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

Introduction

The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from July to October 2020.

COVID-19 has continued to dominate the BIA's influence activities in the third quarter of 2020 through our work with the Government's Vaccine Taskforce, regulators and industry partners. The pandemic has put the life sciences sector into sharp focus and BIA data reveals that UK biotech has raised a record £1 billion in equity finance this quarter. To encourage more generalist investors to invest in the sector, we have published a report to help demystify biotech and inspire investors to look more deeply at the opportunity the sector offers. As many parts of the economy are struggling, we are making the case for increased public investment in the sector ahead of the Comprehensive Spending Review.

We have also demonstrated that our team can make virtual lobbying work well – the BIA's 20th annual Parliament Day and our joint conference with the MHRA were highly successful online events which saw great engagement from ministers, MPs and government officials. As the end of the transition period on 31 December is getting ever closer without a breakthrough in the UK-EU negotiations, we have continued to highlight the sector's priorities to the Government, including the importance of a Mutual Recognition Agreement and the need for clarity around the Northern Ireland Protocol. Read on for more detail about this and much more.

This quarter in numbers:

28+ influence meetings with 22+ different MPs, Peers and MEPs, including 5 Ministers

17 consultation responses and briefings submitted

3 letters to Ministers

Contents

BIA engagement with the Government and Parliament

The focus on COVID-19 was maintained in the third quarter of 2020, with the approaching end of the transition period for the UK's exit from the EU and plans for a Comprehensive Spending Review (CSR) also featuring prominently in the BIA's engagement with the Government.

The Life Sciences COVID-19 Response Group continued its collaborative work as a frequent ministerial virtual meeting with industry, led jointly by DHSC Life Sciences Minister, Lord Bethell and BEIS Life Sciences Minister, Nadhim Zahawi. This group is supported by officials in an OLS COVID-19 Industry Group which convenes between the ministerial meetings. 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 also continued.

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 European Union Relationship Group** (EURG), an expert group of the LSC, met on 7 September and was co-chaired by Phil Thomson of GSK and DHSC Minister Lord Bethell, who was joined by Edward Argar (the Health Minister with responsibility for the future relationship with the EU) and BEIS Minister Nadhim Zahawi. The meeting discussed the MHRA's **Innovative Regulation Project** with Dr June Raine and received an update on **EU negotiations** and preparations for the end of the **Transition Period**, as well as hearing from Steve Oldfield of DHSC on the **continuity of supply** of medicines. There was also an official-led call on 5 August to update EURG on the progress on negotiations with the EU. The BIA takes part in the weekly government/industry meeting to take these agendas forward between EURG meetings.

A sub-Council of the LSC, the **Patient Access to Medicines Partnership** (PAMP) met on 18 September co-chaired by DHSC Minister, Lord Bethell and John Young of Pfizer. As well as reflecting on the COVID-19 response, PAMP heard from Meindert Boysen on the **NICE Methods Review** and access to medicines. Also discussed was the uptake of innovation; the Commercial Framework; the new Innovative Medicines Fund; and branded medicines procurement and tendering with Gareth Arthur and Blake Dark of NHSE/I. The BIA was represented on PAMP by the chair of our Rare Disease Industry Group (RDIG), Charlie Galvin, who also represents the BIA on the NICE Methods Review working group.

The 20th BIA **Parliament Day** was held virtually on 9 September and was a great success, full details below. Also going virtual this year for the first time (but with rather bumpier technology) was the **Conservative Party conference** Business Day, at which the BIA met BEIS Minister for Science, Research and Innovation Amanda Solloway to discuss IP, Health Minister Lord Bethell and Alan Mak MP.

BIA holds its first virtual Parliament Day

In September, we held our 20th annual Parliament Day, which brought senior leaders from bioscience companies and policymakers at the heart of Westminster and Whitehall together. Due to the pandemic, we held the event completely virtually.

In total 40 BIA members participated, representing the broad spectrum of the sector. We had 26 meetings with Ministers, Shadow Ministers, MPs and officials across the day. Meetings included Michelle Donelan MP, Universities Minister; Rt Hon Emily Thornberry MP, Shadow International Trade Secretary; Rt Hon Greg Clark MP, Chair of the Commons Science and Technology Committee; Prof Gillian Leng CBE, Chief Executive of NICE; Catherine Lewis La Torre, Chief Executive, British Business Bank; and Kristen McLeod, Director of the OLS. We were also pleased to hear from the former Justice Secretary and Lord Chancellor, Rt Hon David Gauke, in our lunchtime webinar. The link to the webinar is here.

Screenshot of discussion between BIA members and Baroness Blackwood on how Genomics England can work with SMEs to grow the ecosystem further to benefit NHS patients.

