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

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 April to July 2020.

COVID-19 has continued to dominate our Influence activities in the second quarter of 2020. The BIA and our members have led the industry's response to the pandemic through vaccine manufacturing and antibody therapy taskforces, worked with regulatory agencies to help companies and patients during the huge disruption to the life sciences supply chains, and lobbied for and won financial support for businesses hit by the lockdown. We have also maintained our dedicated BIA COVID-19 web portal and continued to host regular webinars to keep our members updated.

Beyond the pandemic, the BIA has continued to influence negotiations on the UK-EU future relationship and global trade agreements, publish valuable data on the sector's performance, and champion the impact of our members, from genomics to cell and gene therapies. Read on to hear about this and more.

This quarter in numbers:

23+ influence meetings with 12+ different MPs, Peers and MEPs, including 6 Ministers

7 consultation responses submitted

3 letters to Ministers

Contents

BIA engagement with the Government and Parliament

In the second quarter of 2020, the mechanisms put in place to enable government to engage with the life sciences industry on the response to the coronavirus pandemic worked to full effect. The **Life Sciences COVID-19 Response Group**, created in the early days of the outbreak, continued to meet weekly as a ministerial virtual meeting with industry, led jointly by Life Sciences Ministers Lord Bethell and Nadhim Zahawi, representing the Department of Health and Social Care (DHSC) and the Department of Business, Energy and Industrial Strategy (BEIS) respectively. The work of this group is supported by a weekly Office for Life Sciences (OLS) COVID-19 Industry Group virtual meeting. As the intense pace of the first response to the crisis has modulated, both meetings have recently moved from weekly to fortnightly.

The joint **government/industry testing webinar series** hosted by the ABPI and chaired by the BIA's Steve Bates or BIVDA's Doris-Ann Williams has continued with government being represented by ministers including Secretary of State for Health, Matt Hancock.

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

The **Life Sciences Council** met virtually on 8 June and was attended by the Business Secretary Alok Sharma and Nadhim Zahawi with Health Secretary Matt Hancock and Lord Bethell. The meeting discussed the role of life sciences in the UK's recovery from COVID-19, the next steps on implementing the Life Sciences Industrial Strategy, the UK commercial environment with an update on the work of the Patient Access to Medicines Partnership (PAMP) and the future relationship with the EU. The BIA was represented at the Council by CEO Steve Bates and Chair Ruth McKernan.

As the deadline by which the UK could have requested an extension of the transition period for leaving the EU passed on 30 June, attention has increasingly focused on the progress of talks to secure a new trade

agreement before the UK leaves the EU on 31 December 2020, with or without a negotiated agreement. After a gap of some months, the **European Union Relationship Group (EURG)** was reconvened in May with Lord Bethell taking the lead for the first time for the Government, joined by the Health Minister with responsibility for the future relationship with the EU, Edward Argar. The Group was updated on the negotiations and discussed the role of the MHRA after Brexit.

EURG met again on in late June with Ministers Lord Bethell and Nadhim Zahawi being joined by Edward Argar and Department for International Trade (DIT) Minister Greg Hands. As well as receiving an update on the progress of negotiations with the EU, concerns about the operation of the Northern Ireland Protocol and the need to ensure continuity of supply of medicines were restated by the BIA. The meeting also considered broadening the role of the group to ensure that the life sciences sector is at the heart of the Government's trade strategy as it seeks to negotiate trade agreements with the world beyond the EU. The BIA takes part in the weekly government/industry meeting to take this agenda forwards between EURG meetings.

The BIA met Trade Minister Lord Grimstone to discuss the UK/Japan trade talks and attended a briefing with Trade Minister Ranil Jayawardena, who updated industry on the progress of the UK/US trade negotiations. We have also briefed Shadow Trade Secretary Emily Thornberry and Shadow Trade Minister Bill Esterton on these issues.

The BIA also engaged with parliamentarians through the **All-Party Parliamentary Group (APPG) for Life Sciences**. Together with the ABPI and BIVDA, we hosted a briefing on the life sciences industry's response to the pandemic. Our speakers, Doris-Ann Williams MBE, CEO of BIVDA, Ian McCubbin OBE, Chair of the BIA Vaccines Manufacturing Taskforce and Haseeb Ahmad, President of ABPI, told MPs about how industry is working together to combat COVID-19. There was a positive discussion around how the UK's diagnostics industry has scaled-up its COVID-19 testing capacity, the importance of UK manufacturing capacity for COVID-19 vaccines, and how the pharmaceutical industry is supporting our NHS. Attendees also discussed the industry's unprecedented collaboration and data-sharing in response to the pandemic, equitable access to therapies and vaccines, and maintenance of NHS stock levels.

