Influencing and shaping our sector – BIA update January – April 2020

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 2020.

Our sector, like the rest of the world, looked very different at the beginning of this quarter compared to now. Since the escalation of the pandemic, the BIA has been busy coordinating our sector to ensure that UK science has a leading role in the global fight against COVID-19 while also ensuring that the sector receives the right business support from government throughout the crisis. We have launched a dedicated BIA COVID-19 web portal and are hosting weekly webinars.

Before the escalation of the pandemic, we continued our work on Brexit and the UK's future trade policy, relaunched the All-Party Parliamentary Group (APPG) for Life Sciences, and engaged with Accelerated Access Collaborative. And as a result of a BIA-led campaign, the Government radically changed the proposed cap on R&D tax credits to ensure genuine biotech companies are not penalised. Read about all this and much more below.

This quarter in numbers:

15+ influence meetings with 13+ MPs, Peers and MEPs, including 4 Ministers

6 consultation responses submitted

8 letters to Ministers

Contents

BIA action on COVID-19

As the seriousness and significance of the COVID-19 outbreak became clear in early February, the BIA quickly flagged that UK science would be at the forefront of navigating the pandemic and finding solutions. We also recognised the potential impact on the sector as a whole and on individual businesses.

As the global efforts to tackle the coronavirus accelerated, we focused on the importance of identifying, sharing and enabling connections across the UK life sciences industry. We began work to co-ordinate and support member engagement in the development of national and international research and scale up efforts to develop solutions.

We have helped to establish and continue to support a UK Vaccines Manufacturing Taskforce (see page 18 for further details). We have also brought together an Antibody Taskforce led by Dr Jane Osbourn, Professor Paul Kellam and Dr Paul Varley to rapidly generate large numbers of doses of therapeutic antibodies against COVID-19 (see page 17).

We also responded with a rapid shift in our focus to reflect the importance of the issue and the need to support the global effort on COVID-19. We established new channels of communication to cascade information to members, including:

- A dedicated COVID-19 information web portal which we built and launched in two days to support businesses and to highlight the important work from across the UK life sciences sector that is being done to help tackle the outbreak
- A weekly series of webinars to build awareness and engagement across our community, open to both members and non-members, to share the latest industry news and guidance
- Regular media briefings and appearances in sector and national media and bulletins, including BBC news, Sky News and BBC Radio 4's Today Programme
- Together with the ABPI, ABHI, BGMA, and BIVDA we made a joint statement on the UK life sciences commitment to fight COVID-19 and support NHS patients

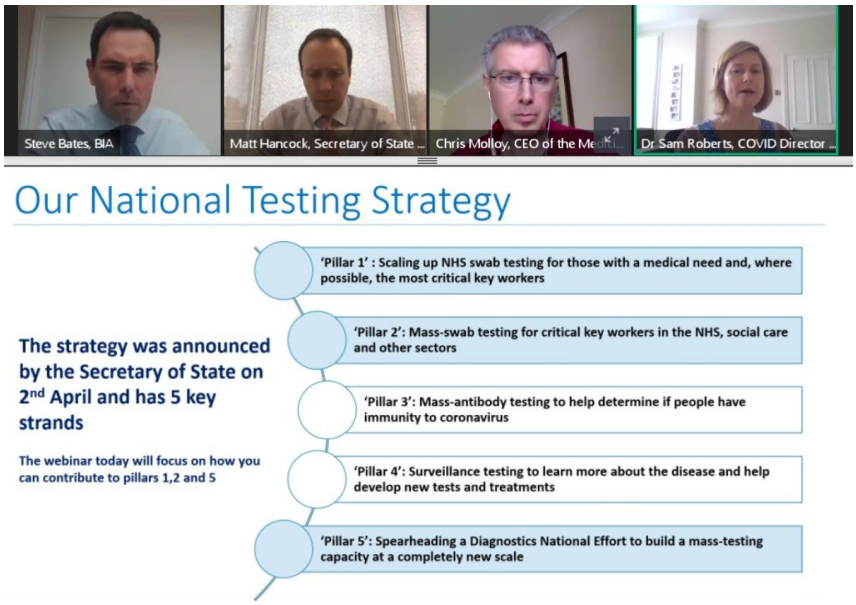
We have also focused on representing the needs of our members as the policies around COVID-19 have emerged:

- Many members expressed concerns about the status of our sector in relation to critical workers. We raised the issue with government ministers and - in collaboration with ABHI, BIVDA, and APBI – we developed a template letter for businesses to confirm employees' status as critical workers
- The BIA, with input from its Regulatory Affairs Advisory Committee (RAAC), provided the MHRA with a list of proposals for regulatory simplifications to help our member companies deal with pressures from COVID-19 (further details are on page 19)
- The BIA engaged with the National Institute for Health Research (NIHR) in March to understand the impact of COVID-19 on any new or ongoing clinical trials in the NHS (further details are on page 17)
- Mitigating the impact of the pandemic on our members has been central to our response. The BIA has been working directly with government officials, our members and partner organisations to establish the case for a support package for the 'knowledge economy', which is described in detail on page 11

Engagement with the Government and Parliament on life sciences policy

Engagement with the Government in the first quarter of 2020 divides, as does so much these days, into BC and AC – before and after coronavirus. The structures originally put in place to enable government/industry collaboration, initially in order to deliver the Life Sciences Industrial Strategy were mobilised extensively in the run-up to Brexit. Having been tested in preparation for a number of potential no-deal exits from the EU, these structures have proved their agility and robustness and have been quickly pressed into service in the current emergency to develop well-informed policy responses to COVID-19.

