Influencing and shaping our sector – BIA update July – October 2018

UK BioIndustry Association

Influence, connect, save

www.bioindustry.org

Introduction

The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences industry, from July to October 2018.

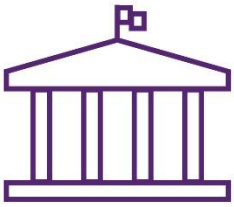
This quarter, the BIA has engaged Ministers, shadow Ministers, and MPs at all four main party conferences to ensure the cross-party support for our sector continues. We have continued to highlight the impact of a no-deal Brexit both publicly and to the government while keeping our members up-to-date with the latest developments. Our engagement on the implementation of the Life Sciences Industrial Strategy and the Sector Deal continues at the highest levels of government.

Our quarterly finance data shows that UK biotech is very strong. We have written to the Chancellor ahead of the Autumn Budget to emphasise the sector's valuable contribution to the economy and we called for a strong industry voice in the UKRI's funding decisions in our submission to a parliamentary inquiry.

To highlight the innovative work of our members, we have also published a series of science explainers to celebrate UK bioscience. Read about this and much more below.

This quarter in numbers:

16+ influence meetings with 33+ MPs and Peers, including 9 Ministers



6 consultation responses submitted

2 letters to Ministers

Contents

BIA activity at party conferences

The busy party conference is over for another year and the BIA's policy and public affairs team were out in force at all four main conferences – Liberal Democrats, Labour, Conservatives, and Scottish National Party.

As in previous years, the BIA organised two roundtables at the Labour and Conservative Party Conferences in collaboration with BIVDA and ABPI. Both roundtables focused on the timely topic of NHS' 70th anniversary, the role innovation has played in its success, and how innovation can ensure its continued success in the next 70 years.

At the Labour event, we had several MPs in attendance: Daniel Zeichner MP, Kevin Barron MP, Julie Cooper MP, Paul Williams MP, and Maria Eagle MP. The policymakers were joined by senior stakeholder and industry representatives for a wide and interesting discussion. Dr Nirmesh Patel of BIA member Cambridge Cancer Genomics explained how the company's technology, using genomics and artificial intelligence (AI), can detect cancer quickly and dynamically. Dr Arthur Roach of Parkinson's UK, the BIA's charity of the year, highlighted the vital role charities have in medical research.

Daniel Zeichner MP (right) highlighted the importance of free movement post-Brexit for the continued success of the NHS and the UK life science ecosystem.

The Conservative roundtable was chaired by Maggie Throup MP, Parliamentary Private Secretary to the Ministerial team at The Department for Health and Social Care. Professor David Dexter of Parkinson's UK emphasised charities' contribution to the research ecosystem and explained Parkinson's virtual biotech model. Jessica Fine of BIA member MSD talked about their new R&D centre in London and MSD's immuno-oncology treatments.

The BIA's Director of External Affairs, Pamela Learmonth, attended the Business Days at the Conservative and Labour conferences, bringing the needs of our members and our sector to the direct attention of numerous ministers and shadow ministers, while the BIA team attended several fringe and networking events.

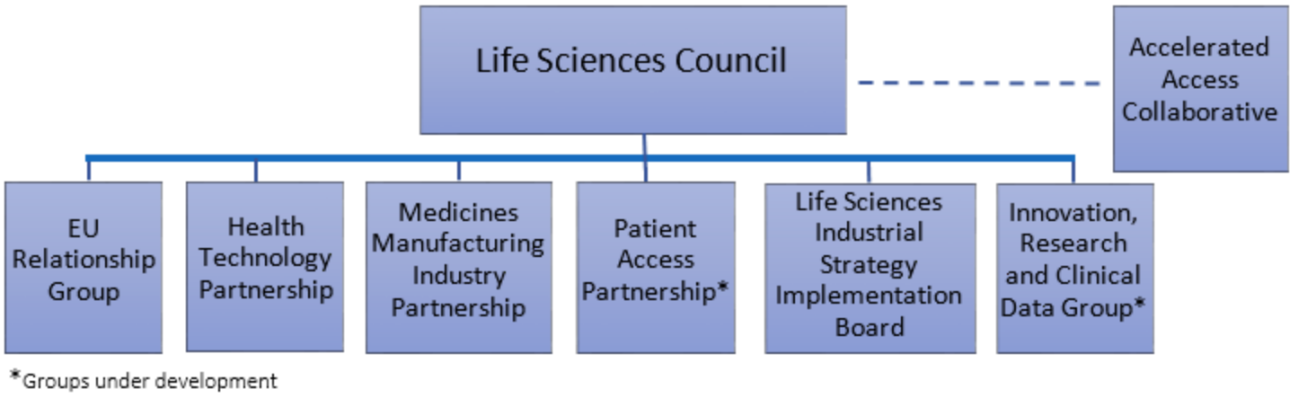
Thank you to all members, stakeholders, and policymakers who attended the roundtables. Also, thanks to our colleagues at ABPI and BIVDA for your help in organising yet another successful round of party conference events.

