

**Influencing and shaping our  
sector – BIA update  
April – July 2018**



## 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 April to July 2018.

This quarter, the BIA has continued to call for clarity and business certainty around Brexit to protect public health and ensure patients' access to medicines. We engaged Ministers, MPs, and senior civil servants at our 18<sup>th</sup> annual Parliament Day to ensure our sector remains high on the government's agenda following the changes in the Cabinet after the "Chequers deal" and the same day as the Brexit White Paper was published. See our updated [Guide to Government](#) for the relevant Ministers to our sector.

We have also organised the launch of the Industrial Biotechnology Strategy in Parliament, responded to several government consultations on valuable finance policies for the sector, and continued to advocate for the importance of Supplementary Patent Certificates (SPCs) for innovation. Read about this and much more below.

### This quarter in numbers:



**20+ influence meetings with 26+ MPs and Peers, including 9 Ministers**



**7 consultation responses submitted**



**3 letters to Ministers**

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## BIA's 18<sup>th</sup> annual Parliament Day

On Thursday 12 July – the same day the government published its Brexit White Paper – more than 35 senior representatives from UK life sciences companies convened in Westminster for the BIA's annual flagship influencing event – Parliament Day. The day enables key engagements between BIA members and policymakers across Westminster and Whitehall.



The delegation of BIA members met with 40 policymakers, including eight MPs, four Peers, and 27 civil servants, in 22 meetings. The meetings were excellent opportunities for our members to highlight the sector's priorities for the implementation of the Life Sciences Industrial Strategy, Brexit, and how to unlock long-term finance for SMEs. We also had lunch in the House of Lords, kindly hosted by Lord Drayson. 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.

This year, we also organised a joint meeting session with the Office for Life Sciences (OLS), where its Director Kristen McLeod gave an update on the Life Sciences Sector Deal, before the delegates discussed what life sciences companies need to grow their businesses with OLS representatives.



## Engagement with the government on life sciences policy

### BIA attends inaugural Life Sciences Council meeting at No 10

This year the Office for Life Sciences has reinvigorated some of the mechanisms by which the government engages with the life sciences industry on policy matters. The previous Ministerial Industry Strategy Group (MISG) has evolved into the Life Sciences Council, a slightly expanded body taking in a wider scope of both the industry and representatives from across Whitehall that have an interaction with the life sciences sector. This new group is a partnership between government and industry to provide strategic oversight of the future of UK Life Sciences, including the delivery of the sector deals.

The BIA was an established member of the MISG and continues to be represented by our CEO Steve Bates at the Life Sciences Council. However, in this new format, the BIA now also has an open spot to bring a member representative to discussions on a rotating basis, matching member expertise with the meeting's agenda.

The Life Sciences Council held its inaugural meeting at No 10 Downing Street in May 2018. BIA Board Member and [BenevolentBio](#) CEO Jackie Hunter joined BIA CEO Steve Bates at the meeting. On the government side, the Council is co-chaired by the Health Secretary (with Matt Hancock replacing Jeremy Hunt at future meetings following the [Cabinet reshuffle](#)) and Business Secretary Greg Clark, while AstraZeneca's Pascal Soriot is the chair for industry. International Trade Secretary Liam Fox and Health Minister Lord O'Shaughnessy also attended the meeting.



*BIA CEO Steve Bates and BIA Board member Jackie Hunter CEO of BenevolentBio at the inaugural Life Science Council meeting at No 10.*

The meeting provided a useful opportunity to discuss high-level issues that are currently impacting the sector, including Brexit, the PPRS, and Industrial Strategy. The BIA emphasised the importance of getting the implementation of the Patient Capital Review right to release new forms of financing into the sector.



The Council will meet twice a year at a minimum, with secretariat support from both government and industry. The upgrading of industry engagement to a full Council – on par with the Automotive Council – is significant in terms of status and impact within government circles. The PM's office released a press notice to mark the event, which you can read [here](#).

### **Sector Deal in focus at Life Sciences Industrial Strategy Implementation Board meeting**

Several other working subgroups report into the Life Sciences Council, including the Life Sciences Industrial Strategy Implementation Board, which held its second meeting in June 2018.

This meeting provided opportunity to hear more about the implementation of the Life Sciences Sector Deal, government thinking for the next stage of this work, and an update from UK Research and Innovation CEO Sir Mark Walport on progress in delivering activity under the banner of the Industrial Strategy Challenge Fund. The BIA highlighted our work with the implementation of the Patient Capital Review, which is closely linked to the growth objectives of the Life Sciences Industrial Strategy and the government's aim to raise R&D investment in the UK to 2.4% of GDP by 2027.

