held on 7 December, with recommendations from that work stream being presented alongside recommendations from another working group on boosting human capital within the investment and life sciences communities. The work done by the taskforce at pace in the final quarter of last year will be a high priority for both government and industry to deliver in 2022.

After a number of false starts, a **Comprehensive Spending Review (CSR)** was completed and unveiled in the Budget on 27 October. The BIA had prepared well for the CSR and conducted an effective campaign to inform and influence its outcomes, launching a report 'Becoming a life sciences superpower' at an event in Parliament alongside our formal submission and coordinating a letter to the Prime Minister from 100+ CEOs of BIA member companies calling for support for our sector. More details of the BIA's successful CSR campaign are on page 8, below.

In the runup to the CSR and Budget, the new Minister for Science, Research and Innovation, George Freeman, spoke at the Bioscience Forum on 14 October, as did Indro Mukerjee, CEO of Innovate UK. Both praised the impact of the Biomedical Catalyst (one of BIA's key campaign objectives) and the Science Minister later tweeted his priorities for 2022 highlighting the BIA and Scale-Up Taskforce work.



Science Minister George Freeman highlights BIA's work in support of the Life Sciences Vision.

The BIA has also been engaging with MPs and Peers from across the political spectrum. A report produced by members of the BIA's Cell and Gene Therapy Advisory Committee (CGTAC) 'Ensuring patient access to

cell and gene therapies: the case for an alternative payment model' was launched in Parliament on 30 November at a briefing event hosted by the Labour MP for Cambridge, Daniel Zeichner MP.

The All-Party Parliamentary Group (APPG) for Life Sciences, to which the BIA provides the secretariat jointly with the Association of the British Pharmaceutical Industry (ABPI) and the British In Vitro Diagnostics Association (BIVDA), hosted a joint event in December with the APPG for Rare, Genetic and Undiagnosed Conditions to discuss the UK Rare Diseases Framework.

Life Sciences Council and other government-industry engagement

The BIA continues to support government-industry engagement through its membership of the **Life Sciences Council (LSC)** and the joint government-industry secretariat that coordinates the work of the Council and its sub-Councils and expert groups.
The Autumn meeting of the LSC was held on 24 November, co-chaired by Business Secretary, Kwasi Kwarteng, Health Secretary, Sajid Javid (at his first meeting of the LSC) and Pascal Soriot of AstraZeneca. Priorities for delivery of the Life Sciences Vision was the main agenda item and the Council heard from Sir John Bell, Sir Jon Symonds and, for the BIA, incoming Chair Dan Mahony, who spoke about the Scale-up Taskforce's work. He called on the Government to ensure wealth created by taxpayer-supported innovation can benefit UK pension savers, while drawing attention to government initiatives in other countries that are having an impact on scaling life sciences businesses. Kwasi Kwarteng paid tribute to the work of the Taskforce, which had been convened incredibly quickly over the summer and was already making an impact.

In the item on the NHS as a delivery partner for the Life Sciences Vision, Steve Bates spoke about the need to rediscover the ambition of the Nice Methods Review in order to solve the problem of access for innovative medicines for the next 10-20 years. He also stressed the importance of properly resourcing the MHRA to be a world-leading medicines regulator (which is central to achieving the Vision) and received an assurance from Sajid Javid that the regulator will be properly funded.

Elsewhere in the agenda, Steve Bates raised the importance of intellectual property (IP) to the innovative ecosystem of SMEs that pioneer novel technologies in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights (*TRIPS*) waiver discussion at the World Trade Organisation (WTO). The Council was assured by Kwasi Kwarteng that the Government would continue to uphold the rights of IP owners. We had planned to follow this up with the Trade Secretary Anne Marie Trevelyan ahead of the WTO Ministerial Council in Geneva, but the meeting was cancelled because Swiss COVID-19 travel restrictions. Steve Bates had recently been to Geneva with the International Council of Biotechnology Associations (ICBA) to lobby on this and will continue to work closely with international partners such as the Biotechnology Innovation Organisation (BIO) on the issue.

Also falling foul of COVID-19 restrictions was the Life Sciences reception at 10 Downing Street, to which a number of BIA members had been invited, sadly cancelled because of the Omicron variant.

