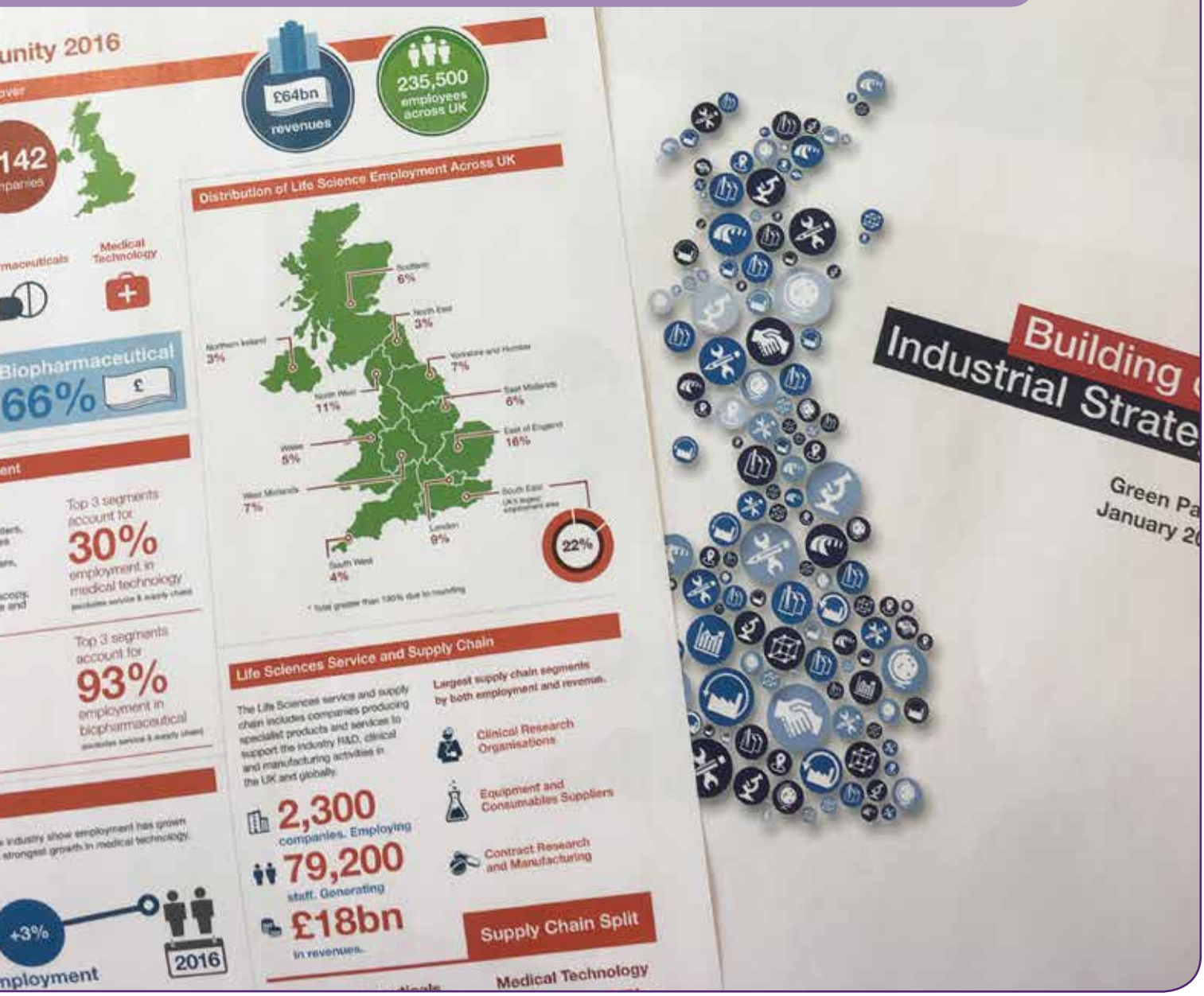
UK BioIndustry Association

Influencing and shaping our sector

BIA update: January – April 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 January to April 2017.