Influence is one of the BIA's three key missions and our Parliament Day is the biggest event we hold to deliver on that mission for our members. It is an opportunity to highlight the key concerns and needs of our sector to policymakers. Our messages focused on the importance of the sector to the post-COVID-19 economic recovery, the clarity needed to ensure the sector can prepare UK's future relationship with the EU, the vital role of public support for early-stage commercial research through the Biomedical Catalyst, and the need for new flexible routes for medicines licensing, evaluation, uptake and reimbursement.

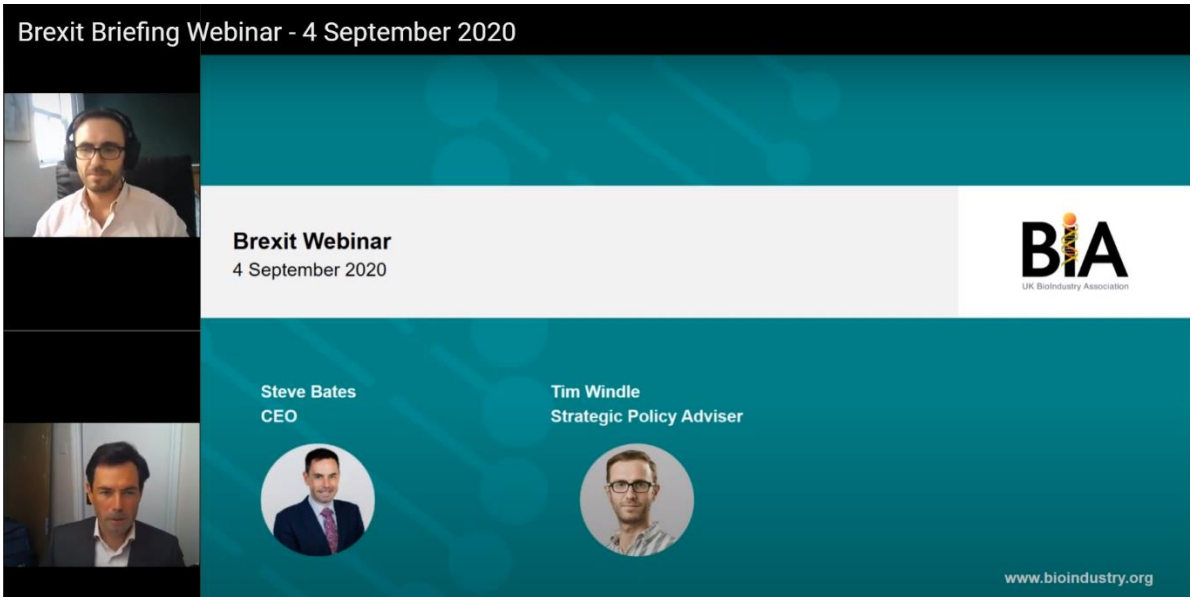
The meetings this year provided an important opportunity for our members to speak directly to decision makers, often providing a perspective and knowledge to which policymakers have limited access. This is particularly important for a relatively new Parliament, as the UK deals with COVID-19 and prepares for the end of the transition period for exiting the EU.

Leaving the EU

General update

The negotiations between the UK and EU hit a crunch point in October. At the time of writing, the UK's initially suggested deadline to agree a deal was 15 October and the EU's suggested deadline was 31 October. If a deal is going to be agreed before the end of transition on 31 December, then we will have to see progress soon. Early signs suggest there has been progress on key issues such as State aid and fisheries, but negotiations are likely to continue into November.

While the negotiations went quiet over the summer period, they quickly restarted in September with two negotiating rounds. The BIA hosted two Brexit webinars the same month to update our members on the developments. There is a further BIA webinar on 22 October, focusing on some of the regulatory questions that remain as the deadline looms. Registrations to our Brexit webinars are free and you can sign up via our Events page.



BIA CEO Steve Bates and Strategic Policy Adviser Tim Windle updates the sector on the latest life sciences news at a BIA Brexit webinar.

BIA works with government to prepare for the end of transition

The BIA has continued to work with t government to ensure systems are in place to maintain the supply of medicines in the UK at the end of the transition period. This has included the publication of Steve Oldfield's letter to medicines manufacturers on the continuity of supply and calling on the Government to release more details, particularly on how the freight capacity framework will work and how companies are likely to use this additional freight capacity. This has also included a focus on Article 40 of the Withdrawal Agreement and seeking clarity on how it applies to medicines. Article 40 defines 'goods on the market' that if made available before 1 January 2021, will continue to be able to be bought and sold between the UK and Europe after 1 January 2021.