The **Life Sciences Industrial Strategy Implementation Board (LSISIB)** meeting on 21 October co-chaired by George Freeman, BEIS Minister for Science, Research and Innovation and Sir John Bell received updates on the implementation of the CSR and Life Science Vision. There were also reflections made on sector deals under the 2017 Industrial Strategy and an update from British Patient Capital on the Life Sciences Investment Partnership.

The Board discussed the refresh of LSC governance which will see the LSISIB evolve into an Implementation Board for the Life Sciences Vision.

Kristen McLeod, Director of the Office for Life Science (OLS) has been replaced by Roz Campion, who had an early meeting with the BIA to discuss her priorities, including delivery of the Life Sciences Vision.

The **Accelerated Access Collaborative (AAC)** Board met on 10 November to hear for the first time from Amanda Pritchard, Chief Executive NHS England and Improvement. There were updates about early-stage support for Advanced Therapy Medicinal Products (ATMPs) and Histology Independent Therapies (HIT) and the Life Sciences Vision. This was the final board meeting for Ruth McKernan, outgoing BIA Chair.

The findings of the **Genomics Nation** report, which the BIA published jointly with the Wellcome Sanger Institute and Medicines Discovery Catapult, were presented to the National Genomics Board (on which David Atkins represents SMEs for the BIA) at the meeting on 13 October.

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 final consultation, with a call to rediscover the ambition of the original Case for Change.

The BIA continues to be an advocate for the sector with the media. COVID-19 continued to dominate international and national headlines, during this period the Government procured two antiviral drugs molnupiravir and Paxlovid. The former Chair of the BIA, Dr Ruth McKernan, led the industry response to these deals. Dr McKernan also explained to the Financial Times (£) the need for government to invest in antivirals to support work for COVID-19 and any future pandemics. Steve Bates' speech on the collaboration seen through the pandemic by industry, academia and government at the Scotsman's life sciences conference was also covered.

Finance, tax and investment

BIA secures increased spending and tax changes at Budget and Spending Review

The Chancellor Rishi Sunak set out the first multi-year Comprehensive Spending Review (CSR) since 2015 and a fiscal Budget on 27 October. Innovate UK received a large funding uplift, as campaigned for by the BIA, so that its annual budget will reach £1.1 billion in 2024/25, providing headroom for the Biomedical Catalyst to be continued and preferably enlarged. The BIA is now holding monthly meetings with the new CEO of Innovate UK, Indro Mukerjee, at which we are pressing the need for this.

In the final stages of the CSR, the BIA delivered a letter to the Prime Minister signed by 100 member company CEOs urging him to invest in R&D. The Chancellor confirmed that he will increase government R&D spending to £20 billion by 2024/25, the largest increase seen in a generation. Increases specifically in health R&D and medicines manufacturing were set out as part of this.

The Budget also brought changes to R&D tax reliefs, some positive and some potentially negative. Crucially, the Chancellor confirmed he would be following the BIA's calls to modernise the scheme and expand it to include data and cloud computing costs. Alongside this, restrictions are to be made to reduce claims on overseas R&D activity (see next story below) and to counter fraud. A full analysis of the CSR and Budget is available on the BIA website.

Concerns with overseas R&D restrictions raised with HM Treasury

Following the Budget announcement to "refocus the reliefs towards innovation in the UK", further information was published on 30 November. The proposals would limit R&D tax relief for payments to subcontractors, in both schemes, to claims where the subcontracted activities take place in the UK. Similarly, where companies claim for expenditure on externally provided workers (EPWs), these will in future be restricted to EPWs who are within UK PAYE/ NIC. The policy intention was said to be to ensure that the spill overs from research activity, such as improved skills, benefit the UK.

On 22 December, the BIA's Finance and Tax Advisory Committee (FTAC) met with Treasury officials to explain that pre-clinical research and clinical trials take place overseas through necessity and therefore the proposed changes would seriously and unfairly impact the sector's R&D investment. The officials appreciated these concerns and agreed to hear further proposals from the BIA on how legitimate and necessary overseas activity can be protected.

