Influencing and shaping our sector – BIA update January – April 2018

UK BioIndustry Association

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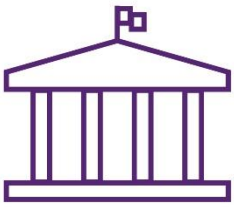
Introduction

Ongoing BioIndustry Association (BIA) 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 January to April 2018.

It has been an eventful start to 2018 at the BIA and for the sector in general. Brexit is continuing to keep us busy as we work with Ministers and their departments, MPs, stakeholders, and our European colleagues. In the Spring Statement, the Chancellor launched two key consultations for the bioscience sector. This quarter, the BIA launched our new Genomics Advisory Committee, the inaugural Chief Medical Officer Summit, and the China Special Interest Group. We have also responded to several consultations on behalf of our members and the sector. Read about this and much more below.

This quarter in numbers:

15+ influence meetings with 20+ MPs and Peers



6 consultation responses submitted

12 letters to Ministers

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Leaving the EU

UK and EU reach political agreement for transition period

In March, the European Council agreed the UK-EU draft Transition Agreement, which details how the transition period will work from March 2019 to December 2020. Having advocated for the importance of a transition period to protect public health and ensure the supply of medicines to patients, the BIA welcomed the development. Whilst the agreement is not yet finalised, and the Irish border is a major sticking point, it does provide some certainty and makes a cliff-edge Brexit less likely. The agreement is expected to be completed in the autumn and will become part of the legal text along with the Withdrawal Agreement (agreed last December) that must then pass through both the European and UK Parliaments before becoming a legal agreement.

The Transition Agreement includes some practical detail which we have been pushing government for, particularly around goods placed on the market during the transition period. BIA CEO Steve Bates discussed this in detail at our latest monthly Brexit webinar.

However, the agreement has not changed the European Medicines Agency (EMA)'s approach of stressing that, in absence of a legal agreement on transition and the UK's future relationship with the EMA, companies should prepare for the possibility that the UK will become a third country to the EU on 30 March 2019. In addition, following the agreement, the EMA announced that the UK's portfolio of centrally authorised products have been redistributed and that EU member states will take full responsibility for the re-allocated products as of 30 March 2019.

The BIA will continue to make the case for regulatory alignment and UK participation within the EMA after we leave the EU.

UK government and Labour positions on the EMA

In March, Prime Minister Theresa May MP delivered her Mansion House speech and stated that the government wants to explore with the EU how the UK could remain part of EU agencies, including the EMA. May stressed that associate membership of the EMA is the only way to meet the government's objective of ensuring that products only need to undergo one series of approvals to have access to the EU Single Market.

A few days after the Mansion House speech, Labour's Shadow Health Secretary, Jon Ashworth MP, also delivered a key Brexit speech. He emphasised the importance of cooperation and alignment on medicine regulation and stated that a Labour government would seek to be part of the EMA and adhere to the EU regulation framework. Ashworth also warned that slow progress on reaching a deal could mean delays in accessing potentially life-saving treatments, harm patients, and public health in both the UK and EU.

The BIA has advocated for regulatory cooperation and alignment for medicines since the outcome of the referendum and we welcomed these statements from both the government and the opposition.

Brexit Health Alliance Campaign - Patient Access to Medical Research

In February, the Brexit Health Alliance, which the BIA is a member of, launched its latest campaign briefing on patient access which focused on how patients across Europe have benefited from pan-European collaboration on medical research. The campaign calls on negotiators to consider how to mitigate the

public health risks of Brexit, including a positive future cooperation UK-EU model for research and continued UK participation in European Reference Networks for rare diseases.

Science and Technology Select Committee – Brexit: Science and Innovation Summit

In February, the BIA attended the House of Commons Science and Technology Select Committee's Brexit Science and Innovation Summit. Several areas relevant to the sector were discussed, including collaboration, Horizon 2020, and medicine regulation. The Committee's report of the Summit calls for an early deal for science (with a deal to be in place by October 2018 or earlier), participation in Horizon 2020's successor Framework Programme 9, and clarity for EU students from 2019.