There is a weekly government/industry conference call hosted by OLS to coordinate the public and private sector effort on COVID-19. This was a valuable forum in which to discuss and inform policy on issues such as the definition of key workers at the beginning of the lockdown. There is also a weekly Ministerial call with industry, led by Life Sciences Minister, Nadhim Zahawi. Another recent initiative, set to become a regular feature, is a joint government/industry webinar on testing, hosted by the ABPI and chaired by the BIA's Steve Bates. The first of these webinars was joined by Secretary of State for Health, Matt Hancock.



BIA CEO Steve Bates chaired a government/industry webinar which was joined by Matt Hancock, Secretary of State for Health.

This quarter has seen changes in both government and opposition. Following the Cabinet reshuffle and the Labour leadership election, the BIA has engaged with new Ministers and Shadow Ministers on our members' priorities.

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 other groups.

The **Life Sciences Industrial Strategy Implementation Board** (**LSISIB**) met virtually on 31 March and was attended by Ministers Nadhim Zahawi and Lord Bethell, the newly appointed life sciences Minister at the Department for Health and Social Care (DHSC). COVID-19 was the main item of business. There was also a

discussion led by Professor Sir John Bell on the future priorities for the life sciences sector, including looking to the 'post-COVID recovery', to cement the UK as the leading global hub for life sciences.

The second meeting of the **Patient Access to Medicines Partnership (PAMP)** was held on 3 February with the Government represented by then Health Minister, Baroness Blackwood. PAMP provides a forum for discussion by industry and government stakeholders on the value, access and uptake environment with a particular focus on innovative new medicines.

The **Innovation, Research and Data Expert Group (IRDG)** on which the BIA is represented by Chris Molloy met on 4 March to discuss the steps needed to meet the 2.4% target of investment in R&D and the importance of ensuring access for SMEs to datasets for research and SME participation in the design and implementation of health data and NHS digital programmes.

We have also engaged with the **new intake of MPs** following the 2019 General Election, seeking meetings and offering an opportunity to provide a briefing on the biotech sector's contribution to the health and wellbeing of people and the UK economy.

We wrote to the new chairs of key **Parliamentary Select Committees**, offering our congratulations and highlighting relevant topics for future committee enquiries. In early April, BIA CEO Steve Bates gave oral evidence on the UK's COVID-19 testing capabilities to the Science and Technology Select Committee.

In February, the **All-Party Parliamentary Group (APPG) for Life Sciences** was relaunched. Chaired by Daniel Zeichner MP, the APPG will raise awareness of UK life sciences among parliamentarians and explore the challenges and opportunities facing the sector. The BIA provides the secretariat for the APPG together with BIVDA and ABPI.

Pictured left to right at the APPG for Life Sciences relaunch: Jerome Mayhew MP, Lord Mair, Darren Stenlake (Sysmex UK), Chris Green MP, Charlotte Casebourne (Theolytics), Haseeb Ahmad (ABPI) and Steve McCabe MP.

BIA holds annual Committee Summit

The BIA's annual Committee Summit took place in February and brought together all eight BIA Advisory Committees. Our Committees have a crucial role in informing and driving BIA's policy work and the Summit is an opportunity for the Committees to network and discuss shared priorities.

In addition to the usual Committee meetings, we hosted a panel of BIA staff experts discussing some of the key questions facing the industry today. The panel was chaired by the Guardian journalist, Gaby Hinsliff.

Michael Warren, Strategic Policy Advisor, discussed the UK's future outside of the European Union how the life sciences sector should respond to the Government's new "global Britain" approach.

Dr Martin Turner, Head of Policy and Public Affairs, looked at the role of biotech in the Government's push towards more regional development.

Peter Wasson, Policy and Public Affairs Manager, discussed how the sector should respond to the increasing scrutiny being directed industry on medicines pricing and access to innovative medicines.

Nicky Edwards, BIA's Director of External Affairs, introduces the panel at the Committee Summit.

Leaving the EU

BIA provides updates and guidance as the UK leaves the EU

On 31 January, the UK left the EU following the ratification of the Withdrawal Agreement. As the final preparations and the UK's withdrawal legislation made its way through Parliament, the BIA followed the development of the Government's position closely. We shared our analysis in a Brexit webinar at the end of January and through updated content on our Brexit portal. We noted the Government's responses to the Parliamentary debates and amendments on the EMA, and also set out the implications for members of the UK moving into the transition period.

As the transition period began, the BIA called for rapid clarity and the opportunity to inform the Government's position going into the negotiations with the EU and our international trading partners. We noted the importance of industry input to ensure effectiveness of future trading arrangements and secure the UK's place in the global regulatory system.