## Leaving the EU

### BIA reaction to the government's Brexit White Paper

On 12 July, the government published its long-awaited Brexit White Paper, "[The Future Relationship between UK and the EU](#)", which sets out the UK's approach in the negotiations with the EU. The paper reflects many policies that the BIA has consistently advocated for since the EU referendum two years ago. A member briefing on the paper is available on [our website](#).

The paper proposes to establish a common rulebook for goods, the phased introduction of a new Facilitated Customs Arrangement, and continued participation in EU agencies. The latter would include participation in the European Medicines Agency (EMA) and involve "accepting the rules of these agencies", being an "active participant", contributing to the Agency's costs, and being able to undertake technical work and acting as a leading authority.

The UK makes clear that freedom of movement will end post-Brexit and the paper sets out proposals for future mobility arrangements with the EU. These new arrangements would support businesses' access to talent in a streamlined process, allow citizens to travel visa-free, and facilitate mobility for students. The paper also proposes that the UK's future relationship includes a science and innovation accord that provides for UK participation in EU research funding programmes, including Horizon Europe.

BIA CEO Steve Bates said:

*"Every month, 37 million packs of medicine arrive in the UK from the EU, with 45 million moving the other way. For patients, today's White Paper sets out the Government's position on the UK's future relationship with the EU."*

*"Our industry's priority throughout these negotiations is to ensure patients in both the UK and EU can continue to access the medicine and vaccines they need."*

*"We are pleased to see further detail on the Government's ambition for the UK's future membership of the European Medicines Agency (EMA). Whilst today's approach depends on agreement from both sides, continued cooperation between the UK and EU on the regulation of medicines is in the best interests of patient and public health."*

### Communicating our message

To support our government advocacy work, the BIA has been seeking to raise the profile of our Brexit messages in the media. We have generated media coverage around how Brexit will impact patients' access to medicines and some members are now speaking publicly about how Brexit may impact their businesses and supply-chains. Our media coverage has been going from strength to strength, with mentions this quarter in several key national publications, including the Financial Times, The Times, Bloomberg, Pink Sheet, and many more. Our monthly Brexit webinars have proved particularly popular and insightful, with mentions and quotes in some key publications including Politico.

If you are interested in speaking publicly about how Brexit impacts your business, please contact our Brexit lead, Laura Collister, at [lcollister@bioindustry.org](mailto:lcollister@bioindustry.org).

### Regulatory alignment accepted into EU Withdrawal Bill

In June, the EU Withdrawal Bill finished its passage through Parliament to become the European Union (Withdrawal) Act. The Act enables the repeal of the European Communities Act 1972 and Parliamentary



approval on the Withdrawal Agreement currently being negotiated by the UK and the EU. During its passage through Parliament, the government voted down several amendments proposed by the House of Lords. However, the government did accept an amendment on regulatory alignment, which enables the UK to continue to participate in EU agencies, such as the European Medicines Agencies (EMA). Prior to it being accepted, the BIA provided a briefing to MPs on the importance of the amendment to the life sciences sector.

### **Brexit Health Alliance campaign – protecting public health**

In June, the [Brexit Health Alliance](#), a group of which the BIA is a member, launched its [latest campaign briefing](#) on public health which calls on the EU Commission and UK government to prioritise public health and access to medicines in the UK-EU negotiations. The campaign calls for a security partnership based on strong coordination between the UK and EU in dealing with serious cross-border health threats, such as pandemics, infectious diseases, safety of medicines (pharmacovigilance), and contamination of the food chain. Ideally, this would be achieved by continued UK access to the European Centre for Disease Prevention and Control and other relevant EU agencies, systems, and databases.

The campaign also calls for alignment with current and future EU regulatory health and safety standards relating to medicines, transplant organs, food, and the environment to avoid the need for replication of inspections and non-tariff barriers at the UK-EU border.

### **Business Select Committee focuses on Brexit and the pharma industry**

The House of Commons Business, Energy and Industry Strategy Select Committee published the report to its [inquiry into the impact of Brexit on the pharmaceutical sector](#) in May. The report made several recommendations which were [welcomed by the BIA](#), including the need to secure the closest possible regulatory alignment with the EU as well as minimum friction at the UK-EU border.

The report also states that patients are at risk of harm and the UK pharmaceutical sector is at risk of losing its status as a world leader. The Committee also concluded that "what little benefits there may be from regulatory divergence, these would be greatly overshadowed by the costs and loss of markets and influence the UK would face." The BIA, together with the ABPI, [provided written evidence](#) to the inquiry in November 2017.

