

**Influencing and shaping our  
sector – BIA update  
July – October 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 July to October 2019.

The BIA has been busy engaging with the new Government this quarter. We have written to key members of Prime Minister Boris Johnson's new Cabinet and met with several ministers and special advisers to ensure the priorities of the sector remain well-understood within government. We have also increased our efforts to help life sciences companies to get ready for a potential no-deal Brexit, including holding weekly webinars and hosting regional workshops.

The party conference season is over, and as usual, the BIA team attended the conferences of the Conservative Party, Labour Party and Liberal Democrats. At the beginning of the quarter, we also published a joint report together with the Alliance for Regenerative Medicine (ARM) on the strength of the UK's advanced therapies sector. We also hosted our annual regulatory conference, published new finance data that shows UK biotech has raised £869m so far this year, and announced a new initiative in China together with AstraZeneca. Read about all this and much more below.

### This quarter in numbers:



**20+ influence meetings with 35+ MPs, Peers and MEPs, including 10 Ministers**



**2 consultation responses submitted**



**10 letters to Ministers**

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## BIA engagement with the new Government

During the election to replace Theresa May as leader of the Conservative Party, the BIA wrote to the two candidates in the final round of voting, setting out our policy priorities. In Boris Johnson's first speech on the steps of 10 Downing Street following his victory, the new Prime Minister directly referenced Gyroscope, a BIA member company which is developing a gene therapy for blindness and has directly benefitted from the UK Life Sciences Industrial Strategy with Innovate UK grant funding.

The BIA also wrote to the key Secretaries of State and Ministers in the new Government, outlining our policy priorities and track record of engaging constructively on a range of departmental issues. At the Department of Health and Social Care (DHSC), both Matt Hancock MP, the Secretary of State and Life Sciences Minister Nicola Blackwood have continued in post. We have followed up our letters by speaking in person to these ministers and Andrea Leadsom MP, Secretary of State at the Department for Business, Energy and Industrial Strategy (BEIS) and her Industrial Strategy Minister, Nadhim Zahawi MP, as well as Michael Gove MP at the Cabinet Office, who has taken charge of no-deal Brexit planning.

The appointment of William Warr as Special Advisor to the Prime Minister on Health and Technology was a very welcome move by Number 10. William is one of the principal architects of the Life Sciences Industrial Strategy (LSIS). The BIA was pleased to have an early meeting with this key advisor to discuss the implementation of the LSIS and other policy areas of mutual interest. Another strong voice for science in the Prime Minister's inner circle, Dominic Cummings is on record as wanting to make the UK the best place in the world to do science. Early on in the new administration, the Prime Minister invited leading figures from life sciences and business to a roundtable to discuss, with the Secretaries of State for DHSC and BEIS how to scale-up innovative life sciences businesses.

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 Council's work. Preparations are currently underway for the Autumn meeting of the LSC.

The Life Sciences Industrial Strategy Implementation Board (LSISIB) met on 9 September attended by Nicola Blackwood (DHSC) and Nadhim Zahawi (BEIS) to discuss the Department for International Trade's Global Sales Pitch, skills and reports on the progress of the Sector Deals.

The EU Relationship Group (EURG) met on 10 September attended by DHSC Ministers, Nicola Blackwood and Chris Skidmore, Department for Exiting the European Union (DExEU) Minister, Lord Callanan and BEIS Minister, Nadhim Zahawi to discuss government and industry preparedness for Brexit. The EURG will meet again before 31 October.

The BIA is also represented on the Patient Access to Medicines Partnership (PAMP), the Accelerated Access Collaborative (AAC) Board and Steering Group, and the NICE Methods Review working group and its various Task and Finish groups.

## BIA engages with key political stakeholders at party conferences

Over the Autumn, the BIA attended the party conferences of the Conservative Party, the Labour Party and the Liberal Democrats. At all three conferences, the BIA team met with ministers, MPs, Peers and MEPs to discuss the life sciences sector's priorities on a range of issues, including Brexit, fiscal R&D incentives and access to medicines.

This year, we organised a roundtable at the Conservative Party Conference in collaboration with our usual partners, BIVDA and ABPI. The roundtable focused on the NHS and the digital revolution and brought together senior representatives from across the life sciences ecosystem, including industry, charities and local organisations.

We were joined by the Prime Minister's Special Adviser on Health and Technology, William Warr, who gave an update on the Government's priorities for the NHS and the life sciences sector. Will Dracup of BIA member [Biosignatures](#) also explained how his company uses machine learning to diagnose disease early and highlighted how the company would not have existed today if it had not been for the fiscal support from R&D tax credits.