BIA engagement with the government on life sciences policy

In our last quarterly update, we reported on the inaugural meeting of the Life Sciences Council and referenced the work of the Life Sciences Industrial Strategy Implementation Board, one of the sub-groups that reports into the Life Sciences Council.

This structure of government/industry engagement is new for 2018 and has been evolving and developing, coordinated by a government/industry secretariat, which the BIA is part of. The BIA has called for greater communication out from OLS on this activity and this has resulted in a new newsletter. The first edition was launched in August.

These communications provide useful top-line summaries of both progress in delivering the Life Sciences Sector Deal as well as emerging themes of focus for the future evolution of Life Sciences Industrial Strategy. They also provide a useful graphic (below) which summarises the different government/industry groups that are now in operation.



The BIA is involved, through direct representation by our CEO Steve Bates or through member representatives at the Life Sciences Council, the EU Relationship Group, the Medicines Manufacturing Industry Partnership, the Life Sciences Industrial Strategy Implementation Board, and the Innovation, Research and Clinical Group. The BIA also hopes to engage with the Patient Access Partnership when it is established and have an input to the National Genomics Board given the expertise of our membership in this area.

The Life Sciences Industrial Strategy Implementation Board has met once again since our last quarterly report. Discussions within this group continue to focus on both implementation of current commitments and the future evolution of the Life Sciences Industrial Strategy. The government is working towards a document by the end of the year that will comprise a “one year on” update on the Sector Deal plus potential new announcements and areas of focus. The BIA will continue to engage with this development of this area of policy and update our members accordingly.

Over the quarter, there have also been developments in the Wave 3 of the Industrial Strategy Challenge Fund. Following the call for expressions of interests to be made to Wave 3, individual applicants have been informed whether their expression will progress for further consideration or not, though there has not been an overall public announcement on this. The BIA understands that several expressions of interest have been thematically grouped together as the process has progressed. We anticipate that further details may be made public at the forthcoming Budget at the end of October.

Leaving the EU

BIA calls reflected in Brexit White Paper

In July, the government published its Brexit White Paper. The paper provided more clarity for the sector on the government's desired Brexit outcome. It is not the final Brexit deal, but it does provide the basis for detailed future relationship discussions with the EU. Turning the policy into reality needs to be a priority now for the government in the negotiations.

Over the last two years, BIA has consistently advocated that government pursue a number of policies essential to members and industry as well as patients and public health. Much of this was reflected in the White Paper and it shows that the government has listened to the needs of patients, public health, and the UK life science ecosystem. The paper builds on previous government communications and provides more public confirmation that government would like the UK to retain regulatory cooperation on medicines with the EU as part of the desired future relationship.

A BIA member briefing on the White Paper is available on our website.

BIA talks no-deal on BBC Newsnight

BIA CEO Steve Bates appeared on Newsnight in July to explain some of the challenges facing businesses in the event of a no-deal Brexit and the difficulties continued uncertainty causes in the form of "double red tape" for biopharmaceutical companies in the UK. He highlighted that the UK makes up just 2% of the global market for pharmaceuticals, and continued uncertainty may mean that companies choose to focus on larger markets which are not subject to the difficulties posed by Brexit. BIA members AstraZeneca and Quay Pharma were also interviewed and gave an insight into what the lack of progress on Brexit negotiations means for them.

The full clip is available on YouTube.

BIA CEO Steve Bates explained some the challenges faced by industry in a no-deal Brexit scenario on BBC's Newsnight.

BIA reaction to technical notices on no-deal Brexit

In August, the government published a series of technical notices on Brexit to provide clarity for the sector if there is no deal. The first tranche included notices on unilateral recognition of batch testing and regulation.

There is now more clarity on how UK medicines regulation will work in a no-deal scenario. The guidance is pragmatic, essentially proposing unilateral recognition of existing processes, and is in line with our discussions with government, echoing the position of Ministers expressed last year. The BIA will continue to work with government on the detail to build greater clarity around how the complex regulation and supply of medicines would work in the event of no-deal and will engage members.

Beyond medicines, several other technical notices are relevant to our sector. Companies importing/exporting from and to the EU27 will be particularly interested in the Customs and Trade Notice, the VAT Notice, and the Tariff Notice. In these notices, the government highlights that companies will need to trade on non-preferential WTO terms with Most Favoured Nation (MFN) tariffs and non-preferential rules of origin to apply from Day 1.

A BIA briefing is available for members on request – contact Laura Collister at lcollister@bioindustry.org for more info.

Medicines Supply Contingency Planning Programme in a no-deal scenario

On the same day as the publication of the sector technical notices, the Department of Health and Social Care wrote to industry and published guidance about their no-deal Medicines Supply Contingency Planning Programme.

The BIA encourages members and other companies that supply medicines for NHS patients from, or via, the EU or EEA, to engage actively with the Department of Health and Social Care's request for information as to how, or whether, they can or cannot, ensure an additional minimum of six weeks supply in the UK, over and above their business as usual operational buffer stocks, by 29 March 2019. The BIA has stressed to government and they recognise that endeavouring to deliver on this in less than 200 days will be a massive challenge for industry and the MHRA alike.

