UK BioIndustry Association

Influencing and shaping our sector

BIA update: April – July 2017

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 April to July 2017.

The BIA's work to address the challenges of Brexit, seize the opportunities of the government's industrial strategy, and raise the profile of UK bioscience internationally has continued apace in the second quarter of 2017.

We have engaged the new government and Parliament at our 17th annual Parliament Day and made significant progress on securing a European partnership for medicines regulation post-Brexit. And we have been extremely active across the policy areas that the BIA covers on behalf of members.

Read on for more details:

General Election

Responding to the General Election

Source: Wikipedia

The snap General Election on Thursday June 8 resulted in the Conservative Party losing their majority, leaving a hung Parliament. The Conservatives are still the UK's largest party, but fell eight seats short of winning the required 326 seats for an overall majority.

Responding to the result, BIA CEO Steve Bates said:

> *"The election has not delivered a Parliamentary majority for a clear way forward on Brexit but both the main parties, as well as the DUP, were clear in the campaign and in their manifestos on the desire to turn the UK into the most innovative country in the world. Our sector is key to taking the UK's outstanding science base and translating it into economic jobs and growth. Measures to support this goal should attract broad support in the new Parliament."*

You can read the full press release here. The BIA also published a blog on the outcome and its implications for the life sciences.

In the run-up to polling day, the BIA published a series of blogs on retiring MPs, prospective MPs friendly to our sector, and party manifesto analysis. All the main parties supported the life sciences sector in their manifestos – a testament that the campaigning of the BIA, our members and partners are keeping science high on the political agenda.

The new government

Prime Minister Theresa May formed a minority government with support from the Democratic Unionist Party (DUP) and its 10 MPs. The formal deal between the Conservatives and the DUP was announced Monday July 26. It specifies that the DUP will support the government on all motions of confidence, such as the Queen's Speech and the Budget. Support on other matters will be agreed on a case-by-case basis. In return, the government will allocate an extra £1 billion over the next couple of years to Northern Ireland.

Before the General Election and in anticipation of a Conservative landslide victory, there was much speculation that May planned a large ministerial reshuffle. However, such a reshuffle could have posed too much of a political risk after the Conservatives lost their majority. As a result, most senior ministers have been re-appointed, while junior ministers have been subject to some reshuffling and a few ministers that lost their constituency seat have been replaced. The BIA has produced a Guide to the Government for BIA members, available here.

The Queen's Speech

The government presented its legislative agenda for the upcoming two-year parliamentary session in the Queen's Speech on June 21. Despite the session being extended to two years to allow time for legislation required for Brexit, the speech was short and lacked detailed policy proposals.

As the UK leaves the EU, the government will introduce a series Brexit bills. The first one, the Repeal Bill, will revoke the European Communities Act and transpose EU laws into UK law. Seven other Brexit bills will follow, including bills on customs legislation, trade policy, and immigration. The BIA is already preparing policy positions on these areas in anticipation.

Non-Brexit bills relating to the life sciences include a data protection bill and a draft patient safety bill. The Industrial Strategy will continue to be a part of the government's plan to boost the economy and we expect the work around the life sciences, led by Sir John Bell, to be published later this year.

Read our blog on the Queen's Speech here.

The BIA's 17th Annual Parliament Day

Lunch on the House of Lords Terrace as part of BIA's annual Parliament Day

On Thursday 6th July, 40 senior representatives from the UK's life science industry convened in Westminster for the BIA's seventeenth annual Parliament Day – a key day of engagement between BIA members and policymakers in Westminster and Whitehall.

Taking place less than a month after the snap general election and just two weeks after Brexit negotiations began, Parliament Day 2017 was an excellent opportunity for our members to engage with key figures from the new government and parliament and to make them aware of the sector's priorities for Brexit and the upcoming Industrial Strategy and Life Sciences sector deal.

The delegation met with 36 policymakers in 22 meetings, strengthening the BIA's relationship with key political contacts. The BIA will now follow-up with these contacts to make sure they are aware of the value of UK life sciences and are actively supporting the sector.

For more information about the day and who we met please visit the BIA blog.

Leaving the EU

Securing a European partnership for medicines regulation post-Brexit

Greg Clark MP and Jeremy Hunt MP

Since the EU referendum last year, the BIA has consistently called for close co-operation with the EU on medicines regulation post-Brexit. On 4 July, the Secretary of State for Health, Jeremy Hunt MP, and the Secretary of State for Business, Greg Clark MP, stated that the UK government would pursue this approach in an open letter to the Financial Times. The text was also made available on the BIA website. The life sciences sector is the first sector to get such a public commitment from the new government on a key area.