It has been a busy start to 2017 for the BIA. Since our annual Gala Dinner in January, attended by over 700 representatives from the sector, we have been focusing our energies on informing the Industrial Strategy and continuing to engage with the Government on Brexit. This edition provides updates on the triggering of Article 50 and the Great Repeal Bill, our response to the Industrial Strategy green paper and a summary of the key announcements for the sector from the Chancellor's Spring Budget. With the recent announcement of a snap General Election in June we will now be focusing on sharing our key messages with the political parties during the campaigning period and the new Government, once it is formed.

Read on for more details:

Leaving the EU

Snap General Election

A snap General Election will take place on Thursday 8 June. For UK life science companies this creates further political uncertainty as policy proposals like the Government's Industrial Strategy and the Life Science sector's response to it, as well as announcements about the UK's approach to Brexit, are formally put on hold for the period of the General Election campaign.

However, this is also an opportunity for UK life sciences. The BIA will use this period to ensure that the role of, and key issues to, our sector are given a prominent voice as each of the parties prepare their manifestos. We will also provide our members with timely commentary on the process itself, and insight into the party positioning on issues relevant to our sector.

As with any election there are likely to be changes of personnel, new and retiring MPs, and at least some, or perhaps full scale, change in Ministerial line-up. We will use our Parliament day on 6 July to ensure our members are comprehensively engaged with the new Parliament and Government within weeks of its establishment.

BIA responds to the Triggering of Article 50

Theresa May triggered Article 50 on March 29, thereby officially starting the two-year negotiation process to determine the UK's future relationship with the EU. In response, BIA CEO, Steve Bates, said:

> *"During the negotiation, the BIA will continue to provide dispassionate insight and commentary on the Brexit process. We will continue to make our members' expertise available to the government and its key agencies in the coming weeks and months as we work through highly complex and technical issues. The BIA remains committed to making the UK the third global cluster for life sciences and we will work closely with government and relevant agencies to deliver this ambition"*

Following the triggering of Article 50, the Government published a **White Paper on The Great Repeal Bill**. Once it has passed through the Houses of Parliament the Bill will do three things:

1. Repeal the European Communities Act 1972 on the day the UK leaves the EU.
2. Convert EU law into UK law – to ensure the same laws and rules continue to apply after leaving the EU.
3. Delegate powers to enable Ministers to adopt secondary legislation to change primary legislation without full parliamentary oversight (the so called "Henry VIII powers") – to make the necessary corrections to the statute book to achieve Brexit.

These delegated powers will be wide ranging in terms of the legislation to which they can be used to make changes. It will include existing legislation, which implements UK obligations, as well as directly applicable EU law, which will be converted into domestic law. It also includes the power to transfer to UK bodies or Ministers powers that are currently exercised by EU bodies.

Section 3.17 of the White Paper states that "the power will not be available where Government wishes to make a policy change which is not designed to deal with deficiencies in preserved EU-derived law arising out of our exit from the EU". The BIA will be closely monitoring how this will be used in practice as part of our work to ensure the Government delivers an effective regulatory environment for bioscience in the UK post-Brexit.