The BIA was among the first to note the potential implications of the Northern Ireland Protocol for our sector in the Autumn of 2019 when the new Brexit deal was announced, and we maintained a leading role on this issue early in 2020. Working with the Health Innovation Research Alliance Northern Ireland (HIRANI) we hosted a roundtable event in Belfast, where we were joined by innovative life sciences organisations to discuss the opportunities and potential issues currently facing their businesses and examine the implications of future EU (see page 13 for more details). The BIA also took part in a number of discussions with the Government and colleagues from across the sector on the Northern Ireland Protocol and called for an urgent technical working group of industry, regulators and health systems to be established and provide clarity and time to plan - and implement - any changes needed to avoid disruption to patients.

BIA advises on negotiations on the future relationship with the EU

In February, we saw clarity emerge from both sides on their positions heading into the negotiations on the future relationship and the BIA explored the potential implications and challenges closely. We hosted an EU future relationship webinar for members in which we shared our analysis and explored the challenges and potential flashpoints for the first phase of the negotiations.

We welcomed the UK ambition to secure a sector-specific annex for pharmaceuticals in the future relationship, to deliver continued close co-operation on medicines regulation, for which we and industry had been steadfastly calling. However, we noted that the positions contained incompatible red lines including on regulatory alignment, jurisdiction for the European Court of Justice over the UK's law on the UK side and level playing field commitments to ensure open and fair competition in areas like State Aid on the EU side.

When the detailed UK objectives were published, we expressed disappointment that the Government's vision was not as ambitious as our sector had hoped. We reinforced the importance of ensuring that a comprehensive trade agreement is in place on 31 December 2020. We also noted that even with a Trade Agreement in place there will be an impact on customs and trading arrangements for life sciences businesses trading with the EU. We led a range of industry/government discussions on this issue, including with our members on RAAC and we continued to push for the best outcome for our sector.

BIA sets out life sciences sector priorities in US-UK trade talks and responds to tariff consultation

At the beginning of March, the Government published its approach to trade negotiations with the US. Having already flagged the key issues for our sector during discussions as members of the Department for International Trade (DIT)'s Expert Trade Advisory Group, we responded noting that the UK's opening position on IP was unambitious and did not fully capture the opportunity for a state-of-the-art IP trade deal.

In March, the BIA also responded to the DIT consultation on the UK Global Tariff, due to take effect from January 2021 as part of the UK's independent trade policy. Our response called for policies that would: reduce the costs of trade through the elimination of tariffs; reduce regulatory divergence and red tape; improve IP protection to support innovation; and provide for continued access to global talent to recruit and retain a highly skilled workforce, such as research scientists, technicians and clinicians.

The BIA's consultation response also reinforced our longstanding call for the UK to become an independent signatory of the WTO Pharmaceuticals Tariff Elimination Agreement and to work with other WTO members to update the agreement to reflect scientific advancements and introduce an ongoing update mechanism. We also proposed a new system of duty reliefs to support businesses undertaking manufacturing and R&D activity in the UK as a more targeted and efficient mechanism than ongoing updates to specific tariffs.

Finance, tax and investment

BIA calls for government support for biotech companies impacted by COVID-19

From the announcement of a lockdown, the BIA started working with members to identify the financial and operational pressures the sector would be put under as a result of the COVID-19 disruption and advocate for a government support package. We organised a letter signed by over 50 biotech CEOs requesting that the R&D tax credit system be used to provide immediate aid to companies facing cash flow problems in the short term. The letter called for advance payments on future claims and expedited payment of outstanding claims. The BIA also wrote to HMRC directly requesting that they prioritise payments to companies during this difficult time and we have received confirmation that extra resources have been committed to clear the backlog.

The BIA submitted a detailed evidence package to HM Treasury officials to help with the case for state intervention, and proposed further measures, including "restart R&D grants" and equity co-investment schemes, to support the sector in the medium and long-term, respectively. The BIA also wrote to the Chancellor to highlight State Aid rules that could prevent a government support package reaching some companies in the sector.

The BIA helped members access the general business support package made available by government in the early days of the lockdown. The Job Retention Scheme, which allows workers to be furloughed with government covering up to £2,500 of their monthly salaries, has been most widely used by the sector. However, the loan scheme delivered by the British Business Bank included viability criteria that largely excluded biotech companies. The BIA's engagement with the bank to unpick this has added to our campaign for a new package of support for the "knowledge economy" of pre-revenue, R&D intensive industries. We will continue to work with the Government, our members and partner organisations, such as the British Private Equity & Venture Capital Association (BVCA) and the "Save Our Startups" campaign, to deliver a support package.