Health Select Committee focuses on Brexit and medicines

In March, the House of Commons Health Select Committee published its report to their inquiry into 'Brexit: medicines, medical devices and substances of human origin'. BIA CEO Steve Bates gave oral evidence to the Committee in December and welcomed the report. The Committee Chair, Dr Sarah Wollaston MP, called on both the UK and the EU to "secure the closest possible regulatory alignment in the next round of the Brexit negotiations" and warned that failure to do so would "signal a triumph of ideology over the best interests of patients".

Following the political agreement on the transition period, Dr Wollaston followed up with a letter to the Health Secretary Jeremy Hunt MP. Dr Wollaston asked for clarification on the UK's future role within the EMA, including whether 'associate membership' of the agency is a realistic ambition and what steps the government has taken to ensure the UK is invited to future EMA meetings.

BIA highlights importance of frictionless trade arrangements as Trade and Customs Bills pass through Parliament

Alongside the Withdrawal Bill, the UK government has introduced the Trade Bill and Taxation (Cross-border Trade) (also known as the Customs) Bill to adjust UK legislation ahead of Brexit. In January, both bills were scrutinised by MPs. The BIA worked together with the ABPI to submit evidence to both Committees, where we highlighted the sector's reliance on the current frictionless trade and customs arrangements with the EU to supply medicines to patients. Our full responses to the Trade Bill and Customs Bill are available on our website.

BIA and its members discuss potential US Free Trade Agreement with government

In March, the BIA and member representatives attended a workshop alongside other industry stakeholders at the Department for International Trade (DIT) to discuss potential benefits of a UK – US Free Trade Agreement (FTA) for the life science sector.

The discussion focused on the industry's overall outlook on the US market, the movement of talent, regulatory concerns, intellectual property, and customs and trade facilitation. While many of these issues rely on the details of the UK's final relationship with the EU, it takes time to develop key UK asks in potential FTA negotiations which is the reason why the government is starting to engage the sector now. The BIA is working with our members and DIT on these areas through our Trade Policy Group, which we coordinate together with the ABPI.

Finance, tax and investment

Two key consultations launched at the Spring Statement

The Chancellor, Philip Hammond MP, delivered the Spring Statement on 13 March announcing that the economic outlook is better than previous estimates and launching two key consultations for the bioscience sector. The Treasury published a consultation on Entrepreneur's Relief following the BIA's long campaign highlighting the problems of the 5% shareholder cap in the regime and another on establishing a new Enterprise Investment Scheme knowledge-intensive fund. Both consultations stem from last year's Patient Capital Review, which the BIA was heavily involved in. The BIA met the Treasury team responsible for both on 13 April and will also be formally responding to the consultations; you can feed in your views to Martin Turner, Policy and Projects Manager, at mturner@bioindustry.org.

BIA launches new China Biotech Special Interest Group

In January, the BIA launched our new China Biotech Special Interest Group, set up in collaboration with the China-Britain Business Council (CBBC) and the Department for International Trade (DIT). The group will provide a platform for BIA and CBBC members to explore opportunities for biotech with regards to Chinese collaboration and investment, with the overall objective to increase the number of UK biotech companies collaborating with, generating revenue from, and receiving investment from the Chinese market.

We had an excellent turnout at the group's launch meeting, with people coming to hear BIA members talk about their different experiences in China. We heard from Congenica, Oxford Nanopore, Cell and Gene Therapy Catapult, Innovate UK, Kymab, and McKinsey & Company. Our second meeting, on 2 May, will provide practical advice on financing opportunities from China and some shared experiences.