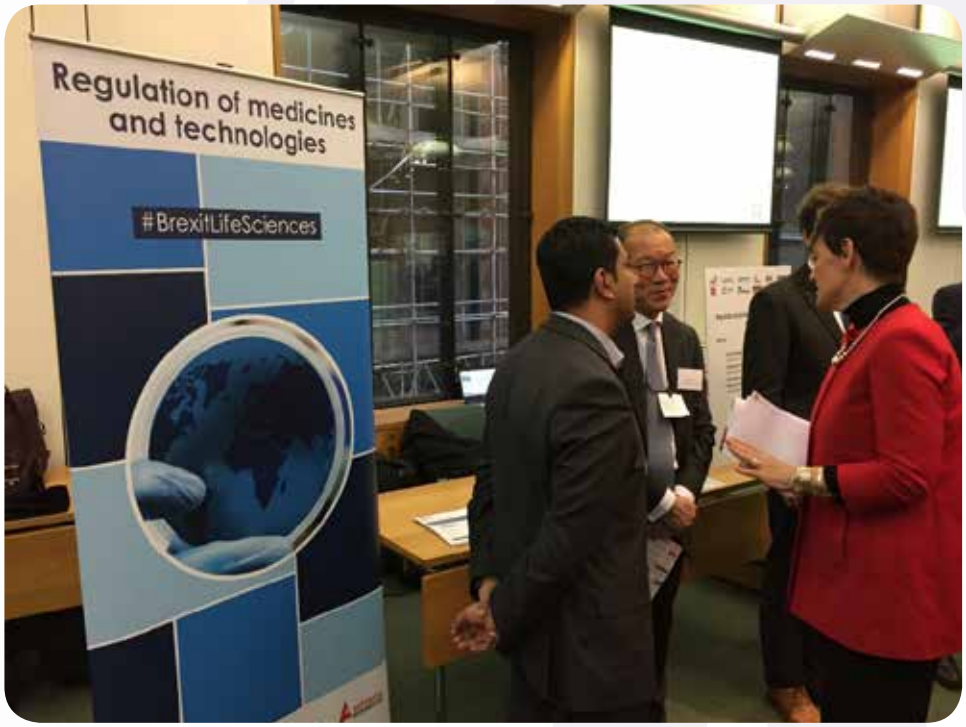
UK-EU Life Sciences Steering Group

The third meeting of the UK-EU Life Sciences Steering Group took place on 1 March. Co-Chaired by the CEOs of GSK and AstraZeneca, the group also includes BIA's CEO Steve Bates, as well as Government representatives including the Health Minister Lord O'Shaughnessy, David Jones MP, the Minister at the Department for Exiting the EU and Ian Hudson and Sir Michael Rawlins from MHRA. The Group guides the collaborative work of industry and the Government for life sciences during the process of leaving the EU.

The Group discussed the case for seeking regulatory cooperation for medicines and issues that may impact future trade, with a particular focus on supply-chains. The BIA is working collaboratively with ABPI to ensure that life sciences gets the best possible Brexit deal, and this work will continue going forward, guided by the Steering Group.

Our monthly Brexit webinars provide regular briefings on key news from the Government alongside updates from the UK-EU Steering Group, focussing on key issues for the sector. Visit our YouTube Channel now to catch-up with our April edition and sign-up for the next webinar on 5 May on our website.

Life Sciences and Brexit Parliamentary drop-in event



Jo Churchill MP speaking to regulatory experts in Parliament

On 7 February the BIA, in collaboration with our partners from the public, private, and charity life sciences community, held a drop-in event in Parliament to give MPs and peers the opportunity to meet patients, researchers and other experts to hear first-hand the opportunities and challenges facing our sector as the UK leaves the EU. The event was attended by over 25 MPs and peers, demonstrating the interest in and support for our sector on this critical issue.

Building our international relationships

BIA delegation to Switzerland

The BIA is continuing to build on our already strong international relationships. Most recently, we travelled to Switzerland with a delegation of representatives from industry, Government, and regulatory authorities to see how Switzerland's life sciences sector flourishes outside the EU.

The BIA has also recently visited Canada and San Francisco. Canada's biotech sector faces several of the same challenges we do – talent, access to finance, and the impact of changes in the US. In San Francisco, the BIA attended JP Morgan to showcase our vibrant biotech sector to interested delegates from the US and wider international community, including holding a Brexit Panel session to communicate how we are addressing the risks and opportunities of leaving the EU. We also partnered with the Department for International Trade to host the UK Biotech Drinks Reception.

Finance, Tax and Investment

Informing the Government's Industrial Strategy

Steve Bates speaking at our member workshop on the Government's Industrial Strategy Green Paper

On behalf of the sector and our members, the BIA has responded to the Government's Industrial Strategy Green Paper. In our response, we outline what the Government can do to further promote and support the life sciences including addressing the UK's chronic shortness of scale-up capital and attracting global management talent.

To inform our submission, we held a workshop with delegates covering the full breadth of our membership – from small discovery-end companies, to service SMEs and large drug manufacturers. We also commissioned interviews and an online survey with leaders from our sector. The views put forward by our members on the challenges and opportunities for the sector provided valuable guidance to inform our response.

On February 22, Steve Bates took part in an oral evidence session on the Industrial Strategy for the House of Commons Science and Technology Committee. The BIA was the only industry voice among the six organisations giving evidence, which demonstrates the success of the BIA team in raising the prominence of our sector within Parliament.