Parliament votes in favour of Trade Bill amendment on medicines

In July, Parliament voted in favour of amendment NC17 to the Trade Bill which will make it a negotiating objective for the government to seek the UK's participation in the European medicines regulatory network. The vote was welcomed by the BIA and as the Bill continues its Parliamentary passage the BIA will be reinforcing the importance of the continued inclusion of the amendment.

HMRC consults BIA delegation on proposed customs arrangement

In August, the BIA and a delegation of our members attended a roundtable discussion with HMRC and Treasury representatives to discuss the Facilitated Customs Arrangement (FCA) proposed by the government in the Brexit White Paper. HMRC representatives explained the FCA in more detail, including the common rule book with the EU, the dual tariff system, and the repayment mechanism. The BIA delegation emphasised how these aspects of the FCA would impact the sector. The BIA will continue to engage with the HMRC as the Brexit negotiations progress and the FCA proposal is developed further to ensure the needs of the sector are met.

BIA highlights impact of no-deal Brexit on health to parliamentary committee

In October, the BIA and the ABPI responded to the House of Commons Health Committee inquiry on the impact of a no-deal Brexit on health and social care. We highlighted that companies supplying medicines to patients continue to do everything they can to ensure the continued supply of medicines, but it remains an enormous challenge. While the technical notices and the government's Brexit Medicines Supply Contingency Planning Programme have provided some certainty, the confirmation of the implementation period remains essential. In addition, we argued that the future relationship between the UK and the EU should include cooperation in areas which protect public health, control infectious diseases and manage medicine safety. The full response will be available on our website in due course.

Call for interest – help shape UK's post-Brexit trade policy

As the Brexit process continues, the BIA is working with our members to influence the government's post-Brexit trade policy, including engagement in the World Trade Organization (WTO) and new Free Trade Agreements (FTAs). We are currently looking for more SME representatives, so if you are interested in helping shape the UK's post-Brexit trade priorities for the sector, please contact Laura Collister at lcollister@bioindustry.org.

Ongoing BIA Brexit activity – Brexit lead network events and webinars

The BIA continues to host regular Brexit lead network events together with the ABPI. The latest event was held in September, with timely updates and Q&As by senior representatives from MHRA and the Department of Health and Social Care. BIA members can register for upcoming Brexit lead network events for free on our website.

We also 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 page.

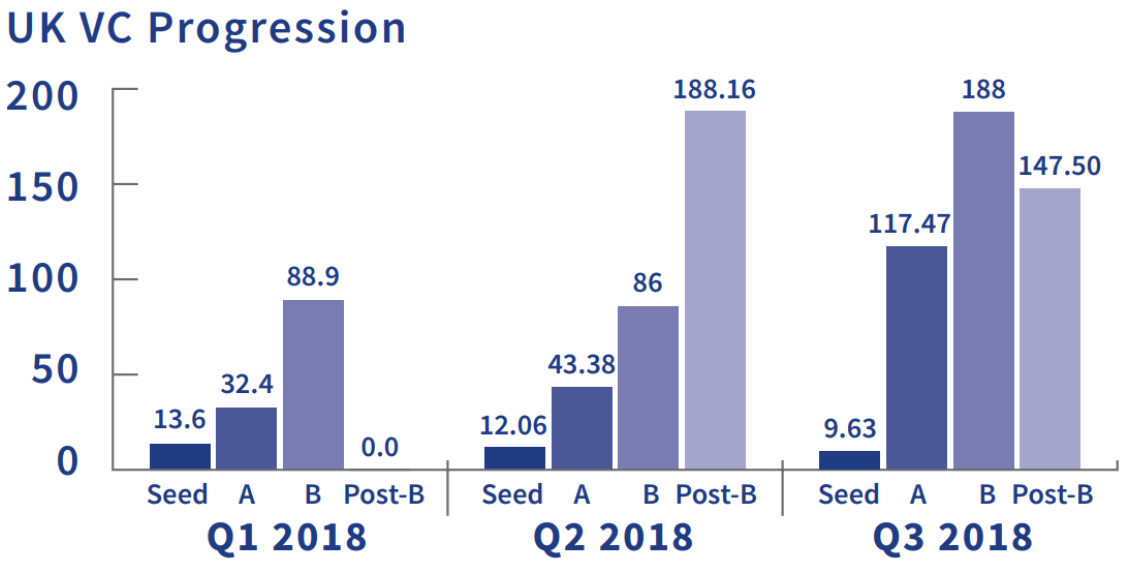
Finance, tax and investment

BIA data shows UK biotech raises more than 1.5 billion so far in 2018

In September, the BIA along with Informa Pharma Intelligence released the Biotech Financing Update June - August 2018 which showed that UK biotech companies have already raised more than £1.5 billion in 2018, surpassing the 2017 annual total of £1.2 billion. In the second half of the year, the data showed an acceleration in venture capital fundraisings and an uplift in amounts raised in Initial Public Offerings (IPO).

Some key figures from this quarter:

- Venture capital fundraising during the period accelerated, with over £462 million raised, double the total for the first half of the year.
- UK biotech companies raised £191.67 million through IPOs during this period.
- AIM has proved a valuable source of follow-on funding for UK biotech companies during this period, providing over £77 million.