Big R&D investment increase announced in Budget 2020

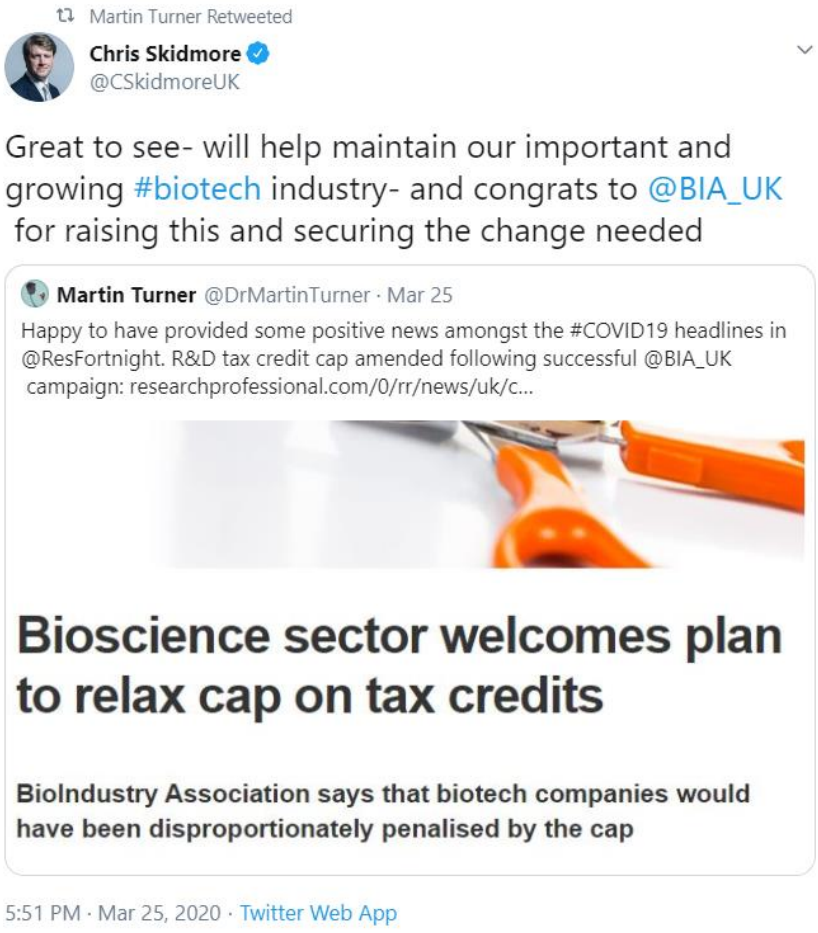
Chancellor Rishi Sunak delivered the Budget on 11 March with the announcement of a substantial increase in the Government's commitment to invest R&D, which is now set to reach £22bn by 2024/25 (from approximately £11bn today). This included a 15% uplift to the 2020/21 budgets, which would likely allow Innovate UK to provide greater support to biotech businesses as called for by the BIA. The Chancellor explained that the exact funding allocations until 2024 would be subject to a Comprehensive Spending Review (CSR), which was due to conclude in July this year, but has since been delayed to a future date.

The Budget also confirmed a £200m life sciences scale-up fund. The fund will be delivered by the British Business Bank through a yet-to-be determined mechanism to increase the availability of equity capital for our growing sector. The Chancellor confirmed the R&D Expenditure Credit (RDEC) rate rise that was promised in the Conservative manifesto and launched a consultation on the inclusion of data in eligible costs, something which the BIA has long called for and which would benefit SMEs if introduced. A reduction in Entrepreneurs' Relief was also announced. For a full analysis of the Budget see the BIA's blog and webinar.

R&D tax credit cap amended following successful BIA campaign

The Government has radically changed the proposed cap on R&D tax credits to ensure genuine biotech companies are not penalised following a BIA-led campaign throughout 2019.

Following the original proposal in November 2018, the BIA engaged with HM Treasury officials to help them understand why the cap, which was intended to prevent abuse of the tax credit system, would inadvertently impact a large proportion of genuine UK biotech companies. The BIA also worked with members to coordinate a cross-sector response to the public consultation and worked with MPs to raise questions in Parliament to scrutinise the Government's approach.



MP and ex-Science Minister Chris Skidmore congratulates the BIA on its successful PAYE cap campaign.

The new cap design, which is now out for public consultation, has adopted some of the recommendations put forward in the BIA's submission to the Spring 2019 consultation. While some details still need to be resolved to ensure it is fit for purpose, it should ensure that the cap achieves the Government's objective of preventing abuse of the R&D tax credit system whilst protecting genuine companies. The BIA is encouraging its members to respond positively to the consultation.

UK biotech raises £309m in Q1 before global market downturn

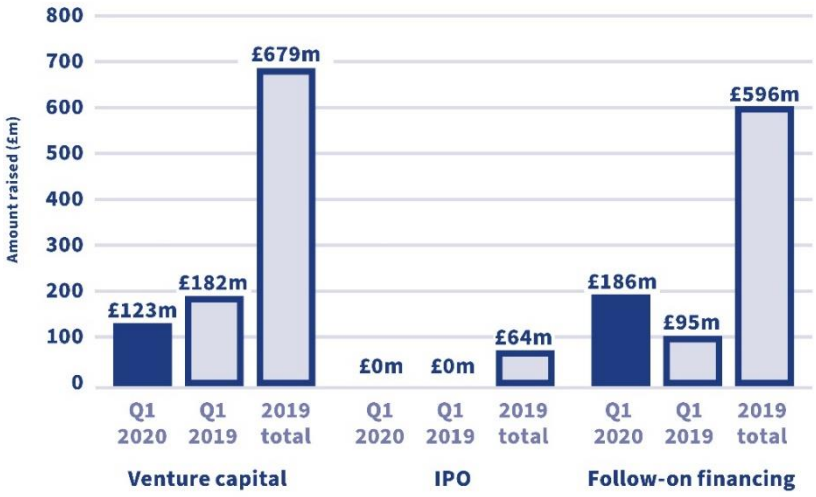
In March, the BIA and Informa Pharma Intelligence revealed that UK biotech companies raised £309m between December 2019 and the end of February 2020. The total was boosted by strong secondary financings on public markets in both the UK and US in the last few months before global markets crashed in response to the COVID-19 pandemic.

