Influencing and shaping our sector – BIA update April – July 2019

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 2019.

With continued political uncertainty around the new government's priorities on Brexit and the Industrial Strategy, the BIA has worked hard this quarter to communicate our sector's needs to policymakers. In July, BIA members were out in force for our annual Parliament Day and met with Ministers, MPs and civil servants. We have also written to the two final contenders for the Conservative leadership, Boris Johnson MP and Jeremy Hunt MP, to highlight the positive impact innovative SMEs have on the health and wealth of the country. We will engage with the new Government as it is formed to ensure innovative life sciences remain high on the political agenda.

Despite political and financial headwinds, our sector continues to thrive. Our most recent finance data show that investors maintain their confidence in the sector. In June, we took this positive message to Philadelphia for the annual BIO International Convention, where we championed UK innovation among the global biotech community. This quarter, we've also published a new report that celebrates innovative SMEs all around the UK and makes the case for the increased investment in our sector ahead of the forthcoming Spending Review. Read about this and much more below.

This quarter in numbers:

19+ influence meetings with 20+ MPs and Peers, including 8 Ministers

11 consultation responses submitted

2 letters to Ministers

Contents

BIA's 19th annual Parliament Day

On 11 July, the BIA brought together 35 senior representatives from across the UK's life sciences sector to meet with parliamentarians, senior NHS leaders, funding bodies and civil servants for our annual Parliament Day. The day enables key engagements between BIA members and policymakers across Westminster and Whitehall.

The delegation of BIA members had 17 meetings with policymakers, including eight meetings with MPs. The meetings were an excellent opportunity for our members to highlight the sector's priorities on Brexit, the upcoming Spending Review and how to unlock access to new medicines in the NHS. We also had lunch in the House of Lords, kindly hosted by Lord O'Shaughnessy, the former life sciences minister. The lunch was an informal opportunity to network with each other and external stakeholders who were keen to hear about our sector's successes and challenges.

For policymakers, the day also offers a rare insight into the technologies of some of the UK's most innovative companies. The BIA will now work to follow-up with these policymakers to ensure understanding of our sector and the value it provides to the country remain high.

Following the Parliament Day meetings, BIA staff led our delegation to Tower Bridge for the BIA's annual Summer Reception.

Influencing life sciences policy at home and abroad

Engagement with the UK Government in high level policy forums

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 Council's work. The Spring meeting was held at 10 Downing Street in May 2019. BIA Board Member and CellCentric Chairman and CEO, Dr Will West, joined BIA CEO Steve Bates at the meeting. Business Secretary Greg Clark MP and Health Secretary Matt Hancock MP co-chaired with Pascal Soriot, CEO of AstraZeneca. Baroness Blackwood, Life Sciences Minister and Lord Henley, Life Sciences Industrial Strategy Minister also attended.

The remit of the Accelerated Access Collaborative (AAC) has been expanded. The AAC will bring together the entire innovation ecosystem and has seen the establishment of a new unit within NHS England led by Chief Executive, Sam Roberts. The BIA has now joined the AAC Board and was represented at its June 2019 meeting by Steve Bates.

The BIA is also represented on the Patient Access to Medicines Partnership (PAMP), an expert sub-group of the Life Sciences Council, which met for the first time in July 2019. The meeting discussed the recently launched NICE Methods Review (the BIA will be joining the review working group) and the NHS England commercial framework.

The Life Sciences Industrial Strategy Implementation Board (LSISIB), which met in March and June 2019, is the forum where government and industry focus on the delivery and development of the Life Sciences Industrial Strategy. The two meetings held so far this year have discussed the Sector Deal progress report and draft implementation plan and the 'Global Sales Pitch' being developed jointly between OLS and the Department for International Trade (DIT). The most recent meeting of the LSISIB discussed business scale-up and access to finance and the importance of data and digital in the life sciences industrial strategy.

During the discussions in these government-industry forums, the BIA has advocated in favour of life sciences policy which supports the UK's position as a global hub for life sciences with an ecosystem in which innovative companies can thrive. We have used our report *Confident capital: backing UK biotech* and other research to make the case for a fiscal incentives landscape which enables companies in our sector to invest in R&D and grow successfully.

BIA takes over Chair of international biotech council

In addition to engaging with the UK Government and the domestic sector, we are working internationally with other biotech associations from all over the world through the International Council of Biotechnology Associations (ICBA). In June, ICBA met on the fringes of the BIO International Convention in Philadelphia to discuss how we can work together to enable biotech companies all over the world to start, grow and develop their technologies for the good of humanity. BIA CEO Steve Bates has taken over the ICBA chair from Andrew Casey of BIOTECananda and we look forward to shape the global biotech agenda during Steve's two-year term.