The UK government publicly communicating its full commitment 'to continuing the close working relationship we enjoy with our European partners' is good news for patients, industry and investors in the UK and EU. It's the first step to a sensible approach to Brexit for our sector and recognises the negative impact in areas like falsified medicine, pharmacovigilance and infectious disease control that a cliff edge Brexit would cause on both sides of the channel.

On 14 July, Lord O'Shaughnessy, Under Secretary of State for Health, gave a keynote address on the future of medicines regulation at the annual joint BIA and Medicines and Healthcare products Regulatory Agency (MHRA) conference *Innovation in life sciences in a changing and dynamic environment*.

The welcome developments follow a notice jointly published by the European Commission and the European Medicines Agency (EMA) in May advising marketing authorisation holders to consider the legal implications and prepare for the UK's withdrawal from the EU. A Q&A document was also published. This was solely on the basis of a 'hard Brexit' outcome – the assumption that the UK will be outside of the European medicines regulatory system as of 30 March 2019.

The BIA, together with the ABPI, highlighted to a number of audiences, that it was premature to request companies to prepare only for one outcome when negotiations are just starting and their outcome is unknown. The EMA has since accepted that they only recognised one scenario and has softened its stance in the statement issued following the June meeting of the EMA Management Board. The EMA confirmed that the UK fully participates in the activities of EMA and all formal meetings and continues to retain its speaking and voting rights. The criteria and process for deciding on the EMA's new location were published, and a decision from the European Council by common agreement is expected in November 2017. The BIA will continue its engagement with the EMA.

In late June, the BIA participated in the first coordinating meeting of the European industry associations to align our positions on medicines regulation. Speaking with one voice with EU and UK policymakers will enable us to find the best possible outcome to the challenges and practicalities triggered by Brexit.

On 13 July, the BIA together with seven other UK and European pharmaceutical and life science industry associations (AESGP, EFPIA, EuropaBio, Medicines for Europe, ABPI, BGMA and PAGB) jointly sent a letter to Mr. Michel BARNIER, Chief Negotiator Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU, and Rt. Hon David DAVIS MP, Secretary of State Department for Exiting the European Union. The letter underlines the importance of securing ongoing cooperation between the UK and EU on medicines as part of the negotiations to agree a new relationship between the UK and the EU.

Promoting UK bioscience abroad

The BIA led a delegation of member companies to the BIO 2017 Convention in San Diego in June and hosted a number of events to promote UK bioscience.

Over 150 guests attended the reception *Celebrating the Future of UK Biotech,* co-hosted with MedCity and LifeArc.

The BIA also hosted a panel discussion on Brexit, chaired by BIA CEO Steve Bates. The panel, which was able to reassure our global colleagues that the UK remains an attractive and vibrant environment for bioscience companies, included Nicole Mather from the Office for Life Sciences, Ronald Jager from Europabio, and BIA members David Tapolczay from LifeArc and Kym Denny from hVIVO.

Steve also spoke at the UK Global Innovation Hub session, championing the UK's attractiveness as a global life sciences cluster. You can read more in the BIA's press release.

Finance, Tax and Investment

BIA report shows the UK is leading Europe

On 22 May, the BIA published its annual finance report, revealing that the UK remains the European leader in venture capital and public market biotech fundraising, and has the most products in clinical development. *Building something great: UK's Global Bioscience Cluster 2016* gained positive coverage in national and trade media.

Despite a challenging year of financial uncertainty, with Brexit and the US election leading to markets cooling across the globe in 2016, a total of £1.13 billion was raised by UK-based biotech companies from private and public sources in 2016: £681 million in venture capital funding, £105m in IPO activity and £344 million from all other public financing.

The report was launched at the BIA's CEO and Investor Forum in Oxford, which brought together more than 100 biotech CEOs with key figures from the investor community.

This is the first year that the BIA has worked with Informa to produce the report and has formed an agreement to update the headline statistics on a quarterly basis to keep all members up to date on the financing landscape for UK biotech businesses.

BIA discusses support for bioscience with the FCA

The BIA met with the Director of Policy at the Financial Conduct Authority (FCA) in April and also formally responded to the FCA's review of the effectiveness of primary markets. The BIA highlighted the challenges that the biotech sector faces when raising capital and warned that new EU financial regulation could damage the sector by reducing the availability of independent analysis of biotech companies available to investors.

