Influencing and shaping our sector – BIA update October 2018 – January 2019

UK BioIndustry Association

Influence, connect, save

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Introduction

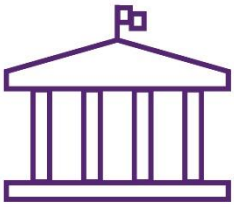
The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences industry, from October 2018 to January 2019.

This quarter saw the publication of the second Life Sciences Sector Deal, which highlights both the importance of UK life science SMEs and the Government's continued confidence in the strength of the sector. And we published new data which showed that UK biotech raised £2.2bn from investors, making 2018 a record year.

Brexit remains uncertain but continues to move at pace. We are working with government, industry, and stakeholders on a range of issues from no deal planning and medicine regulation, to intellectual property and future trade. But it is not all about Brexit – to highlight the strength of the sector further, we relaunched a parliamentary group for life sciences and built new connections during a BIA members' visit to China. Read about this and much more below.

This quarter in numbers:

16+ influence meetings with 17+ MPs and Peers, including 5 Ministers



12 consultation responses submitted

3 letters to Ministers

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BIA welcomes the second Life Sciences Sector Deal

In December, the Government published the second Life Sciences Sector Deal. The document details both public and private sector commitments, including a £1bn R&D investment from BIA member company UCB and a new partnership between government and industry using artificial intelligence (AI) to develop the next generation of treatments.

BIA CEO Steve Bates OBE attended the launch of the document in Downing Street and said in a press release:

> *"The UK life sciences sector continues to go from strength to strength. One year on from the first ever sector deal agreed between government and an industry sector, it is great to see the sustained importance that the UK government places on the UK life sciences sector as an engine for the country's future growth."*

On the day of the launch, the BIA sent out a briefing to its members. We will continue to engage on the future delivery and evolution of the Life Sciences Industrial Strategy through representation at the Life Sciences Council and Life Science Industrial Strategy Implementation Board to ensure that industrial strategy continues to both support and benefit from the innovation coming out of UK life sciences.

On the same day as the publication of the Sector Deal, the Government also published the long-awaited Bioeconomy Strategy - "Growing the Bioeconomy". The strategy is a collective approach from government, industry and the research community to transform the UK economy through the power of bioscience. The vision set out in the strategy is to make the UK a global leader in the development, manufacture, use and export of bio-based solutions. This is something the BIA has been championing, primarily through its Engineering Biology Advisory Committee, which is working on the next steps.

Professor Sir John Bell and BIA CEO Steve Bates outside No 10 at the launch right before Christmas.

Leaving the EU

General Brexit update

At time of publication, Brexit remains uncertain. The Prime Minister's deal was rejected by Parliament on 15 January and she is going to take the Withdrawal Agreement back to Parliament for another vote.

The Prime Minister has laid an amendable Motion, which has enabled backbench MPs to table amendments. A key focus of these amendments has been to take no deal off the table, delay or suspend Brexit and enable a second referendum. The House of Commons will debate and vote on one of these amendments on 29 January. This vote may mean that the politics of Brexit could change yet again. The BIA continues to represent the sector's policy priorities to the Government, the Opposition, and backbenchers. Every month, we also explain the latest developments to our members in our Brexit webinars.

Withdrawal Agreement and the importance of avoiding no deal Brexit

Following the publication of the Withdrawal Agreement in November, the BIA has highlighted the importance of avoiding a no deal cliff-edge Brexit to the Government, Parliament, and external stakeholders.

The BIA has stated that the UK crashing out of the EU without a deal must be avoided. A cliff-edge Brexit will negatively impact patients, public health, and the life sciences sector. If the UK and the EU reach a deal, it significantly improves the chance of stability and gives increased certainty for business. The UK life sciences industry has already endured considerable disruption, duplication, and uncertainty, which is likely to continue in the months ahead.

Although the Withdrawal Agreement would help to protect medicines supply to patients, BIA members still have major concerns about how medicines regulation will work in practice during the implementation period as set out in the Agreement.

No deal medicines supply contingency planning

The BIA continues to provide sector input into the Government's no deal planning, with a focus on stockpiling and contingencies. In December, Health Secretary Matt Hancock MP wrote a letter to companies with a new update on progress in the event of no deal.

The letter stated that there will be significantly reduced access across the short straits (Dover/Calais) for up to six months. The Government subsequently signed agreements with ferry companies for contingency capacity.

Responding to the publication of the letter, BIA CEO Steve Bates OBE said:

> *"UK life sciences companies know that patients are at the end of their supply-chains and for over two years have been doing all they can to ensure that UK patients will continue to get their medicines whatever Brexit outcome occurs.*
>
> *"Companies have worked hard on this massive challenge to put in place plans to ensure a minimum of six weeks additional supply in the UK, over and above existing business-as-usual buffer stocks, by 29 March 2019."*

Prioritising patients throughout the Brexit process

The BIA has worked to ensure that patients are prioritised during Brexit ever since the referendum result. Following the publication of the Withdrawal Agreement and a draft Political Declaration on the future relationship, the BIA, together with the ABPI and the NHS Confederation, called for patients to be prioritised in the final version of the document.