Leaving the EU

General Brexit update

The direction of Brexit and the nature of UK's future relationship with the EU has dominated the Conservative leadership contest, which began after Theresa May MP announced on 7 June that she would step down as Prime Minister. The BIA has written to the leadership contenders, Boris Johnson MP and Jeremy Hunt MP, to highlight the sector's policy priorities and ask to meet with their respective teams to discuss Brexit and the impact of a no-deal. As the new Government is formed, we will continue to engage with Ministers to ensure that they understand the implications of Brexit for the sector.

The EU Relationship Group, a forum for industry and government to coordinate Brexit work, has continued to meet in April and July and the BIA engages closely in the meetings. The group continues to focus on contingency planning for a no-deal Brexit.

BIA CEO Steve Bates highlights risks of no-deal to parliamentary committee

In June, BIA CEO Steve Bates gave evidence to the House of Commons Exiting the EU Select Committee inquiry into no-deal planning. Steve highlighted the importance of avoiding a no-deal Brexit to protect the supply of medicines and the need for clarity from government on no-deal contingency planning, including freight capacity and customs arrangements. He also argued that the Government is risking weighing the scales against recent positive investment decisions and undermining the UK's reputation for science excellence that it has built over the years through industrial strategy by successive governments.

Steve Bates gave evidence to the House of Commons Exiting the EU Select Committee.

BIA briefs new MEPs on the life sciences sector's Brexit priorities

In July, 73 MEPs from the UK took their seats in the EU Parliament, many of them for the first time. As Brexit and its impact on the UK are high on their agendas, the BIA briefed them to highlight the sector's priorities for EU withdrawal and the future UK-EU relationship. In particular, we highlighted the need for regulatory partnership between the MHRA and the EMA. A more detailed summary of the briefing is available on our blog.

Government publishes new no-deal contingency plans

In June, the Government published a Written Ministerial Statement on EU Exit preparedness. The BIA has highlighted both to the Government and externally that companies will continue to do all they can to ensure that patients will be able to get their medicines, regardless of the Brexit outcome.

However, we have also stressed that no-deal Brexit must be avoided, as it will negatively impact patients, public health and the life sciences sector. We are continuing to provide input into the Government's contingency planning to highlight the challenges posed to the sector.

BIA informs Labour's Brexit policy

In anticipation of the possibility of an early general election, the Labour Party is preparing for government by establishing a series of policy commissions to develop the contents of a manifesto. In June, the BIA submitted a response to the Labour Party Policy Forum's consultation on Brexit and international policy. Our submission focused on the life sciences sector's policy priorities of a medicines regulatory partnership with the EU, continued frictionless trade, access to talent and R&D collaboration. We also highlighted the need to avoid a no-deal Brexit.

BIA calls for continued UK-EU collaboration at BIO International Convention

In June, the BIA attended the annual BIO International Convention in Philadelphia together with 17,000 people from the global biotech community. Throughout the conference, the BIA team championed UK biotech by highlighting the strength of the sector. BIA CEO Steve Bates spoke at two events – one private EMA roundtable with Guido Rasi and one panel session organised by the Belgian biotech association. At both events, Steve made the case for the value on all sides of regulatory cooperation and highlighted that investors have been maintaining their confidence in the UK biotech sector despite the political uncertainty.

We also co-sponsored a lively UK reception and celebrated the unveiling of the UK's newest collaboration between academia, local government and life science organisations – Health Innovation Research Alliance Northern Ireland (HIRANI). Read about all our BIO activities on our blog.

Ongoing BIA Brexit activity –webinars and Brexit Lead Network events

We continue to hold our free monthly webinars where our CEO Steve Bates and Brexit Lead Laura Collister explain the latest Brexit updates and what they mean for the sector. Register for the next webinar on our website or tune into past webinars on our YouTube channel.

We also hold regular Brexit Lead Network events together with ABPI. The events have a members-only session to discuss industry views, as well as a government update from senior civil servants. There will be three further events this year and BIA members can register for free on our website.

Medicines Regulation

BIA continues engagement with regulators on Brexit

The BIA continues to have a constructive dialogue with the MHRA and the Government on the future of medicines regulation post-Brexit. The BIA and our members are taking part in roundtable meetings with Life Sciences Minister Baroness Blackwood on the Future Economic Partnership to define regulatory priorities in the negotiations with the EU. These stakeholder engagement meetings aim to ensure that, as negotiations proceed, the UK Government remains focused on delivering the best possible outcome for UK patients and the life sciences sector. If you are interested in attending a roundtable, please contact Laura Collister at lcollister@bioindustry.org.