*Our roundtable at the Conservative Party Conference was attended by senior representatives from the life sciences sector and William Warr, the Prime Minister's Special Adviser on Health and Technology.*

The BIA's Interim Director of External Affairs, Nicky Edwards, attended the Business Days at the Conservative and Labour Party conferences (as well as the standalone Liberal Democrat Business Day), 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.

## Leaving the EU

### General Brexit update

With the arrival of a new Prime Minister in July, the Government stated its intention to leave the EU on October 31 with or without a deal. In the face of continued uncertainty, over the last three months the BIA has maintained a strong position on Brexit. Through our regular engagement with government departments and ministers we have continued to make the case for:

- A close regulatory partnership between the UK and EU post-Brexit to ensure continued supply of medicines to patients; safeguard rapid and effective patient safety and public health systems; ensure UK patients can continue to be able to get the latest medical treatments; and avoid duplication of red tape
- Maintaining and growing the life sciences industry in UK
- Enabling the movement of people to ensure continued access to skills and expertise
- Protecting existing R&D and funding routes through continued engagement with Horizon 2020 (and Horizon Europe) and EIF/EIB

### BIA helps life sciences businesses prepare for Brexit

Through our engagement across the sector over the summer, the BIA identified that a wide range of life sciences companies, particularly SMEs, required more information on what a possible no-deal Brexit would mean for their company. On that basis we undertook to significantly expand our programme of outreach and support to support the sector to be ready for October 31.

To build on our ongoing Brexit activities, BIA was successful in securing a grant from the Government's Business Readiness Fund to deliver a comprehensive programme of events, advice and guidance to the life sciences sector.

Working with regional partners One Nucleus, Bionow, MediWales and Scottish Enterprise, we have developed and launched a broader range of activities to ensure that we provide as much opportunity as possible for companies to participate. The programme is designed to gather feedback on the issues and concerns of our sector which we are using to challenge government and seek additional clarity where necessary. The programme includes:

- A dedicated [Brexit microsite](#), which includes the latest advice on the key issues facing businesses in our sector, covering regulation and IP; customs, tax and trade; R&D and funding; and people & employment
- [Weekly webinars](#) to provide a regular update on the latest news and additional information on the big challenges. These webinars are available to all and are also available afterwards on our [YouTube channel](#)

A series of Brexit "Business Readiness" events, including regional events with our partners across the UK. More details about the events are available [here](#).

We also continue to hold regular [Brexit Lead Network events](#) together with the 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](#).

### **BIA conveys concerns about the Government's proposed new Brexit deal**

With a month to go before the Government's 31 October deadline, the Prime Minister outlined new Brexit proposals, which focused on alternative solutions to the Irish border question. Whilst there was a disappointing lack of detail in the public proposals, these suggested the need for two sets of regulatory red tape and complex new customs arrangements, with the possibility for a significant reorganisation every four years.

The proposals moved the UK government's negotiating position away from the life science sector's preferred position of continued close regulatory alignment and co-operation with the European Union. The BIA raised these concerns directly with ministers in the Cabinet Office and Department of Health and Social Care about the risks of more complex regulatory and customs arrangements for our sector.

### **BIA cautions about government no-deal plans on the continuity of medicines supply**

In early August the government published its '[Yellowhammer](#)' assessment of the significant impact that a no-deal Brexit will have on several critical areas, including medicine supply to the UK. Mitigation measures had already been taken by much of our sector to develop stockpiles, expedite batch releases and determine alternative routing plans. However, these remained untested in practice.

Subsequently, the National Audit Office published a [report](#) on government plans to ensure continuity of supply. It stated that there remained risks to medicines supply and that additional freight capacity may not be fully available until the end of November, a month after the UK is scheduled to leave the EU.

The Department of Health and Social Care announced its procurement exercise for a £25m express freight service contract to deliver small parcels of medicines or medical products into the country in the event of a no-deal Brexit on a 24-hour basis.

The BIA has continued to stress that having freight capacity for medicines and medical devices in place on 1 November was fundamentally important for the continued supply of medicines to NHS patients in the case of a no-deal Brexit. We also continued to push government to provide sector-specific 'trader readiness' support for companies, especially smaller companies, and the government responded by putting in place plans for a 'trader readiness support service' for life sciences businesses, albeit late in the day.

In September, BIA CEO Steve Bates joined a media briefing at the Science Media Centre, where he raised the sector's concerns around a no-deal Brexit. Steve explained the challenges companies are facing in securing ferry capacity to bring medicines into the UK in the event of a no-deal Brexit. His comments were reported on [BBC News](#) and [Reuters](#), as well as many local news channels.