BIA CEO Steve Bates said:

> "In just eight months of 2018, innovative UK biotech companies have surpassed the fundraising total reached in the whole of 2017, demonstrating the worldwide demand for the fantastic science coming out of the UK.
>
> "Positive data in this quarter follows on from changes to venture capital tax incentives, which the BIA called for. These changes were implemented as part of the Patient Capital Review. The BIA will continue to monitor the sector to assess the benefits of these changes on investment in biotech."

The report was launched at the BIA in the City Finance Breakfast event. BIA member CEOs and experts formed a panel to discuss market challenges for biotech companies in the UK. The BIA and Informa Pharma Intelligence will release their annual report on biotech financing for 2018 in January 2019.

BIA responds to inquiry on science funding

In September, the BIA responded to the House of Commons Science and Technology's inquiry on the balance of science funding. The inquiry is timely given the government's ambition to increase UK R&D investment to 2.4% of GDP, the publication of UKRI's Strategic Prospectus in May and next year's Comprehensive Spending Review.

Our submission was informed by our Finance and Tax Advisory Committee and Science and Innovation Advisory Committee. In the submission, we emphasised that public R&D funding leverages private investment and highlighted the value of sector specific funding from Innovate UK and the Biomedical Catalyst. We welcomed the Industrial Strategy Challenge Fund as a mechanism to deliver the vision set out in the Life Sciences Industrial Strategy. We also stressed the importance of the overall commercial environment for encouraging the business R&D investments required to hit the 2.4% target, including the tax regime, availability of patient capital and access to global talent. Committee rules prevents us from publishing our response, but a summary of the submission is available on our blog.

BIA writes to Chancellor ahead of Budget

The BIA has written to the Chancellor, Philip Hammond MP, ahead of the Autumn Budget highlighting the strength of the UK bioscience sector and its significant contribution to the economy. We called for targeted support to boost the sector's manufacturing capabilities and international collaboration.

The BIA also formally responded to HM Treasury's call for views at the end of September. In our submission, we set out our detailed policy proposals: giving pre-revenue SMEs the option to surrender R&D Allowance losses arising on capital expenditure for up-front cash credits; introducing grants for manufacturing investments; enhancing R&D Tax Credits to better reflect 21st Century life sciences R&D, notably the purchase of data for R&D purposes; updating the HMRC list of eligible foreign institutions for R&D Expenditure Credits to underscore the government's commitment to global collaboration; and reviewing fiscal policies to support early-stage companies to offer competitive salaries relative to more established companies.

The BIA's Finance and Tax Advisory Committee also met with Treasury officials ahead of the submission to discuss the proposals in more detail. The officials stressed that the promised increase to the NHS budget and previous expansion of the R&D Expenditure Credit left little flexibility for costly new policies. However, they welcomed BIA proposals that may be cost-neutral.

The Chancellor will deliver the Autumn Budget on Monday 29 October.

Stock exchange representatives debate performance of international exchanges

In September, the BIA and investment bank Stifel hosted a panel event to discuss the performance of the international public markets for biotech financing. Representatives from AIM, Nasdaq and the Hong Kong exchange, which has recently relaxed its rules to allow pre-revenue companies to list, debated the role each market plays in supporting the sector. Joined by a vocal audience of City investors and C-level sector executives, the need for liquidity and gateways to other markets emerged as two key themes. The event was part of the BIA's work to engage the City and promote the investment opportunities presented by the UK sector.

BIA introduces Chinese investors to members

After several successful meetings of the China Special Interest Group, this quarter we decided to go one step further in helping our member companies gain investment from China. Three investors with Chinese funds, but themselves based in the UK, held one-to-one meetings with 20 of our member delegates. Each BIA delegate was able to talk to two investors and find out if the funding scope aligned with their company profile. This meeting marked the start of a fruitful engagement between Chinese investors and UK biotech SMEs.

Dr Peng, CEO of CMS Medical Venture, introduces the fund to BIA delegates.

BIA challenges authors of Biomedical Bubble

Over the summer, innovation foundation Nesta published the Biomedical Bubble, written by Professors Richard Jones and James Wilsdon. The report questions the promise of the biomedical sector and argues it receives a disproportionate amount of funding compared to other sectors. The BIA and the Resolution Foundation brought together the authors and key policy, industrial, and political stakeholders under Lord Willetts' neutral chairmanship to discuss the report and the wider policy context of UKRI spending priorities and Industrial Strategy. The meeting was held under Chatham House rules at the Resolution Foundation.

The BIA agreed with the report's call for a public debate on science funding but challenged many of the report's core arguments. The UK life sector is world-leading but requires continued funding to maintain its strong global competitive advantage against strong competitors such as the US and China. Industrial strategy is not just about UKRI spending, but also about supporting businesses, creating jobs, attracting foreign investment, and driving economic growth through a range of policy interventions. The sector described in the report does not reflect today's vibrant and dynamic life science ecosystem, with companies developing innovative platform technologies in several areas, including artificial intelligence (AI), genomics, and engineering biology.