The APPG for Life Sciences hosted a virtual briefing with Daniel Zeichner MP, Chi Onwurah MP, Philip Dunne MP and Lord Lipsey on the industry's response to COVID-19.

Leaving the EU

General update

Negotiations between the UK and the EU continued virtually in the second quarter of 2020, with face to face negotiations resumed from June. There continues to be limited progress on a range of contentious issues such as State Aid, fisheries, and the role of the European Court of Justice. On 15 June, a high-level meeting via video conference took place between Prime Minister Boris Johnson, President of the European Commission Ursula von der Leyen, the EU's chief negotiator Michel Barnier and other top EU officials. The parties noted the UK's decision not to request any extension to the transition period and agreed to intensify the talks in July with a view to concluding and ratifying a deal before the end of 2020.

Industry calls for medicines deal in EU-UK negotiations

The publication of the Government's draft UK-EU Comprehensive Free Trade Agreement on 19 May was a key moment. Government has listened to industry and the measures proposed in Annex 5D would enable pharmaceutical and biotech companies to have reduced friction in trade. This is particularly important as continued scientific, regulatory and political cooperation will be needed to develop vaccines and therapeutics to tackle COVID-19 and maintain medicine supply at this challenging time.

After the UK and EU leaders agreed that "new momentum" was required in the negotiations to deliver a future EU-UK relationship, European pharmaceutical and biotech industry associations issued a joint letter on 18 June calling on the presidents of the European Commission, Council and European Parliament, as well as Trade Commissioner Phil Hogan and the EU's chief negotiator Michel Barnier "to prioritise health and patients' access to medicines over larger political considerations".

With only 6 months until the end of the transition period in December 2020, the associations said it is crucial to secure a Mutual Recognition Agreement (MRA) to minimise delays in products reaching UK and EU patients, similar to existing agreements with many third countries. This would cover batch and import testing by manufacturers and Official Medicines Control Laboratories (OMCLs) as well as Good Manufacturing Practice (GMP) inspections and CE-marking of medical devices.

BIA raises concerns about the implementation of the Northern Ireland Protocol

On 20 May, the Government published its command paper which sets out the UK's approach to the Northern Ireland Protocol. Paragraphs 38 and 39 cover regulation of goods that are of particular relevance for the life sciences sector. Specifically:

- NI would also align with all relevant EU rules relating to the placing on the market of manufactured goods
- The same authorities and bodies operating today, whether they are based in NI or the rest of the UK, will continue to be responsible for approving goods on the NI market and enforcing these rules
- Where NI traders gain product approvals and certification for the NI market from EU authorities and bodies, the UK will recognise those for the purpose of placing goods on the GB market.

The BIA participated in roundtable discussions with government officials to address the questions we raised regarding operational aspects, licensing and regulation, placing goods on the market and importation when moving goods from Great Britain to Northern Ireland. We will continue our engagement with Government and request that guidance and clarity on the implementation of the Protocol be provided to the life science industry before the end of the transition period.

BIA continues to monitor and inform Government trade negotiations

The BIA has remained engaged with government officials and ministers, as well as shadow ministers, as the UK seeks to secure new Free Trade Agreements (FTAs) with key nations around the globe. The BIA and a member of our Intellectual Property Advisory Committee (IPAC) also sit on the Government's Expert Trade Advisory Group (ETAG).

UK-US FTA

In March, the Government published the UK's objectives in trade negotiations with the US. The Government projects that a comprehensive FTA with the US will provide opportunities for businesses and boost jobs across the country and across almost all industries. Around 200 negotiators from the UK and the US held the first round of virtual negotiations between 5 and 15 May. Discussions were held across almost all areas normally covered by a comprehensive FTA. The second negotiating round took place between 15 and 26 June, following almost 20 intersessional meetings held between rounds one and two. Among others, there was progress on a separate SME chapter in the second negotiating round.

UK-Japan FTA

In May, the Government published the UK's objectives in trade negotiations with Japan. The agreement will build on the existing EU-Japan deal but aims to go further by securing additional benefits in areas such as digital trade and providing support for the UK's small businesses. Furthermore, the agreement aims to reduce barriers to trade for UK exporters, include ambitious digital provisions, and make it easier for UK professionals to operate in Japan. Formal talks started on 9 June and both parties are committed to securing a deal that will enter into force by the end of 2020.