### **Government response to Health Committee's report on Brexit and medicines**

In May, the government [published a response](#) to the House of Commons [Health Select Committee's report](#) on its inquiry into Brexit's impact on medicines, medical devices, and substances of human origin. BIA stated that the government's response demonstrates understanding of the complexities of Brexit in getting medicines to NHS patients, however it does not provide the detailed answers needed for the sector to plan with clarity.

BIA CEO Steve Bates [commented](#):

*"Our priority remains ensuring that NHS patients continue to receive their medicines, both day 1 post-Brexit and in the future. There are measures the UK government can take unilaterally to increase certainty for our sector, as they work to ensure that they can continue to supply medicines to patients, and I strongly encourage them to do so immediately."*

### **BIA continues to engage with the government through Steering Group**

Following the EU Referendum, the government established the UK-EU Life Sciences Steering Group to provide top-level engagement for the sector. The Steering Group has now been renamed to the EU Relationship Group and reports into the Life Sciences Council. The remit and membership of the Group remains the same, with BIA CEO Steve Bates an active participant. The Group met in April and June 2018 and will meet again in July. The meetings continue to provide a key opportunity for us to ensure that government understands the priorities of the life sciences sector.

### **Government consults BIA and its members on post-Brexit trade framework**

In June, the BIA and member representatives attended a workshop at the Department for International Trade (DIT) to discuss the continuation of the existing Mutual Recognition Agreements (MRAs) that the EU has with third countries. The representatives around the table highlighted the importance of the MRAs and the need for business continuity throughout the Brexit process. The government is seeking to adopt all EU MRAs and is working with the MRA partner countries to ensure the agreements continue after the UK leaves the EU.

In July, DIT held a workshop on key IP considerations for the life sciences in a possible US Free Trade Agreement (FTA). The discussion focused on data and marketing exclusivity, patent linkage, patent term adjustment, and supplementary protection certificates.

BIA also attended the second UK-US SME Dialogue in July. The purpose of the cross-sector meeting was to explore the future US-UK trade and investment relationship post-Brexit and to look at how trade barriers faced by SMEs on both sides of the Atlantic may be addressed. The meeting was organised by the [US-UK Trade and Investment Working Group](#), which is laying the groundwork for a potential future free trade agreement once the UK leaves the EU.

## Finance, tax and investment

### BIA consultation submissions set out sector's needs to government

This quarter, the BIA responded to four government consultations to highlight the bioscience sector's needs on a range of finance and tax issues.

In May, [we called](#) on the government to introduce a novel venture capital fund structure that provides a new "Holding Relief", which will reward individuals with income tax relief if they stay invested in the long-term. [The proposal](#) was in response to a HM Treasury consultation on a new EIS knowledge-intensive fund structure.

We also responded to a HM Treasury and HMRC consultation on allowing Entrepreneurs' Relief on gains made before dilution. [Our response](#) argued that the proposed changes will not benefit life science companies and urged changes. Members of the BIA's [Finance and Tax Advisory Committee](#) also met with Treasury and HMRC officials to discuss the consultation. The outcome is expected to be announced in the Autumn.

Also in May, [the BIA responded](#) to an HMRC review of the UK's intangible fixed assets tax regime. We supported the removal of the pre-2002 exclusion, the goodwill and customer-related intangibles exclusion, and the de-grouping charge. We also supported the option for companies to elect for a fixed-rate relief of 4% per year.

In July, [we responded](#) to the government's review of business productivity, providing an overview of the UK bioscience sector. The aim of this response was to help government's understanding of how the life sciences sector differs in its business model compared to other sectors, and the importance of government policy support to increase access to private finance and grant funding.

### A new £2.5bn fund for innovative UK businesses

In June, the BIA [welcomed](#) the creation of British Patient Capital, a £2.5 billion fund run by the British Business Bank. The fund, which is one of the outcomes of last year's Patient Capital Review, will provide long-term funding to support the growth of innovative UK bioscience companies and other sectors.

BIA CEO Steve Bates said:

*"We're delighted that our calls for ambitious public investment have been heeded. Through leveraging a further £5 billion private investment, the fund can now create a step-change in the availability of funding to help UK life science members to scale and reach their global ambitions. The appointment of Russ Cummings, former CEO of Touchstone, today as a non-executive director of British Patient Capital adds fantastic weighty life science insight and experience to the leadership team."*

### BIA works with HMRC to clarify regulatory costs for R&D Tax Credits

Members of the BIA's Regulatory Affairs and Finance and Tax and Advisory Committees met with HMRC officials in June to discuss the eligibility of regulatory affairs costs in the R&D Tax Credits regime. The meeting follows concerns raised by members that these costs are not being uniformly dealt with by tax inspectors and some claims are being rejected. The BIA believes regulatory affairs is an integral part of the R&D process and so should be eligible for relief. We are working with HMRC officials to resolve this issue.