The Life Sciences Industrial Strategy

The BIA continues to engage in the Life Sciences Industrial Strategy work being led by Professor Sir John Bell. The Strategy aims to make the UK a global hub for clinical research and medical innovation. It will set out a vision of a globally-unique life sciences ecosystem, supported by collaboration across industry, the NHS, academia and research funders, delivering health and wealth and supporting NHS transformation.

Steve Bates is a member of the Strategy Board and the BIA is feeding into the process of developing the Strategy through a number of different routes, including at Board meetings, direct engagement with Sir John and through the Office for Life Sciences and the Wellcome Trust who are supporting the Strategy's development. As detail has become available we have engaged our Board and our Advisory Committees and we have reflected their input in our feedback.

Additionally, the Government hosted a "Life Sciences Reception" event on 20 February. The event brought together 200 people from life sciences companies, including a number of BIA members, research organisations and academia. Health Minister Lord O'Shaughnessy spoke about the importance of the life sciences sector to the UK economy. NHS England Chief Executive, Simon Stevens, spoke about the importance of innovative medicines to NHS patients and the Public Health Minister, Nicola Blackwood, focused on the importance of treatments for rare conditions.

The Reception included a number of roundtables. Steve Bates hosted a roundtable on finance and investment which considered the UK's tax environment for attracting new inward investment and supporting further investment from businesses already operating in the UK, how the current tax system could better incentivise investment in R&D and priorities for the sector for the Patient Capital Review.

Government's Spring Budget

In our submission to the Treasury on the Spring Budget, we emphasise the need for ongoing Government support for the life sciences sector and welcomed the R&D Tax Incentive review and the ongoing Patient Capital (Buffini) Review.

Following Chancellor Philip Hammond's Budget on 8 March, the BIA provided an in-depth analysis of the Budget's impact on the life sciences. It was great to hear the Chancellor put biotechnology first in the list of areas the Industrial Strategy will support.

The Industrial Strategy Challenge Fund will allocate a little below £100m to new medicines manufacturing following proposals put forward by the Medicines Manufacturing Industry Partnership (MMIP), which the BIA is part of.

Although the Government did not take the opportunity to enhance the R&D tax credit system through its review, we are pleased that it listened to our suggestion to reduce the administrative burden for businesses claiming R&D tax reliefs. We will continue to press for enhancements to this valuable scheme.

Access to finance and patient capital

Addressing the shortage of long-term patient capital for UK businesses is a current key concern for the Government, with the Patient Capital Review announced at the Autumn Statement in November 2016. The BIA has met with Treasury officials running the review and on 13 March, the BIA's CEO, Steve Bates, attended a roundtable to discuss access to finance with leading life science investors, CEOs and Government officials from the Office for Life Sciences and the Treasury.

Separately, the BIA's Finance and Tax Advisory Committee met with officials from the Office for Life Sciences on 24 February to discuss R&D Tax Credits and other forms of Government support for biotech companies.

The public consultation for the Patient Capital Review is expected to be published in the coming weeks and the BIA will be formally responding as well as continuing to engage with relevant officials and members of the review's Industry Advisory Panel directly.

A day in the City for British biotech

On 26 January, the great and the good of British biotech descended on the City for a day of BIA events.

It began with Lord Prior, the Minister for life sciences at the Department for Business, ringing the bell to open the London Stock Exchange. He then delivered the keynote speech at the Future of Healthcare Investor Forum, an event co-organised by the BIA to give generalist investors an introduction to the opportunities of the UK life sciences sector. The BIA also

published *The UK Life Science Industry and the Public Markets, 2016/17* report to accompany the event.

In the afternoon, the BIA and Osborne Clarke hosted an audience with the authors of *Science, the State, and the City*, a book about the rise of our sector and how it has been supported by successive Government industrial strategies.

The day concluded at the annual BIA Gala Dinner, with over 700 guests celebrating the successes of 2016. Kate Bingham of SV Life Sciences received the Lifetime Achievement Award for her services to the bioscience industry and Lord Prior delivered a speech praising the work of the BIA and our members.