A particular focus of the BIA has been on the challenges of supply associated with Northern Ireland. With the Northern Ireland Protocol effectively placing a trade barrier in the Irish Sea, there is a risk that normal processes of transporting medicines from Great Britain to Northern Ireland will no longer be possible. We have been working with the Government on potential solutions to this, and how those solutions might interact with regulatory challenges and the Falsified Medicines Directive.

We have continued to engage with the Government through the Life Sciences EU Relationship Group (EURG). In these meetings, we have continued to push for a Mutual Recognition Agreement (MRA), IP rights around Supplementary Protection Certificates (SPCs) and supply issues. We have also been working closely with the MHRA on their guidance for the end of the transition period, including helping to identify issues and questions that remain – please see p. 20 for a detailed update.

BIA promotes sector priorities ahead of Brexit deadline

The BIA has continued to highlight the importance of agreeing a Mutual Recognition Agreement (MRA) to politicians and government officials. We believe that the UK and the EU both understand the importance of an MRA to ensure the continued supply of medicines, including those for clinical trials, in both the UK and the EU. We have also continued to communicate concerns around changes to protections for intellectual property (IP) as we leave the EU, and specifically changes to the start time for Supplementary Protection Certificates (SPCs) (please see page 15 for a more detailed updated on SPCs.)

We have also challenged government messaging around stockpiling, as the ask of industry to stockpile medicines appeared to be creeping up from 'around six weeks' supply' to 'at least six weeks' supply'. We also worked with industry colleagues to respond to changes to the MHRA guidance that batch testing from the EU would no longer be accepted from 1 January 2023. With a potential MRA still possible, we argued that this guidance was unhelpful.

Finally, we have been working with other stakeholders beyond the Government. BIA CEO Steve Bates met with Hilary Benn MP, Chair of the EU Exit Committee and raised issues including the MRA, SPCs and specific concerns around the Northern Ireland Protocol. We also worked with the Brexit Health Alliance to launch a briefing entitled 'How can we protect patients as we approach the end of Brexit transition'.

Finance, tax and investment

BIA calls for transformative settlement for biotech in government spending review

The BIA has called on the Government to position the UK to lead the world into a new age of technological advances that will address humankind's greatest challenges, from a vaccine to free us from COVID-19 to biological fuels that will help to deliver net-zero carbon. In our submission to the Government's Comprehensive Spending Review (CSR), which will determine public investment priorities until 2025, the BIA has proposed targeted policies to support the life sciences sector from discovery research through to NHS procurement. The proposals, which include refilling the Biomedical Catalyst and a new fund structure to unlock pension funds, are designed to:

- Increase access to finance for start-ups and scale-ups
- Support world-class R&D in universities and businesses
- Establish the UK as a destination for high-value manufacturing
- Make the UK a world-leading drug development and launch market

The full submission can be read here. Alongside the formal submission, the BIA has met with ministers and civil servants to discuss the sector's needs. The Chancellor is expected to announce the outcome of the CSR in November.

Relaxation of R&D tax credit cap and expansion of eligible costs welcomed by BIA

The BIA has responded to a second consultation on the proposed PAYE cap on R&D tax credits, welcoming the relaxation of a stringent cap that would have been extremely damaging to the UK biotech SME community. The change in government approach comes after a BIA-led campaign and a series of meetings between Treasury officials and the BIA's Finance and Tax Advisory Committee (FTAC), in which alternatives to the initial cap design were discussed. The new approach will allow almost all biotech companies to be exempted from the cap, which is intended to prevent abuse of the scheme by overseas companies and not impact genuine companies.

In a separate consultation, the Government is exploring expanding the scope of R&D tax credit eligible costs to include data and cloud computing used in R&D. This has been a central request from the BIA over successive years, so we are very pleased to see the proposal adopted by the Conservative Party and explored by the Treasury. The BIA has responded to the formal consultation and held two roundtables with Treasury and HMRC officials in which BIA members were able to explain how and why they use data and cloud computing in R&D, and the benefits of expanding the R&D tax credit scheme to incentivise this activity.

Biotech businesses supported through emergency COVID-19 schemes

Since the beginning of the coronavirus crisis, hundreds of biotech companies have been supported by emergency government schemes, including the Future Fund, continuity grants and loans from Innovate UK, and the furlough scheme. Following the launch of these schemes, the BIA has continued to work with the Government and its agencies to ensure the schemes function as intended. This has included securing a relaxation of State aid rules for small companies, confirming the furloughed workers will remain eligible for EMI relief, and liaising directly with the British Business Bank to help members experiencing difficulty accessing the scheme.