## Engagement with Labour Party policy development

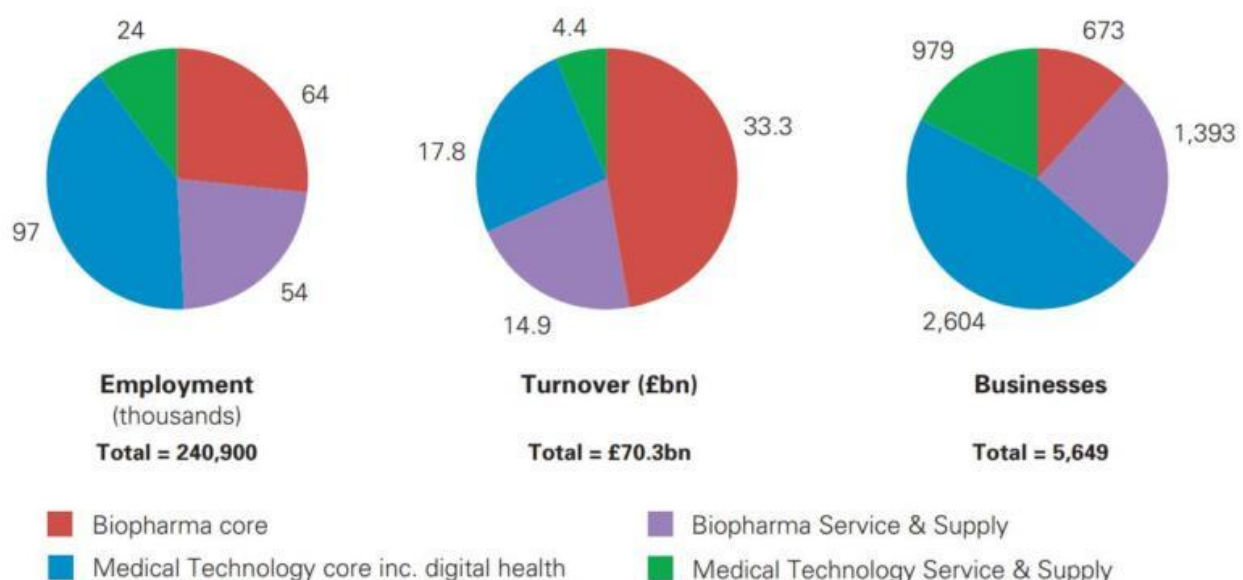
The BIA continues to follow and influence the development of Labour's Industrial Strategy policies. We have been arranging for members to attend regional roundtables with the Shadow Business Secretary and our Finance and Tax Advisory Committee met with the author of [a new report](#), published on 20 June, that sets out how Labour will coordinate and promote investment in R&D and infrastructure. The BIA will now be engaging with Labour MPs as they consider making the recommendations of the report official party policy, including following up on our meetings at Parliament Day.

## New statistics show strength of UK life sciences sector

Two new datasets published by the government's Office for Life Sciences provide interesting insights into the strengths of the UK's life sciences sector. [Strength and Opportunity 2017](#) reveals the sector employs almost 240,900 people, approximately 1.0% of all private sector employment. There are 5,649 businesses generating approximately £70.3bn in annual turnover. Biopharma and med tech employ roughly equal numbers of people and, despite med tech accounting for two-thirds of businesses (63%), biopharma generates over two-thirds of the total industry's turnover (68%).

The [Life Sciences Competitiveness Indicators](#) provides metrics on the UK's performance compared to a range of comparator countries. For example, the UK accounts for 3.1% of global patients recruited into clinical trials, ranking us fourth, but our recruitment speed could be improved – the UK is seventh for the time taken to enrol the first patient. For medicines first marketed between 2012 and 2016 and recommended by NICE, median UK uptake per capita of NICE-approved medicines in the first year after launch was at 21% of comparator countries. This rose to 78% by the fifth year. These figures represent a decline in uptake when compared to the previous set of indicators.

For further analysis of the statistics visit the [BIA blog](#).



## Strategic technologies and areas of scientific focus

### BIA promotes the launch of new Industrial Biotech Strategy in Parliament

In June, the Industrial Biotechnology Leadership Forum (IBLF) launched “[A National Industrial Biotechnology Strategy to 2030](#)” in Parliament, promoted in partnership with the BIA. The Strategy aims to ensure that the UK becomes a leader in the global shift towards clean growth by fostering the development of industrial biotech SMEs.

The BIA organised the launch at a breakfast roundtable in Parliament, which was hosted by Cambridge MP Daniel Zeichner. The breakfast brought together stakeholders in both industry and academia, civil servants, and MPs to discuss the potential of the UK industrial biotech sector and how its challenges may be overcome. A summary of the Strategy and the breakfast roundtable is available on [our blog](#).