### **BIA hosts dinner to raise UK-EU research collaboration up the Brussels agenda**

In September, Science Business and the BIA hosted a dinner in Brussels to discuss how strong pan-European collaboration in healthcare research can be maintained as the UK leaves the EU. Industry and European Commission representatives were joined by MEP Barbara Ann Gibson on a panel, exploring the factors affecting the success of European life sciences, including collaboration. The event was part of the BIA's work to ensure the UK sector continues to have a prominent voice in the European ecosystem post-Brexit.

## Finance, tax and investment

### UK biotech raises £869 million in first three quarters of 2019

In October, the BIA and Informa Pharma Intelligence published data that shows UK biotech companies are continuing to raise significant new funds despite investment across all sectors slowing. £869m has been raised by UK-based biotech companies for the year up to 31 August.

The report on fundraising activity in the third quarter shows:

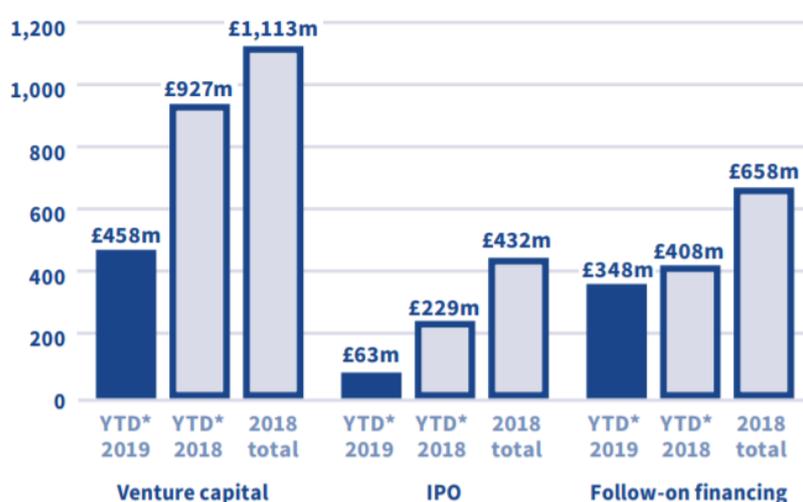
- £114m was raised in venture capital investment by UK biotech companies between 1 June and 31 August 2019 (Q3)
- £100m was raised in follow-on financing in public markets by UK biotech in Q3
- There were no Initial Public Offerings (IPOs) by UK or European biotech companies in Q3
- The UK slipped to fourth place in European venture financing behind Germany (£280m), Switzerland (£249m) and the Netherlands (£148m)

BIA CEO Steve Bates OBE said: “Across all sectors, companies looking to raise new funds are facing considerable headwinds at the moment. Not every year can be a record breaker for UK biotech and in this quarter, Brexit and global uncertainty are factors at the forefront of investors’ minds.

“It would be over simplistic to read longer-term trends from one quarter’s data, but the shape of some of the questions we may examine in our annual data report next year are starting to emerge. Is the British Business Bank stepping up fast enough to support UK life science venture funds as the European Investment Fund prepares for Brexit? And to what extent are new investors that are taking a greater interest in the UK, such as those from China, able to fund scaling companies to grow as Neil Woodford offloads many of his positions in our sector?”

The report was covered by The Times as well as other trade press.

### UK biotech fundraising



\* Year to date = 1 December 2018 to 31 August 2019.

## **BIA welcomes Chancellor's commitment to raising R&D investment in Spending Round**

In September, the Chancellor delivered a fast-tracked Spending Round on behalf of the new Government. The purpose of the quick Spending Round was to allow government departments time to focus on Brexit, while at the same time giving them financial certainty by determining department day-to-day budgets for 2020-21.

While the Spending Round did not allocate R&D funding, the Government confirmed its commitment to increase R&D investment to at least 2.4% of GDP by 2027. The BIA [wrote to the Chancellor ahead of the Spending Round](#), urging him to recommit to the 2.4% target.

Commenting on the Spending Round, BIA CEO Steve Bates said: "We are pleased to see the new administration's confirmation that the UK is still committed to raising R&D investment and that a new plan to give long-term certainty to the scientific community will be delivered in the Autumn.

"There's now cross-party support for significantly raising public and private R&D investment. We look forward to working with the Chancellor as he develops his plan to be launched in the Autumn, which should include a new cash commitment to the Biomedical Catalyst and expanding R&D tax credits. This will allow the UK to seize the economic, social and health benefits of our world-leading life sciences sector."