A new guide to demystify biotech for generalist investors

A seminal new guide to the UK biotech sector and how to invest in it was published by the BIA in September. Called *Opportunity on your doorstep*, the guide aims to demystify the sector for generalist investors and inspire them to look more deeply at the opportunity it offers. As such, it is written as an introduction to the sector – it explains the different scientific subsectors and business models, the R&D and regulatory process, the role of IP protection and what government support is available for biotech businesses and the different ways to invest in it, with the associated risks. A comprehensive communications campaign, working with the London Stock Exchange and other partners, will ensure the guide engages potential investors directly and through the media and investment platforms, which we hope will lead to meaningful and lasting improvements in the availability of finance to fuel our rapidly growing community.

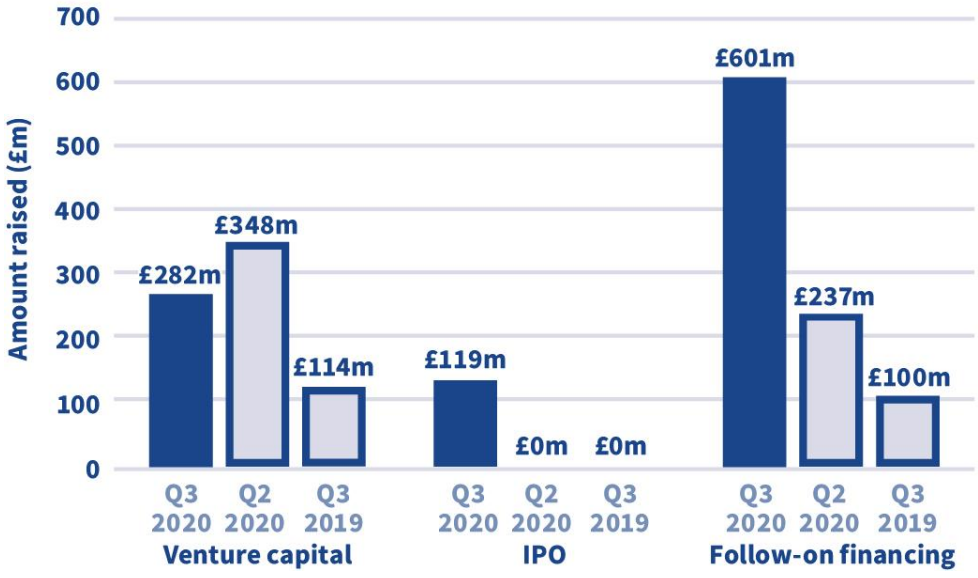
Record quarter for UK biotech as £1bn is raised

New data published by the BIA and our data partner Clarivate on 12 October reveals that UK biotech companies raised more than £1bn in equity finance between June and August 2020, the highest quarter for investments in the sector on record. With £1.9bn raised to date this year, 2020 is on target to be the best year ever recorded for this rapidly expanding sector.

The new report shows:

- £119m was raised through the year's first Initial Public Offering, showing continued US appetite for UK biotechs on NASDAQ
- £282m was raised through Venture Capital, including a return to pre-COVID 19 levels of seed and early-stage VC deals
- £601m was raised through other public financings on both London and New York exchanges as biotech share prices continue to perform well on both sides of the Atlantic

Steve Bates OBE, Chief Executive of the BIA said: "In a year when COVID-19 has caused major disruptions to the global economy, it is fantastic to see strong investment in UK biotech continue to gather pace."



UK biotech Q3 2020 fundraising data compared to Q2 2020 and Q3 2019.

Strategic technologies and areas of scientific focus

Emerging data technologies in focus at the annual UK Bioscience Forum

The BIA Bioscience Forum brings together the whole BIA membership for insightful panel discussions, inspiring keynotes and networking every October. This year, the event was held virtually for the first time, and focused on emerging data technologies. Use of AI, machine learning, and other data technologies has grown dramatically in recent years, and the conference looked at this from two different angles. Firstly, by considering how the use of these technologies can address longstanding challenges in the life sciences industry, particularly around drug discovery and path to market, and secondly, by taking a look at how new challenges introduced or exacerbated by the technology should be addressed. Sessions on using real world evidence and integrating digital strategy complemented sessions on ensuring diversity in data and how to think about IP for digital technologies. Professor Dame Ottoline Leyser and Tony Blair gave keynote addresses providing insight into big picture issues in the sector.

BIA CEO Steve Bates and Tony Blair, Executive Chairman of the Tony Blair Institute For Global Change and Former Prime Minister of Great Britain and Northern Ireland, during their live session at the Bioscience Forum.