*Cambridge MP Daniel Zeichner hosted the Parliamentary breakfast that launched the Industrial Biotechnology Strategy.*

### BIA continues to oppose the incorporation of Digital Sequence Information into the Nagoya Protocol

In July, an intergovernmental advisory body of the Convention on Biological Diversity met to discuss several issues under the Convention, including the possible incorporation of Digital Sequence Information (DSI) into the Nagoya Protocol. Ahead of the meeting, the BIA engaged on both national and international

levels to continue to highlight the immensely negative effects the incorporation of DSI into the Nagoya Protocol would have for public health and the life science sector.

We submitted a position paper developed by our colleagues at EuropaBio to the Department for Environment, Food and Rural Affairs (DEFRA), attended a DEFRA stakeholder meeting, and organised for the International Council of Biotechnology Associations (ICBA) to sign a [joint statement coordinated by the International Chamber of Commerce](#). The BIA will continue to work with the UK government and international colleagues to oppose the incorporation of DSI into the Nagoya Protocol.

### **BIA responds to Health Select Committee's inquiry on AMR**

The BIA has responded to the [Health and Social Care Select Committee's inquiry](#) into how the government is responding to the challenge of antimicrobial resistance (AMR). In our [submission](#), we highlighted that progress has been made on improving the knowledge and understanding of AMR. However, not enough progress has been made to create a vibrant market for novel antibiotics so that biotech investors actively seek out opportunities in this area, which needs to be addressed in the updated government strategy. We also emphasised that BIA SME member companies working within the AMR space are well positioned to give compelling oral evidence of innovation.

### **AMR in international focus at BIO in Boston**

In June, the BIA went to BIO 2018 in Boston to promote UK bioscience. We co-hosted a UK Innovation Reception with AstraZeneca and the Department for International Trade, where Trade and Export Minister Baroness Fairhead represented the UK government. BIA CEO Steve Bates spoke at several antimicrobial resistance (AMR) events, where he highlighted that the UK's small biotech companies have a vital role to play in the global fight to curb AMR. He also highlighted the importance of R&D partnerships in overcoming the challenges faced in bringing products to patients.

AMR was also high on the agenda at the meeting of the [International Council for Biotech Associations](#) (ICBA), which met in Boston the day before the official opening of BIO. The group agreed on the global importance of working together to ensure the right policies are in place to tackle AMR and enable industry to play their part. ICBA issued a [statement](#) on AMR that coincided not only with BIO, but also the G7 Summit, which took place in Canada the same week.



## Skills, people and talent

### Visa restrictions lifted due to coordinated efforts by science and engineering sectors

In March, the BIA joined 44 other organisations in writing to the Prime Minister to call for visa restrictions to be revised for skilled workers. The Campaign for Science and Engineering organised [the letter](#), which noted that hundreds of business-critical recruits were refused visas as a result of the monthly cap for Tier 2 (General) Visas.

In June, these joint efforts by science and engineering sectors were acknowledged when the Home Secretary exempted NHS doctors and nurses from the Tier 2 visa cap. This allows the NHS to recruit the vital staff needed to provide care for patients and opens around 8,000 more places for other roles, including in the life science sector. Ensuring the sector has access to the top global talent through a flexible visa system is one of the BIA's four [Brexit priority areas](#).

### BIA highlights value of movement of people to MPs

In June, the BIA emphasised the importance of movement of people in the life science sector during the House of Commons Science and Technology evidence session on “[An immigration system that works for science and innovation](#)”. The BIA took the opportunity to highlight that non-UK employees are a vital part of the life science sector's global competitiveness, and that a flexible immigration system is vital for life science companies' ability to attract top global talent.

At the end of the inquiry, the committee intends to develop its own proposals for immigration and visa rules for scientists. This work follows the government's rejection of the committee's call for the conclusions of the Migration Advisory Committee (MAC) relating to science to be brought forward to form part of an “early deal” for science and innovation as the UK leaves the EU. The BIA [submitted evidence](#) to the MAC's review in October 2017.

Also in June, the BIA, together with the ABPI, [submitted written evidence](#) to the House of Commons Home Affairs Select Committee's inquiry into the [UK's post-Brexit immigration system](#). In our submission, we stressed the life science sector's reliance on access to global talent and the importance of a simple and flexible immigration system, particularly for SMEs. We also proposed that the post-Brexit immigration system could be used to deliver other objectives, such as increasing investment in UK science and technology sectors via an investor visa.