Kate Bingham of SV Life Sciences receiving the Lifetime Achievement Award at the BIA Gala Dinner

New reports on the success of UK life science

According to a report published by PwC in March, the productivity of the UK's life science industry is more than double the UK average. The report, *The Economic contribution of the UK Life Sciences industry*, commissioned by the ABPI and supported by the BIA, ABHI and BIVDA, also found that the industry supports 482,000 jobs and contributed £30.4bn to UK GDP.

Additionally, the Government recently published their annual Strength and Opportunity report on the medical technology and biopharmaceutical sectors, showing that the UK remains a world-leader in these developments (also on the front cover).

BIA response to the HMRC consultation on the venture capital schemes Advanced Assurance Service

The BIA has responded to a consultation on the HMRC's Advanced Assurance Service, which is a critical service underpinning investment through the Enterprise Innovation Scheme and Venture Capital Trusts.

Strategic technologies and areas of scientific focus

Ensuring UK businesses can benefit from advancements in human genome-editing

The BIA submitted written evidence to the House of Commons Science and Technology Committee's inquiry on Genomics and Genome-editing. In our response we stress the importance of achieving broad societal consensus regarding the clinical use of germline editing to allow businesses that emerge from this frontier science to establish themselves in a supportive and properly regulated environment in the UK.

Our CEO, Steve Bates, also commented on the recent National Academies of Sciences and National Academy of Medicine report on human genome editing, which recommends allowing the clinical use of germline editing in exceptional cases and where stringent safeguards are in place. Steve said:

> *"We welcome the publication of this cautious but reasoned report and the continued international focus on enabling this pioneering area of biotechnology. With its renowned science base, and a world-leading regulator in the HFEA, the UK is well placed to lead in this innovative genetic revolution."*

The BIA will continue to follow the Committee's inquiry as it progresses.

Skills, people and talent

Closing the STEM skills gap

In January, the BIA submitted a response to the House of Commons Science and Technology Committee inquiry on closing the STEM (Science, Technology, Engineering, Maths) skills gap. Our submission specifically addresses the current skills deficit identified for manufacturing of Advanced Therapies, following in-depth work undertaken as part of the Advanced Therapies Manufacturing Taskforce. It pushes for the creation and implementation of an end-to-end talent plan for the sector. This plan must support the development of a range of skills, from Manufacturing Technicians through to Post-doctoral and Professional levels.

MAC skills bioproduction leadership initiative

The Skills Networking Tour visiting FUJIFILM Diosynth Biotechnologies

The BIA's Manufacturing Advisory Committee (MAC) launched their Skills Networking Tour at FUJIFILM Diosynth Biotechnologies in Billingham in January, followed by a second visit to AstraZeneca Speke in March. The programme was created to support the development of the next generation of bioprocess leaders, as part of BIA MAC's objectives of connecting, advising and influencing. The group will attend a series of site tours to get an overview of the work of other companies and to develop a network of peers. The third visit will be hosted by the Cell and Gene Therapy Catapult in May. For more information or to join the next cohort of this initiative, please contact Netty England on aengland@bioindustry.org

Intellectual Property and Technology Transfer

Improving Technology Transfer

In March, the House of Commons Science and Technology Committee released a report on managing intellectual property and technology transfer that stated improvements are needed to the commercialisation of university research. Responding to the findings of the report, BIA CEO Steve Bates said:

> *"BIA members, large and small, form partnerships with universities to access expertise, facilities and IP. Innovation is highly dependent on constructive academia and industry collaboration and we welcome the Committee's recommendation for the government to examine what skills are needed in universities to successfully value IP and broker negotiations."*