BIA engages with the Labour Party business and finance policy teams

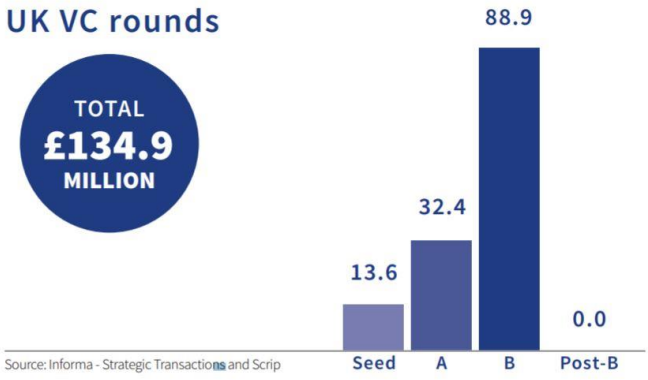
The BIA has been engaging with the Labour Party through several routes to ensure the bioscience sector's voice is heard as they develop their policies ready for the next General Election. Shadow Business Secretary Rebecca Long-Bailey MP has been touring the UK hosting regional roundtables on industrial strategy. The BIA arranged for members to attend these in Sheffield, Newcastle, and Reading to provide the sector's views. Thank you to MEDQP, Orla Protein Technologies, Glythera, and Oxford Nanopore for participating.

The BIA's Policy and Projects Manager also attended a roundtable in Birmingham with Shadow Chancellor John McDonnell MP and the BIA's Finance and Tax Advisory Committee (FTAC) met with Peter Rice, who is supporting McDonnell on developing Labour's finance policy.

Latest BIA finance data shows solid start in 2018

On 10 April, the BIA released our latest quarterly Biotech Financing Update, covering the period of December 2017 – February 2018, produced with our data partner Informa Pharma Intelligence. The report shows that venture capital financing and follow on financing on the public markets are off to a solid start in 2018. It also sees the continuation of many of the trends shown in the annual report 'Pipeline progressing: the UK's Global Bioscience cluster in 2017' that we released in January this year. Highlights include:

- Venture capital funding was dominated by strong B rounds that are already more than half of the 2017 total (largely made up of Orchard Therapeutics' £85m raise), and seed funding which is already nearly half of the 2017 annual total.
- Follow on financing was dominated by the GW Pharma follow on public offering on Nasdaq, which raised £221.6m.
- The public markets have had a quiet start to the year, much like 2017 where we just saw one biotech IPO in the first half of the year. The main market has been quiet overall with February seeing just £31m raised in IPOs and £233m in follow on financing across all sectors.
- Three UK biotech companies have used debt financing so far this year and the total accessed (£18.8m) represents around a quarter of the total from 2017.



Company Name	Deal Date	Round	£m
Orchard Therapeutics	20/12/2017	B	85
Vaccitech Ltd	15/01/2018	A	20
Juvenescence	08/01/2018	Seed	8.9
Biosceptre International Ltd	14/12/2017	A	8

Source: Informa - Strategic Transactions and Scrip

Follow on financing by market in £ million	
Main Market follow on	0
AIM follow on	43.88
Nasdaq follow on	221.6

Further resources added to the BIA website to support your communications strategy

In March and April, the BIA hosted a webinar and published a Q&A on communicating R&D progress to investors and the public. Both provide practical tips from experts on maximising impact and avoiding common mistakes. They can be found in the resources library for the BIA Best practice in communicating R&D progress guide, which was published in January.

BIA responds to London Mayor's economic strategy

In March, the BIA responded to a consultation on the Mayor of London's Economic Development Strategy.

In our submission, we highlighted the need to support NHS-industry partnerships and secure access to data for research, address the short supply of long-term patient capital, and promote the interests of the life sciences sector as the UK leaves the EU.

BIA launches Patent Box guide

The Finance and Tax Advisory Committee has published a new guide to the Patent Box regime, which provides a reduced corporation tax rate on profits from eligible patented products.

Strategic technologies and areas of scientific focus

BIA holds its fourth annual Committee Summit

In February, the BIA held its fourth annual Committee Summit at Simmons & Simmons' offices in central London. The Summit gathered our nine Advisory Committees, each focused on strategic technologies or specific policy areas, and the broader BIA membership. The event is a forum to explore issues facing different parts of the sector and an opportunity for the Committees to update each other and the wider community on their work. Many thanks for Simmons & Simmons for hosting the event.