The BIA will continue to debate these issues as the UKRI works to develop its priorities further to deliver the 2.4% R&D of GDP target.

Strategic technologies and areas of scientific focus

BIA publishes new Explainers to promote UK's world-leading bioscience

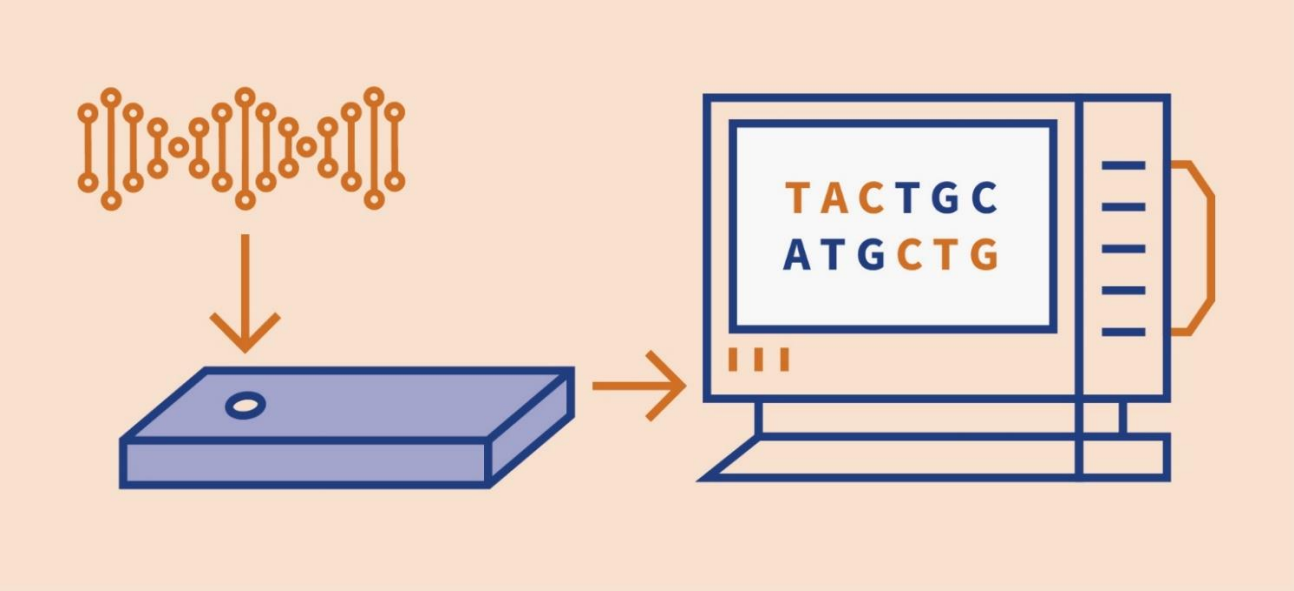
In October, the BIA published a series of Explainer documents, covering four areas of focus for UK bioscience companies:

- Engineering biology
- Cell & gene therapy
- Antimicrobial resistance
- Genomics

The Explainers seek to give the reader some background on these strategic areas of focus and showcase the important contributions being made by UK bioscience companies. They also highlight the external environment needed for these companies to continue to thrive and benefit patients and society.

> "UK bioscience companies are at the forefront of these innovative, converging disciplines. These companies are a key part of the BIA's membership and as the trade association for innovative life science companies in the UK, the BIA provides a home for these groups through our Advisory Committees and working groups on antimicrobial resistance, cell and gene therapy, engineering biology and genomics."
>
> Steve Bates, BIA CEO

Alongside the Explainers, the BIA has produced a series of videos profiling company case studies in these areas of strategic technologies, as well as a video exploring a partnership between BIA Charity of the Year Parkinson's UK and BIA member Benevolent AI.. You can find all these resources on the Strategic Technologies section of our website.



Oxford Nanopore's minION has revolutionised genomics – weighing under 100g, it can generate 10-20 Gb of DNA sequence data and has decentralised the process of DNA analysis. The minION can be used in the field or in the laboratory and was used by astronaut Kate Rubins to perform the first DNA sequence analysis in space on the International Space Station.

Skills, people and talent

MAC paper recognises importance of highly skilled migrants for UK innovation

The Migration Advisory Committee (MAC), an independent and non-departmental public body that advises the government on migration issues, published its final report European Economic Area (EEA) migration in September. The report's intention is to provide an evidence base for the design of the new post-Brexit migration system.

Earlier this year, the BIA and the ABPI submitted written evidence to MAC to highlight the sector's dependence of highly skilled migrants and the importance of a frictionless migration system. Many of our recommendations were reflected in MAC's report, including the recognition that high-skilled immigrants increase innovation, that the Tier 2 (Intra Company Transfer) should remain as free as possible, and improvements to the Tier 2 (General) visa system.