Industry-led Taskforce makes recommendations to increase scale-up capital

Throughout the final quarter of 2021, the BIA worked was part of an industry-led Life Sciences Scale-Up Taskforce convened by the Secretary of State for Business to develop recommendations on increasing UK-based institutional investors' participation in the sector.

The BIA collaborated with the financial services membership organisation TheCityUK to commission and lead PwC in conducting over 50 stakeholder interviews and desk-based research to provide a comprehensive analysis of the challenges faced in raising capital from UK institutions. Recommendations were developed based on this insight, approved by the Taskforce and submitted to the Secretary of State for consideration. An event planned for the 27 January will also provide the opportunity for the

recommendations to be discussed with the Science Minister, George Freeman MP. We will update members of the outcome in the next Influence report.

BIA welcomes changes to pension fund rules

The Government has followed the BIA's recommendation to remove performance-related fees and carried interest from the 'charge cap' for workplace pensions. It is hoped that this will remove a key barrier which the pensions industry says limits their ability to invest in venture capital.

The change, which is currently being consulted on, is the latest step in the Government's 'productive finance' agenda to ensure innovative businesses and infrastructure receive sufficient investment. Currently, pension funds say they cannot invest in these assets because there are high fees involved, which are prohibited by the charge cap, as well as an industry-wide focus on keeping fees low. The BIA's submission welcomes the initiative but identifies further action that will be needed to address the risk-averse and low-fees culture prevalent in the pensions industry.

Strategic technologies and areas of scientific focus

New strategic technology 'TechBio' gets own BIA policy agenda

In the final quarter of 2021, the BIA has been consulting with members in the health data, digital and AI space to plan a new 2022 influence agenda. This follows the publication of the BIA's Tech Bio report in October. Following a series of one-to-one meetings with TechBio members, the BIA convened a workshop in December to receive feedback on our policy agenda going forward. The workshop has informed our key focus areas for 2022:

- **Data Access**: Lobbying for publicly funded health data assets to be made available to industry in optimal data environments.
- **Governance and Collaborations**: championing simplified, standardised approaches for establishing collaborations and sharing data between organisations.

Skills and talent, working with the NHS, and public engagement are also key areas of interest to this group. The BIA will be working with members alongside external stakeholders, including Health Data Research UK (HDRUK), the Health Research Authority (HRA) and NHSX, to improve data access for SMEs. If you are interested in supporting this work, please contact our Senior Policy and Public Affairs Manager Emma Lawrence.

BIA presents Genomics Nation report to the National Genomics Board

In October 2021, Adrian Ibrahim, chair of the BIA's Genomics Advisory Committee (GAC) presented our report Genomics Nation to the Government's National Genomics Board (NGB). The NGB is made up of senior decision makers from across the public and private sector, including senior civil servants and delivery partners and is chaired by the Minister for Technology, Innovation and Life Sciences, Lord Kamall.

The report and presentation showcased the UK's thriving genomics sector, highlighting investment, growth and employment opportunities in the field and reiterated the vital role of public investment in leveraging private investment. The Board recognized the importance of SMEs in the ecosystem and discussed ways to increase private investment in the sector.

The BIA successfully lobbied for representation on the NGB in 2021 and will continue to use this position to highlight the sector's importance. Genomics Nation was published by the BIA in collaboration with the Sanger Institute and the Medicines Discovery Catapult in July 2021.

BIA hosts roundtable with DCMS on flagship data strategy

The BIA convened a discussion with members, stakeholders, and civil servants from the Department for Digital, Culture, Media and Sport (DCMS) in November. The session sought to examine the Government's new strategy Data: A New Direction. The strategy sets out changes to data legislation to 'create an ambitious, pro-growth and innovation-friendly data protection regime'. Any organisation that processes personal data may be impacted by changes to the UK General Data Protection Regulation (GDPR), however,

the Government particularly wants to remove barriers to innovation, which would benefit the life science sector.

The session was chaired by BIA member Bird & Bird, who were joined by representatives from the Health Research Authority. Members discussed reducing barriers to responsible innovation, covering topics on consent, re-use of data, medical confidentiality, anonymisation and data intermediaries. Feedback from the session was used to respond to DCMS' consultation on reforms to the UK's data protection regime, which will in turn be used to help shape future reforms.