BIA launches new Genomics Advisory Committee

At the Committee Summit, we launched our newest Advisory Committee, focused on genomics.

The Genomics Advisory Committee has been established to support the strategic objective that the UK starts, scales, and builds world leading genomic businesses. It will act as a leadership platform for sharing and discussing issues of common concern between genomic businesses and will provide expert advice on important issues such as the use of data and embedding genomic medicine in the NHS.

The committee chair, Dr Adrian Ibrahim of the Wellcome Sanger Institute said:

> *"I am honoured to be the first Chair of this exciting new BIA Advisory Committee. Developments such as the 100,000 Genomes Project and research carried out by the Sanger Institute at the Wellcome Genome Campus in Hinxton Cambridge provide a solid foundation on which UK SMEs can build and grow. The BIA Genomics Advisory Committee will provide strength to the voice of this community."*

The impact of the Nagoya Protocol on R&D discussed at the Committee Summit

As part of the Committee Summit, we held a briefing seminar on the Nagoya Protocol. Government representatives Simon Trevenna and Katie Beckett introduced the Protocol and explained the government's approach to overseeing the implementation of the Protocol. Nigel Budgen then highlighted AstraZeneca's compliance work, before Rocky Cranenburgh from Prokarium offered his SME-perspective.

The Nagoya expert panel offering their views of the Protocol and whether it will impact R&D in the sector.

The Protocol remains a relatively misunderstood piece of regulation affecting our sector and the seminar was very valuable in increasing awareness. The presentation slides are available here. Many thanks to Simon, Katie, Nigel, and Rocky for an interesting and useful session.

What does regenerative medicine mean for the future of surgery?

The BIA's Cell and Gene Therapy Advisory Committee (CGTAC) responded to the Royal College of Surgeon's Commission on the future of surgery, setting out some of the ways regenerative medicines techniques will transform healthcare and surgical procedures.

The Commission is looking 20 years into the future to explore the innovations that will most likely affect surgical treatment, evaluate their possible relevance and value, and their implications for patients, surgical training, and clinical outcomes. As part of this they asked for input, evidence, and contributions from experts, researchers, innovators, and future gazers from around the world.

CGTAC's response highlights the UK's strengths in regenerative medicine and suggests how surgeons can work with others in the regenerative medicine community to ensure these new techniques become embedded in routine healthcare. This includes changes to training to ensure surgeons have a greater understanding of manufacturing and supply chain issues for regenerative medicine products.

Skills, people and talent

BIA launches new Programme for Up-and-coming Life Science Entrepreneurs

A busy week at the start of March saw the launch of our new 3-day PULSE programme in collaboration with the Francis Crick Institute. We had 25 up-and-coming life science entrepreneurs participating; 10 researchers with early stage projects selected from the Crick and 15 entrepreneurs from different stages of pre-seed investment selected from BIA referrals. The workshop was held at the iconic Francis Crick Institute with the sessions run by experienced life science professionals and seasoned entrepreneurs, largely from BIA membership. We look forward to supporting this cohort further this year and planning for another PULSE workshop next year.

The PULSE cohort of up-and-coming life science entrepreneurs.

BIA calls on the Prime Minister to relax visa restrictions

On 8 March, the BIA joined 44 other organisations in writing to the Prime Minister calling for visa restrictions to be revised for skilled workers. The letter, organised by the Campaign for Science and Engineering, noted that the monthly cap for the Tier 2 (General) visa had been reached in each of the last three months, meaning hundreds of business-critical recruits were refused visas.

At the end of March, the government's independent Migration Advisory Committee published an interim report for its review of European Economic Area (EEA) workers in the UK labour market, which was commissioned by the Home Office to inform post-Brexit immigration policy. The report does not make any recommendations but notes that many EEA workers are in highly-skilled roles and that most sectors report a necessity to recruit non-British workers due to skills shortages. The BIA submitted evidence to the review in October 2017.