Highlights from the report include:

- £186m was raised in public follow-on financings, up from £95m in the same period last year
- £123m was raised in private venture capital, down from £182m in the same period last year
- There were no IPOs by UK or European biotech companies in the three-month period

BIA CEO Steve Bates OBE said:

"This was a positive start to the year, but it is clear there are challenging times ahead for all sectors as governments and global markets respond to the coronavirus crisis. The importance of a strong and diverse life sciences sector comes into sharp focus at times like this. UK companies and academic research teams are part of the global fight against COVID-19 and we will keep doing everything we can to support them and the rest of the sector."



BIA engages with biotech companies and officials in Northern Ireland

In late February, a team of BIA staff travelled to Northern Ireland to meet with biotech companies. The trip started with a reception in Belfast, hosted by the Health Innovation Research Alliance Northern Ireland (HIRANI) and attended by leader Northern Irish biotech companies, such as Randox and Almac, and representatives from the scientific community at Queen's University Belfast.

This was followed by a roundtable hosted jointly by the BIA and HIRANI at Invest NI, where BIA CEO Steve Bates discussed key issues for the biotech community in Northern Ireland, including the future relationship with the EU, the challenges of attracting investment and the developing sciences making new treatments possible. We also met with officials from the Northern Ireland Department of Health, including Chris Matthews, Director of Primary Care and Elaine Colgan, Head of European Unit. The meetings focused on the Northern Ireland Protocol and the future of cross-border cooperation.

Strategic technologies and areas of scientific focus

BIA hosts international biotech associations in London

In February, the BIA hosted the meetings of EuropaBio's National Associations Council and the International Council of Biotechnology Association (ICBA), which is chaired by BIA CEO, Steve Bates. The meetings were a great opportunity to discuss the priorities and future of biotech the with a community of associations from across the globe. The international delegation also visited the Francis Crick Institute and the Wellcome Trust.

The International Council of Biotechnology Association and EuropaBio's National Associations Council outside the Francis Crick Institute.

BIA co-hosts Wuxi Global Forum at JP Morgan

The WuXi Global Forum at the J.P. Morgan Healthcare Conference brought together thousands of leaders to promote new thinking on a global stage as the sector strives to provide transformative solutions for patients. The BIA co-hosted the event, which focused on advancing breakthroughs for patients, and included panels on the future of cell and gene therapies and how technology is shaping the future of healthcare. BIA CEO Steve Bates gave the closing address.

Skills, people and talent

BIA supports Life Sciences 2030 Future Skills Strategy launch

BIA made a significant contribution in development of the Life Sciences 2030 Future Skills Strategy as a key deliverable in the Life Sciences Sector Deal. The final report was launched in the House of Commons at the end of January 2020 and will play a central role in delivering the skills ambition of the Government's industrial strategy.

BIA member companies gave varied and valuable input to shape the action plan recommendations which come under four themes: Global Operating Environment, Integrated Skills, Apprenticeships, Sector Attraction and Perception. These themes now represent the views of both large companies and the SME community that face challenges working with, and attracting talent from, the international scientific community, maintaining the global research reputation and continuing to develop the high level of domestic talent pipelines.

At the Parliamentary launch event, supported by Life Sciences Minister, Nadhim Zahawi, apprentices from BIA member companies Oxford BioMedica, AstraZeneca, NHS Blood and Transplant and the Cell and Gene Therapy Catapult presented their compelling career stories and represented the future talent of the UK life sciences industry.

The Strategy's Action Plan is now being carried forward through a broad coalition of both industry and government officials, and reports into the Life Sciences Industrial Strategy Implementation Board (LSISIB). Without BIA member input, particularly from the SME community, the recommendations may have had quite a different focus and it is thanks to those who gave their time and opinions that these recommendations are well placed to address skills demand across our sector.

BIA hosts third PULSE for early start-ups

In early March, the BIA held its third Programme for Up and coming Life Sciences Entrepreneurs (PULSE) event, in collaboration with the Francis Crick Institute. PULSE is a three-day entrepreneurship training workshop, focused on providing inexperienced CEOs of early start-up companies with the knowledge, contacts and insight they need to develop their companies further. The event culminated in a session where the attendees delivered their company pitch to a panel of investors, who provided feedback on how the pitches could be developed further.

As well as forming connections with investors and other high-profile speakers, attendees took part in a networking evening with previous PULSE cohorts, other start-up CEOs, and supporters of the start-up community. The connections forged will doubtless serve the attendees well as they move forward. The event was a success, and feedback from both speakers and attendees was extremely positive, with the pitch session and the contacts developed during the event standing out as particular highlights.

UKRI Innovation Scholars Programme

The BIA has partnered with UKRI on the Innovation Scholars secondments pilot career development programme, which launched in January 2020. This skills funding opportunity invited applications from individuals wishing to spend up to 36 months (full or part time) on secondment in the biomedical sciences sector. The key objectives of this pilot call are to create porosity between sectors by enabling career mobility, boost the skills, knowledge and career development of people and intensify knowledge exchange between the biomedical industry and academia.