Key findings from the session included confirmation that proposed changes to legislation would not affect access to medical data, which is subject to UK common law. Concerns were raised that changes to legislation would take the UK out of step with EU GDPR, meaning the UK would lose data adequacy with this key partner. For more information, read the full BIA consultation response.

National Security and Investment regime goes live

The National Security and Investment (NSI) Act – the biggest shake-up of the UK's national security regime for 20 years – became fully operational on 4 January 2022. It gives the Government powers to scrutinise and intervene in certain acquisitions made by businesses and investors that could harm the UK's national security. The BIA successfully worked with government to refine the definitions relevant to the life sciences sector to ensure that scrutiny was correctly targeted at deals that pose genuine threats. A full suite of guidance, which government developed in consultation with the BIA, has now been published. The BIA has also published its own guidance specific to our sector.

BIA continues to engage nationally and internationally on the Nagoya Protocol

The BIA has continued to engage with the Department for Environment, Food and Rural Affairs (Defra) to call for improved guidance on the application of the Access and Benefit Sharing (ABS) Regulation and Nagoya Protocol in the UK. The BIA's Nagoya and ABS subcommittee attended a webinar hosted by Defra and the Office for Product Safety and Standards (OPSS) which informed stakeholders on the current process of developing the UK guidance on the Nagoya Protocol and ABS. The BIA will continue to engage with Defra and OPSS and feedback on the forthcoming guidance and implementation, which is to be shared with stakeholders for comment in the first quarter of 2022.

The webinar also touched upon the potential inclusion of Digital Sequence Information (DSI) within the remit of the Nagoya Protocol, following a statement on DSI by the UK delegation to the Convention on Biological Diversity (CBD) in August 2021 that ''the UK recognises that where benefits arise, they should be shared fairly and equitably". The details of what a benefit sharing mechanism for DSI would look like, as well as the Government's position on it, remain unclear.

The CBD hosted a webinar on 14 December attended by BIA members, at which the difficulty of introducing a form of ABS agreement for DSI was acknowledged by countries from around the world. However, there is international political desire for introduction of such an agreement for DSI. The CBD will hold its next meeting in March where this issue will be discussed further.

The BIA will continue to engage with senior officials on this issue to understand the Government's intentions and to express the strong concern of the industry. We will conduct a short survey to collate members' understanding of Nagoya, difficulties encountered so far and views on DSI. Members can get in touch with Policy and Public Affairs Manager Linda Bedenik to share any views and feedback.

People, skills and talent

Addressing the UK's life sciences talent gap

As the UK life sciences sector continues to grow, it must attract, retain, and develops the technical skills, scientific leadership and specialist knowledge needed to develop. The BIA chaired a lively and well-attended workshop at its annual bioProcessUK Conference in November 2021, facilitating discussions on addressing skills gaps through apprenticeships, collaboration on skills development and immersive technology solutions, as well as reflecting on five years of the BIA Manufacturing Advisory Committee (MAC) Leadership Programme (LeaP). The session received excellent feedback, highlighting skills challenges, and leaving BIA member companies with tangible next steps towards finding solutions. More information on the BIA's role in skills and talent for the sector can be found on our website.

A report on sector-wide skills demand published by the Cell and Gene Therapy Catapult in December 2021 found that over 6,000 new bioprocessing jobs will be required by 2026. The shortfall in talent and skills is already being reported by BIA member companies which research, develop, and manufacture advanced therapies. The BIA was a significant contributor to a roundtable held at the Advanced Therapies Congress in October 2021, exploring creative solutions to skills shortages within the cell and gene therapy industry. As a key member of the Medicines Manufacturing Industry Partnership (MMIP)'s skills workstream, the BIA has continued to represent the SME community and championed its skills needs across the life sciences sector.