In consultation with the BIA's Regulatory Affairs Advisory Committee, we submitted questions and points for clarification regarding the MHRA processes described in guidance documents that were issued by the Agency in the event that the UK leaves the EU without a deal. This covered baseline submissions in the context of 'grandfathering' and managing the lifecycle changes of medicinal products, new assessment routes including targeted assessment, pharmacovigilance requirements and procedures for UK Paediatric Investigation Plans (PIPs). If you have queries about these guidance documents, please contact Christiane Abouzeid at CAbouzeid@bioindustry.org.

We believe it is vital to ensure that the UK retains the MHRA's international standing and its regulatory science expertise in the eyes of global companies and investors. We called on the Government to commit investment to the MHRA, allowing it to embed deeper in the science base to support innovation and deliver patient benefits in our new report 'Life sciences: Catalysing investment and growth' (more on page 11).

EMA updates on industry preparedness for Brexit

In June, the EMA Management Board noted that just three out of the 400 marketing authorisations for human medicines still needed to be transferred from the UK to an EU27 Member State. Good progress was reported for products with qualified persons for pharmacovigilance (QPPVs) and pharmacovigilance system master files (PSMFs) based in the UK.

However, Brexit and the relocation to Amsterdam have impacted on the Agency's resources. The EMA is anticipating losing between 20% and 25% of the 901 staff members it had at the end of 2018. Most activities that were temporarily suspended at the end of 2018 as part of the EMA's business continuity planning remain on hold. This includes guideline development, working party meetings, international activities, as well as the Agency's initiative on proactive publication of clinical data. Some activities that focus on increasing the efficiency of EMA's operations will start to be reinstated; for example, initiatives relating to the regulatory science strategy (see page 10). More detail on the EMA's business continuity plan is found on the Agency's website.

NHS England updates guide on biosimilar medicines

The newly updated guide 'What is a biosimilar medicine?' was developed by NHS England, in partnership with BIA and key organisations including MHRA, NICE, ABPI and the Royal Pharmaceutical Society.

This document provides an update for key clinical and non-clinical stakeholders about the role of biosimilar medicines in the NHS in England. It also supports the safe, effective and consistent use of all biological medicines, including biosimilar medicines, to the benefit of patients, in line with the principles of shared decision making to ensure individuals are able to make decisions that are right for them.

BIA contributes to consultation on EMA's strategy on Regulatory Science to 2025

In June, the BIA provided input together with EuropaBio to the EMA's consultation on its proposed strategy on Regulatory Science to 2025. 'Regulatory science' refers to the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the product lifecycle.

We welcome the EMA's initiative to set out its vision for the next five years for a more adaptive regulatory system that will encourage innovation in medicines. This will also help shape the next strategy for the EU Medicines Agencies Network, which is the cornerstone of the EMA's success.

In our submission we identified the following top three priorities among those proposed in the strategic reflection paper:

- Support the translation of advanced therapy medicinal products (ATMPs) into patient treatments
- Reinforce patient relevance in evidence generation
- Contribute to HTA's preparedness and downstream decision making for innovative medicines

We also highlighted some additional recommendations in the paper which are important to the sector, in particular: (i) diversify and integrate the provision of regulatory advice along the development continuum; (ii) foster innovation in clinical trials; (iii) expand benefit-risk assessment and communication; and (iv) promote the use of high quality real-world data in decision making.

We believe these recommendations will deliver significant change to the EU regulatory system to enable the development and access to new, innovative medicines for the benefit of patients and public health in Europe. We also stressed the need for human and financial resources, and capabilities within the EMA and EU Network to deliver on the ambition set out in the proposed strategy.

EMA's SME Office – 2018 highlights

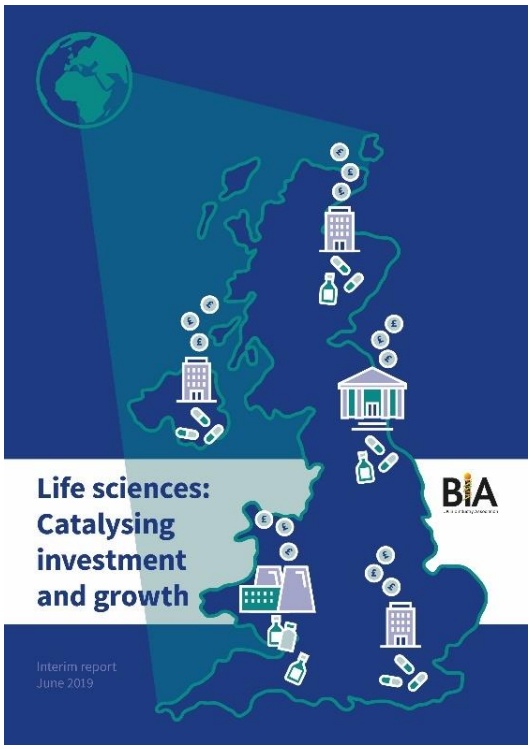
The EMA launched its SME Office in December 2005 to address the particular needs of smaller companies. The 2018 annual report published in June recorded the largest number of SMEs registered with the EMA since the launch of this initiative – 1,922 SMEs as of December 2018. The product pipelines of these SMEs include 23% orphan medicines and 7% advanced therapies, and two thirds of SMEs amongst sponsors received Priority Medicines (PRIME) eligibility recommendations. The SME Office also supported UK-based SMEs with centrally-authorised medicines for Brexit preparedness.