Intellectual property and technology transfer

BIA asks government to oppose new mandatory declarations in patent applications

Discussions at the World Intellectual Property Organisation (WIPO) in the first part of 2020 were building towards an international diplomatic conference at which a new treaty might be agreed to introduce mandatory declarations of the origin of genetic resources in patent applications. The campaign aims to ensure the countries and communities from where the genetic resources are sourced receive some benefit from their commercialisation. However, the Nagoya Protocol already exists to achieve this through reporting and legal sanctions. The BIA has therefore met with UK officials and submitted written evidence to urge the Government to oppose the diplomatic conference and new treaty. We have argued that the patent system is not an appropriate mechanism to support access and benefit sharing for genetic resources and, combined with the Nagoya Protocol, would place an unacceptable burden on innovators. WIPO discussion have been put on hold until after the COVID-19 crisis.

BIA voices disappointment over UK decision to not participate in UPC

The BIA voiced its disappointment at the Government's decision not to participate in the Unitary Patent system and Unified Patent Court (UPC), which would have placed its life sciences division in London and provided more cost-effective IP enforcement for SMEs across Europe.

The UK negotiating mandate for the future relationship with the EU, published on 17 February, stated any deal "has to respect our red lines of no commitments to follow EU law and no acceptance of the [rulings of] the European Court of Justice. There are very limited options for third country membership of EU bodies". The UK Intellectual Property Office (IPO) confirmed to the BIA that this meant the Government would not be seeking participation in the UPC, despite previous commitments. The Court's future is now in doubt as the UK was a key participant of the new system and a German court has also ruled Germany's ratification unconstitutional.

Pre-clinical and clinical research

BIA launches COVID-19 Antibody Taskforce

In March, the BIA launched the Antibody Taskforce under the leadership of Dr Jane Osbourn (Alchemab and BIA Board), Professor Paul Kellam (Kymab and Imperial College London) and Dr Paul Varley (Kymab). While vaccination will play a key role in the fight against COVID-19, complementary antibody strategies will also be required, and the Taskforce seeks to utilise the UK's world-leading expertise in the area.

The BIA Antibody Taskforce brings together a broad coalition of companies, academics and public sector across the UK and internationally to rapidly generate large numbers of doses of therapeutic antibodies against COVID-19 using innovative, integrated approaches across the therapeutics discovery and development value chain. The Taskforce has formed a steering committee involving Alchemab, Kymab, Abcam and NIBSC, which will guide and drive work across three main teams: early material supply and assays; manufacturing; and clinical and regulation. The Taskforce is taking an open innovation approach and is putting commercial considerations aside.

The Taskforce is working with the NHS to source samples from patient cohorts with different responses to infection (mild, moderate, severe, convalescent) to profile functional B cell repertoire responses. As well as providing the start point for antibody therapeutics, these insights will provide an important dataset to enable the better definition of at-risk groups, develop diagnostics and provide information to help inform the most appropriate vaccine and vaccination strategy, particularly where paired viral genome evolution and host genome data is available. The Taskforce is also developing innovative approaches to antibody manufacturing and is working with the BIA Vaccine Manufacturing Taskforce (see page 18) to ensure that manufacturing capabilities can rapidly be scaled-up.

Impact of COVID-19 on NIHR research

On 26 March, the National Institute for Health Research (NIHR) introduced a single, national process to prioritise COVID-19 studies which hold the most potential for tackling the challenges faced, as part of the Government's response to the pandemic. This process will cover funded studies, irrespective of the source of funding – whether by the public sector, industry or charities and also, in partnership with UKRI, studies that require funding. All NHS Trusts, healthcare providers and universities will need to prioritise support for studies which have been nationally prioritised. A live list of these studies, which includes commercial studies, will be regularly updated. Details of the process and the new single point of entry can be found here.

This was preceded by a statement, which was updated here on 19 March, that the NIHR Clinical Research Network was pausing the site set up of any new or ongoing clinical trials in the NHS that are not nationally prioritised COVID-19 studies, so that the research staff can focus on delivering these nationally prioritised COVID-19 studies or the redeployment to frontline care where necessary. More information in available in the Q&A on the impact of COVID-19 on NIHR research. This development will have a knock-on effect for the life sciences sector, and the BIA is working with our members to address the challenges as their trials are being de-prioritised.

The MHRA and HRA will continue to operate their approval processes for all trials, thus ensuring trials can restart promptly after the pandemic. Additionally the HRA produced new guidance for sponsors, sites and researchers about the COVID-19 pandemic. The guidance covers the setup of new studies, amendments to existing studies and changes being made by sponsors at this time.

Manufacturing

BIA launches COVID-19 Vaccines Manufacturing Taskforce

The BIA has networked the UK medicines manufacturing community and convened a COVID-19 Vaccines Manufacturing Taskforce, led by Ian McCubbin OBE. The Taskforce brings together companies that have the skills and capabilities needed to urgently find a way to manufacture millions of doses of innovative vaccines as they emerge, be that viral, mRNA or antibody based.