The BIA continues to work with the Government to highlight how public R&D investment in the sector helps companies develop innovative technologies while also driving economic growth and creating new highly skilled jobs all around the country. As part of this work, we recently met with the Science Minister's adviser to share our ideas of how the Government can enable the sector to increase its levels R&D investment. We also met with the Office for Life Sciences to discuss how we can work together to develop the evidence of the returns on public investment in the sector ahead of an anticipated long-term Spending Review in 2020.

## **BIA criticises the Science and Technology Committee over R&D tax credits**

In September, the House of Commons Science and Technology Committee published the [report on its inquiry on the balance of science and innovation funding](#). The BIA [submitted evidence to the inquiry](#) last year. In its report, the Committee argued that R&D tax credits are widely supported but questioned the evidence of the effectiveness of R&D tax credits and called for an analysis of the scheme.

In response to the report, BIA CEO Steve Bates said the Committee could have gone further by backing calls to expand the scheme and that the Committee could be more ambitious in backing policies that support and leverage industry R&D. Steve also highlighted that tax credits has been very successful in increasing investment and innovation and that companies increase their R&D investment by approximately 33 per cent in response to more generous R&D tax credits. Steve's comments were covered in Research Professional.

## **Biotech sector concerns with Innovate UK grants raised with Matt Hancock's SpAd**

The BIA has met with the Health Secretary's Special Adviser to raise the sector's concerns that Innovate UK is applying EU State Aid Rules too stringently and cutting off a valuable source of funding for early-stage biotech. The BIA has also raised its concerns in the past year with Innovate UK directly, UKRI's CEO Mark Walport, and the then-Secretary of State for Businesses, Greg Clark MP. BIA members continue to be stymied by the "Undertaking in Difficulty" definition, which disproportionately impacts biotech due to its high R&D spend and reliance on multiple venture capital rounds. We will continue to support members affected and lobby for a more flexible approach from Innovate UK and the European Commission.

## **BIA responds to parliamentary inquiry on UK trade with China**

In October, the BIA responded to the International Trade Committee's [inquiry into the UK's trading relationship with China](#). In our response, we highlighted the many opportunities China offers for UK life sciences companies, explained recent key changes to the Chinese healthcare market, and outlined how we are working to build strong links between the UK and Chinese innovation systems.

As part of this work, we hosted a delegation from the Xiamen Municipal Government, including the Xiamen Mayor, to discuss the investment and business opportunities between UK and Xiamen and to establish relationships with our member companies who have interests in making investment or having a business presence in Xiamen.



*Zhuang Jiahua, Mayor of Xiamen Municipal People's Government, and BIA CEO Steve Bates during the Mayor's visit.*

## **BIA welcomes new government-backed scale-up fund**

On 29 September, [Boris Johnson announced](#) £200m for a new "life sciences scale-up fund", which is intended to leverage £400m private capital for investment in growing businesses. BIA [welcomed](#) the commitment, which recognises the BIA's calls for such a fund, but noted that the details of how it will be allocated will be crucial to its success.

BIA CEO Steve Bates OBE said: "It is vital that government money leveraging in private sector investment works at both the pace and scale needed by growing life science businesses. The BIA is meeting with the British Business Bank in October and will press to ensure the "new dedicated fund to support the growth of more UK-based cutting-edge health and life sciences companies" can get money into companies as soon as possible. This is particularly important in the coming weeks as UK based life science venture capital funds look set to lose access to European Investment Bank money, which has been a cornerstone investor in funds supporting our sector, as a result of Brexit."

### **BIA engagement on PAYE cap, regulatory costs, R&D guidance, plastic packaging tax, and EMI shares**

The BIA has met with officials from HM Treasury and HMRC in several meetings this quarter to discuss a range of tax issues impacting the sector. Most pressing for our members is the Government's [proposed cap](#) on payments made through the SME R&D tax credits scheme, which would limit payments to three-times a company's PAYE and social security liabilities. Progress is being made in establishing a test that will distinguish claims from genuine biotech companies from the abusive claims seen in other sectors. The BIA is also leading sector discussions with HMRC on clarifying how regulatory affairs costs should be included in R&D tax credit claims and updating the HMRC pharmaceutical guidance used by tax inspectors, which remains largely unchanged since it was published in 2004.

The BIA met with HM Treasury officials in September to help them understand the impact a tax on plastic packaging would have on the sector. The Government is [consulting](#) on a tax on any plastic packaging that does not contain at least 30% recycled material. The BIA has explained to HM Treasury how the sensitive and in many cases highly regulated nature of packaging in our sector will make it hard for companies to avoid the tax, as recycled products of sufficient quality do not exist. Discussions are ongoing and an announcement on how the Government will proceed with the tax is expected in the Autumn.