Finance, tax and investment

BIA launches report on the biotech sector ahead of 2019 Spending Review

In June, the BIA launched a new report, 'Life sciences: Catalysing investment and growth'. The report aims to inform the Government's thinking ahead of the forthcoming Spending Review and makes the case for increased cost-effective public investment in the sector.

The report sets out key recommendations for public funding streams, fiscal R&D incentives, patient capital and support for the full ecosystem. Through a series of case studies, the report also celebrates our innovative sector by highlighting the pioneering work of SMEs all over the country.



Our new report celebrates the strength of our sector and makes key policy recommendations to government.

To coincide with the publication of the report, we also organised a roundtable with our members, civil servants and funders and to discuss the key recommendations of the report and how we can all work together to boost life sciences R&D in the UK. The roundtable was an opportunity to explore how the Government and funders can best enable life sciences SMEs to scale up, create new jobs and bring their innovations to patients. You can read more about the report and the roundtable on our blog.

This quarter, we have also met with members of the UKRI Board to understand UKRI's priorities for the Spending Review and the 2.4% R&D target, explain the needs of the life sciences SMEs and how the sector can contribute to increasing R&D investment in the UK.

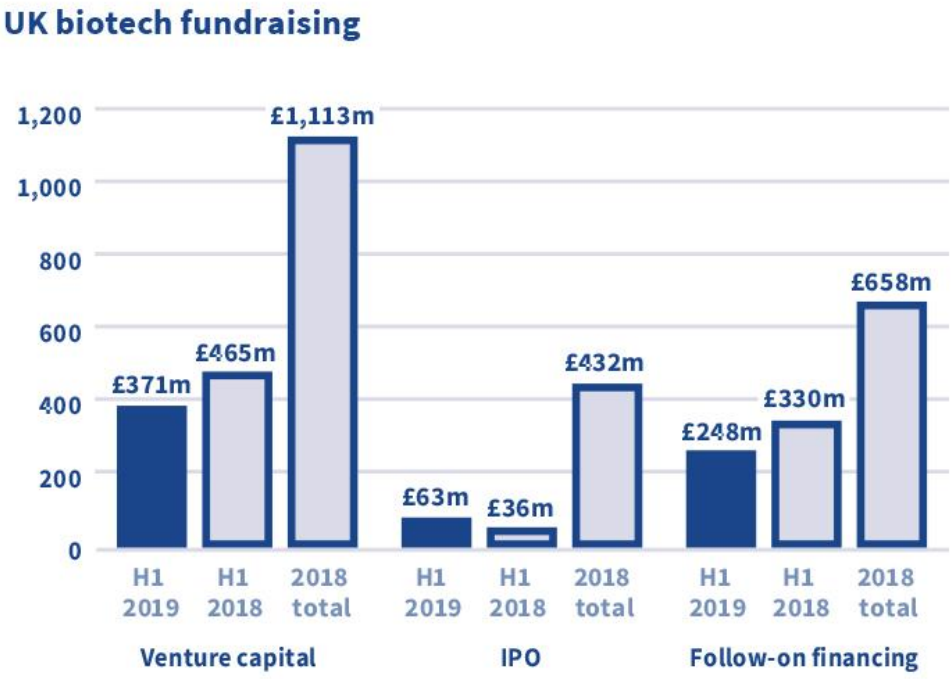
New BIA and Informa data shows continued investor confidence

On 24 June, the BIA and Informa Pharma Intelligence published new data that shows UK biotech companies raised £682m between December 2018 and June 2019, demonstrating that investors have been maintaining their confidence in the UK's biotech sector despite challenging global political and financial headwinds.

Highlights from the report reveal:

- UK biotech companies raised £214m from public markets between March and May 2019, more than double compared to the previous quarter, bringing the half-year total to £311m
- The first UK biotech to IPO in 2019 was Belfast-based Diaceutics, which raised £17m on AIM. Bicycle Therapeutics achieved the biggest IPO of the year so far with a £46m raise on NASDAQ
- Venture capital financing remained steady, with £189m invested between March and May 2019, bringing the half-year total to £371m
- The UK accounted for over two-thirds (37%) of biotech investment in Europe

The report was launched at the BIA's CEO and Investor Forum – a private retreat for leaders of the sector to discuss the current landscape and future of the industry. The two days in a Buckinghamshire hotel featured practical workshops, company pitches and engaging panel sessions with the UK's top biotech venture capitalists and public market investors.