BIA urges DEFRA to re-evaluate UK guidance on access and benefit sharing post-Brexit

In October, the BIA together with representatives from the IP Advisory Committee (IPAC) and the Engineering Biology Advisory Committee (EBAC) attended a DEFRA stakeholder meeting on the Nagoya Protocol and Access and Benefit Sharing (ABS). After the transition period with the EU ends on 31 December 2020, the EU ABS Regulation will be carried over into UK law. As part of this process, the UK will need to develop its own guidance document to the UK regulation. The new UK guidance document is likely to be largely based on the EU guidance document. However, as the EU guidance document is highly problematic for innovative organisations, the BIA is urging DEFRA, as the government department responsible for ABS policy, to re-evaluate the UK guidance document to ensure that it sets out unambiguous and helpful guidance that recognises how contemporary life sciences R&D is conducted.

BIA's Genomics Committee continues to engage positively with Genomics England

This quarter, the BIA Genomics Advisory Committee (GAC) has continued to engage positively with the leadership of Genomics England's, including its chair Baroness Nicola Blackwood and its CCO, Parker Moss. The discussions have focused on Genomics England's strategy and how the organisation can support the growth of UK genomic start-ups and SMEs.

Related to these discussions, the Government published a new strategy for genomics, '*Genome UK: The Future of Healthcare*'. *Genome UK* sets out the plan to extend the UK's leadership in this field and deliver world-leading, genomics-driven healthcare to patients. The strategy identifies three pillars: diagnosis and personalised medicine; prevention; and research, which the Government will focus on in partnership with the third and private sectors. In the BIA's recent submission to the Comprehensive Spending Review (CSR; see p. 9 above), we argued for public investment in genomic SMEs, so it was great to see the strategy recognising the important role of industry, and smaller companies in particular, in the development of innovative genomic technologies.

BIA joins ATTC Network Industry Advisory Group

The BIA has joined the Advanced Therapy Treatment Centre (ATTC) Network Industry Advisory Group, bringing the unique expertise of our members to key discussions on a range of issues relating to ATMPs, including standardisation and logistics. We have also been invited to join a working group under the Industry Advisory Group focusing specifically on commercialisation, which is an increasingly important area of work as more ATMPs enter the market.

Skills, people and talent

BIA provides input into to the UK's new global immigration policy

As of 1 January 2021, the rules for how talent from the EU is recruited is changing, as the UK will no longer have free movement across its borders. The BIA has influenced the development of the Government's new immigration policy to ensure global mobility of skills to support, develop and grow the life sciences sector.

There will no longer be an unskilled entry route. Skilled entry for those with job offers from a licensed sponsor and the ability to speak English, will be points based. After consultation, the minimum level of job offer has been reduced from graduate level (RQF6) to any role above entry or technician level (RQF3). The BIA collaborated with SRG, a resourcing company, and the New Scientist, to complete a salary survey. The survey was used to inform a submission to the Government's Migration Advisory Committee (MAC).

The Government has now reduced the minimum salary threshold from £25,600 (20pts) to £20,480 (0pts) with consideration for 'going rates' and 'new entrant' salaries. The resident labour market test and cap on numbers has been removed completely and extra tradeable points are based on qualifications with a STEM focus. The highly skilled route, which replaces Tier 1, is available through the Global Talent visa, Innovators route or Start-up route for Entrepreneurs. More details on these can be found on the BIA website.

Intellectual property and technology transfer

Government U-turns on post-Brexit SPC waiver following BIA lobbying

The BIA has successfully argued for a significant change in approach to the UK's Supplementary Protection Certificate (SPC) manufacturing waiver. Last year, the Government consulted on secondary legislation to amend the law for the SPC waiver so that it functions in the event of the UK leaving the EU without a deal. (For an explanation of the SPC waiver see the BIA guide here.) The Government proposed to permit the production of SPC-protected medicinal products for export to the EU, which the innovative life sciences industry objected to on the grounds that it could erode their IP rights in some EU Member States. Following the BIA's formal response and meetings between members of its IP Advisory Committee (IPAC) and officials, the Government has changed its approach to restrict the export market under the 'making for export' waiver to countries outside the EU and UK only. Further details can be found here.

BIA helps shape post-Brexit SPC regime

The UK's departure from the EU without an agreement in place on the future relationship would result in medicines in Great Britain and Northern Ireland being subject to separate market authorisations, by the MHRA and the EMA, respectively. As a result, the Government is working on a new Supplementary Protection Certificate (SPC) application procedure that will allow for separate applications covering the two regions. The BIA's IP Advisory Committee (IPAC) has provided advice to the UK Intellectual Property Office on their proposed operation of this procedure and met with officials to discuss options for its implementation. Secondary legislation is expected in the coming weeks and IPAC will continue to monitor this on behalf of the sector.