Government unveils plans to boost apprenticeships

In October, the government announced a package of reforms to ensure that the Apprenticeship Levy provides people with the skills they need to succeed. The package includes an extra £90 million of government funding to allow employers to invest a quarter of their apprenticeship funds on people working for businesses in their supply chain, and £5 million for the apprenticeships scheme to strengthen the education and training of new apprenticeships. The government will introduce a new revamped training system for apprenticeships from the academic year beginning 2020/2021. The government will also shortly set out a process to seek views on the levy. The ability to invest in apprenticeships in the supply chain rather than just their own companies, reflects advocacy from the BIA and others in the life sciences community and should support better outcomes for both employers directly affected by the levy and the wider ecosystem.

ATMP apprenticeships leads the way

The advanced therapy medicinal product (ATMP) apprenticeship work, sponsored by the Medicines Manufacturing Industry Partnership (MMIP) and delivered by the Cell and Gene Therapy Catapult through the Industrial Strategy Challenge Fund as recommended by the Advanced Therapies Manufacturing Taskforce, continues at pace. The initial cohort of 18 apprentices from nine organisations embarked on the first ever ATMP apprenticeship in September – a Level 5 Technician Scientist standard that has been modified for ATMPs. Next on the list is a Level 3 Science Manufacturing Technician, with recruitment beginning now.

The skills directorate within the Office of the Mayor of London was interested to learn from the successful approach our industry has taken to develop an ATMP specific apprenticeship programme and visited the Catapult to discuss the programme as they explore a series of apprenticeships to support local industries in London.

If you would like to learn more, or join the MMIP AT Apprentice LinkedIn group, please contact Netty England at aengland@bioindustry.org.

Intellectual property and technology transfer

BIA submits views on EU IP studies

In May, the European Commission published two studies on the legal and economic effectiveness of IP incentives as part of a wider review. The UK Intellectual Property Office (IPO) called for views, which the BIA's IP Advisory Committee responded to in September. While the BIA welcomed the studies, we emphasised that the economic measure used may underestimate the true period of exclusivity IP rights provide holders. The BIA supported a broader, EU-wide Bolar Exemption to promote greater consistency in allowing the use of patented products in research across Europe, and a Unitary Supplementary Protection Certificate to completement the Unified Patent. The BIA also argued for SPCs for reformulations. The BIA's IP Committee is continuing to work with the IPO has the review progresses and specific proposals are taken forward for a manufacturing waiver.

BIA in talks with government on IP in FTAs

Over the summer the BIA has been participating in government roundtables and forums on potential free trade agreements (FTAs) with a range of countries. IP is often a contentious and complex part of FTAs and, with patents of critical importance for biotech companies, the BIA has been working to ensure government officials understand the needs of the sector. The meetings are early in the development of the government's trade policies, but this crucial engagement is necessary to ensure the BIA is at the heart of the trade negotiations that are expected to be front and centre of government activity post-Brexit.

Pre-clinical and clinical research

European Commission latest Brexit notice in the field of clinical trials

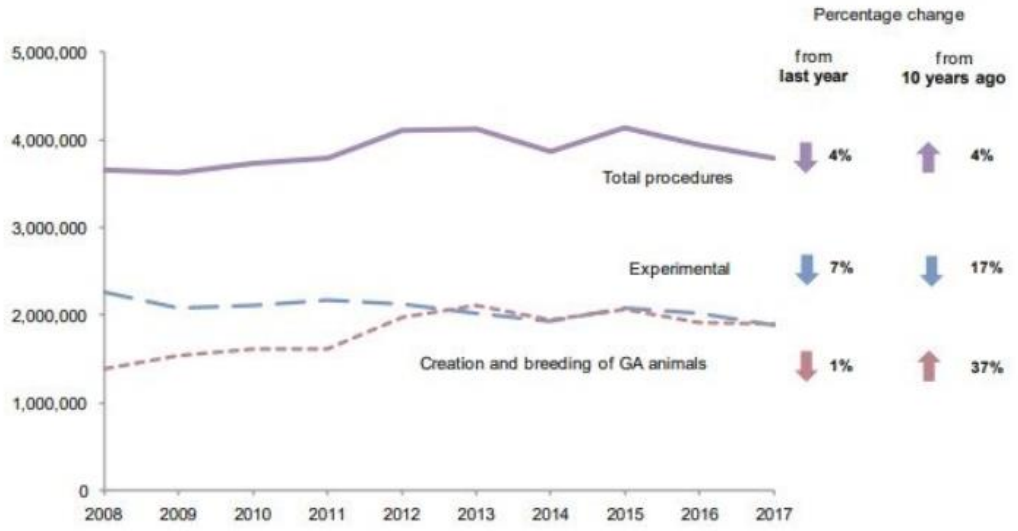
In September, the European Commission issued its latest Brexit notice in the field of clinical trials. This notice unsurprisingly provides a strict interpretation of EU law, based on the assumption that the UK will become a third country from 30 March 2019, as we have seen for previous Brexit related guidance and Q&As. This means that, after the UK leaves the EU, the sponsor or legal representative for any clinical trial conducted in the EU27 will need to be based in the EU27. An import authorisation will be needed for any investigational medicinal products (IMPs) and comparator IMPs coming from the UK, and Qualified Person release of these IMPs and comparator IMPs would need to take place in an EU country. It is worth noting that information on paediatric trials conducted in the UK as part of an agreed Paediatric Investigation Plan will continue to be submitted to the EU clinical trials database EudraCT, as required for non-EU/EEA studies.