BIA meets Innovate UK to put forward views on repayable grants

Innovate UK has been reported in the press to be developing new repayment terms for its R&D grants, with the intention that the agency would be paid back when a grant-funded company is "successful". The BIA raised concerns, which were reported in the media, that repayable grants would make it harder for companies to raise follow-on finance and might not be workable in practice.

The BIA has now held two meetings with Innovate UK's Chief Investment Officer, Tim Sawyer, to better understand the proposals and put forward the sector's views. Members of the BIA's advisory committees attended one of the meetings in July where they explained the impact that convertible grants would have on their companies, but also suggested ways in which Innovate UK could secure direct repayment when a grant leads to commercial success. Innovate UK is still working on its plans, which will be part of a Spending Review proposal put to the next Government. The BIA will remain engaged on the issue.

R&D tax credits cap concerns raised by the BIA

The BIA has submitted its formal response to the Government's consultation on the introduction of a cap on R&D tax credit payments to SMEs. The cap, which would limit cash payments to three-times a company's PAYE and National Insurance liabilities, would be highly damaging to the UK biotech sector due to high R&D outsourcing in the sector. The submission used new data published by the BIA and the Medicines Discovery Catapult that shows that the R&D outsourcing business model has created a vibrant and valuable ecosystem of specialist biotechs and service companies across the UK. We strongly urged the Government not to cap payments to all companies and instead proposed a gateway test to demonstrate the claimant company is genuine.

To complement the formal submission, the BIA led a cross-sector campaign to raise concerns about the cap in the media, in Parliament and direct to the Treasury. Several MPs have raised the issue with ministers following BIA member engagement, and the Treasury has received a high volume of submissions from companies stating that they support the BIA's proposed gateway test. Thank you to all BIA members who have contributed to the campaign, which has made a big impact. The BIA is now working with the Treasury to develop the test to identify genuine companies, so they are not impacted by the cap.

BIA responds to consultation on international collaboration on research and innovation

Professor Sir Adrian Smith has been commissioned by the Government to provide independent advice on future frameworks for international collaboration on research and innovation and the BIA responded to the consultation in May. In our submission, we emphasised the importance of EU funding and international collaborations for life sciences research and explained five principles for efficient public funding streams. The five principles are set out in our recent report ahead of the forthcoming Spending Review, which is available on our website.

We have also met directly with civil servants working on future international funding streams and attended a roundtable with Sir Adrian, organised by the Campaign for Science and Engineering (CaSE), to put forward our sector's views.

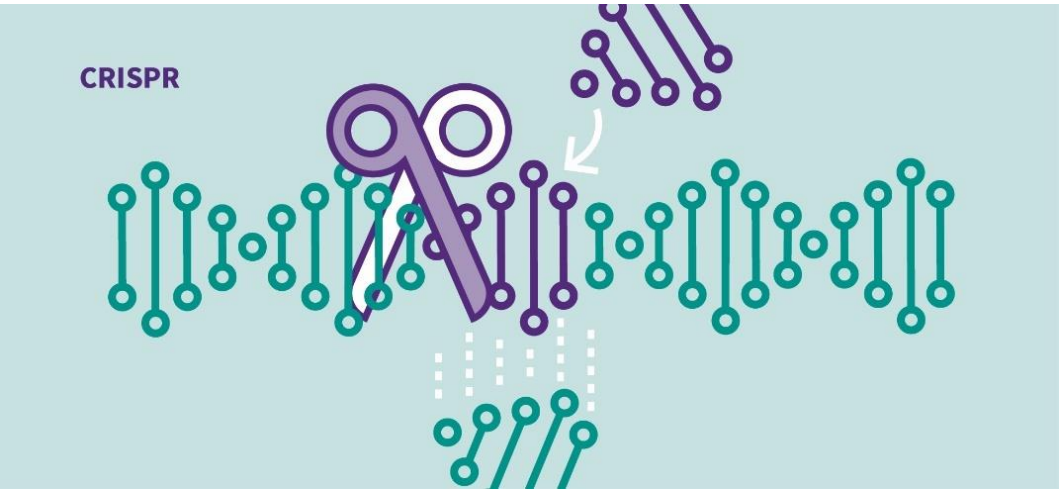
BIA highlights potential of biotech to Labour policy commission

In anticipation of an early general election, the Labour Party is preparing for government by establishing a series of policy commissions to develop the contents of a manifesto. The BIA has submitted views to the Economy, Business and Trade Commission, supporting Labour's vision of "an innovation nation" with 3% of GDP spent on research by 2030 and for the UK to have the highest proportion of high skilled jobs in the developed world. Our submission sets out how the biotech sector can help the party achieve this vision and what the party could do in government to help support the growth of the sector. The BIA is also meeting with several Labour MPs to put forward the sector's needs and potential in person. .