A key part of the BIA's skills programme for 2021 included engaging and signposting talent opportunities to BIA members. We achieved this by attending a number of technical events, conferences, and networking sessions over the last quarter. Of particular note in Q4 has been our continued work on future leadership development through the BIA's LeaP webinars, participating in the peer review of UKRI Future Leaders Fellowship applications, and providing industry representation on the newly formed UKRI Talent and Skills Advisory Group, an external forum which brings together expertise across the research councils to provide strategic input into UKRI talent and skills priority projects. The group's inaugural meeting in December 2021 focused on challenges to the UKRI strategic framework for talent and skills, what is working well and what is missing from the current system in the UK, as well as a more detailed debate on the New Deal for Postgraduate Research. The group's next meeting will be held in the first half of 2022.

BIA raises sector skills issues with new Education Secretary

Ensuring education and skills programmes are inclusive and attract new life sciences talent, as well as upskilling across sectors, will be essential to achieve the UK's vision of becoming a leading life sciences superpower. The BIA has written to the new Secretary of State for Education, Nadhim Zahawi MP, to raise our sector's priorities. These include addressing current market failures in life science degree apprenticeships, international student fee barriers that reduce the numbers of EU students entering postgraduate academic programmes and supporting Institutes of Technology specialising in health and life sciences.

BIA responds to S&T Select Committee's consultation on improving diversity in STEM

In a submission to the Science & Technology Select Committee's inquiry on diversity in STEM, the BIA has said that there is a lack of data to assess the extent of underrepresentation of women and minority ethnic groups across the UK life sciences sector. We detailed research carried out on the diversity of investors and boards of UK life science companies, as well as programmes such as Board Placement Initiatives and the BIA's own Women in Biotech network. The BIA also recommended that the Government and its agencies report on and include diversity in R&D grant awards processes and invest in and build on existing best practice diversity initiatives. Further details can be found in the BIA's submission.

Intellectual property and technology transfer

BIA responds to second UK IPO consultation on AI and IP

Following on from the BIA's submission to the UK Intellectual Property Office (IPO)'s 2020 call for views on IP and AI, the UK IPO has taken another step to consult on protecting AI-devised inventions. In January, the BIA's Data and AI subcommittee to our Intellectual Property Advisory Committee (IPAC) responded to the new consultation, which focused on copyright in works made by AI, text and data mining using copyright material, and patents for inventions devised by AI.

Key points made in our submission included the importance of affording AI-devised inventions the same protection as human-conceived inventions, where appropriate and to achieve international harmonisation on this issue, particularly across Europe. Relating to the consultation, the BIA took part in an IPO roundtable and a one-to-one conversation with the IPO on the same topic, highlighting the importance of adequate protection for AI-devised inventions for the UK life sciences sector.

AI technology has the potential to make important innovative contributions across many areas of technology, especially R&D in life sciences. Adequately protecting AI systems, and their outputs, through IP rights will encourage further innovation and investment in those systems. The BIA will continue to engage with the UK IPO on this issue.

Manufacturing

BIA hosts 18th annual bioProcessUK conference in Cardiff

The appetite for the close-knit bioprocessing community to meet again face-to-face after working virtually for so long was clear to see at the 18th annual bioProcessUK Conference, which took place on 23-25 November in Cardiff. The conference was completely sold out by October, both for delegate tickets and sponsorship/exhibitor packages.

The atmosphere at the pre-party at voco St David's and the conference dinner at The Coal Exchange was vibrant, with attendees enjoying connecting again in person.

During the conference, we hear excellent speakers from eXmoor, LifeArc and Cytiva celebrating recent investments in UK manufacturing and case studies from Ipsen/Touchlight, National Horizons Centre and Dame Kate Bingham, ex-Chair of the UK Vaccines Manufacturing Taskforce, showcasing the power of collaboration.