### New Future Leaders Fellowships complements BIA's PULSE

The government has announced a [new £1.3 billion fellowship scheme](#) to attract, train, and retain the world-class talent needed for the UK to remain at the forefront of global science and innovation. Early-career researcher applicants can be from the UK or abroad and must be hosted by UK academic institutions or businesses. Funding will cover the fellow's salary and research, staff, and training costs. The scheme complements the BIA's Programme for Up-and-coming Life Science Entrepreneurs (PULSE), which provides training to researchers and entrepreneurs at the Francis Crick Institute and pre-seed-stage companies. The scheme also answers the BIA's calls to government to ensure the UK remains open to global talent in response to Brexit.

## Intellectual property and technology transfer

### BIA welcomes UK ratification of the UPC Agreement

The UK government formally ratified the international agreement to form the Unified Patent Court in April. The BIA has been heavily involved in the development of the court, which will provide a lower cost way for bioscience companies to protect their innovations across most of Europe. It will also have its life sciences division based in London. The government also indicated its intention to seek to remain in the system after it leaves the EU in the [Brexit White Paper](#) published on 12 July.

BIA CEO Steve Bates [commented](#):

*“Being able to protect intellectual property is vital for life science companies and is often the key value in emerging bioscience companies. We welcome the announcement that the UK has ratified the UPC Agreement to create a single system for the registration, prosecution and enforcement of patents across much of Europe.”*

However, the agreement still requires ratification by Germany, which is currently being held up by a constitutional challenge.

### BIA raises concerns about SPC waiver proposal

On 28 May, the European Commission published a [Proposal](#) to introduce an exception to supplementary protection certificates (SPCs). This proposal allows for the manufacture of protected products within the EU for the sole purpose of exporting outside the EU to countries where IP protection does not exist or has expired.

The BIA has met with UK and EU officials to express our concern that the legislative change could undermine the attractiveness of the UK and EU as a place for life sciences investment, as well as damage the competitiveness of bioscience SMEs and reduce the development of new medicines for patients. We have also submitted [detailed comments](#) on the draft legislation to the UK Intellectual Property Office.

### BIA to work with IPO on new licensing toolkit

In May, the government [published its response](#) to its call for views on maximising the incentives of the IP system to stimulate collaborative innovation and licensing opportunities. The response reflects comments and calls [submitted](#) to the consultation by the BIA, and includes policies to increase financial support for businesses to protect their IP, and the development of a business-to-business licensing toolkit. The BIA has joined the toolkit working group to ensure it meets the sector's needs.

## Pre-clinical and clinical research

### BIA responds to proposed Labour Party policies for animal research

In May, the BIA and the ABPI responded to the Labour's draft [plan for animal welfare](#). In our submission, we highlighted that animal research helps scientists better understand diseases and has led to many advances in the treatment of debilitating and life-threatening diseases.

We also emphasised that UK has some of the highest regulatory standards for animal research globally, which promote high standards of welfare, and that Labour policy should continue to permit the use of animals in research within the current regulatory framework. BIA is a proud member the [Concordat on Openness on Animal Research](#) which promotes and maintains high levels of transparency on how animals are used in research across the bioscience sector.

### BIA responds to government consultation on animal exports via the Royal Society of Biology

In May, the BIA worked with the Royal Society of Biology to respond to a consultation by the Department for Environment, Food and Rural Affairs (DEFRA) on [live animal exports and improvements to animal welfare during transport](#) after the UK leaves the EU. In [the submission](#), we emphasised that undue restrictions on the movement of laboratory animals could disrupt ongoing and upcoming collaborative international projects, and thereby impact the UK biosciences sector, medical progress, and animal welfare.

The BIA is part of the [Animal Science Group](#), coordinated by the Royal Society of Biology. The Group represents the broad spectrum of UK organisations actively involved in supporting, formulating policy, or directly involved in animal research.

### BIA contributes to consensus paper on Platform Trial Designs

In June, the BIA provided input into a consensus paper on the efficient set-up and management of platform trials. The work is being led by the Experimental Cancer Medicines Centres (ECMC) Programme Office and key stakeholders involved include the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), and the Department for Health and Social Care.

The consensus paper, aimed to be published in October 2018, will provide cross-sector recommendations on the benefits of novel trial designs and an insight into the UK's capability for the conduct of such trials. Maintaining UK competitiveness in this area is a key priority of the Life Sciences Industrial Strategy.

### EU Clinical Trials Portal and Database

The development of the EU Clinical Trials Portal and Database, which is essential for the application of the EU Clinical Trials Regulation, will be affected by Brexit. The Regulation is now expected to come into effect in 2020.