Finally, in October, the BIA wrote to the Acting Chief Executive of HMRC to complain about inconsistent practice with EMI share option valuations and an apparent change of methodology being employed by some officials resulting in minimal discounts on market value being applied. This is having the effect of undermining the policy intention of the scheme. The BIA will continue to push for clarification and reinstatement of the more appropriate and long-established HMRC approach.

### **British Business Bank backs BIA calls for greater pension fund investment in early-stage companies**

On 25 September, the British Business Bank [published research](#) showing the potential returns that could be enjoyed by pension savers if a greater proportion of their money was deployed in venture capital; it also explored the barriers and options for a collective investment vehicle to pool pension funds' money to invest in the asset class. The report follows on from a commitment made by the Government in the Patient Capital Review to encourage greater pension fund investment in early-stage companies, which the BIA has been [vocally campaigning on for several years](#).

## Strategic technologies and areas of scientific focus

### **BIA and ARM publish joint report confirming the UK's leadership in advanced therapies**

In July, the BIA and the Alliance for Regenerative Medicine (ARM) launched a joint report on the Advanced Therapy Medicinal Products (ATMP) environment in the UK. The report, '[Leading Innovation: The UK's ATMP Landscape](#)', set out the scope of the UK's robust and growing ATMP sector.

The report emphasised that in Europe, the UK leads the way in cell and gene therapies – almost a quarter of European ATMP developer companies are headquartered in the UK. However, it is imperative that stakeholders from across the sector continue to promote a positive environment to support the research, development, approval, and commercialisation of ATMPs.

To mark the launch of the report, we hosted a panel discussion, moderated by Steven Hansen, Associate Editor of Biocentury, on the current landscape for cell and gene therapies and how it will develop in coming years. The panel was made up of BIA CEO Steve Bates, Janet Lambert, Chief Executive of ARM, Keith Thompson, Chief Executive of Cell and Gene Therapy Catapult, and Henny Braund, Chief Executive of Anthony Nolan.

Following an interesting discussion, we invited attendees to join us for a reception in the House of Commons, sponsored by Daniel Zeichner MP, the Chair of the All-Party Parliamentary Group (APPG) for Life Sciences. Mr Zeichner addressed attendees, noting the role of the life sciences industry in making ATMPs a reality. Life Sciences Minister Baroness Blackwood also joined us and shared her thoughts on the ATMP landscape. She remarked on the value of cell and gene therapies, particularly CAR-T therapies, to patients and importance of supporting the sector as it grows and develops.



*Janet Lambert (Chief Executive, ARM), Steve Bates, Nicola Blackwood (Life Sciences Minister) and Daniel Zeichner MP (Chair of the APPG for Life Sciences) at the reception celebrating the success of the UK's ATMP sector.*

## **BIA announces major initiative with AstraZeneca and new state of the art life science innovation campus in Wuxi China**

The BIA has signed a memorandum of understanding with the Wuxi International Life-science Innovation Campus (I-Campus) and AstraZeneca in China. The state-of-the-art campus will enable UK SMEs companies to easily explore, partner and engage with China's rapidly expanding healthcare innovation market. The I-campus will also serve as AstraZeneca's new China headquarters. The opening of the Wuxi I-campus will do much to de-risk and de-mystify China for UK companies. Wuxi is a city renowned for manufacturing and being at the centre of the 'internet of things' in China. The I-campus will build on Wuxi's innovation heritage and be a significant landing pad for UK biotech companies looking to expand and collaborate in China. More details are available on [our website](#).

BIA member [Abcodia](#) (a leader in ovarian cancer early detection) also announced its partnership with the Wuxi National High-Tech Industrial Development Zone (WND) supporting Abcodia's expansion into China. Abcodia will establish offices in the I-Campus. From this location, Abcodia will work collaboratively with AstraZeneca and other partners in a life science innovative ecosystem to establish its ovarian cancer screening technology in China.



*Jane Osbourn, Chair of the BIA, attended the official launch of the I-Campus in Wuxi in September.*

## **BIA continues to engage with government on the Nagoya Protocol**

This quarter, the BIA has continued our engagement with the Government on the Nagoya Protocol. The Department for Business, Energy and Industrial Strategy (BEIS), which is the department responsible for the enforcement of the EU regulation derived from the Protocol in the UK, has previously taken a 'soft' approach to its enforcement, but we now understand that BEIS will shift its approach by actively ensuring companies are complying with the regulation.

However, as the regulation is ambiguous and hard for companies to comply with, we are working with BEIS to organise a workshop specifically for our sector to allow companies to directly raise their concerns and ask for clarifications directly with the regulator. You can sign up for the workshop [here](#).