UK-Australia FTA, UK-New Zealand FTA, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)

In June, the Government published UK's objectives in trade negotiations with Australia, New Zealand, and for accession to the CPTPP. Although the economic benefit projections are modest for both trade deals, they are part of UK's strategy of eventually acceding to the CPTPP. CPTPP reduces tariffs on 95% of goods between its members and include Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. Negotiating deals with individual CPTPP members will help UK achieve accession to the free trade area once it formally submits a request. Joining the CPTPP could boost UK trade in areas such as digital trade, data, financial, professional, and business services. Talks with Australia and New Zealand commenced in June.

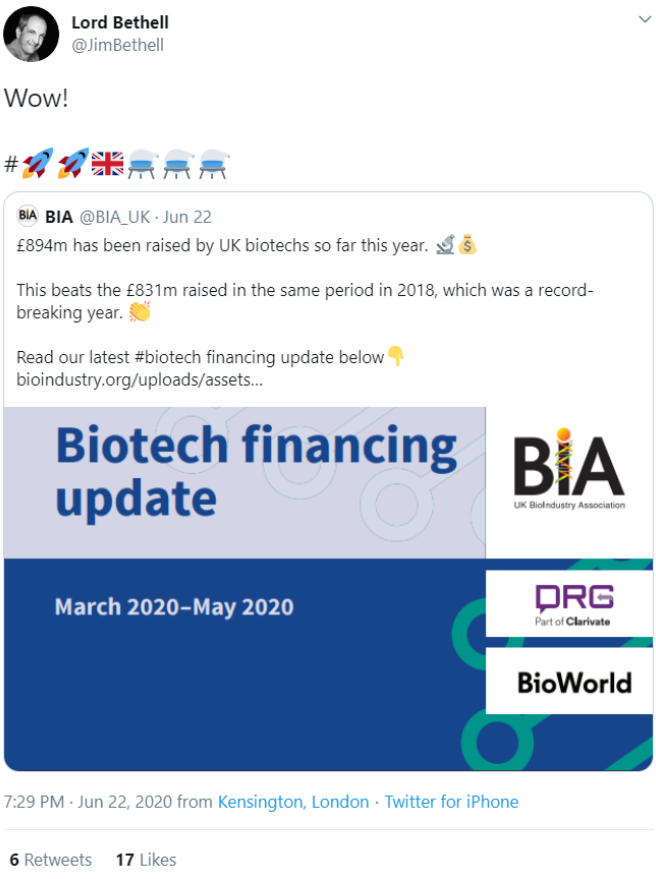
Finance, tax and investment

BIA data reveals financial ups and downs for sector during COVID-19 lockdown

Data published on in June by the BIA and Clarivate Group revealed that the UK biotech sector raised £585million from March to May 2020. Venture capital and follow-on financing during this period came in at £348m and £237m respectively. There were several large late-stage VC deals that drove the strong performance. This is despite expectations that the COVID-19 pandemic would severely impact investments. However, seed and early-stage VC deals have been heavily suppressed, dropping significantly from Q1 levels and compared to the same period last year. There were also no IPOs.

The BIA also partnered with BioCentury to survey UK biotech leaders to determine the impact of COVID-19 on their businesses. Only 33% reported seeking financial support as a result of the disruption, with the Future Fund (see next page) the most popular source of government support. Despite the difficulties posed by COVID-19, over 90% of respondents were confident that they would be able to raise the finance they need. 45% of private companies will be fundraising within six months, and another 15% within a month.

In contrast to other sectors, UK biotech appears to be riding the storm in a relatively comfortable position. Share price performance on AIM suggests that generalist investors are also taking a greater interest in the sector than previously. The BIA will be working with the London Stock Exchange and others to develop this opportunity for the sector in what could be a successful year for fundraising. A total of £894m has now been raised from all sources in the first half of 2020, surpassing the £831m raised in the same period in 2018, which was a record-breaking year.



Innovation Minister Lord Bethell reacts on Twitter to the positive fundraising data published by the BIA.

Biomedical Catalyst refilled following successful BIA campaign

In June, Innovate UK CEO Ian Campbell confirmed that innovative biotech companies will be able to access a share of £30 million in grant funding through a relaunched Biomedical Catalyst. The announcement, **made on a BIA webinar**, follows the BIA's consistent campaigning for the funding competition, which is proven to leverage over £4 of private investment for every £1 of public money invested. The Biomedical Catalyst has been a leading campaign focus of the BIA for over a decade and has been used by many BIA member companies to build world-leading British life science companies since its launch in 2012. A recent report from Ipsos Mori showed that companies in receipt of Biomedical Catalyst grants increased their R&D investment by 93%, which will help the Government reach its target of raising UK R&D investment to at least 2.4% of GDP by 2027. The competition opens 27 July and closes 7 October, and more information is available here.