The EMA has agreed that some further adjustments to the project planning may be required as its relocation plans are being finalised. The audit of the clinical trial system, due to start in early 2019, will need to accommodate the EMA's staff relocation to Amsterdam in early March 2019. Mitigation measures are being put in place, in particular in the event of loss of key EMA or developer staff. The clinical trial system continues to be prioritised in the [EMA's Brexit preparedness business continuity plan](#).

The BIA will continue to keep a watching brief on the development of the future clinical trial portal and database system.

## Manufacturing

### Medicines Manufacturing Innovation Centre launched in Scotland

Launched in June, the [Medicines Manufacturing Innovation Centre](#) (MMIC) will offer biopharmaceutical companies – from start-ups through to multinational organisations – a unique service to develop and adopt novel manufacturing techniques to adapt into their own manufacturing processes. The £56 million investment in Renfrewshire, Scotland, comes from a collaboration between Scottish Enterprise, the Industrial Strategy Challenge Fund, GSK, and AstraZeneca.

The centre will be led by the Centre for Process Innovation (CPI) in partnership with the University of Strathclyde's Centre for Continuous Manufacturing and Crystallisation (CMAC) and the Medicines Manufacturing Industry Partnership (MMIP) and aims to help the UK capture a bigger slice of the global £98 billion small molecule pharma market. By transforming processes and technologies, the speed of bringing new drugs to market could improve drastically.

BIA CEO Steve Bates said:

*“Improving productivity in drug development is vital to economic innovation for our sector. Enabling that to happen in the UK gives us competitive advantage and is a good example of joined up industrial strategy in action.”*

### BIA sponsors second annual MMIP Conference

In June, the Medicines Manufacturing Industry Partnership (MMIP) held its second annual conference. Leaders from across the industry and academia, including BIA CEO Steve Bates, came together for a focussed day of thought-provoking discussion at GSK's Stevenage site. The conference was delivered by the Knowledge Transfer Network (KTN) and sponsored by the BIA and the ABPI. The discussions focused on the future of medicines manufacturing in the UK, including powering our sector with enabling technologies and delivering the Life Sciences Sector Deal for MMIP.

### Innovate UK invests in Advanced Therapies Manufacturing Apprenticeships

Innovate UK has announced a £1.5m investment over the next three years to develop Advanced Therapies Manufacturing Apprenticeships at the [Cell and Gene Therapy Catapult](#). This was one of the six recommendations from the MMIP Advanced Therapies Manufacturing Taskforce Action Plan led by Ian McCubbin, with BIA working alongside Autolus' Jim Faulkner to drive the skills workstream.

Keith Thompson, CEO of the Cell and Gene Therapy Catapult, said:

*“Cell and gene therapies live at the leading edge of medical and scientific possibility, but medicines discovery and clinical development are only half the story. Key to widespread adoption in health services is the unique skills and capability set required to manufacture, supply and administer these important medicines to patients. We're therefore pleased to be announcing a £1.5 million allocation to develop apprenticeships in partnership with MMIP, and £1.5 million for capability development through the ATTCs.”*

## Medicines regulation

### EMA updated guidance to prepare for UK's withdrawal from EU

In June, the European Medicines Agency (EMA) and the European Commission published updated guidance for biopharmaceutical companies in preparation for Brexit, based on the assumption that the UK will become a third country as of 30 March 2019.

Updates to the [Q&A document](#) include information on:

- status of inspection outcomes by MHRA, the UK national competent authority
- batch release processes for medicines that are subject to Official Control Authority Batch Release (OCABR) and Official Batch Protocol Review (OBPR)
- back-up arrangements for Qualified Persons for Pharmacovigilance (QPPVs)
- marketing multi-country packs of medicines, where one of the countries in which the packs will be sold includes the UK

The EMA also issued an updated version of its [practical guidance](#) in conjunction with the updated Q&A document for procedures within the framework of the centralised procedure.

### BIA participates in EMA industry stakeholder platform on R&D support

In May, the BIA participated in the third EMA industry stakeholder platform on research and development support. This regular meeting between regulators and representatives of industry stakeholder organisations is an opportunity to address all areas of product-development support, including scientific advice and support for innovation.

Topics discussed included:

- implementation of the revised orphan medicine significant benefit notice
- 'histology-independent indications' in the context of orphan designations
- digital technology proposals in medicine development programmes
- integration of assessment for co-development of medicines and companion diagnostics
- updates on post-authorisation evidence generation activities, paediatric medicines and the PRIME scheme

The EMA also introduced the upcoming rollout of a new tool for orphan designation applications – a [secure online portal](#) launched in June. The [presentations](#) published on the EMA website provide further information.

### EMA PRIME 2-year review

The EMA published in May its [report](#) on the first two years of the [Priority Medicines scheme, PRIME](#). The EMA has received and assessed 177 requests for eligibility to the scheme since its launch in March 2016. The overview of the 36 medicines accepted for PRIME, representing 21% of all eligible applications, shows that 83% concern rare diseases and 44% are intended to treat paediatric patients.