Strategic technologies and areas of scientific focus

BIA launches summarised explainers on innovative scientific areas

In May, we launched new summarised versions of the Explainer series, which we originally launched last year. Whether you are interested in Antimicrobial Resistance, Cell and Gene Therapy, Engineering Biology or Genomics, these documents explain the science and highlight BIA members that are at the cutting edge of each of the research areas. If you would like hard copies of the Explainers, please get in touch with Jack Fellows at jfellows@bioindustry.org.



BIA responds to international consultation on digital sequence information

In June, the BIA responded to the Convention on Biological Diversity (CBD) Secretariat's consultation on Digital Sequence Information (DSI) on Genetic Resources. In our submission, we argued that DSI should not be included within the scope of the objectives of the CBD and the objective of the Nagoya Protocol on both legal and practical grounds. In addition, the inclusion of DSI would do more harm than good by, amongst other things, presenting additional compliance challenges and problems which could seriously stifle innovation, particularly for SMEs. Our full response is available here.

BIA committee hosts workshop to enable SME engagement with UKRI

In April, the BIA's Science and Innovation Advisory Committee (SIAC) hosted a workshop with BIA members and funding bodies to address how SMEs influence funders' strategy on what should be funded and how funders can better disseminate their funding opportunities for SMEs.

As SMEs are time-limited, and knowledge is often restricted to the focus of their company, the key recommendation to influence strategy was to enable input through a collective voice of SMEs. The BIA is considering how we could coordinate this by having a collective SME place on funders' strategy boards.

To better enable the dissemination of funding opportunities, workshop attendees recommended the creation of a one-stop-shop website on all available funding streams for the sector. The BIA is working with the Knowledge Transfer Network (KTN) to explore how we could take this recommendation forward.

Government supports pro-science GMO regulation following BIA letter

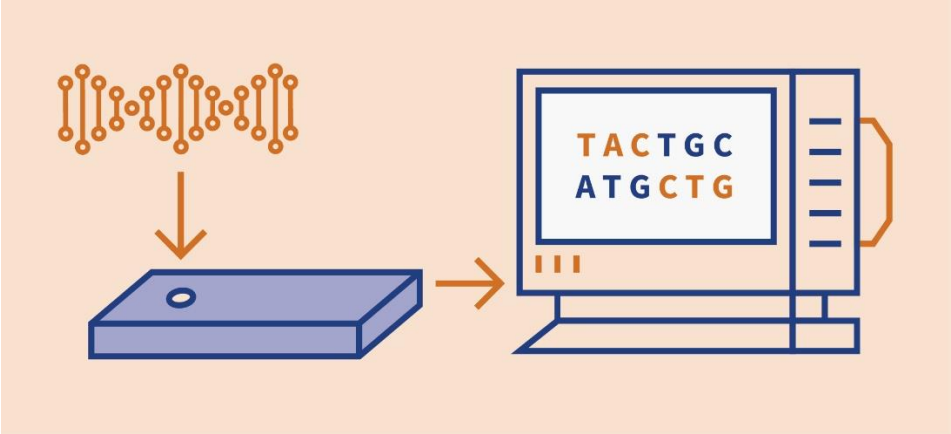
The Government has backed the BIA's pro-science position and condemned a ruling on the regulation of GMOs by the Court of Justice of the European Union following concerns raised by BIA to the Environmental Secretary Michael Gove MP in May.

The Government acknowledged the "serious consequences" of the Court's decision in a meeting of EU Member States on the modernisation of GM legislation. In a letter to the BIA, Robert Goodwill MP, the Minister responsible for the policy area, said "our view is that GM controls should not apply to organisms produced by directed mutagenesis if the changes to their DNA could have occurred naturally or through traditional breeding methods."

BIA responds to parliamentary inquiry on commercial genomics

In May, the BIA responded to the House of Commons Science and Technology Select Committee's inquiry on commercial genomics. Our response was developed by our Genomics Advisory Committee (GAC) and highlights that the strength of the UK's genomics sector is the result of the successful implementation of continuous industrial strategy, including the 100,000 Genomes Project and the establishment of Genomics England.

However, we emphasised that for Genomics England to fully succeed with its aim to kick-start and build a UK genomics industry, it is vital that it continues to work transparently and constructively with SMEs, including by adopting a flexible intellectual property (IP) model and enabling SMEs to provide input into its policies. We also argued that SMEs should be represented both throughout the development and in the outcome of the new National Genomic Healthcare Strategy. Our full response is available on our website.