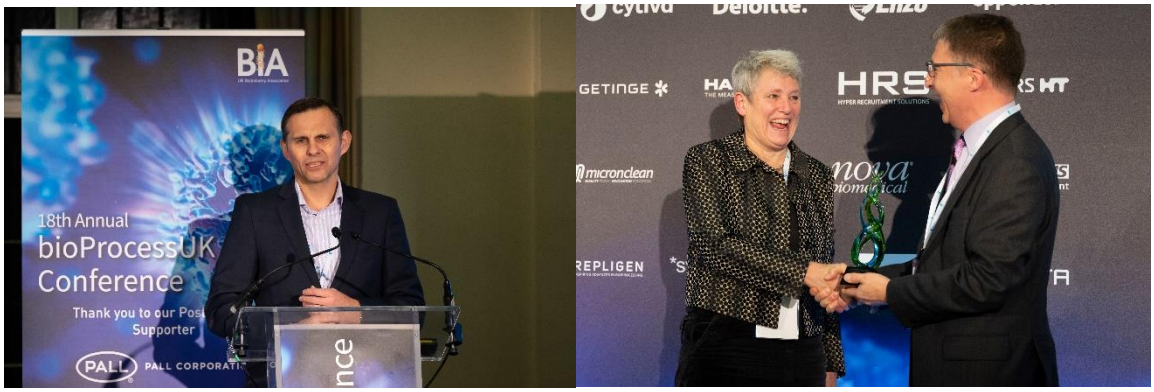
A bioProcessUK Conference attendee experiencing Cytiva's latest technology.

In the afternoon of day one, following early career researcher poster flashes, delegates attended parallel workshops on 'Addressing the bioprocessing talent gap' and 'Curing ovarian cancer together', with a moving testimony from our very own Jo Nunn of FUJIFILM Diosynth Biotechnologies, who is now taking the very drugs she has helped develop over her career.

Day two kicked off with a Medicines Manufacturing Industry Partnership (MMIP) update, followed by a drug delivery themed Dragon's Den-style technology showcase that saw Enesi Pharma receive the most votes to win two tickets to the BIA's Gala Dinner. The conference finalé, looking at what's next for pandemic response, shone a light on the continued work our bioprocessing community is doing in response to COVID-

19, focusing on RNA capability, building the UK vaccine landscape and the importance of global vaccine manufacturing.

The event was also an opportunity to celebrate outstanding achievements: congratulations to Stephen Ward, Chief Manufacturing Officer of the Cell and Gene Therapy Catapult and Dame Kate Bingham, ex-Chair of the UK Vaccines Manufacturing Taskforce, who were awarded the prestigious Peter Dunnill award and Richard Wilson impact award, respectively. The two worthy recipients have been recognised for their work and contributions to the bioprocessing and biologics manufacturing sector.



Stephen Ward (left) and Dame Kate Bingham (right) received the prestigious Peter Dunnill award and Richard Wilson Impact Award respectively.

Medicines regulation

MHRA and BIA hold annual Regulatory Innovation Conference

On 8 December, the BIA and the MHRA delivered their joint annual conference on 'Transforming regulation | Driving Innovation | Enabling safe patient access', which was attended virtually by over 200 delegates across the life sciences sector. Speakers from the MHRA, the Clinical Practice Research Datalink (CPRD) and NICE, along with industry and patient representatives, discussed a range of timely topics in relation to two themes which defined the 2021 event: transforming the regulatory environment to drive innovation and enable patient access to cutting-edge medicines; and how new innovative technology is transforming product development.

Lord Kamall, Parliamentary Under-Secretary of State for Technology, Innovation and Life Sciences, gave the keynote address, in which he discussed the Life Sciences Vision with the MHRA as an innovative, world-leading regulator at its heart, noting the importance of partnership working.

We would like to pay tribute to the co-chairs of the conference, Dame June Raine, Chief Executive of MHRA, and Tim Stonehouse, Chair of BIA Regulatory Affairs Advisory Committee (RAAC), as well as thank delegates and expert speakers for a highly engaging event with some great discussions.

BIA continues to engage with government on the Northern Ireland Protocol

On 20 December, the BIA took part in a Northern Ireland Advisory Group meeting organised by the Department of Health. Officials sought industry views on the EU proposals to address the supply chain challenges caused by the Northern Ireland Protocol and provided some detail about the Northern Ireland MHRA Authorised Route (NIMAR) arrangements, which were welcomed by the BIA.