Enhanced interaction with EU regulators through PRIME is particularly useful for developers of innovative/novel types of medicines that often present new scientific and regulatory challenges. Two years on, 22 of the medicines accepted for PRIME received scientific advice, many including input from health technology assessment bodies and patients. Moreover two chimeric antigen receptors (CAR) T-cells

medicines were the first medicines supported through PRIME to be [recommended for approval](#) by the Committee for Medicinal Products for Human Use (CHMP) at its June 2018 meeting.

In the light of experience gained over the last two years, the EMA has also published a new [guidance for applicants on interactions in the context of PRIME](#) which covers the preparation and conduct of kick-off meetings, and an updated version of its [guidance document on PRIME, questions and answers](#), and the [template for applicants' requests](#).

### **EU updates orphan similarity concept**

The European Commission published in May [Commission Regulation \(EU\) 2018/781 of 29 May 2018 amending Regulation \(EC\) No 847/2000](#) which provides an updated definition of “similar medicinal product” in the context of the EU Orphan Medicine Regulation. The definition needed updating to take account of new scientific and technical knowledge in the field of advanced therapy medicinal products (ATMPs) and in the light of experience gained with regard to the designation and regulation of orphan medicines.

The definition forms the cornerstone for determining whether a new medicinal product is similar to an already authorised orphan medicine and whether an application for a marketing authorisation can be accepted for evaluation and the medicine granted 10-year market exclusivity.

This amending Regulation, which was prepared in collaboration with the EMA, was issued for consultation in 2016. The BIA responded endorsing the comments submitted by the EFPIA-EuropaBio Orphan Medicinal Products Joint Task Force.

The Commission has also issued a [Q&A document](#) to provide practical guidance to developers of ATMPs regarding the application of the concept of similarity in an ATMP setting. This document will be updated to reflect new developments.



## Access to medicines

### **BIA continues to work for patient access to treatments for rare conditions**

The [BIA Rare Disease Industry Group \(RDIG\)](#) is a coalition of BIA member companies that specialise in treatments for rare and ultra-rare diseases. The Group is committed to developing recommendations that can pragmatically inform and improve the challenge of ensuring patient access to treatments for rare and ultra-rare conditions.

In May, the RDIG met with Peter Huskinson, National Commercial Director of Specialised Commissioning, and Gareth Arthur, Director of Strategy and Policy, both at NHS England and Sheela Upadhyaya, Associate Director of Highly Specialised Technologies at NICE to review the impact of changes to the assessment process for ultra-rare medicines, one year on from their implementation. Senior representatives of the RDIG also had dinner with Sir Andrew Dillon, Chief Executive of NICE, in May to share their reflections on how the changes are working. Both NHS England and NICE welcomed the Group's feedback and agreed to continue an open dialogue.

The RDIG will hold a workshop in the autumn with key stakeholders including patient associations, clinicians, and academics to increase awareness of the challenges around patient access to orphan and ultra-orphan medicines. To find out more contact BIA's Policy and Public Affairs Manager Rachael Stewart at [rstewart@bioindustry.org](mailto:rstewart@bioindustry.org).

### **BIA attends NICE Annual Conference**

The BIA attended the NICE Annual Conference in June. Speakers from across the life science sector provided updates on the implementation of [the Accelerated Access Review](#) and the [Life Sciences Industrial Strategy](#) as well as changes to NICE processes for assessing medicines and med-tech.

Prior to the NICE Conference, the BIA and several members attended a breakfast briefing for industry, hosted by NICE and the Department for International Trade. The discussion focused on NICE's strategic and business plans, including the creation of a Commercial Liaison Unit to support NICE's increasing involvement in commercial discussions between companies and NHS England.

### **Lord Ara Darzi appointed Chair of the Accelerated Access Collaborative**

In June, it was [announced](#) that Lord Ara Darzi will Chair the [Accelerated Access Collaborative](#) (AAC), replacing Sir Andrew Witty who stepped down in April to become Chief Executive at Optum. Lord Darzi is an NHS surgeon, Chair of the Institute of Global Health Innovation at Imperial College London, and a former Health Minister, making him well-placed to drive the work of the AAC and to ensure it delivers benefits for all parts of the UK life science ecosystem. In his recent [Review of the Future of Health and Care](#), Lord Darzi advocates for the implementation of the recommendations of the Accelerated Access Review in full, a position strongly supported by the BIA. The BIA has written to Lord Darzi asking for a bilateral meeting ahead of the next AAC meeting in the autumn.

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 Executive, 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 sciences 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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