Financial support for biotechs struggling due to COVID-19 rolled out

Following intense BIA campaigning on behalf of its members since the beginning of lockdown, the Government launched a £1.25bn support package for innovative firms in May. It consisted of the Future Fund, which makes available convertible loans matched by private investment, and a mix of grants and loans from Innovate UK. Both target earlier-stage companies, which as BIA data shows (see above) have been particularly badly affected by the disruption. The BIA hosted a webinar with senior representatives of the British Business Bank and Innovate UK to help members understand and access the support available.

Since the roll-out of the package the BIA has stayed in contact with members and government officials to address problems that have emerged both in the design of the schemes and in individual members' applications to them. Please contact Martin Turner at mturner@bioindustry.org for more information or support.

European Commission updates state aid rules to benefit BIA members

This quarter, among the developments on COVID-19 support measures that the BIA has been involved with is an amendment the EU State Aid Temporary Framework to enable micro and small companies that are technically classed as "Undertakings in Difficulty" to access government grant and loans. This applies to all companies with fewer than 50 employees and less than €10 million of annual turnover and/or annual balance sheet total.

The "Undertaking in Difficulty" definition blocks companies from receiving State Aid if they are more than three years old and have accumulated losses of more than 50% of their subscribed share capital. Many biotechs are caught by this due to their high R&D spend and pre-revenue status. The BIA raised this with Innovate UK and wrote to the Chancellor in April. The amendment now in place is welcome for the BIA's smaller members, but we will continue to work with the UK Government and our European partner associations to address the wider problem with this definition for our sector.

R&D tax credits are an effective policy, BIA tells MPs

The BIA has submitted evidence on the effectiveness of R&D tax credits to the House of Commons Public Accounts Committee inquiry on the management of tax reliefs. In our submission, we argued that the scheme is the most valuable form of innovation support provided by government and highlighted independent academic evidence on the positive impact R&D tax credits have on SME's investment.

The BIA calls on the Labour Party to forge an industrial strategy for life sciences

With Keir Starmer taking over as Leader of the Labour Party, new policy commissions have been launched to develop the Party's agenda. The BIA has submitted a response to the Economy, Business and Trade Commission, promoting the opportunities the life sciences sector holds for creating high-value and rewarding jobs across the UK and urging Labour to put the sector at the heart of its industrial strategy. The submission proposes policy initiatives on skills, supporting the full innovation ecosystem, creating the right environment for private investment, and incentivising medicines manufacturing.

Takeover law amendment will increase government scrutiny of biotech transactions

The Government has expanded the scope of its powers to intervene in foreign investment and takeovers. It now has additional powers to intervene in transactions where there is need to preserve the capability of the UK to respond to a public health emergency or mitigate its effects. This brings many biotech companies into the realm of scrutiny. The BIA is keen to ensure this does not have a detrimental impact on its members or the UK sector's international standing and ability to operate globally. The Finance and Tax and Intellectual Property Advisory Committees are helping the BIA provide input to the Government on this matter.

Strategic technologies and areas of scientific focus

Ensure SMEs can access Genomics England data, BIA tells MPs

In a submission to the House of Commons Science and Technology Select Committee, the BIA has highlighted the breadth and strength of the UK's genomics sector, including its crucial role in the COVID-19 response.

The BIA stressed that the upcoming Genomics England strategy must have a strong industry component to support the sector, and the importance of the Government-owned company making its datasets more broadly available for commercial genomic research, particularly for UK SMEs. The BIA also said that commercial genomics companies have an important role to play in health promotion and disease prevention for the public and that the development of clear NHS standards could help facilitate this.

BIA urges the Government to continue to oppose inclusion of DSI in global ABS framework

The BIA has taken part in an informal government consultation on proposed models to allow access and benefit sharing (ABS) of digital sequence information (DSI). ABS rules already apply – in the form of the Nagoya Protocol – to physical genetic material, which means that researchers and companies conducting research using these resources must ensure they have agreements in place with the source countries. The BIA has been engaged in international discussions about bringing the access and use of DSI of these genetic resources into scope of the Nagoya Protocol, which is something industry and the Government both oppose. The recent consultation was exploratory and is no indication the Government is changing its position, but the BIA has restated its firm opposition to any moves to introduce DSI to ABS frameworks.

BIA joins the ATTC Industry Advisory Group

The BIA has been invited to help guide the implementation of a world-first network of Advanced Therapy Treatment Centres (ATTC) within the NHS. The ATTC Network Programme is being coordinated by the Cell and Gene Therapy Catapult to address the unique and complex challenges of bringing pioneering advanced therapy medicinal products (ATMPs) to patients.