Skills, people and talent

BIA hosts roundtable to inform future immigration system

The Home Office has started its engagement on the Immigration White Paper, which looks at the UK's future immigration system. The BIA, together with ABPI, held a roundtable for member companies with the Home Office and Office for Life Sciences to inform the Government's thinking and convey the sector's priorities.

Members in attendance highlighted that skilled people are vital to maintain the UK as a world-leading location for science and innovation, not just for industry, but for the whole life sciences ecosystem. The importance of lowering the proposed salary threshold of £30k for skilled workers was also discussed.

Kate Barclay joins the BIA team

Dr Kate Barclay has recently joined the BIA team as our Skills Strategy Consultant. Kate spent many years working in industry, with both AstraZeneca and Pfizer. She now works independently as a national consultant in healthcare and the life sciences sector, specialising in early talent development strategies, including apprenticeship reform, undergraduate, graduate and post-graduate programmes.

She will work with the BIA on the people, skills and talent workstreams anchoring our knowledge and partnerships in these important areas. She is already working with the Science Industry Partnership (SIP) Skills Strategy 2030, building a clear evidence base of the status of life science skills and future scenarios. She is scoping and contributing to the vocational, management and entrepreneurial talent development within our sector. Kate will also be working with BIA companies and government stakeholders on immigration and people issues and the ongoing development of appropriate apprenticeships for our sector.

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Intellectual property and technology transfer

New SPC manufacturing waiver becomes law with safeguards proposed by the BIA

New rules that will allow generic drug makers to manufacture medicines in Europe for export even as they remain under Supplementary Protection Certificate (SPC) protection in the EU have become law. The 'SPC manufacturing waiver' was opposed by the innovative life sciences industry, and many of the safeguards called for by the BIA and others to mitigate the risk the waiver poses to IP infringement have been included in the final legislation. The BIA's Intellectual Property Advisory Committee is producing a guide for members to explain what the waiver could mean for them.

BIA urges government to resist demands to add Nagoya requirements to patents

In June, the BIA wrote to the Government urging it to resist attempts by some Member States of the World Intellectual Property Organisation (WIPO) to call a diplomatic conference to introduce requirements of the Nagoya Protocol into the patent system. The BIA argued that requiring access and benefit sharing agreements to be specified in patent applications would not help advance the objectives of the Nagoya Protocol and would add undue burden on UK biotech SMEs. The Government responded positively to the BIA's letter and the WIPO meeting did not result in a diplomatic conference.

Pre-clinical and clinical research

Progress update with the EU Clinical Trials Information System

The BIA continues to keep a watching brief on the development of the Clinical Trials Information System (CTIS) and will participate in the next EMA meeting with stakeholders taking place on 16 July. The CTIS, formerly known as the clinical trial portal and database, is essential for the application of the EU Clinical Trials Regulation, which was adopted in 2014.

In June, the EMA issued an update stating that the CTIS project methodology and plan was revised to improve delivery. EU Member States and stakeholders are now directly engaged in the CTIS development through nominated 'product owners' to ensure that their expectations are taken into account. This means that industry experts have a continuous opportunity to review, select and verify functionalities. Safety reporting functionalities have been developed.

It is worth adding the European Commission, EMA and EU Heads of Medicines Agencies issued a joint letter in July, reminding sponsors of clinical trials conducted in the EU of their obligation to provide trial summary results for publication in the EU Clinical Trials Database (EudraCT).

European Commission updates guidance on the EU Clinical Trials Regulation

In June, the European Commission issued an updated Q&A guidance document on the EU Clinical Trials Regulation.

A new detailed section on trial safety reporting requirements was added to this guidance, which was drafted by the Clinical Trials Facilitation and Coordination Group of the EU Heads of Medicines Agency and endorsed by the Commission's Expert Group on Clinical Trials. This section starts by considering the definition of 'adverse event' and the differences between an adverse event and an adverse reaction, and covers a range of issues from the Reference Safety Information, the reporting of suspected unexpected serious adverse reactions (SUSARs) and the annual safety report.

This guidance also includes updates on the scope of the Clinical Trials Regulation, the definition of 'substantial modification', responsibilities shared in co-sponsorship, the requirements for the legal representative, and the definition of 'early termination'. Some sections of the Q&A document are not yet complete and updated version of the guidance will be published progressively.