The Markets in Financial Instruments Directive (MiFID II), which will become law in January 2018, could create disincentives for investors in the life sciences by forcing them to pay extra for investment advice from expert sector analysts. The BIA is concerned this will have a negative impact on the already low amount of scale-up capital available for bioscience companies in the UK. The FCA is expected to publish a policy paper in response to the consultation in the autumn.

Strategic technologies and areas of scientific focus

BIA CEO Steve Bates brings synthetic biology to the Palace

Steve at Buckingham Palace

On June 16, BIA CEO Steve Bates visited Buckingham Palace to be awarded an OBE for services to innovation.

Steve lived up to his award by wearing a tie made from synthetic spider silk – the first tie of its kind and the first time such a tie has been worn among British royalty. Read Steve's blog about the tie here.

House of Commons Science and Technology reports on Regenerative Medicine and Genomics and Genome-editing published

Prior to the snap general election, the House of Commons Science and Technology Committee published reports on regenerative medicine and genomics and genome-editing as part of a process known as parliamentary wash-up – the wrapping-up of unfinished parliamentary business before Parliament dissolves. The BIA submitted written evidence to both inquires, and members of BIA's Cell and Gene Therapy Advisory Committee gave oral evidence to MPs as part of the inquiry on regenerative medicine.

The Committee's report on regenerative medicine focused on two key areas: research and commercialisation, and the adoption of regenerative medicine in the NHS. It called on the government to align its approach on regenerative medicine to the results of the Accelerated Access Review and to the Industrial Strategy.

The genomics and genome-editing report summarised the Committee's progress on this inquiry, which was still in the process of collecting oral evidence when the snap general election was called, in case the new Committee wish to continue the former Committee's work on the issue.

The Chairmanship of the new Committee has been allocated to the Liberal Democrats for this parliamentary session. It was previously held by Stephen Metcalfe, Conservative MP for South Basildon and East Thurrock. Liberal Democrat Deputy Leader, Jo Swinson, and Spokesperson for Health,

Norman Lamb have both put themselves forward for the role and the successful candidate will be announced before Summer Recess. The BIA will be seeking a meeting with the new Chair to encourage them to continue the previous Committee's inquiry on Genomics and Genome-editing and to maintain a focus on strategic technologies important to UK biotech.

New Industry Alliance on Antimicrobial resistance

The new Antimicrobial Resistance Industry Alliance was launched on May 18. The Alliance is hosted by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and brings together biotech, genetics, diagnostic, and research-based pharma companies to drive and measure industry progress to curb antimicrobial resistance. The BIA is part of the Alliance via the International Council of Biotech Associations (ICBA).

In the press release announcing the Alliance, BIA CEO Steve Bates emphasised that small and medium-sized enterprises (SMEs) stand ready to be powerful innovators to develop new and pioneering medicines adding to our arsenal of antimicrobial drugs.

Skills, people and talent

Informing the future immigration system

Source: Google

Throughout the second quarter of 2017, BIA has been facilitating discussions between members and the migration and labour team at the Department for Business, Energy and Industrial Strategy. The team is undertaking research into the science sector's needs for international talent and experiences with the current immigration regime.

There will be a new immigration system when the UK leaves the EU and it is anticipated that the Home Office will publish a public consultation in the near future. The BIA will consult with members and respond to the consultation.

Gatsby funding for advanced therapies manufacturing apprentices

The Medicines Manufacturing Partnership (MMIP) Advanced Therapies Manufacturing Taskforce has secured a £60,000 grant from The Gatsby Charitable Foundation to continue with essential work of assisting advanced therapy manufacturing companies to hire apprentices. The grant money will be used to kick start apprenticeship activities and it is also anticipated that it will leverage funding from BEIS and Innovate UK later this year. Many organisations are not used to taking on apprentices and the Taskforce aims to provide the support required to embed apprenticeship thinking in the sector. Increasing the number of apprenticeships in the sector, as it moves into a manufacturing phase, should reduce staff turnover and contribute to anchoring investment in the UK.

Ian McCubbin, chair of the Advanced Therapy Manufacturing Taskforce said: "This is fantastic news and means that we keep momentum going on this really important project for the sector. Building the apprenticeship workforce in UK medicines manufacturing will help to ensure that it continues to grow and succeed in the future."