The BIA was invited to join the ATTC Industry Advisory Group following a presentation by Matthew Durdy, Chief Executive of the Cell and Gene Therapy Catapult to the BIA's Cell and Gene Therapy Advisory Committee. The group is looking at a range of issues, including standards, training, and institutional readiness. We are looking forward to working closely with the group, particularly on developing standards for ATMPs to support their development, manufacture, and delivery.

Skills, people and talent

BIA supports cross-industry skills funding bid to government

Earlier this year, the Life Sciences 2030 Future Skills Strategy was published. The BIA made a significant contribution in development of the report, which will play a central role in delivering the skills ambition of the Government's industrial strategy.

Throughout this quarter, the BIA worked with industry partners to build a comprehensive industry ask which was well supported and evidence based. The proposal received government support and elements are being taken forward which will provide an immediate response to skills demand in advanced therapies, viral vector and vaccine manufacturing. This includes a virtual learning platform which will showcase the learning pathways available to students or people new to the sector, targeted educational programmes, and specific training content to enable professionals in other industries to start working in the life sciences sector. The proposal also includes a national network of training facilities which will seek to expand collaboration between GMP facilities to expand their role in vaccine and advanced therapies manufacturing in the long-term.

BIA launches alumni association for future bioprocessing leaders

The BIA Manufacturing Advisory Committee (MAC) Leadership Programme (LeaP) was established in 2017 to develop senior leaders of the future in the bioprocessing industry. To date, 68 participants from 24 companies have taken part, with each graduating cohort producing enthusiastic future leaders in the early stages of their careers. The newly formed LeaP Alumni Association aims to expand the benefits of the initiative beyond the initial two years of the programme, providing graduates with a growing network of past participants and opportunities to meet at BIA networking events. The Alumni Association will also provide support for new LeaP cohorts.

As recent graduates of the programme Will Milligan (eXmoor Pharma) and Chris Sadler (Allergan) will provide initial leadership as Chair and Vice-Chair, respectively. Christina Baklori (Pall Biotech) and Luke Cutmore (Oxford Biomedica) will be the first LeaP Advocates, meaning they will be on hand to support the most recent cohorts through their journeys and give friendly advice and guidance when needed. Please contact Netty England for further details of this programme, which is free for BIA members.

LeaP celebrating at bioProcessUK 2019

Intellectual property and technology transfer

BIA input to global debates about access to COVID-19 innovations and IP

As research teams around the world race to develop vaccines and treatments for COVID-19, there has been intense political and public debate about how to ensure universal and equitable access to these products when they become available. The World Health Organisation (WHO) has been at the heart of this and the BIA has been in deep consultation with the Government and Opposition to inform their approach in the international discussions. Guided by the BIA's Intellectual Property Advisory Committee (IPAC) and other members, the BIA has demonstrated the great efforts our industry is already going through to pave the way for global distribution of products developed by our sector. We also raised concerns about the unintended consequences of some proposals put forward by some WHO Member States and NGOs, such as patent pools, which could harm innovation and would not aid equitable access. These discussions are ongoing, and the BIA will continue to engage with all interested parties, including via the International Council of Biotech Associations (ICBA), which is chaired by BIA CEO Steve Bates.

BIA writes to Supreme Court to take up case on preliminary injunction refusal

In late June, the BIA wrote to the UK Supreme Court asking it to accept a referral from Neurim Pharmaceuticals for its case against Generics UK (also known as Mylan). The request for a Supreme Court review followed the High Court's denial of a preliminary injunction to prevent Mylan launching a generic version of Neurim's patented medicines Circadin and Slenyto, which are prolonged release melatonin formulations. The BIA raised concerns that the decision could make it harder for other innovative companies to secure preliminary injunctions, which are an established and essential practice in life sciences patent cases.

The Supreme Court refused the referral and upheld the decision, meaning Mylan may launch their competitor drug. However, the judges said that the refusal of the injunction was specific to matters of the individual case, and as such should not have wider impact on the sector. The BIA is reviewing the decision and has written to the UK Intellectual Property Office (IPO) to ensure the Government understands the potential impact of the High Court's judgment.

Pre-clinical and clinical research

UK R&D Roadmap published

On 1 July. the Government published a UK R&D Roadmap that sets out a vision to attract global talent and cement the UK as a world-leading science superpower.