Intellectual property and technology transfer

BIA makes case for SPCs to UK IPO

With an ongoing review of the Supplementary Patent Certificate (SPC) system being conducted by the European Commission, the BIA has been engaging the UK's Intellectual Property Office (IPO) to reiterate the sector's view that SPCs are a critical incentive for pharmaceutical innovation in the EU.

Members of the BIA's Intellectual Property Advisory Committee met with IPO officials to share the findings of two economic reports (see here and here) that demonstrate the value of SPCs and the potential impact of introducing an SPC manufacturing waiver, which is being considered by the Commission.

BIA's Supreme Court intervention impacts case

From 12 to 15 February, the Supreme Court heard arguments from parties in Warner Lambert vs Actavis, a case in which the BIA formally intervened in January (see previous BIA Update). Tom Mitcheson QC, representing Warner-Lambert, highlighted the BIA's submission to the Supreme Court in support of his argument that plausibility should be kept in its 'proper place' to be used as a tool in the assessment of sufficiency and not as a pseudo stand-alone right. He also said that all the interveners appear to accept that there is a role for plausibility in the assessment of sufficiency. The outcome of the case is expected in the coming months.

Pre-clinical and clinical research

BIA holds inaugural Chief Medical Officer Summit

In March, we held the BIA Chief Medical Officer (CMO) Summit, a new annual event aimed at supporting the skills required to be a CMO in a biotech SME. The Summit was developed by our Science and Innovation Advisory Committee.

Current and aspiring CMOs and clinical scientists attended the Summit and enlivened the day by their active participation. The Summit was opened by Dr Louise Wood, Director of Science, Research and Evidence at National Institute for Health Research (NIHR), who reviewed the NIHR's role in supporting clinical research. The keynote speech was followed panel sessions, covering topics such as CMO skill requirements and regulatory considerations around clinical trials.

Dr Louise Wood of the NIHR gives the CMO Summit opening keynote address.

BIA welcomes UK-wide applicability of revised model Clinical Trial Agreement

The BIA has welcomed the revised model Clinical Trial Agreement (mCTA) and Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA) templates that biopharmaceutical companies and CROs can use without modifications for industry-sponsored trials in National Health Service/Health and Social Care hospitals throughout the UK. The model agreements can be found on the IRAS website.

The updated templates came into effect on 1 March and can be used for trials in England, Scotland, Wales, and Northern Ireland, replacing the 2011 nation specific versions. The accompanying Guidance Notes provide an overview of the changes from the 2011 versions and information on how and under which circumstances the templates should be used.

The mCTA revision should allow sponsors to rapidly sign off contracts so that clinical trials can get started more quickly, improving UK international competitiveness for research and development of new, innovative investigative medicines.

BIA team visits animal research facilities

In March, the BIA team visited the animal research facilities at King's College London to see how pre-clinical research looks in practice. Animal research is vital and legally required in the development of new medicines to ensure medicines are safe and efficient before human clinical trials start. The BIA supports transparency and openness about animals in research and is signatory of the Concordat on Openness on the Use of Animals in Research. The Concordat is an agreement supported by a range of organisations across the sector to commit to being open about the use of animals in research in the UK.

You can read a blog about our visit here. Understanding Animal Research recently wrote a guest blog about how public perception of animal research has changed over the past 15 years.

BIA contributes to Cancer Research UK study on the future of clinical trials

Cancer Research UK (CRUK) is conducting a study exploring how the clinical trials landscape might evolve in the context of Brexit. This will inform advocacy work as the UK and the EU move into phase two of the Brexit negotiations.

The BIA shared its views at a workshop early April bringing together stakeholders from the clinical research ecosystem including regulators. We explored scenarios for the future of UK and EU clinical trials over the next ten years, with the aim to identify what can be done today to ensure the best outcome under different conditions. CRUK outputs from the workshop and the wider project will be shared with BIA members.

BIA involved in ECMC initiative on complex trial designs

On 5 February, the BIA participated in a collaborative workshop, organised by Experimental Cancer Medicines Centres (ECMC), with the aim to develop guidelines for newer study designs to support the research community and sponsor organisations. The ECMC Network is made up of centres across the UK supporting early-stage clinical trials and translation of scientific discoveries into new cancer treatments for patients.