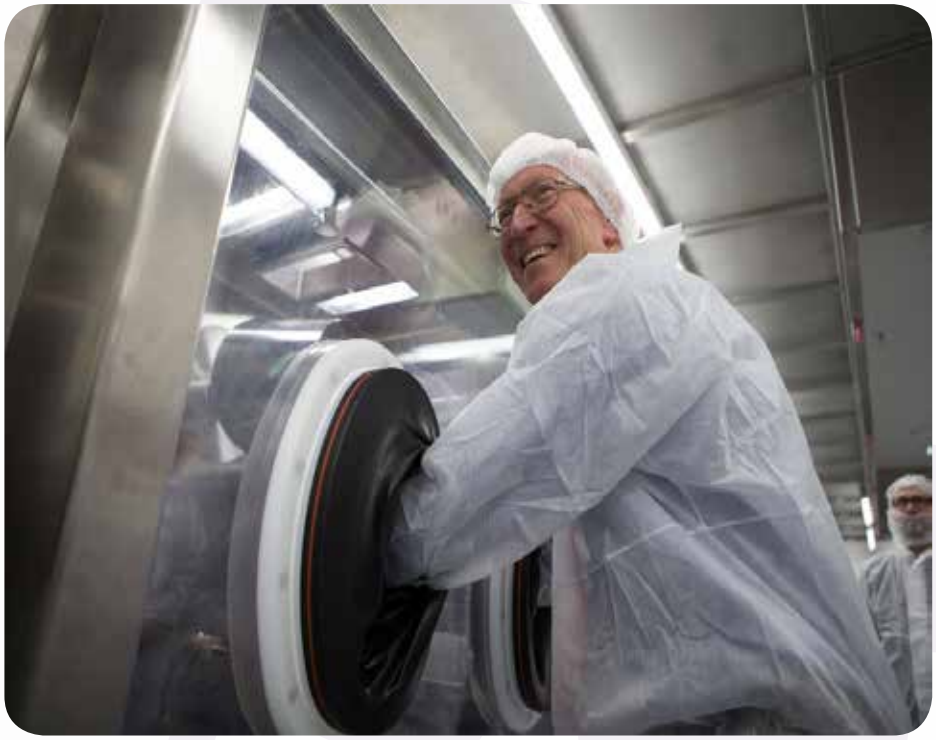
The BIA previously submitted written evidence to the inquiry and BIA Board member Will West appeared in front of the Committee in November last year.

On 29 March, the BIA brought together representatives from across the biotechnology and academic community for a lunch workshop to discuss how we can all work together to improve technology transfer between universities and industry. By bringing together all the relevant parties and encouraging an open dialogue, the BIA aims to address some of the issues highlighted in our submission to the Science and Technology Select Committee, such as friction around IP licencing.

The workshop was organised by the BIA's Science and Innovation Advisory Committee and kindly hosted by law firm, Fieldfisher.

Manufacturing

Lord Prior addresses the Medicines Manufacturing Industry Partnership's first conference



Lord Prior touring AstraZeneca's plant in Macclesfield

The Medicines Manufacturing Industry Partnership (MMIP), a partnership of the BIA, ABPI and Innovate UK's Knowledge Transfer Network, recently welcomed Lord Prior, the life sciences Minister in the Department for Business, Energy and Industrial Strategy, to see modern medicine manufacture at AstraZeneca's plant in Macclesfield. Lord Prior told the conference that medicines manufacturing can play a key role in boosting UK economic growth through the Government's Industrial Strategy. The event saw stakeholders from across the sector come together to find out what MMIP has achieved to date and to hear about the partnership's plans for the future.

Delivering the Advanced Therapies Manufacturing Action Plan

Work is already underway to deliver many of the recommendations outlined in the Advanced Therapies Manufacturing Action Plan, published in November last year. Innovate UK have announced a Health and Life Sciences funding call to support the expansion of the UK's viral vector capability. In addition, £11m has been awarded through Innovate UK's Cell and Gene Therapy industrial manufacture competition, with many BIA member companies receiving grants including Cell Medica, Cell Therapy Catapult Ltd, Cellular Therapeutics Ltd, Asymptote, ReNeuron, Autolus, and NightstaRx Ltd.

The Action Plan Taskforce, which includes the BIA, is also exploring how to close the technical skills gap through a Gatsby funded project and it is working very closely with the Department for Business, Energy and Industrial Strategy, Office for Life Sciences and the Department for International Trade on other actions. These include the ongoing recruitment of a specialist in medicines manufacturing and advanced therapies to support a simplified process of engagement to target and capture internationally mobile investments.