Intellectual Property and Technology Transfer

European Patent Office provides clarity on patenting GM animals following BIA engagement

The European Patent Office has announced that it will amend the Implementing Regulations of the European Patent Convention to exclude from patentability plants and animals produced exclusively by essentially biological processes. The BIA engaged the UK Intellectual Property Office and European partners to object to the amendment on the grounds that it could disincentivise investment in the R&D of genetically modified animals, valuable for drug development and other uses.

Following this, the published amendment contained explanatory notes that addressed the concerns raised by the BIA. These explicitly stated that descendants of a genetically modified animal are still patentable, even where the given mutation could also have occurred naturally, and that embryos are patentable. The BIA regrets that the amendment was accepted but welcomes these clarifying notes and is working to ensure they are incorporated into the official patent examination guidance.

BIA publishes a members' guide to the Unitary Patent and Unified Patent Court

The BIA's Intellectual Property Advisory Committee (IPAC) has published a guide to a new form of patent covering most European countries and a new patent court system that is expected to come into force in early 2018. The new system – which will run alongside the UK's existing patent regime – is likely to have a significant effect in the biotechnology sector. It is important for companies to talk to their advisers about these changes now and start reviewing their existing patent portfolios and consider their strategy for future portfolios and enforcement.

The final legislation required for the UK's ratification was laid before Parliament in late June 2017 and is expected to be approved by MPs and peers in the autumn. However, Germany has halted its process while constitutional questions are addressed. The exact date of implementation of the new system is therefore uncertain but assumed to be in early 2018. IPAC will continue to monitor and engage with the process.

BIA members Slaughter and May LLP led on the production of the guide on behalf of IPAC.

BIA urges CJEU to provide clarity on SPCs

Working with the UK Intellectual Property Office, the BIA has urged the Court of Justice of the European Union to provide clarity on the criteria for deciding whether "the product is protected by a basic patent in force" when issuing a Supplementary Patent Certificate (SPC).

Led by the Intellectual Property Advisory Committee (IPAC), the BIA argued that the wording of Article 3(a) of the SPC Regulation is being applied inconsistently across the EU. This leads to disparate protection across the European Community and uncertainty both for SPC applicants and third parties and increased costs for applicants. The CJEU has not yet responded to the request.

BIA responds to European Commission survey on SPCs

The BIA has responded to a European Commission survey on the effectiveness and functionality of Supplementary Patent Certificate (SPC) law. In line with the wider biopharma sector, the BIA urged the Commission not to reopen the SPC Regulation and said that in most areas the law is functioning as it should. However, the BIA did highlight where further clarity is required.

The Commission is currently conducting a wide-ranging review of the SPC regime, including a legal study and an economic study. The BIA will also be responding to a survey as part of the economic study, which is expected in the coming months, and is contributing to wider efforts at an EU level being coordinated by Europabio.

Pre-clinical and clinical research

The Patient is Waiting workshop

On 27 April, the BIA's Science & Innovation Advisory Committee (SIAC) and the Faculty of Pharmaceutical Medicine (FPM) brought together representatives from Biotech, Pharma, the MHRA, Academia and Medical Charities, to discuss strategic options for expediting clinical research.

The workshop attendees from across the biotech and healthcare community agreed that the UK remains an extremely attractive region in which to conduct the clinical development of new treatment modalities; both early and late phase. They highlighted the excellent science base supporting pre-clinical to clinical translational science and the many opportunities for patient recruitment via specialized networks.

The following features that could enhance modern trial approaches, which are being increasingly adopted by the pharma industry, were highlighted and discussed:

1. Support for translational medicine collaborations and stratified medicine approach
2. Enhancing disease understanding and improving trial efficiency by design
3. Facilitating access to clinical trials across the nation
4. Reducing points of delay in trial start up processes
5. Increasing, and earlier, interaction with the MHRA Clinical Trials Unit and Innovation Office

A full meeting report is available on the BIA website.

Manufacturing

Championing the UK as a location for medicines manufacture

Source: British Council

The Medicines Manufacturing Industry Partnership (MMIP) – a collaboration between the BIA, ABPI and government – has produced a set of materials setting out the case for the UK as the location of choice for medicines manufacture. They are intended for use by the UK life sciences community to help communicate the tax and financial benefits of research and manufacture in the UK to potential investors and global companies.