## Skills, people and talent

### **BIA engages with government on new immigration system**

Shortly after the formation of the new Government in July, the Prime Minister and Home Secretary made announcements about changes to the skilled immigration system, including fast-tracked visas for scientists. However, it is important to note that these announcements have not replaced the proposed immigration system set out in the [Immigration White Paper](#), which was published by the Home Office late last year.

The BIA is working on several areas of interest in the White Paper, including the proposed salary threshold and the new 'Points based system'. Both these areas are currently under review by the Migration Advisory Committee. At present, the Government plans for the salary threshold to be the Committee's recommended threshold of £30,000. BIA members raised concerns about this proposed threshold during a roundtable with the Home Office in June and we are now working with the Scientific Recruitment Group to provide evidence of the impact of this threshold and provide data for future recommendations.

### **BIA ensures SMEs are heard on future skills**

As part of the Life Sciences Industrial Strategy and the Sector Deals, the Science Industry Partnership (SIP) has been commissioned to deliver a [strategic report on the skills needed by life sciences](#). The industry led report will build a clear evidence base of the status of life science skills and future scenarios to 2030, focusing on research and development, advanced manufacturing and emerging technologies to identify what skills will be needed in terms of type, level and quantity. Development of the report is a collaboration between SIP employers, the Office for Life Sciences (OLS), the ABPI and the BIA.

Over the summer, the BIA has conducted a series of in-depth interviews with our SME members to ensure that their needs are reflected in recommendations of the report. The BIA also attended a workshop in September to finalise the recommendations ahead of the publication of the report in January 2020.

### **New life sciences apprenticeships launched**

Apprenticeships have undergone significant reform over the last few years, which focuses on addressing skills gaps, employer need and high-quality programmes. In September, two new apprenticeship programmes in the life sciences sector were launched.

The [Senior Leader apprenticeship](#), in collaboration with Open University, has a cohort of 13 leaders across seven companies, many BIA members, and aims to develop talented colleagues through a structured 30-month leadership programme through blended on-line, residential school and tutorial-based learning.

The [Regulatory Affairs Specialist apprenticeship](#) was also launched, which is designed for professionals entering a career in regulatory affairs and run in collaboration with The Organisation for Professionals in Regulatory Affairs (TOPRA).

Apprenticeship training and assessment costs are funded through the apprenticeship levy for large organisations or a co-investment model for companies who do not pay the apprenticeship levy where 95% of the cost is covered by government funding.

## Intellectual property and technology transfer

### **BIA highlights flaws in Labour's proposed medicines patents and pricing policy**

The Leader of the Opposition, Jeremy Corbyn used his [speech](#) at the Labour Party Conference to call out companies that he believes are charging too much for medicines and proposed to change the patent system to lower prices. A [policy document](#), which the BIA understands is not yet formal party policy, was published alongside the speech proposing radical changes to the way medicines are developed, manufactured and patented. The document proposes funding R&D through grants and challenge prizes, removing companies' patent-backed monopoly on medicines, and installing a publicly owned generics manufacturer.

In response to Corbyn's speech, the BIA CEO Steve Bates said: "NHS patients and the UK economy would both lose the chance of new life saving treatments if the UK becomes a hostile environment for intellectual property.

"Sadly, there are still many life-threatening conditions for which there are no viable treatments available. The development of medicines in the UK and globally is underpinned by a strong and robust intellectual property system that incentivises investment.

"New life-saving medicines are not just being developed by a few large pharmaceutical companies but also hundreds of innovative SMEs across the UK. Labour's proposal to use compulsory licenses risks cutting off investment in the small companies up and down the UK that are working hard to develop new treatments for patients that have few options."

The BIA also briefed a number of journalists on the detail and potential ramifications of the proposals, with comments reported by [BBC News](#), [The Telegraph](#) and [The Daily Mail](#), among others.

### **SPC manufacturing waiver guide published for BIA members**

The BIA's IP Advisory Committee has published [a new guide](#) to the new SPC manufacturing waiver, which came into force on 1 July 2019 and will allow for the production of SPC-protected medicines within Europe for export purposes. The guide will help companies assess what the impact of the waiver might be on their business and how to protect their IP rights. The guide's lead author, Andrew Hutchinson of Simmons and Simmons, wrote a [blog](#) introducing it to the BIA membership.