Manufacturing

Medicines manufacturing excellence in focus at annual MMIP Conference

Over 150 delegates attended the annual Medicines Manufacturing Industry Partnership (MMIP) Conference on 20 June at Discovery Park in Kent, hosted by Pfizer, where the theme was Medicines Manufacturing Excellence in the UK. BIA CEO Steve Bates set the scene for the day in the opening session, followed by panels and speakers throughout the day focusing on the impact of advanced digital technologies on the future of medicines manufacturing, as well as the skills required to embrace these technologies.

One highlight from the conference was hearing from Pfizer's digital apprentices in a panel chaired by BIA's Skills Strategy Consultant, Dr Kate Barclay. The apprentices were great ambassadors and highlighted the importance of the apprenticeship route into science.

The final session of the day focused on anchoring manufacturing in the UK through a competitive fiscal landscape, end-to-end skills strategy and analytical capability. James Miskin of Oxford Biomedica showcased the ongoing work in the cell and gene therapy sector to ensure the UK retains the health and economic benefit of these new therapies.

Upskilling existing staff through apprenticeships

The Advanced Therapies Apprenticeship Community (ATAC) programme, sponsored by the MMIP and delivered by the Cell and Gene Therapy Catapult as recommended by the Advanced Therapies Manufacturing Taskforce, continues to deliver apprenticeships to support the sector. The most recent programme, a Senior Leader Master's Degree Apprenticeship (MBA), is perfect for upskilling existing employees. The training provider, Open University, allocated 12 places to ATAC for the Autumn 2019 cohort and these were filled quickly.

Full details of this and other currently live programmes can be found on the ATAC website. If you would like to know more, or join the MMIP Advanced Therapies Apprentice LinkedIn group, please contact Netty England at aengland@bioindustry.org.

Access to medicines

MPs briefed on the value of new medicines in the NHS at APPG event

In May, the All-Party Parliamentary Group (APPG) for Life Sciences hosted an event in Parliament to give MPs an overview of the Voluntary Pricing and Access Scheme (VPAS) and the key challenges around access to medicines and diagnostics. The BIA provides the secretariat for the APPG together with ABPI and BIVDA.

The event was chaired by Daniel Zeichner MP, Chair of the APPG and Labour member for Cambridge, and we had several other MPs in attendance. Paul Catchpole from ABPI started off the discussion by explaining the key elements of the VPAS, before Sarah Byron from NICE gave its perspective on the VPAS and access to medicines. Darren Stenlake from BIVDA offered the perspective of the diagnostics industry before finally Charlotte Galvin from BIA member Amicus Therapeutics highlighted the specific challenges around evaluating medicines for rare and ultra-rare diseases.

Following the speeches, MPs and members in attendance discussed how to best work together to achieve our shared goal of ensuring that NHS patients can access innovative new medicines.

A full summary of the event is available on our blog.

Darren Stenlake (BIVDA), Charlotte Galvin (Amicus Therapeutics), Daniel Zeichner MP and Paul Catchpole (ABPI) at the APPG event in Parliament.

BIA briefs MPs ahead of debate on access to medicines

In June, MPs held a Westminster Hall debate on access to Orkambi and other cystic fibrosis drugs in the NHS following petitions that reached the 100,000 signatures required to trigger a debate. The BIA shared briefings with MPs who had expressed interest, including Labour MP Paul Scully who led the debate.

While it was a heated debate, several MPs, including Mr Scully, recognised the importance and value the biotech sector. However, Minister of State for Health, Seema Kennedy MP, signalled a concerning shift in the Government's position when she said that "unless Vertex change their approach and behave responsibly" then the Government will have the moral obligation to consider Crown Use Licensing. The BIA is working with our Rare Disease Industry Group and Advisory Committees to engage with Ministers and MPs to ensure they understand the deleterious impact any such move would have. While we believe that this message is broadly understood by current Ministers, we will need to continue our engagement given the ongoing political uncertainty.

BIA joins the NICE Method Review Steering Group

The BIA has been asked to join the NICE Methods Review Steering Group following our engagement with the Centre for Health Technology Evaluation Centre. We will be nominating a BIA member to sit on the group, which will help to design and guide the upcoming NICE Methods Review in 2020.

BIA promotes biotech-NHS relationship to Labour policy forum

In anticipation of an early general election, the Labour Party is preparing for government by establishing a series of policy commissions to develop the contents of a manifesto. The BIA has submitted views to the Health and Social Care Commission to outline the benefits that a successful UK biotech sector can bring to the NHS and Labour's ambitions to improve patients' access to innovative new medicines. We highlighted that the evaluation of orphan and ultra-orphan medicines should put patients' needs front and centre and that the NHS and NICE should take a holistic approach to value. We also called on the Labour Party to uphold IP rights to support innovation. The BIA is also meeting with several Labour MPs to put forward the sector's needs and potential face to face.

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, Membership and Business Development Manager, on 0207 630 2194 or mmcgivern@bioindustry.org

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