Richard Turner, who has led on the work on behalf of the BIA's Finance and Tax Advisory Committee, has blogged about the project. The Fiscal Paper and a more concise summary in the Fiscal Guide are available on the BIA website.

Medicines Regulation

One-year experience with the EMA's PRIME scheme

Source: The EMA

On 19 May the BIA participated in the European Medicines Agency stakeholders meeting to review the experience gained with the PRIME (PRIority MEdicines) scheme. Launched in March 2016, the scheme provides early and enhanced support to medicines that have the potential to address patients' unmet needs.

The meeting brought together medicine developers who have applied to PRIME as well as patients, healthcare professionals, academics, industry representatives and health technology assessment (HTA) bodies. Representatives of EMA's scientific committees, which have a key role in the operation of the scheme, presented their perspective.

EMA informed attendees that 20 of the 96 eligibility requests assessed had been granted, while 71 requests had been denied and 5 applications were out of scope – 27 are now granted out of 118 requests as of June 2017, resulting in a 22% success rate. The requests covered a wide range of therapeutic areas and product type. More than 50% of applications were from SMEs.

The Agency said about 70% of the denials were due to insufficient data, and about 40% of the treatments' therapeutic advantages were not sufficiently justified. In some 20% of cases, development of the rejected therapies was too advanced to qualify.

Implementation of the EU Clinical Trial Regulation delayed

On 15 June, the EMA Management Board discussed the progress made regarding the development of the EU clinical trial portal and database following the endorsement of a delivery timeframe in December 2015. It was agreed that the go-live date for the EU Clinical Trial Regulation and accompanying portal and database had to be postponed again because of technical difficulties experienced with the IT system development. The EMA Management Board will discuss a new delivery time frame in October 2017 when progress with development has been confirmed.

The EMA's priority is to ensure that a high quality and functional system is delivered to the EU regulatory network and its stakeholders. The portal is intended to serve as a single-entry point to submit clinical trial authorisation applications, and support coordinated assessment and oversight by EU Member States. Information on the full lifecycle of clinical trials conducted in the EU will be stored in the database.

Due to these delays, the EU Clinical Trial Regulation will now come into application in 2019 instead of October 2018, as previously scheduled.

More details are available on the EMA Clinical Trial Regulation website.

Update on the implementation of EMA policy on publication of clinical data

On 27 June, the BIA participated in a webinar held by the EMA to update industry associations on the implementation of its policy on the publication of clinical data (Policy 0070) for human medicines. The presentation will be made available on the EMA's website.

The EMA informed industry that there are more than 230 procedures falling under the scope of this policy as of June 2017, of which 27 procedures have been published since October 2016, with more than 1,000 documents published.

The webinar also discussed future updates to guidance and procedural changes. In particular:

- For duplicate products, the EMA will request a stand-alone submission of document packages for the purpose of publication - duplicate products may not be exactly identical (different salts, different excipient or different manufacturing sites), and each medicinal product has its own regulatory lifecycle.
- For documents requested under Regulation (EC) No 1049/2001, the Agency will provide clarity to avoid two procedures running in parallel.

The EMA has launched a survey to collect the views of the users and gather feedback on the usability of the new clinical data publication website. It closes on 31 August.

New guide on biosimilar medicines for healthcare professionals

The BIA welcomes the publication of an information guide for healthcare professionals on biosimilar medicines. The guide was developed by the EMA and the European Commission in collaboration with EU scientific experts, in response to requests from healthcare professionals.

The guide was launched on 5 May at the European Commission's third stakeholder workshop on biosimilar medicines, a discussion forum for stakeholders interested in biosimilars, including healthcare professionals, patients, authorities and biopharmaceutical companies.

Access to Medicines

Now More Than Ever: Seizing the opportunity to make the UK a world leader in the life sciences

Following the announcement of the snap general election, the BIA published a report, calling on the political parties to provide concrete proposals for how government can support UK life sciences in their manifestos. This included a request for all the parties to commit to implementing the recommendations of the Accelerated Access Review (AAR).

Now More Than Ever: Seizing the opportunity to make the UK a world leader in the life sciences argues that without lasting political commitment, the momentum of the UK's life sciences industry will be lost. The report finds that despite the efforts of successive governments to support the UK life science sector and encourage uptake of innovation, policies have not been fully implemented or led to lasting change.

The Conservative Party manifesto did include a commitment to implement the AAR, but the government are yet to publish their response to the review. We now expect their response to be published in the Autumn, following which the BIA will host a parliamentary roundtable to share the findings of our report and discuss to what extent the government's response addresses our concerns.