### **BIA comments on the no-deal statutory instrument for the SPC manufacturing waiver**

The BIA has [responded](#) to a Government [consultation](#) on draft legislation intended to ensure the EU SPC manufacturing waiver continues to function post-Brexit if the UK leaves without a deal. The BIA also met IPO officials directly to raise multiple concerns with the approach suggested by the Government, which would erode innovator's IP rights and appears to introduce a new policy, which could be perceived to contravene the Withdrawal Act. The Government is yet to announce how it intends to take forward the legislation.

## Pre-clinical and clinical research

### **DHSC latest guidance on Brexit preparedness for clinical trials supply**

On 20 September, the Department of Health and Social Care (DHSC) issued their [latest guidance](#) on Brexit preparedness, advising sponsors of clinical trials to review their supply chains for investigational medicinal products and materials used in clinical trials and ensure they have arrangements in place to assure supplies post-Brexit. Chief investigators of clinical trials or investigations are advised to contact trial sponsors regarding these arrangements.

BIA members will have the opportunity to ask questions and raise any concerns they may have at [our webinars](#) throughout October. For more information on the DHSC guidelines, please contact [ctcontingencyplanning@dhsc.gov.uk](mailto:ctcontingencyplanning@dhsc.gov.uk).

## Manufacturing

### Upskilling existing staff through apprenticeships

There are now 65 apprentices from 21 companies on five Advanced Therapies Apprenticeship Community (ATAC) programmes, which were established following a recommendation by the Medicines Manufacturing Industry Partnership (MMIP) Advanced Therapies Manufacturing Taskforce and delivered by the Cell and Gene Therapy Catapult.

The number of apprentices and companies will continue to grow through existing programmes. In addition, an industry-led User Group is meeting this month to validate which additional standards will be prioritised for delivery in 2020. A pilot regional ATAC networking meeting took place at Immetacyte in Manchester in September to help sustain the programme as it grows, with the second regional meeting now taking place at Replimune, Oxford in November. In September, the first ATAC cohort started on the Modern Apprenticeship in Life Sciences (Scotland) and discussions are now underway to support ATMP apprenticeships in Wales.

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](mailto:aengland@bioindustry.org).

### Applications open for BIA Manufacturing Advisory Committee's Leadership Programme in 2020

The BIA [Manufacturing Advisory Committee's Leadership Programme](#) (LeaP) was established in 2017 to develop next generation leaders, firstly through cross-sector learning by seeing other companies across biopharma, vaccines and cell and gene therapies in action through site visits; and secondly by developing a network with peers to share best practice and develop relationships to encourage possible future collaborations.

Currently 44 participants from 23 member companies are benefitting from LeaP and applications are now open for the 2020 cohort, starting in January. LeaP is free to BIA members with a UK bioprocessing facility – if you would like to hear more please contact Netty England at [aengland@bioindustry.org](mailto:aengland@bioindustry.org).

### BIA enables new standards group for advanced therapies engage with industry

In 2016, the Medicines Manufacturing Industry Partnership (MMIP) Advanced Therapies Manufacturing Taskforce made a [series of recommendations to anchor Advanced Therapy Medicinal Products \(ATMP\) manufacturing in the UK](#). One of the recommendations was to “develop a long-term regulatory strategy and plan for the MHRA to lead in global standards, supporting the scientific activities and international outreach of the National Institute for Biological Standards and Control (NIBSC).”

As a result of the recommendation, a UK Standards Liaison Group for Advanced Therapies (UKSLGAT) has now been established with representatives from the MHRA (British Pharmacopoeia, Inspectorate and NIBSC), Cell and Gene Therapy Catapult, the National Measurement Laboratory and Innovate UK. BIA held a workshop in July together with the MHRA and the Cell and Gene Therapy Catapult to enable the UKSLGAT to engage with industry to help identify which reference, analytical and documentation standards should be prioritised for ATMPs. The outcomes were excellent, providing real and concrete descriptions of industry challenges and possible solutions to the UKSLGAT.

## Medicines Regulation

### Life sciences community gather for BIA's annual Regulatory Conference

In September, we held the BIA's annual regulatory conference, '[Innovation and regulatory science in an evolving environment](#)', which brought together regulators, medicine developers, academic researchers, research charities as well as senior officials from the Department of Health and Social Care (DHSC), the National Institute for Health and Care Excellence (NICE), NHS England and the Accelerated Access Collaborative. Dr June Raine, incoming Interim Chief Executive of the MHRA, joined us at the closing drinks reception.



*Dr June Raine, interim of Chief Executive of the MHRA, at the BIA's regulatory conference.*

Our speakers discussed a range of timely topics across the whole lifecycle of medicine development as we navigate these uncertain and fast changing times, including:

- The UK's global capability for clinical trials
- Bringing innovative medicines to market
- Evidence generation in support of regulatory decision-making
- Looking into the future at the role of the regulator as part of the global innovation ecosystem

[Please follow this link](#) to view the speakers' presentations.