New guide for BIA members on employee inventor compensation

The BIA's IP Advisory Committee (IPAC) has published a guide for members on the implications of a recent UK Supreme Court case decision, which found that employees who are named as inventors on patents that result in substantial profit for companies are legally entitled to a share of those proceeds. The guide also describes more broadly current common practice for employee inventor reward schemes within our industry. The guide can be downloaded here.

BIA opposes Ministry of Justice proposals on diverging from CJEU case law

The BIA has responded to a consultation by the Ministry of Justice on proposals to allow the lower courts of England and Wales to diverge from past decisions of the Court of Justice of the European Union (CJEU). The BIA said that only the UK Supreme Court should have this power, as this would provide more certainty for businesses, particularly in the field of intellectual property law, which is subject to a lot of case law.

BIA takes part in Labour Party roundtable on commercialisation

The BIA's Head of Policy and Public Affairs, Martin Turner, participated in a roundtable organised by Labour Shadow Science Minister, Chi Onwurah MP, on improving research commercialisation in life sciences. The meeting was an opportunity to influence the development of Labour's new policy agenda under the new leader, Keir Starmer. Ms Onwurah took strong interest in the challenges surrounding scale-up finance and the BIA has since followed up with further information and connected her to some BIA members to help inform her thinking further.

Pre-clinical and clinical research

BIA Antibody Taskforce continues work to identify COVID-19 antibody candidates

The BIA Antibody Taskforce, a consortium consisting of UK biotech SMEs, academia and charities led by Dr Jane Osbourn OBE, is continuing its work to identify COVID-19 antibodies. In September, IONTAS, an SME member of the Taskforce, announced that they have identified potent antibodies that can block COVID-19 infection at doses as low as 20pM in pseudoviral assays and 100pM in live coronavirus assays. The announcement highlights some of the early work coming out of the Taskforce, which has developed an accelerated and rigorous multifaceted approach to create a pool of novel candidates and identify the antibodies with the best potential.

New R&D Roadmap and UKRI CEO welcomed by the BIA

The BIA has welcomed and commented on a comprehensive and broad-ranging new R&D Roadmap, in which the Government has set out how it intends to reach its target of the UK investing 2.4% of GDP in R&D by 2027. To achieve the Government's over-arching ambition that the planned increase in public investment in R&D should lead to increased business investment, the BIA calls on the Government to work collaboratively with the life sciences sector and develop a holistic approach to innovation policy. This should consider the role of the wider business environment in raising R&D investment and capturing the full economic, environmental and social benefits.

The BIA also supported the expansion of Innovate UK's role in underpinning business innovation and champion the importance of sector-specific funding programmes like the Biomedical Catalyst. In line with our submission to the Comprehensive Spending Review (see page 9), the BIA recommended a bold and ambitious new government-backed investment fund to support scaling life science businesses and funding for the MHRA to maintain the UK's position as a world-leading regulator, among other measures.

The BIA also had the opportunity to welcome the new CEO of UKRI, Professor Dame Ottoline Leyser, and discuss the R&D Roadmap in a meeting between Dame Ottoline and BIA CEO Steve Bates. The productive meeting established the BIA as a trusted partner of the UKRI and BIA Board members will be meeting with Dame Ottoline in the coming weeks to further discuss her vision for UK R&D and provide our sector's input as she seeks to strengthen the environment for business innovation. In addition, Dame Ottoline outlined her vision for the UK's innovation at our annual Bioscience Forum on 15 October.

UKRI CEO Dame Ottoline outlines her vision for the UK's research and innovation system at the BIA's Bioscience Forum.

NIHR Guidance for a 'second wave' of COVID-19 activity

On 12 October, the National Institute for Health Research (NIHR) issued guidance on how to protect both COVID-19 and non-COVID-19 research during a 'second wave' of high COVID-19 activity. We support the key message in this NIHR guidance that research staff funded by NIHR should not be deployed to front line duties except in exceptional circumstances. This contrasts with the 'first wave', when many staff members from the NIHR's Local Clinical Research Networks and Clinical Research Facilities were deployed to the clinical front line in anticipation of heightened need. The study prioritisation levels in the Restart Framework (May 2020) to support the restarting of clinical trials paused due to COVID-19 is unchanged, and the NIHR's restart decisions continue to be locally led. The framework also highlights the importance of non-COVID-19 studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm. The guidance applies to England but has been developed in consultation with representatives of the devolved administrations.

The BIA sits on the NIHR Restart Advisory Group, which was established to provide advice and guidance to the NIHR Senior Responsible Officer (SRO), Dr William van't Hoff, who leads the coordinated delivery of the NIHR Restart Programme. BIA members can contact Dr Christiane Abouzeid for feedback on restarting their studies.