BIA participates in accelerating access to medical innovation workshop

On 13 June, the BIA participated in a workshop on accelerating access to medical innovation, jointly organised by the Academy of Medical Sciences and the Centre for the Advancement of Sustainable Medical Innovation (CASMI).

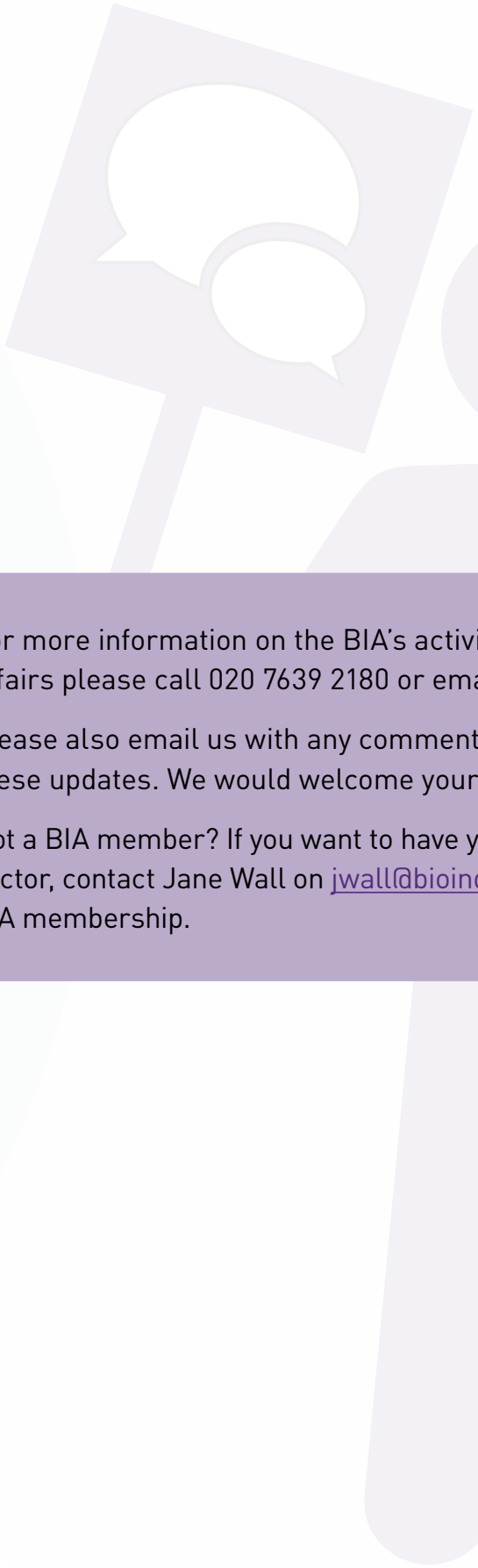
The workshop brought together senior representatives from across the life sciences ecosystem including academia, NHS, funders, industry and regulators to discuss novel approaches that can be pursued as part of a research agenda to overcome barriers to adoption of innovation in the NHS.

Discussions also focused on the value proposition for medical innovation from different stakeholders' perspectives, noting in particular the view from clinical scientists to have 'quality of innovation'.

BIA members come together to inform how patient access to medicines for rare and very rare diseases can be improved

A group of BIA members that specialise in treatments for rare and very rare diseases have come together to form the BIA Rare Disease Industry Group (RDIG) - The work will be moving forward from July.

The RDIG will be working with patient associations, as well as government and Parliament, to develop thinking that can pragmatically inform and support the challenge of ensuring patient access to treatments for rare and very rare conditions.



For more information on the BIA's activities in policy and regulatory affairs please call 020 7639 2180 or email policy@bioindustry.org

Please also email us with any comments on the content and usefulness of these updates. We would welcome your feedback.

Not a BIA member? If you want to have your say on policy areas key to the sector, contact Jane Wall on jwall@bioindustry.org now to find out about BIA membership.

We are at the forefront of UK bioscience, connecting individuals and organisations, helping to shape the future of the UK sector

BIA Supporters

Arthur J. Gallagher
BUSINESS WITHOUT BARRIERS™

horizon

VWR
We Enable Science

Engage with the BIA

www.bioindustry.org

blog.bioindustry.org

bia.me/BIA_LinkedIn

twitter.com/BIA_UK

www.youtube.com/bioindustry