There are two parts to the EU package of measures to ensure the continuity of supply of medicines from Great Britain to Northern Ireland: the current grace period, which had postponed the requirements for medicines and had been due to expire in January would be extended until the end of 2022; and legislative proposals amending EU medicines legislation which were sent to the European Parliament and the Council for approval. For companies this will mean that:

- Patients in Northern Ireland will have access to innovative life-saving medicines at the same time as any other person in the UK. For new novel medicines, companies will, in future, be able to make use of a new bridging mechanism to ensure their product is authorised for the whole of the UK if the MHRA authorises a product before the EMA/European Commission, for example, under Project Orbis. This bridging solution is in addition to the existing compassionate and emergency use mechanisms under EU law.
- Generic medicines can be authorised either through the EU mutual recognition/decentralised procedure (EU MR/DCP) or using the UK national process.
- The regulatory importation requirements will be removed for all medicines brought into Northern Ireland from the rest of the UK – this means that batch testing does not need to be repeated if it has already been carried out in Great Britain or the EU.

- All regulatory functions can remain in the UK if they are currently located here, such as the marketing authorisation holder (MAH) or qualified person (QP) based in Great Britain for EU MR/DCP applications for Northern Ireland.
- Authorisation by the MHRA can allow companies located in Great Britain to use a single pack and leaflet when supplying markets in Great Britain and Northern Ireland.
- On the Falsified Medicines Directive, there will be an extension to the existing derogation on all medicines for three years.

BIA meets with MHRA on outcome of the Early Access to Medicines Scheme consultation

The BIA held a bilateral meeting with the MHRA in December to discuss the outcome of the consultation on The UK Early Access to Medicines Scheme (EAMS). The MHRA received 50 responses, including the BIA's response. There was broad agreement to introduce the core principles on a statutory basis, reducing the existing administrative burden for EAMS medicines supply and simplifying the requirements for data collection. A statutory instrument will be laid before Parliament by the end of January. This will ensure that EAMS remains relevant 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.

Discussion also focused on funding and providing support to SMEs. The BIA recommended developing a mechanism for recovery of discovery costs for new innovative medicines to incentivise SMEs participation in EAMS. The BIA will provide BIA members' views on the detailed EAMS guidance to help with the interpretation and implementation of the new legislation and contribute to the development of the new real-world evidence (RWE) guidance.

BIA takes part in MHRA ILAP Summit

On 19 January, the BIA participated by invitation in the MHRA Innovative Licensing and Access Pathway (ILAP) Summit, which was chaired by Dr Marc Bailey, MHRA's Chief Scientific and Innovation Officer and Senior Responsible Officer (SRO) for the delivery of ILAP. Dame June Raine, Chief Executive of MHRA, provided the future vision of the ILAP and outlined the five priority areas– from building partnership with stakeholders to creating the right environment for innovators and making the UK attractive to R&D companies post-Brexit. This was followed by opening remarks from Gillian Leng, Chief Executive of NICE, and representatives from the Scottish Medicines Consortium (SMC) and the All-Wales Therapeutics and Toxicology Centre (AWTTC). The online event celebrated the successes of ILAP one year on since going live in 2021. The Agency received 76 applications for the Innovation Passport (IP) designation – the entry point to the ILAP – from large and small companies, including 11 for products for FDA Orbis in oncology.

The Chair of the BIA Regulatory Affairs Advisory Committee (RAAC) was the BIA representative on the panel session and provided feedback from the BIA ILAP Group which brings together companies that have been awarded, or are applying for, the IP designation.

Discussions focused on future development of the ILAP. This includes developing case studies to highlight the benefits of engaging with ILAP, a new HTA Access tool, further collaboration with the UK life sciences ecosystem to drive the end-to-end ILAP pathway and consideration of a medical device pathway.

MHRA consults on proposals for the future of UK clinical trial legislation

On 17 January, the Medicines and Healthcare products Regulatory Agency (MHRA) launched an eight-week public consultation on a set of proposals to update the current UK clinical trials legislation, The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended, which transposes the EU Clinical Trials Directive 2001/20 EC into UK law. This will provide the opportunity to design a world-class regulatory environment for clinical trials to support the development of new innovative medicines and ensure that the UK retains and grows its reputation as world leading base for life sciences, in line with the ambitions of the Life Sciences Vision.

The legislative proposals outlined in the consultation aim to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, promote patient and public involvement in clinical trials, as well as ensure the legislation builds international interoperability to conduct multinational trials. These proposals have been developed by the MHRA and Health Research Authority (HRA), in collaboration with an Expert Working Group of stakeholders from across the clinical research sector, including the BIA and patient representatives.