Home Office reports use of animal in science statistics for 2017

In July, the Home Office published its annual statistics relating to regulated scientific procedures that are carried out on protected living animals in the UK. The 2017 report is available on the government website.

The report shows that 3.79 million procedures were carried out that involved living animals in the UK. Half of these were experimental procedures, while the other half can be attributed to the creation and breeding of genetically altered specimens. This number is a decrease of 4% in 2016 and is the lowest number of procedures since 2010. The proportions of species used for experimental procedures have remained stable for the past ten years, with mice, rats, and fish the most commonly used in experimental procedures.

Figure 1: Scientific procedures on living animals, 2008 to 2017



The BIA is a proud signatory of the Concordat on Openness on the Use of Animals in Research. This agreement is supported by a range of organisations – including universities, companies, research funders, and umbrella organisations – to commit to being open about the use of animals in research in the UK. The UK continues to rank among the highest in the world for the welfare of animals used in research and these statistics show that we are moving from strength-to-strength in this area. You can keep up to date on Twitter by searching #AnimalStats.

Manufacturing

BIA sponsors workshop on accelerating UK advanced therapy R&D

The BIA recently sponsored a workshop where representatives from the Medicines Manufacturing Industry Partnership (MMIP) and the British Society for Gene and Cell Therapy (BSGCT) met to discuss how best to satisfy academic demand for cost effective materials and advanced therapy manufacturing from the existing UK supply base, borne out of the recommendations of the Advanced Therapies Manufacturing Taskforce.

James Miskin of Oxford BioMedica led on behalf of the MMIP and Uta Griesenbach of Imperial College on behalf of the BSGCT. The catalyst for this work was a report produced by MedCity that described the next three to five years pan-London academic demand for GMP manufactured cell, gene, and regenerative therapies. This document shows unequivocally that the demand growth very quickly exceeded available capacity. The group concluded that a model was needed where contract development and manufacturing organisations (CDMOs) and academia form a long-term productive relationship, including a clear understanding of IP ownership and dedicated funding for the early years until the model can become self-sustaining after three to five years. Work now needs to be urgently done to build a project around this model that industry and academia can support and deliver together.

BIA continues successful leadership programme

The development of managers in the biopharmaceutical and cell and gene therapy industries is an important part of the training landscape to deliver senior leaders of the future. The BIA's Manufacturing Advisory Committee (MAC) Leadership Programme (LeaP) supports this in two key ways: firstly to promote cross-sector learning by offering an overview of the work of other companies across biopharma, vaccines and cell and gene therapies by seeing them in action; and secondly to develop a network with peers to share best practice and develop relationships to encourage possible future collaborations.

The pilot programme was launched in January 2017 and this is now nearing completion – come and hear more at bioProcessUK in Edinburgh on 20-22 November 2018. On the back of the success of this, a second programme started in January 2018 and is now well underway, and a third cohort is scheduled to start in January 2019 – please contact Netty England at aengland@bioindustry.org if you would like to hear further details.

Cohort 1 of the BIA MAC LeaP.

Medicines regulation

BIA and MHRA publish report "Collaborative Working in the UK, Driving Innovation Forward"

The BIA and the Medicines and Healthcare products Regulatory Agency (MHRA) have published a report "Collaborative Working in the UK, Driving Innovation Forward" following their eighth annual joint conference in July.

The BIA and the MHRA brought together experts from across the life sciences sector to discuss some hot topics and important developments through a series of presentations and panel discussions. Key themes for the day included the UK regulatory environment now and post-Brexit, the accelerated access pathway for breakthrough therapies and technologies, drug device combinations, and the importance of real-world evidence in regulatory decision-making. Sir Michael Rawlins, Chairman of the MHRA, delivered the keynote address on accelerating access to innovative therapies and implementing the Accelerated Access Review recommendations under the Life Sciences Industrial Strategy.

The report brings together highlights from the day including perspectives from senior experts from across the sector including: MHRA the UK regulator, the National Institute for Biological Standards and Control (NIBSC), the Clinical Practice Research Datalink (CPRD), the Department of Health and Social Care, the National Institute for Health and Care Excellence (NICE), the Office for Life Sciences, notified bodies, the life science industry, research charities, and patient organisations. The full report is available on the conference website, where you can also find the full programme and slide presentations.

Alan Morrison, former chairman of the BIA Regulatory Advisory Committee and Dr Ian Hudson, CEO of Medicines and Healthcare products Regulatory Agency, co-chaired the conference.

MHRA consults on EU exit no-deal legislative proposals

The MHRA is now consulting on EU exit no-deal legislative proposals in the event of the UK not securing a deal with the EU, with no transition/implementation period. Our discussions with regulators over the last few months around EU exit contingency planning for the regulation of medicines and clinical trials fed into the no-deal Statutory Instruments and consultation documents issued on 4 October on the Department of Health and Social Care's website. The overall approach is for the MHRA to be a stand-alone regulator, taking any decisions and carrying out any functions currently done at EU level. This would include decisions on marketing authorisation applications currently authorised through the Centralised Procedure, paediatric investigation plans and orphan designation, as well as pharmacovigilance responsibilities. The BIA is working with its members in partnership with the ABPI to respond to the MHRA consultation which closes on 1 November. Please contact BIA's Head of Regulatory Affairs Dr Christiane Abouzeid at cabouzeid@bioindustry.org if you would like to contribute to the consultation response.