BIA attends roundtable on the future of UK clinical trials regulation

On 9 October, the BIA participated in a roundtable on the future of clinical trials regulation, hosted by Sir Gordon Duff, Principal, St Hilda's College, University of Oxford, and BIA member Silence Therapeutics, and chaired by Lord Patel. Attendees discussed how to make the UK a world-leading place to conduct clinical research for the benefit of patients in a post-Brexit UK, capitalising on the world-leading reputation of the MHRA as an innovative regulatory body.

Manufacturing

BIA Vaccine Manufacturing Taskforce transforms into smaller advisory group to government

The BIA COVID-19 Vaccine Manufacturing Taskforce led by Ian McCubbin OBE, which was swiftly formed in March this year to support vaccines manufacturing, has now stepped down as the vaccines it was supporting have been integrated with the Government's Vaccine Taskforce. The BIA would like to thank all members of the Taskforce for mobilising without question and their unreserved readiness to collaborate, often with competitors, in the efforts to support vaccine candidates from Oxford University and Imperial College London and to assess the supply chains required to scale and rapidly deploy the vaccines.

A smaller BIA Expert Advisory Group, again led by Ian McCubbin, has replaced the Vaccine Manufacturing Taskforce. This independent group is providing advice and guidance directly to the Government's Vaccine Taskforce.

You can find out more about the UK's efforts to manufacture a COVID-19 vaccine in a podcast from the Government's Vaccine Taskforce. Speakers include Kate Bingham, chair of the UK Vaccine Taskforce, Netty England, secretariat and member of the BIA Manufacturing Advisory Committee (MAC), Andy Jones, Industrial Strategy Challenge Fund Medicines Manufacturing Director, and Ian McCubbin, UK Vaccine Taskforce Manufacturing Lead.

BIA welcomes Catapult funding to kick-start Centre for Advanced Therapies Training and Skills

The BIA welcomed the announcement that the Cell & Gene Therapy Catapult has received £4.7m to launch a Centre for Advanced Therapies Training and Skills (CATTS) programme to boost skills in vaccines and cell and gene therapies. The Catapult has also been given additional resources to kick-start an Advanced Therapies Skills Training Network which will include a network of centres, starting with expansion of existing training facilities, plus the development of an online virtual learning platform to showcase existing learning programmes available. The platform will help build new career routes and develop targeted educational programmes and specific training content to support bringing in new people from across sectors and upskill existing staff within organisations across the UK.

Medicines Regulation

BIA and MHRA hold annual Regulatory Innovation Conference

In September, the BIA and MHRA once again delivered a joint conference on "Transforming innovative medicines development in the UK". A line-up of high-profile speakers from the MHRA, NICE, NIBSC, CPRD, HRA, UKRI, AMRC and industry discussed a wide range of crucial topics, including:

- Future vision – Interactive and responsive regulation for expediting patient access
- Integrating innovative approaches to clinical development in the UK
- Real World Data: what is possible and when?

Lord Bethell, Minister for Innovation, DHSC, gave the keynote address, in which he discussed the future ambition for the UK life sciences sector in 2021 and beyond.

Dr June Raine, Chief Executive of MHRA, speaks at the BIA-MHRA conference.

Our first virtual regulatory conference was a success and, considering the challenges the life sciences sector faces in a global pandemic and with the end of the Brexit transition period looming, it could not have come at a more pivotal time. We would like to pay tribute to the co-chairs of the conference, Dr June Raine, Chief Executive of MHRA, and Emma Du Four, Chair of BIA Regulatory Affairs Advisory Committee (RAAC) and Head of International Regulatory Policy at AbbVie, as well as thank delegates and expert speakers for a highly engaging and enthusiastic event with some great discussions around the post-Brexit UK regulatory framework.

BIA takes part in joint MHRA-OLS project on the future of regulation

Over the summer, the BIA provided input into a project jointly led by the MHRA and the OLS on innovative regulation and the MHRA's future. This was initiated in response to the Life Sciences Council (LSC) decision at its June meeting to develop the MHRA as a world leading innovative regulator for innovative new products, such as in personalised medicine, digital and AI-enabled treatments.

The BIA and members from the BIA's Regulatory Affairs Advisory Committee (RAAC) participated in deep dive workshops and contributed to discussions on several subject areas, including clinical trials, vaccines, medicines regulation and advanced therapies. A report on a 'new vision' for future regulation was produced for DHSC Minister Lord Bethell, which took account of stakeholders' views and made a series of recommendations, including in support of Comprehensive Spending Review bids, noting the Government's commitment to make the UK the leading global hub for life sciences.