We are working with our Regulatory Affairs Advisory Committee (RAAC) to provide a consolidated BIA response to the consultation and help shape the future UK legislation for clinical trials. If members would like to contribute to the BIA submission, please contact BIA Head of Regulatory Affairs, Christiane Abouzeid.

Access to medicines

BIA launches report on ensuring patient access to cell and gene therapies

In November, the BIA launched a report exploring the potential benefits of cell and gene therapies for patients, the challenges they face in the UK's evaluation and reimbursement system, and some of the solutions being explored in other countries. The report was produced with the support of the BIA's Cell and Gene Therapy Advisory Committee (CGTAC).

In order to ensure patients can access these novel and potentially life-changing treatments, the report calls for the consideration of innovative payment models, including annuity and pay-by-performance models, for cell and gene therapies. Such models are already being explored and trialled in other countries to enable fair reimbursement for higher cost single administration treatments.

To mark the launch of the report, the BIA convened a roundtable in Parliament hosted by Cambridge MP and Chair of the All-Party Parliamentary Group for Life Sciences, Daniel Zeichner. The roundtable provided a valuable opportunity to further discuss with Parliamentarians the challenges and solutions explored in the report and to seek their advice on how to raise the standing of this issue on the political agenda. Following the roundtable, the BIA arranged for a letter to be sent to Health Minister Edward Argar. The letter, which was co-signed by the MPs in attendance, recommended the trialling of innovative payment models for cell and gene therapies and the reduction of NICE's discount rate for health effects to 1.5%, as called for in the report.

The BIA will continue to work with members to advocate the calls to action detailed in the report and will offer continued support to parliamentarians in the endeavour to bring these issues to the fore.

BIA engages in public consultation on proposals for the Innovative Medicines Fund

In November 2021, NHS England and system partners published the initial proposals for the new Innovative Medicines Fund (IMF) and launched a public consultation on these proposals. The IMF, which was first announced in July 2021, will be an extension of the current £340m Cancer Drugs Fund (CDF) and will cover treatments beyond oncology, including for rare and genetic diseases. The purpose of the IMF is to provide patient access to promising new innovative treatments while additional data is collected to resolve clinical uncertainty. The BIA is working with members to provide a comprehensive response to the consultation.

The BIA strongly supports the purpose of the IMF, as we believe it could be an important vehicle for enabling greater access to the growing pipeline of innovative medicines, including advanced therapy medicinal products (ATMPs) and treatments for rare and ultra-rare diseases. However, the BIA is concerned that the principles and entry criteria currently proposed will not make the fund accessible to these treatments in the way that was intended.

The BIA will seek to work with system partners throughout this engagement process to support the development of an IMF that delivers on the ambitions set out in the UK Government's Life Sciences Vision and the UK Rare Diseases Framework.

APPG for Life Sciences hosts event on UK Rare Disease Framework

The All-Party Parliamentary Group (APPG) for Life Sciences, to which the BIA provides the secretariat jointly with the ABPI and BIVDA, hosted its well-attended last event of 2021 on 7 December. Together with the APPG for Rare, Genetic and Undiagnosed Conditions, the event discussed the implementation of the UK Rare Diseases Framework which was released in January 2021, as well as the Government Action Plans that will implement the framework and that will be announced in early 2022. These action plans are vital in leading to systematic change so that people with rare conditions are given the care they need.

The event, co-chaired by Liz Twist MP and Daniel Zeichner MP and attended by a further 7 MPs, featured speakers from both patient groups and industry, including a BIA member, ensuring that all stakeholders are effectively represented in the Action Plans. The meeting highlighted important features of the framework which impact both people with rare conditions and the rare disease pharmaceutical sector.

Following on from the event, the APPGs will send a joint letter to the Secretary of State for Health and Social Care to influence the development of the action plans so they best serve the rare disease community. The APPG for Life Sciences will host events throughout 2022 to promote the life sciences sector and continues to inform MPs and interested organisations about the sector through its newsletter. If you would like to receive the newsletter, please send us an email.

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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