It is encouraging that the roadmap acknowledges not only the importance of leveraging private investment in R&D but also turning academic research into commercial success and societal impact. The roadmap echoes many BIA policy positions, including the need to strengthen Innovate UK and increase the availability of scale-up capital, including unlocking pensions funds, to help achieve its ambitions. BIA CEO Steve Bates attended a UKRI roundtable shortly after the Roadmap's launch to inform the funding agency's approach to taking forward the document's questions and proposals.

The focus on building on the UK's strengths in sectors like life sciences and boosting international collaboration is particularly welcome, as COVID-19 has shown these are essential to be able to effectively respond to the great challenges of our times. We look forward to continuing to engage with the Government as it takes up Boris Johnson's mission to 'build back bolder'.

The roadmap follows the Prime Minister's speech on the economy where he highlighted that the UK is a world leader in life sciences and genomics and has some of the best pharmaceutical companies in the world.

Antibody Taskforce update

The BIA's Antibody Taskforce has continued to work at pace under the leadership of Dr Jane Osbourn (Alchemab and BIA Board), Professor Paul Kellam (Kymab and Imperial College London) and Dr Paul Varley (Kymab). The consortium of over 11 companies and organisations has been focused on identifying candidate antibodies that will be assessed for their potential therapeutic value so that a select set can be taken forward for development.

The Taskforce has also been connected to the Government's Vaccines Taskforce (see page 17) to ensure it is coordinated with the wider COVID-19 response, including securing the necessary biologic manufacturing facilities to ensure the programme can continue with its rapid progress.

BIA welcomes NIHR framework for restarting clinical research activities in the UK

On 21 May, the National Institute for Health Research (NIHR) published a 'Framework for restart', a guidance document to help sponsors planning to restart clinical trials or to initiate new clinical trials which have been paused, as well as to support local decision-making. In March, the NIHR paused the set-up of new clinical trials and those ongoing at NHS sites that were not nationally prioritised COVID-19 studies to enable the NIHR research workforce to focus on delivering those studies or redeploying to frontline care where necessary. The framework will be updated in the light of experience in implementation and the evolving COVID-19 situation, and will help improve the health and wealth of the nation, given the impact that paused studies have had for patient participants, BIA members and the sector.

The BIA responded to the NIHR consultation on the proposed Restart Framework at the beginning of May and continued discussions with the DHSC and NIHR during the development of the framework to restore a fully active portfolio of research. We welcomed the letter of 6 May from the Chief Medical Officers and NHSE Medical Directors to the NHS about recruiting patients into clinical trials for COVID-19 therapeutics, which also highlighted that a lot of other valuable research is being undertaken across the health and care system:

"*It is important that this other research continues, subject to it not having a negative impact on the system's ability to recruit participants and provide the resources needed to support priority clinical studies."*

The BIA has joined by invitation the NIHR Restart Advisory Group established to provide advice, support and guidance to the NIHR Senior Responsible Officer (SRO), Dr William van't Hoff, who leads the coordinated delivery of the NIHR Restart Programme, reporting to DHSC. For members feedback on the process, please contact Dr Christiane Abouzeid.

EU Clinical Trials Information System update

On 22 April, the BIA attended the European Medicines Agency Stakeholders meeting which provided the opportunity to discuss progress in the development of the Clinical Trials Information System (CTIS) for the EU Clinical Trials Regulation. The EMA reported that development activities were on track for the audit to begin in December 2020, a key milestone for CTIS. The CTIS 'go-live' plan was endorsed by the EMA Management Board at its June meeting. As a working assumption, the go-live date of CTIS is proposed for December 2021.

Manufacturing

BIA COVID-19 Vaccine Manufacturing Taskforce continues to support vaccine candidates

Earlier this year, the BIA formed a Vaccine Manufacturing Taskforce, which is led by Ian McCubbin OBE and brings together companies that have the skills and capabilities needed to urgently manufacture millions of doses of innovative vaccines as they emerge, be that viral, mRNA or antibody based.

This industry-led vaccine manufacturing group is now working closely with the Government's Vaccine Taskforce and will support vaccine candidates as they are developed and scaled up for clinical trials and beyond. The BIA Taskforce initially worked alongside both the University of Oxford and Imperial College London to assess supply chains and understand how to scale and rapidly deploy their vaccines.

Kate Bingham, Managing Partner of BIA member SV Health Investors, has been appointed to lead the Government's Vaccine Taskforce and BIA CEO Steve Bates is sitting on the Taskforce's steering committee.

In May, AstraZeneca announced a collaboration with the University of Oxford for the further development, large-scale manufacture, and international distribution of the COVID-19 vaccine, now named AZD1222. A phase II/III trial of AZD1222 in 10,000 adult volunteers also started in the UK in May, and other late-stage trials are beginning in several other countries. With the Imperial vaccine, phase I trials are now underway and if the vaccine is safe and shows a promising immune response in humans, then larger Phase III trials will begin later in the year.