BIA welcomes DHSC announcement that MHRA is joining Project Orbis

The Health Secretary, Matt Hancock, recently announced in the House of the Commons that the MHRA will be joining Project Orbis, an initiative led by the US Food and Drug Administration (FDA) Oncology Centre of Excellence. It is designed to provide a framework for concurrent regulatory review and approval of oncology products. This is a welcome move enabling the MHRA to join FDA Project Orbis on 1 January 2021, and collaborate with global regulatory authorities, including Australia's Therapeutic Goods Administration, Health Canada, Singapore's Health Sciences Authority and Swissmedic, so that patients can get faster access to innovative treatments. The BIA welcomed the announcement because, as nearly all innovative cancer medicines are launched in the US, this could become a key route for the UK to remain an early and priority market for global launches after the end of the Brexit transition period.

MHRA guidance for end of transition period

The BIA continued engagement with the MHRA this quarter and participated in workshops bringing Industry Associations together for detailed review of MHRA guidance or proposed regulatory arrangements for Great Britain and Northern Ireland under the Northern Ireland protocol following the end of the Brexit transition period. From 1 January 2021, the MHRA will be the UK's standalone medicines and medical devices regulator.

The MHRA post-transition period guidance was finalised and communicated to industry in September – two years initial application from 1 January 2021 in line with cross-government approach. The guidance for Great Britain is based on 'no deal' preparations, while Northern Ireland will be operating to the EU medicines regulatory system under the Northern Ireland Protocol. Subsequently, the MHRA published guidance on supplying medicines to Northern Ireland from 1 January 2021. Medicines placed on the market in the EU or the UK before 11pm GMT on 31 December 2020 may continue to circulate between these two markets from 1 January 2021.

Article 41 of the Withdrawal Agreement enables these medicines to remain available for sale or supply between Great Britain, Northern Ireland and the EU after 1 January 2021, without additional regulatory checks. However, clarification on interpretation of Article 40 of the Withdrawal Agreement is still subject to agreement from government and may result in changes to these arrangements. Further guidance on Northern Ireland and unfettered access of medicines from Northern Ireland into Great Britain is expected to be published in October.

To help all stakeholders understand the detail of this guidance published (more than 30 items), the MHRA is holding a series of webinars from 20 to 29 October on topics ranging from UK supply chain regulation, clinical trials, UK marketing authorisation procedures to conversion of Community authorisations to GB licences and pharmacovigilance requirements. Original capacity for these webinars was set at 500 and the sessions quickly became full given the high demand from companies that need to get ready for 1 January 2021. Following representations from the BIA, the capacity was increased to 3,000 for each of the nine webinars. MHRA is also offering recordings of the webinars for those who cannot attend.

Access to medicines

BIA continues to work with industry partners on NICE Methods Review

Following the launch of NICE's anticipated review of its methods last year, it has been a key area of work for the BIA. We have been working hard since then to ensure that the voice of our members is at the heart of that process. This has been driven by our Rare Disease Industry Group (RDIG) and we have secured direct representation on the Working Group of the Methods Review and are supporting members on the Working Group's Task and Finish Groups.

In the last quarter, we have been supporting members engaging with the final stages of the first part of the Review. We have been encouraged by the progress of the Review and as it moves out of the technical discussions and into a more political phase, we have been working with ABPI and EMIG to develop a joint industry position – particularly in areas where there has been positive movement. This has included a series of meetings with key stakeholders focusing on the Review, including with Will Warr, Adviser to the Prime Minister; Lord Bethell, Life Sciences Ministers; and Munira Wilson MP, Liberal Democrat Health Spokesperson.

We are expecting the near-to-final draft of the consultation document at some point in October ahead of the next NICE Board meeting. The first consultation will be in November, focusing on the case for change, followed by a detailed technical consultation in February next year. The BIA will keep our members updated as these processes progress.

BIA holds RDIG workshop on the future of rare disease medicine evaluation

In July 2020, the BIA held a workshop with our Rare Disease Industry Group to consider future work on engaging with Parliament and the Government on rare diseases. The workshop focused on identifying and agreeing key recommendations for our future rare disease advocacy work.

The workshop was facilitated by Richard Sloggett, formerly a Special Adviser to Matt Hancock and currently the Head of Health at Policy Exchange. We look forward to going into 2021 with a renewed and ambitious programme following this workshop.

BIA presents to Findacure charity workshop

In September, the BIA presented to a Findacure Charity workshop, which discussed how patient groups and industry can best work together to ensure access to medicines for rare diseases. Our presentation focused on the value of the patient voice to biotech companies throughout the entire medicine development process. The panel also included BIA member companies, which provided a unique perspective on patient advocacy in this area.

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

www.bioindustry.org

BIA Supporters

cytiva

lifeArc

VWR part of avantor

Johnson & Johnson INNOVATION

Gallagher Insurance | Risk Management | Consulting

AstraZeneca

BIA UK BioIndustry Association