After two years at the helm of MMIP, Ian McCubbin is stepping down as Chair and is passing the mantle to Andy Evans, the Head of AstraZeneca's manufacturing site in Macclesfield. The BIA would like to thank Ian for his brilliant leadership of MMIP, and are delighted to announce that Ian will continue to remain engaged by leading the delivery of the Taskforce Action Plan.

To engage with this work, please contact us at MMIP@bioindustry.org or join our LinkedIn group at http://bia.me/MMIP_LinkedIn

Medicines Regulation

Review of the similarity concept in the context of the Orphan Regulation

The BIA responded to the European Commission consultation on the concept of 'similar medicinal product' in the context of the orphan legislation and endorsed the comments submitted by the EFPIA-EuropaBio Orphan Medicinal Products Joint Task Force.

The Commission sought stakeholders' views on the changes suggested to Article 3 (3) of Commission Regulation (EC) No 847/2000 to adapt the definition of the similarity concept to technological progress due to major developments in the field of biological medicines.

The introduction of a specific section on advanced therapy medicinal products (ATMPs) was welcomed to clarify the requirements for assessing similarity for cell and gene therapy products. However, industry urges caution as research and development in this area is rapidly evolving and there are no precedents for similarity assessment of ATMPs yet.

The Commission's initiative to revise the similarity concept targets the cornerstone of the Orphan Regulation – 10-year market exclusivity for an authorised orphan medicine. This means no application for a marketing authorisation for a similar medicinal product for the same therapeutic indication will be accepted by the EMA and EU Member States during this period.

More information on orphan medicines is available on the Commission website.

US FDA Commissioner Nomination – potential implications for the sector

Dr Scott Gottlieb, President Trump's nomination for Commissioner of the Food and Drug Administration

President Donald Trump has nominated Dr Scott Gottlieb, a conservative physician with longstanding ties to the pharmaceutical industry, to be the new Commissioner of the Food and Drug Administration.

Dr Gottlieb has previous regulatory experience – he served as Deputy Commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration and has also worked as a senior official at the Centres for Medicare and Medicaid Services. More recently, he has worked with venture capital firms and is a Venture Partner at New Enterprise Associates.

It is worth noting that the Senate Health, Education, Labor and Pensions Committee confirmation hearing on 5 April was dominated by questions on drug development issues such as accelerated approval, adaptive trial designs and improving review division performance. Dr Gottlieb also received some questions from Democrats with regards to his industry ties and potential conflicts of interest.

The Committee vote on Gottlieb's confirmation is expected after Congress returns from its Easter recess in late April. If his nomination is confirmed, Dr Gottlieb will oversee America's largest regulator of medical and consumer products at a time when the President has vowed to reduce regulations to ease the burden on US companies.

Triggering Article 50 and marketing authorisation applications under the mutual recognition and decentralised procedures

On 29 March the Heads of Medicines Agencies' Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) issued its procedural advice on changing the Reference Member State (RMS), which for many procedures is the UK. The HMA cooperates with the EMA and the European Commission in the operation of the European medicines regulatory network.

It is important to highlight that EU Member States have agreed that a marketing authorisation holder (MAH) may request a change of RMS if that "RMS has triggered Article 50 of the Treaty on European Union", and that a "switch back to that Member State who has triggered Article 50 will also be allowed if there will be an exemption agreed as a result of the negotiations between that RMS and the EU". Resource implications will be considered when a request to change the RMS has been received by the regulatory authorities.

It is the BIA's view that such a pragmatic and flexible approach is an encouraging sign that post-Brexit a European regulatory partnership between the UK and 27 EU Member States could be achieved.

BIA participates in DIA EuroMeeting

The BIA's Head of Regulatory Affairs, Dr Christiane Abouzeid, joined the DIA EuroMeeting in its 29th year in Glasgow. The overall theme 'Translational Healthcare: From Bench to Bedside and Back' reflected the growing impact of back translation of learnings and patient data into research and development of innovative medicines. The conference discussed and shared insights into the evolving European and global healthcare environments from alternative regulatory pathways to developments in HTA and access, bringing together more than 1,500 healthcare professionals from industry, regulatory agencies and patient organisations.