BIA continues engagement with EU regulators on Brexit

In September, the BIA alongside EuropaBio and other European trade associations participated in an EMA Industry Stakeholder meeting to discuss the status of both the Agency's and biopharmaceutical companies' preparations for the UK's withdrawal from the EU in March 2019. Representatives from the European Commission's DG Health and the Taskforce on Article 50 negotiations with the UK were also in attendance.

The meeting provided the opportunity to get an update on the EU-UK negotiations with a focus on pharmaceuticals and to hear the EMA/Commission views in response to our questions and points for clarification regarding the EMA Industry survey and updated Q&As following the Life Sciences Industry Coalition letter sent in July 2018, of which BIA is a partner organisation.

The agenda and presentations are available on the EMA website.

BIA responds to European Commission consultation on the EMA fee system

The European Commission launched a public consultation in May to gather stakeholders' views on the EMA fee system. This included fees paid by industry for EMA activities relating to the approval and monitoring of medicines, as well as the remuneration to national competent authorities for the assessment of centralised marketing authorisation applications and performing regulatory services including pharmacovigilance at EU level. The findings will feed into a study, conducted by RAND Europe on behalf of the European Commission's DG Health, to assess the extent to which the current EMA fee and remuneration system is cost-based, fair, proportionate, and not unduly complex.

The BIA has worked in collaboration with EuropaBio to develop a consolidated response based on members' input. The response is available on our website.

BIA participates in EMA CAT Interested Parties meeting

In September, the BIA attended the EMA's Committee for Advanced Therapies (CAT) meeting with its Interested Parties. Topics discussed included: guidelines under development, comparability for Advanced Therapy Medicinal Product (ATMPs), the European Commission-EMA action plan on ATMPs, clinical trials with ATMPs containing GMOs, Good Clinical Practice for ATMPs, and CAT interactions with other committees.

Access to medicines

Addressing barriers to adoption of cell and gene therapies

In September, the BIA, the ABPI, and the Cell and Gene Therapy Catapult co-hosted a workshop to consider the clinical infrastructure, affordability, and reimbursement challenges presented by cell and gene therapies. Representatives from each of the three Advanced Therapy Treatment Centres and from the London Network gave attendees an update on their progress, both at a local level and as a national network, since being formally established earlier this year. Attendees then broke out in to small groups to discuss the current barriers to the adoption of advanced therapies in the NHS and potential solutions. The Cell and Gene Therapy Catapult will be publishing a summary of the discussion shortly.

NHS patients to be the first in Europe to benefit from ground-breaking CAR-T therapies

Patients in England will be the first in Europe to benefit from two ground-breaking CAR-T therapies following their approval by NHS England and NICE. Novartis' Kymriah will be given to patients up to 25 years old with a certain type of leukemia, while Gilead's Yescarta has been approved for use in up to 200 adults per year who have large-cell lymphoma and have stopped responding to other treatments. Both treatments will be funded via the Cancer Drugs Fund.

Commenting on the announcements BIA CEO Steve Bates said:

> "Away from the headlines, industry, government and the NHS have laid the groundwork for adopting this type of innovation for a number of years so it's fantastic to see UK patients starting to see the benefit of years of research and development. This step should enable the UK to be the first country in Europe where patients benefit from full access to this breakthrough treatment.
>
> "We look forward to more fast collaboration between all parties as treatment opportunities from advanced therapies broaden over the coming months and years."

Changes to the commercial environment for medicines

This quarter the BIA responded to two government consultations which are likely to have significant impacts on the commercial environment for medicines in England. Over the summer, the Department for Health and Social Care published consultations on proposed changes to the statutory pricing scheme for branded medicines and the introduction of regulations to allow NICE to charge companies for their health technology appraisal programmes.

The consultation on the statutory pricing scheme proposes changes to legislation to introduce new payment percentages. This would prevent any notable growth in the spend on branded medicines, despite the new funding settlement for the NHS which will see its budget grow by 3.4% over the next 5 years. If the government goes ahead with their proposals, the new payment percentages will come in to force in January 2019. The measures set out in the second consultation will allow NICE to charge companies between £88,000 and £251,000 to apply for its health technology appraisal programmes from 1 April next year.

In our responses to both consultations, we argued that the proposed measures are sending a damaging message to the international life sciences community about the UK as a location to research, develop, and launch innovative medicines at a critical time for the sector. As the UK prepares to leave the EU, the delivery of an internationally-competitive industrial environment for bioscience companies is more important than

ever. Rather than showcasing the UK as a good place to do business, the proposals set out in the two consultations have caused alarm in the life sciences industry and have sent a negative signal to globally-minded companies.

For more information read our blog or see our full responses to both consultations here and here.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Eric Johnsson, Senior Policy and Public Affairs Executive, 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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