In the future, the BIA Taskforce will consider any COVID-19 vaccines or therapies that emerge, regardless of whether they are UK or internationally based and look to support these candidates where possible. The BIA is pleased to see the UK's life sciences ecosystem play such an important role in responding to this health emergency. The collaborations and manufacturing capacity developed to tackle the pandemic will provide solutions now and in the future.

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 this BIA manufacturing capability audit or contact Netty England.

LifeArc and MRC partnership to create new £16m fund to establish Gene Therapy Innovation Hubs

In April, the Medical Research Council (MRC) and LifeArc announced a £16m fund to establish a network of Gene Therapy Innovation Hubs that will offer clinical grade viral vectors, and translational and regulatory guidance to support academic-led patient trials of new gene therapies.

Operating as centrally coordinated facilities, these Hubs aim to address challenges faced by academics as they seek to progress novel gene therapy research into early stage clinical trials. These challenges include a shortage of viral vector production capacity and a complex and evolving translational pathway for gene therapies. LifeArc and the MRC will create the network by providing UK-based research organisations with grants for up to five years. More information about the grants available here.

The partnership is the result of a recommendation in 2016 by the Medicines Manufacturing Industry Partnership (MMIP) Advanced Therapies Manufacturing Taskforce, of which the BIA is a member, to boost the manufacture of academic advanced therapy clinical materials in the UK. As a result, a consortium was formed through a BIA workshop in 2018, sponsored by Cobra Biologics, British Society for Gene and Cell Therapy, Cell and Gene Therapy Catapult, Knowledge Transfer Network (KTN), and Oxford Biomedica. The consortium submitted a business case to the Department for Business, Energy and Industrial Strategy (BEIS) and funders in December 2019.

Medicines Regulation

BIA looking at long-term use of COVID-19 regulatory flexibilities

The MHRA catalogue of finalised regulatory flexibilities is an important document to consider, as the MHRA and industry will start discussions as to which of these regulatory flexibilities will be COVID-19 specific and which will be kept long-term, and look at the future of regulation post-Brexit transition. This document, which was shared with industry associations, reflects all regulatory flexibilities agreed and published on the MHRA website over the last couple of months, as well as a comparison of UK against EU regulatory flexibilities.

Following on from the MHRA guidance on Managing clinical trials during coronavirus (COVID-19), the EU has issued revised guidance to ensure that clinical trials can continue taking place during the COVID-19 pandemic. The joint European Commission, European Medicines Agency and Heads of Medicines Agencies guidance provides a harmonised set of recommendations on flexible measures (for exclusive use during the pandemic) that sponsors can take to mitigate disruption of clinical research in Europe without compromising data quality and safety of trial participants.

Developments in COVID-19 treatments

One promising treatment that has been making the headlines over the past weeks is Gilead's antiviral medicine remdesivir, which was originally developed for the treatment of Ebola virus disease. On 3 July, the European Commission granted a conditional marketing authorisation for remdesivir, making it the first medicine authorised for treatment against COVID-19 in the EU and UK. This authorisation comes within one week after a recommendation by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) compared to the usual 67 days, and less than a month after the application was submitted. These are extraordinary times – the data on remdesivir were assessed under a short timeframe through a rolling review procedure, an approach used by EMA during public health emergencies to assess data as they become available. For more information on the rapid assessment of remdesivir can be found on the EMA website.

Remdesivir is just one of over 260 treatments currently being investigated, with innovation advancing at speed across the globe. The EMA announced that as of 3 July it had been in discussion with the developers of 35 potential vaccines and 144 potential treatments, including immunomodulators, antivirals and hyperimmune serums.

BIA joins EuropaBio-EMA bilateral meeting

On 26 May, Christiane Abouzeid as Chair of EuropaBio Regulatory Policy Working Group participated in the EMA-EuropaBio bilateral discussion on EuropaBio's life sciences and biotechnology strategy vision document and the COVID-19 pandemic response. It was a good open exchange with MHRA senior officials led by EMA Executive Director Professor Guido Rasi on a range of issues, with key take-aways including:

- A review of the pharmaceutical legislation may give opportunities to build in new regulatory approaches/flexibilities in the future.
- Supply chain security – bringing manufacturing back to Europe seems to be a priority for the system post-COVID-19.
- EMA acknowledged that the biotech ecosystem in Europe needs support. A cross-sector approach is needed with recommendation to engage with a number of different Commission's DGs.