Access to Medicines

Changes to the evaluation and funding of medicines for very rare diseases

At a NICE Board meeting on 15 March, NICE and NHS England confirmed that they would implement changes to the way medicines for very rare diseases are evaluated and funded, proposed in October last year. The changes came in to force on 1 April.

Responding to the announcement BIA CEO, Steve Bates said:

> *"Today's decision by NICE and NHS England to implement this new policy in just two and half weeks' time sends an immediate, stark, negative signal to the global life science investors and companies that the UK needs to attract in the Brexit era. The changes announced will limit patient access to novel, breakthrough potentially life-saving medicines, especially for rare diseases –an area of research the UK government has prioritised in the 100,000 Genome project.*
>
> *"In addition the proposals will damage the United Kingdom. They will build a Hadrian's Wall for English patients who will no longer be able to access innovative new treatments that will continue to be available in Scotland."*

Steve's response was quoted in two recent parliamentary debates, one on the UK Rare Disease Strategy in the House of Commons and one on the future prosperity of medical research in the House of Lords. The BIA's response also received coverage in both the national and trade press.

Since the announcement, the BIA and some of our members have jointly written to the Secretary of State for Health, Jeremy Hunt, and Dr James Kent, the new Health Advisor at No.10, asking them to review the changes.

On Rare Disease Day in February, Jo Churchill MP wrote a blog for the BIA explaining how the changes would affect patients with very rare and complex conditions.

Accelerated Access Review

Following the publication of the Accelerated Access Review (AAR) report, which sets out recommendations to streamline and accelerate patient access to innovative medicines, the BIA held a roundtable with Lord Prior and representatives from across the Department of Health, the NHS, MHRA, charity and industry to discuss the Review's recommendations. We will be publishing a note of the discussions in due course.

The BIA recently participated in an MHRA/NICE/Industry meeting to discuss data sharing, one of the key issues explored by the AAR. Increased information sharing about products in the regulatory processes between MHRA and NICE to support technology appraisal (TA) reviews has been under active discussion to minimise the time between the granting of a marketing authorisation (MA) and access to clinically and cost effective medicines.

Changes to the Cancer Drug Fund mean that the full NICE TA process for new cancer drugs should be completed before MA and the draft guidance issued shortly after the EMA's Committee for Human Medicinal Products (CHMP) opinion.

NICE is therefore seeking access to CHMP assessment reports during the regulatory process to facilitate earlier issue of NICE guidance, rather than waiting for the publication of the European public assessment report (EPAR) by the EMA.

The BIA shared concerns that the run up to the CHMP opinion is a time of flux and likely changes to the approval and label. We suggested that the period between CHMP opinion and the European Commission decision should be explored further as an opportunity for enhanced dialogue between industry and NICE and finalising TA assessment.

It was suggested lessons could be learnt from the Early Access to Medicines Scheme (EAMS). Discussions will continue at a follow up MHRA/NICE/Industry meeting in Q2 2017.

NHS England's follow-up on the Five Year Forward View, published at the end of March, commits the NHS to implementing many of the AAR's recommendations. We are still awaiting the Government's formal response to the Review.

European Parliament Report on Access to Medicines

On 2 March, the European Parliament (EP) adopted a resolution on EU options for improving access to medicines by 568 votes to 30, with 52 abstentions. The EP own-initiative (2016/2057(INI)) should be seen in the wider context of the emergence of new and expensive technologies and the threat posed by the economic crisis to the sustainability of health care systems.

Members of the European Parliament (MEPs) called for greater clarity on R&D costs, including the share of publicly-funded research, and on the marketing of medicines, as well as on the Council and the European Commission to strengthen the negotiating capacity of Member States in order to ensure affordable access to medicines across the EU.

The initial text of the resolution was openly hostile towards the pharmaceutical industry. Several MEPs tabled amendments to balance the text, but the general consensus among MEPs was the need to assess the current regulatory and incentive framework for pharmaceuticals. It is important to add that this is a non-legislative resolution and not legally binding.

As to next steps, this will depend on the outcomes of the incentives review being carried out by the European Commission, following the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States.

The BIA will keep a watching brief on developments in this area, in collaboration with its sister organisation EuropaBio.

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.

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