The Taskforce is engaging with government and is supporting vaccine candidates reaching clinical trials scale and beyond, including the ChAdOx1 nCov-19 vaccine from the Jenner Institute at the University of Oxford (see below) and the mRNA vaccine from Robin Shattock's group at Imperial College London. We have identified key workstreams and secured leads for these from Cobra Biologics, the Cell and Gene Therapy Catapult, CPI, Alchemab, Innovate UK, Fujifilm Diosynth and University College London, and have engaged with supporting organisations such as the MHRA, GlaxoSmithKline, the Knowledge Transfer Network (KTN) and the Vaccines Manufacturing Innovation Centre (VMIC).

The Taskforce is also in regular communication with Coalition for Epidemic Preparedness Innovations (CEPI) to co-ordinate capacity and ideas from our network to support the global supply for the pandemic. In March, CEPI and the Taskforce delivered a webinar on global manufacturing capabilities and capacities to engage the wider sector.

If you would like more information on the Taskforce or feel like you can contribute in any way, please visit the BIA COVID-19 website, complete the BIA's manufacturing capability audit or contact Netty England at aengland@bioindustry.org.

Jenner Institute launches COVID-19 vaccine clinical trials

In mid-February, BIA launched a UK manufacturing capability audit to mobilise manufacturing capability for COVID-19 therapies and vaccines as they develop and support their rapid scale up. The response from the community was remarkable and immediately resulted in the formation of a consortium between the Oxford Clinical Biomanufacturing Facility with Pall, Fujifilm Diosynth, Cobra Biologics, the Cell and Gene Therapy Catapult, the Vaccines Manufacturing Innovation Centre (VMIC) and Oxford Biomedica to scale up the work being done by the Jenner Institute at the University of Oxford.

The consortium is working to rapidly develop, scale-up and manufacture a potential vaccine candidate for COVID-19, called ChAdOx1 nCov-19. The vaccine has been shown to generate a strong immune response from one dose and has demonstrated a good safety profile in pre-clinical and clinical trials conducted to date. It is one of the leading candidates currently in development globally, and is listed in CEPI's portfolio of prioritised vaccines. The Jenner Institute and the Oxford Vaccine Group have already recruited over 500 healthy volunteers to study the vaccine's safety and efficacy in Phase I/II trials, which are ready to start in April. Preclinical tests and manufacturing at scale of the clinical material is taking place in parallel with the trials.

Medicines Regulation

MHRA issues guidance on COVID-19 and takes flexible approaches to regulation

The MHRA has been working with industry, the Department for Health and Social Care (DHSC) and other stakeholders to identify areas of regulatory flexibility to support the global healthcare response to the COVID-19 pandemic and the medicines supply chain in the UK.

The BIA has been engaged in weekly meetings with the MHRA alongside other trade associations to prioritise regulatory flexibilities. We would like to acknowledge and applaud the MHRA's pragmatism and flexible approach in this current challenging situation, noting participant safety is of paramount importance. The MHRA guidance on COVID-19 and latest information covering many areas is available here.

The BIA, with input from its Regulatory Affairs Advisory Committee, provided the MHRA with a list of proposals for regulatory simplifications to help our member companies deal with pressures from COVID-19. Having considered the proposals, the MHRA proposed to update their COVID-19 guidance on managing clinical trials to address some of the points raised and to provide further clarify on confidentiality considerations when accessing health records remotely. The Agency agreed to develop guidance for medical devices (e.g. inhalation devices) that are being used to deliver drugs in COVID-19 clinical trials outside their current CE mark intended use, so that the clinical trial application can be submitted and the investigational medical device application be waived. Moreover, the BIA proposals with respect to safety reporting have been included in the MHRA's proposed pharmacovigilance flexibilities or are currently under consideration.

Finally, the BIA welcomes the European Commission's proposal to delay the implementation of the EU Medical Device Regulation by one year, in response to calls from industry to allow them to focus on urgent priorities related to the COVID-19 pandemic.

BIA continued engagement in shaping the post-Brexit UK regulatory framework

The BIA has continued its engagement with the MHRA, the Office for Life Sciences and DHSC on the future of medicines regulation post-Brexit. The BIA provided its views on the post-Brexit UK regulatory framework and MHRA future role as part of the UK innovation ecosystem and at a global level at the BIA/MHRA bilateral meeting in March. The BIA and members of the BIA Regulatory Affairs Advisory Committee contributed to the discussion on the future relationship with the EU, as well as on the transition period and the Northern Ireland Protocol at the MHRA Medicines Industry Associations meeting on 10 March.

Government introduces the Medicines and Medical Devices Bill

In February, the Medicines and Medical Devices Bill 2019-2020, was introduced by Baroness Blackwood to the House of Commons. The Bill is an enabling vehicle and is designed to introduce targeted delegated powers in the fields of medicines, clinical trials and medical devices to update the existing regulatory frameworks in line with international and scientific standards after the transition period.

Representatives from the Bill team and the Office for Life Sciences joined the BIA Regulatory Affairs Advisory Committee meeting at our annual Committee Summit on 12 February, providing the opportunity to discuss the Bill ahead of its publication. A second reading took place on 2 March and the Bill Committee meetings have been postponed, noting COVID-19 measures are taking priority. The BIA will be monitoring the Bill as it progresses through Parliament to ensure that it enables faster patients access to new, innovative medicines while supporting the growth of the UK's world-leading life sciences sector.