The Medicines and Healthcare products Regulatory Agency (MHRA), the Health Research Authority (HRA), CRUK, ECMC, and the Medical Research Council Clinical Trial Units contributed to this workshop in addition to BIA and ABPI representatives. There was consensus to use 'platform' trial design as the default terminology instead of 'adaptive', 'complex', or any other trial design definitions that are currently in use. It was agreed that the ECMC Programme Office will lead, in consultation and input from all interested stakeholders, the development of a consensus paper relating to platform trial designs which will provide recommendation for a guidance document. The BIA will continue its involvement in this area as part of the Platform Trial Designs Consensus Paper Working Group going forward.

BIA responds to NHS England consultation on clinical research

In February, the BIA responded to NHS England's consultation on supporting research in the NHS. The consultation presented proposals for further improving clinical research set-up and reporting.

In our response, we highlighted the UK's strong reputation for supporting innovative clinical development and the importance of making it seamless to set-up clinical studies, but that NHS contracting mechanisms are often too bureaucratic. NHS England is currently evaluating the consultations responses and we will keep our membership updated on the outcome.

Manufacturing

Securing the Advanced Therapies talent pipeline through apprenticeships

Early March saw the launch of National Apprenticeship Week (#NAW18), and the Advanced Therapies (AT) sector marked the occasion with an AT Manufacturing Apprenticeship event at GSK Stevenage, the finale to a piece of Gatsby funded work that came out of the Medicines Manufacturing Industry Partnership (MMIP) Advanced Therapies Manufacturing Taskforce. The Taskforce recommended the creation and implementation of an end-to-end talent plan for the sector as part of an Action Plan to set the conditions for productivity and commercial scale industrialisation to anchor AT manufacturing in the UK.

Prospective and current employers joined the apprentices, training providers, funders, and accrediting bodies at the event to explore the benefits of apprenticeships within AT Manufacturing, where information was provided through presentations and an interactive networking area. The highlight of the day was undoubtedly when the inspirational apprentices shared their experiences and reasons for going down this more practical route of learning, both through individual case studies and a Q&A panel.

Two existing apprenticeship standards are being adapted to include practical and theoretical modules on AT manufacturing, Science Manufacturing Technician (Level 3), and Technician Scientist (Level 5). Recruitment for these apprentices is underway, with the Level 5 standard scheduled to begin in September.

If you would like to learn more, or to join the AT Apprentice LinkedIn group to build the community and receive updates and relevant news, please contact Netty England at aengland@bioindustry.org.

> *"I full-heartedly believe apprenticeships are capable of being a key education pathway of the future; it's a scheme that is hugely beneficial to both the apprentice and employer. I have flourished professionally, academically and personally throughout my apprenticeship, all whilst contributing to the completion of genuine company goals against rigid deadlines and forging networks with some remarkable people."*
>
> **Amy Mercer, Life Sciences Apprentice, Pfizer**

Medicines regulation

BIA continues engagement with EU and UK regulators on Brexit

On 20 February, the BIA contributed to the Medicines and Healthcare products Regulatory Agency (MHRA) Cross-Trade Brexit Deep Dive meeting on medicines regulation held in preparation for March's Life Science Steering Group meeting. The meeting explored preparations for various scenarios with or without a transition period and built upon the series of BIA informal meetings which had been held in collaboration with the ABPI looking at specific topics (licensing, clinical trials, GMP).

The BIA, together with EuropaBio (the European association for bioindustries) and other European trade associations, continue to engage with the European Medicines Agency (EMA) and the Heads of Medicines Agencies' Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) on operational issues around the centralised and decentralised procedures.

On 23 March, the BIA's Head of Regulatory Affairs participated in the EMA Industry Stakeholder meeting, which focused on Brexit preparedness activities to ensure business continuity. The EMA informed the trade associations in attendance on the methodology agreed for re-distribution of UK portfolio for the evaluation of medicines in the centralised procedure. This is based on EU Member States' expertise with certain medicine classes and aims to build on existing knowledge. Further details were published on the EMA website after the meeting.