- In the context of the COVID-19 pandemic response, there is an unprecedented level of international cooperation between regulators and more can be built on this experience and momentum.
- The European Medicines Agencies Network Strategy to 2025, released for consultation on 6 July, has been re-assessed against the COVID-19 pandemic, and EuropaBio was invited to provide comments on the draft strategy.

On a related note, the BIA wish every success to Emer Cooke who has been nominated as the new EMA Executive Director by the EMA Management Board at an extraordinary virtual session on 25 June. The appointment will be made after she gives a statement to the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) on 13 July 2020.

Access to medicines

BIA supports the deployment of new initiative for rapid access to COVID-19 medicines

The BIA joined a new initiative with NHS England, NICE, MHRA and NIHR, along with key industry representatives, to understand and discuss the access framework for medicines for COVID-19 and how to ensure rapid access is achieved.

The initiative, called RAPID-C19, aims to ensure that there is a rapid, systematic and collective approach to taking promising medicines from clinical trials through existing processes to enable rapid patient access. The goal is that this coordinated approach will take no longer than 10 days from the receipt of the clinical trial evidence for treatments of significant clinical value. The RAPID-C19 initiative covers new and repurposed medicines that could significantly improve the treatment of COVID-19 patients. The process broadly follows the below:

- Collective, proactive identification of clinical trials with significant promise (national and international), led by NIHR and NICE.
- Collective prioritisation of timely/promising trials to be collectively fast tracked, through the Oversight Group, which meets weekly.
- Agreeing and then organisationally supporting the appropriate 'routing' of priority treatments through existing processes (including early access to medicines scheme (EAMS), NHS England Interim Commissioning policies, licence through MHRA).

The BIA welcomed this process and worked with other life sciences trade associations to bring it to the attention of our members. We also highlighted some of the challenges within the Early Access to Medicines Scheme (EAMS) process which are faced by the many of members. We are continuing to engage with NICE and others to understand the timelines for the full Health Technology Assessment (HTA) process to ensure normal commissioning and appropriate reimbursement.

BIA continues to represent the sector in the NICE Methods Review

National Institute for Health and Care Excellence (NICE) launched a review of its methods in autumn 2019. Since then, the BIA has secured representation for our members on the overarching Working Group, which will be making final recommendations to the Government. We also secured representation on the task and finish groups, which are exploring the detailed policy in areas such as uncertainty, the cost of HTAs and equality.

Throughout the last quarter, we have supported our members sitting on those groups and provided oversight to the discussion of the potential policy changes through our Rare Disease Industry Group (RDIG). We have also been working with the ABPI and EMIG to ensure that the Methods Review delivers tangible and realistic change, that will ultimately secure faster and sustainable access to innovative medicines for patients.

As the Methods Review enters its next stages over the summer, we will be working with the other trade associations to engage with stakeholders across the health and political economies to secure the progress already gained in discussions with NICE.

Revived AAC develops new Innovation Service

The work of the Accelerated Access Collaborative (AAC) was paused for much of this quarter to allow capacity for officials to tackle the COVID-19 crisis. However, work is starting up again, and the BIA has been briefed by the AAC on the development of its Innovation Service. This service aims to be the go-to place for innovators to navigate the path to market and to coordinate organisational partners in accelerating the best products to market. We look forward to engaging with them further as the project continues.

In addition, workstreams on advanced therapy medicinal products (ATMPs) and histology-independent treatments are starting up again and we are supporting the BIA representatives sitting on them.

BIA influences the Labour Party's health policy development

In Spring, the Labour Party launched a broad-ranging National Policy Forum to support its policy development process under its new leader, Sir Keir Starmer. The BIA submitted a response to inform the Party's health policy. The submission focused on NICE's ongoing methods review and the potential for further work to support patient access to medicines, the specific challenges for rare disease medicines in the current system and the need for a broader understanding of value to support patient access to them, and the proposed Innovative Medicines Fund and its potential role in delivering rapid access to new and innovative medicines. We will be following up with the Labour Party as the Forum continues to explore potential policy development.

BIA engages on the Innovative Medicines Fund

During the General Election in December 2019, the Conservative Party committed to introducing a new Innovative Medicines Fund to replace the Cancer Drugs Fund, which would support faster access to innovative medicines. Due to the COVID-19 crisis, the development of the fund has been delayed, but we are expecting more progress as we begin to return to normality.

The BIA has worked with members of RDIG to prepare its position on the Innovative Medicines Fund. We are keen to ensure that the Fund works for all medicines and serves as a new and effective route to access for rare disease medicines. We will be engaging with NHS England and the Office for Life Sciences (OLS) in coming months to support the development of the Fund.

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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