## **BIA engagement with MHRA on Brexit**

The BIA continues to have a constructive dialogue with the MHRA and the Government on no-deal planning, as well as on regulatory priorities in the negotiations with the EU if there is a deal. The MHRA updated some of the no-deal [guidance documents](#), which were issued earlier this year, and removed some outdated information, reflecting the publication of more specific guidance in some areas. Please [contact the MHRA](#) if you have queries about their planning and procedures if there is a no-deal Brexit.

On 24 September, the MHRA [sent letters to industry](#) regarding the conversion of Centrally Authorised Products (CAPs) to UK Marketing Authorisations. The MHRA will take a similar approach with parallel traders for the grandfathering of parallel traded products.

The BIA position is that close cooperation with the EU in the regulation of medicines, including mutual recognition of regulatory activities and quality testing, is essential in ensuring that patients in the UK and the EU can continue to access safe and effective medicines.

## **BIA meets with DHSC on Serious Shortages Protocol**

In August, the BIA met with the Department of Health and Social Care (DHSC) to discuss the process that they would undertake for issuing Serious Shortage Protocols (SSPs) in case a protocol should be required for a medicine affected by a serious shortage. This meeting helped us understand the role of the Medicine Shortage Response Group (MSRG) which advises DHSC on serious medicines shortages and strengthens the 'Business as Usual' processes.

It is important to highlight that MSRG managed to resolve shortage cases without the need to develop and issue SSPs over the last eight months since legislation came into effect. The necessary legislative changes to the Human Medicine Regulations 2012 and the NHS Pharmaceutical and Local Pharmaceutical Services Regulations 2013 have been made following consultation in December 2018 to which the BIA responded.

## **European Commission issues conference report on medicines for rare diseases and children**

The European Commission's Directorate-General for Health and Food Safety has published its report of the conference '[Medicines for rare diseases and children: learning from the past, looking to the future](#)', which took place in June 2019. The event was opened by Commissioner Vytenis Andriukaitis and former MEP Françoise Grossetête, and brought together some 150 experts from across the EU, representing national governments and health authorities, academia, patient and health professionals' organisations and the pharmaceutical industry.

This conference was organised in the context of the joint evaluation of both the EU Orphan Regulation 2000 and the EU Paediatric Regulation 2007, giving stakeholders the opportunity to put forward their views and suggestions, which will be part of the evaluation process regarding the two Regulations. The BIA will keep a watching brief on future developments in this area.

## Access to medicines

### **BIA engages with the NICE Methods Review**

The National Institute for Health and Care Excellence (NICE) launched a review of its methods in May 2019, to examine how it undertakes the appraisal of medicines. This is an important opportunity to ensure that NICE's approach to health technology appraisal is fit for the new medicines becoming available, including those for rare diseases and cell and gene therapies.

The BIA has engaged with NICE to ensure that industry is appropriately represented on its Working Group and several Task and Finish Groups on a range of issues relating to health technology appraisals. The Working Group and Task and Finish Groups will be starting to meet from October 2019, with a view to report later in 2020, with NICE publishing its draft methods in the Summer of 2020.

Working with colleagues at the ABPI and the Ethical Medicines Industry Group (EMIG), the BIA will be supporting our members' engagement with the process as it goes forward.

### **BIA's Rare Disease Industry Group hosts dinner with Blake Dark**

In September 2019, UK General Managers from the BIA's [Rare Disease Industry Group](#) met with Blake Dark, NHS Commercial Medicines Director at a dinner in central London. The dinner was an opportunity for the General Managers to engage with Dark both on the upcoming commercial framework, but also the wider access landscape.

As a result of the meeting, the BIA was invited to join a workshop on commercial framework in October 2019, when the first draft of the document will be confidentially unveiled.

In addition, Dark discussed his ongoing thinking around new mechanisms to ensure that rare diseases are made available to patients. We will continue to engage with Dark and NHS England's commercial directorate to develop the conversation on rare diseases.

### **BIA's Rare Disease Industry Group to promote the value of rare disease medicines**

The BIA has been working with its Rare Disease Industry Group members to develop a new campaign to develop a new understanding of the value of rare disease medicines and how that can realistically be integrated into how NICE and NHS England appraise medicines.

This will be kicking off in the fourth quarter and we have developed a comprehensive work plan covering an analysis of value, promoting a better understanding of patient experience and engaging with parliamentarians on these complex issues.

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](mailto: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](mailto:mmcgivern@bioindustry.org)

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