The BIA has long advocated on the need for EU-UK regulatory cooperation on medicines to ensure minimal disruption to patient access. The UK government's preferred outcome is also to have a close working relationship with the European regulatory network and the EMA.

MHRA launches GXP data integrity guidance

On 9 March, the MHRA published a new guidance document clarifying their position on data integrity and the minimum expectation to achieve compliance. 'GXP' refers to the various good practices regulated by the MHRA – Good Clinical Practice, Good Distribution Practice, Good Laboratory Practice, Good Manufacturing Practice, and Good Pharmacovigilance Practice.

The GXP data integrity guidance has a high degree of alignment with documents issued by other regulators and international bodies, such as the EMA, the Pharmaceutical Inspection and Cooperation Scheme (PIC/S), the World Health Organization (WHO), and the Organisation for Economic Co-operation and Development (OECD). This should be the standard on data integrity that biopharmaceutical companies aim for globally.

Access to medicines

BIA's Rare Disease Industry Group in Parliament

Following changes to the way medicines for very rare conditions are assessed by NICE and NHS England last year, the BIA's Rare Disease Industry Group (RDIG) is continuing to engage with the broader rare disease community to highlight the challenges patients face in accessing innovative, potentially life-saving medicines.

On 6 February, the group held a roundtable in Parliament to discuss these issues with MPs and Members of the House of Lords, many of whom showed a keen interest and offered to support the group's ongoing activities. The National Institute of Health and Care Excellence (NICE) were also represented and agreed to meet with the RDIG to discuss our concerns in more detail.

The roundtable is part of the RDIG's programme of work for 2018. If you would like to find out more about the group please contact BIA's Policy and Public Affairs Manager, Rachael Mann at rmann@bioindustry.org.

The One Voice Choir singing in Westminster Tube Station.

The BIA RDIG also took part in the One Voice Choir for Rare Disease Day on 28 February. The Choir, which was organised by Sanofi and its speciality care unit global business, Sanofi Genzyme, brought together parliamentarians, patients, charities, and industry representatives to sing in Westminster tube station to raise awareness of the challenges people with rare conditions face.

How far has the Government delivered on the ambitions of the Accelerated Access Review? BIA roundtable with Lord Prior

On 6 March, the BIA held a roundtable with Lord Prior to discuss the extent to which the government has delivered on the original ambitions of the Accelerated Access Review (AAR). Attendees included representatives from the Academic Health Science Networks, MHRA, charities, industry, and government.

The discussion focused on the impact of changes to the external environment since the AAR was commissioned in 2014. While Brexit and the publication of the Life Sciences Industrial Strategy have placed

greater importance on the successful implementation of the AAR, additional challenges now exist including increasing financial pressures in the NHS and regulatory changes as the UK leaves the EU.

To support the discussion the BIA produced an infographic showing the results of polling we commissioned last year to assess the extent to which NHS staff are aware of government initiatives aimed at improving the uptake and adoption of innovation. The data shows that only 11 % of NHS staff are aware of the AAR.

BIA participates in NICE workshop on regulatory information sharing

On 15 March, the BIA participated in a NICE workshop to discuss how NICE should receive regulatory data about products in the regulatory processes to help expedite technology appraisal reviews and reduce the time between the granting of a marketing authorisation and patient access to clinically and cost-effective medicines. This workshop was held following on from earlier discussions with MHRA and NICE in 2017 as part of the implementation of the Accelerated Access Review recommendations.

There was positive engagement from NICE officials. The workshop outcome for a less formalised process that integrates into the new appraisals process was a good step forward, which was welcomed by member companies in attendance. NICE were also supportive of companies retaining control over the data sharing and indicated they were not requesting clinical study reports. There was understanding for the need to protect commercially confidential information in the context of global drug development programmes.

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.

Not a BIA member? If you want to have a say on policy areas key to the sector, contact Michael McGivern, Membership and Business Development Manager on 0207 630 2194 or mmcgivern@bioindustry.org

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BIA Supporters