Access to medicines

BIA continues to engage on NICE Methods Review

As activity on the NICE Methods Review gathered apace, the BIA has worked with members to support our representatives of the Working Group and its supporting task and finish groups.

We also continued to develop our thinking on the future of NICE by commissioning PwC to undertake a review of the evidence and landscape. PwC produced recommendations on how NICE should develop its appraisal process for rare disease medicines to ensure swift access. We look forward to holding a workshop later in the year with our Rare Disease Industry Group to agree next steps on taking these recommendations out to the wider health economy.

BIA highlights rare disease perspective at the Accelerated Access Collaborative

The BIA is a key partner in the Accelerated Access Collaborative (AAC), after having been brought onto the Board and Steering Groups last year.

Nicky Edwards, BIA's Director of External Affairs, attended the Steering Group meeting in February. The meeting looked at the development of the AAC's workstreams on advanced therapy medicinal products (ATMPs) and histology independent treatments. The BIA has secured representation on the subject-specific working groups of both workstreams, which are currently being set up and will meet in coming months.

Nicky Edwards presented for the BIA at the AAC Innovation Surgery on 19 February as one of the AAC's partner organisations. The aim of the morning was to give innovators the chance to engage with the AAC and its partner organisations as well as networking through a series of roundtable 'speed dating' discussions with the partners.

We also worked with AAC officials to contribute to the ongoing development of an 'Innovation Portal', which is planned to be a 'one-stop-shop' for companies working in biotech with questions about any stage of the development process. We highlighted to importance of ATMPs and the challenges they face in the context of product development and the role of universities in development and spinning out new treatments and companies. We hope to host a webinar with senior leaders from the AAC in coming months to support the roll out of the Innovation Portal.

The AAC Board met on 4 March and the BIA was represented by our Chair, Ruth McKernan, who highlighted the need for action of rare disease medicines in the context of the work of the AAC.

BIA's Rare Disease Industry Group hosts dinner General Managers' dinner

In March, BIA hosted its quarterly General Managers' dinner for the Rare Disease Industry Group (RDIG). The dinner was an opportunity for RDIG members to meet BIA's new Chair, Ruth McKernan, and discuss current issues around access to rare disease medicines. Ruth and RDIG members discussed the upcoming AAC Board meeting. The debate revolved around whether there is an opportunity for rare diseases to be part of the AAC, either in the form of a separate category or within the ATMPs category. There was also a more general discussion on the purpose of the AAC and how the group should approach it. Beyond the AAC, members discussed the NICE Methods Review, RDIG's workstreams, and the UK's future trade policy.

BIA engages with the Early Access to Medicines Scheme

This quarter, the BIA worked with the Early Access to Medicines Scheme (EAMS) Working Group to support the development of new processes and routes into EAMS. We met with representatives from the Office for Life Sciences and the MHRA to discuss these options and are participating in their ongoing development.

BIA highlights challenges in treatment pipeline on Rare Disease Day

To mark Rare Disease Day on the 29 February, the BIA contributed to a dedicated pull-out booklet published in the Guardian. In the booklet, BIA CEO Steve Bates highlighted the challenges faced by developers in the rare disease treatment pipeline and noted that better understanding of them will help to lead to better outcomes for patients. Other contributors in the booklet included Genetic Alliance and the ABPI.

BIA informs EuropaBio's rare disease key messages

Peter Wasson, BIA's Policy and Public Affairs Manager, attended EuropaBio's Rare Disease Connect Day in Brussels in January, which brought together rare disease experts from national associations across Europe. The event was an opportunity for information sharing between member associations about what is working well in their countries and what they have learnt from what other countries are doing. It was also an opportunity for national member associations to contribute to EuropeBio's messaging on access to rare disease medicines and their thinking new activity to highlight the challenges faced by developers, both at a European and national levels.

BIA surveys MPs on views on industry and medicines pricing

In February, BIA commissioned YouGov to conduct a survey of 103 MPs from across the political spectrum to gauge their perception of the pharmaceutical industry and their knowledge of rare diseases and the access landscape. The purpose of this survey is to understand the new Parliament's position on these issues in order to tailor our messaging and outreach to the various political cohorts. The following key takeaways were identified based on MPs' responses:

- 40% of MPs' opinions on the pharmaceutical industry are solely informed by pricing/access issues
- As expected, there is a clear dichotomy between Conservative and Labour MPs' positions on the industry, with Conservative being generally positive and Labour being comparatively negative
- Around half of MPs know little or nothing about the issue of patient access to medicines through the NHS but two thirds are unaware or neutral on how well NHS provides access to rare disease medicines
- Around half of MPs think the NHS is doing a good job at assessing the value of medicines generally, while only 18% think they are doing a good job at providing access to rare disease medicines

MPs are generally aware of costs/benefit measures being an integral part of the NHS/NICE assessment criteria. Yet there are misunderstandings around what criteria are used; notably, several MPs perceive the number of patients affected by a disease to be part of the NHS/NICE criteria.

The results confirm that the current Rare Disease Industry Group (RDIG) workstreams around access will have a real impact when it comes to informing MPs about access issues for rare disease medicines. The BIA will use the data to build and tailor our campaigns around the workstreams to have highest possible impact on the specific Parliamentary cohorts.

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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