The final Political Declaration now addresses many of the priorities for which the BIA (in coalition with others across Europe) has advocated. The document includes ongoing science and innovation collaboration, cooperation for medicines regulation, a focus on future trade and customs and borders, a future relationship with the European Investment Bank, and on conformity assessment – and is therefore a key step in the right direction.

Going forward, it is already clear that there is a long way to go from a political declaration on a future relationship to a legally binding, effective, and workable future framework. When discussions about the future relationship begin, it is vital patients are prioritised. The BIA is committed to working on the practical detail that will matter to our member companies.

BIA responds to trade consultations

In October, the BIA responded to the Department for International Trade (DIT)'s consultations on future Free Trade Agreements (FTAs) with the US, Australia, New Zealand, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Our response is available on our website.

In our submission, we highlighted that because of our sector's integrated links with the EU, a close UK-EU relationship is more important than future FTAs. We emphasised that our top priority on trade continues to be the secure supply of medicines to UK patients as we leave the EU. Together with a comprehensive deal with the EU, the continuation of current EU FTAs and Mutual Recognition Agreements (MRAs) provides important foundations for the UK's post-Brexit trade policy.

We explained that the current lack of clarity on the future UK-EU relationship makes it difficult to comment on what the UK's priorities in potential future FTAs should be and, as the future relationship becomes clearer, so does the sector's ability to provide more detailed information about both the UK's overall post-Brexit trade policy and specific FTAs. The BIA continues to work with DIT to emphasise our sector's priorities.

Ongoing BIA Brexit activity – Brexit lead network events and webinars

The BIA continues to host regular Brexit lead network events together with the ABPI, where senior civil servants give timely updates and Q&As. BIA members can register for upcoming Brexit lead network events for free on our website.

We also continue to hold our free monthly webinars where our CEO Steve Bates and Brexit lead Laura Collister give the latest Brexit updates and discuss what they mean for the sector. Register for the next webinar on our website or tune into past webinars on our YouTube page.

Finance, tax and investment

2018 a record year for UK biotech fundraising

New figures published in January 2019 by the BIA and Informa Pharma Intelligence reveal that the UK biotech sector raised a record £2.2bn from investors in 2018. The report *Confident capital: backing UK biotech* shows that the UK is the leading life sciences cluster in Europe and continues to challenge clusters in California and Massachusetts. Highlights from the report include:

- £2.2bn was raised by UK-based biotech companies in 2018, compared to £1.2bn in 2017
- Over £1.1bn of venture capital was invested into UK biotech companies
- Over £1bn was raised on public markets: £432m in Initial Public Offerings (IPOs) and £658m in all other public financings
- Across Europe, UK companies accounted for 40% of all biotech venture capital raised and 45% of funding raised through IPOs

BIA CEO Steve Bates OBE said:

> "*The UK biotech ecosystem is a key engine of innovation that is delivering jobs, economic growth and most importantly, life-changing new treatments for patients. Our data shows global investors see this value and want to be part of the UK's exciting and fast-growing biotech opportunity.*"

The report was launched by the Exchequer Secretary to the Treasury, Robert Jenrick MP, at a BIA event in central London.

Robert Jenrick MP, Exchequer Secretary to the Treasury, said:

> *"The life sciences sector plays a key role in the economy and has attracted record-breaking investment for our biotech SMEs.*
>
> *"We want to make sure life science SMEs can access the finance they need to reach their global potential. Our Patient Capital Review will help generate £20 billion over the next ten years to help fund innovative firms like these, and we are encouraging further investment from pension funds to boost growth in this sector."*

Robert Jenrick MP, Exchequer Secretary to the Treasury, and BIA CEO Steve Bates at the report launch.

BIA engages Treasury on key policy changes in the 2018 Budget

On 29 October the Chancellor delivered the 2018 Budget, which included a number of important policy announcements that could have a significant impact on the sector. These included:

- A cap on cash credits in the SME R&D Tax Credits scheme
- Tightening of the Entrepreneurs' Relief rules
- A feasibility study for a patient capital collective investment vehicle for pension funds
- Changes to the Intangible Fixed Assets regime

The BIA published a full analysis of the Budget.

The tax credits cap will limit cash payments to three-times the company's PAYE and National Insurance contributions, with the intention to limit fraud in the system. The BIA has presented strong evidence to the Government that this will have a serious impact on legitimate biotech businesses due to the outsourcing model used in widely in the sector. The BIA continues to work with officials on a legislative solution that will protect the sector whilst meeting the Government's policy aim to prevent fraud.

The proposed changes to Entrepreneurs' Relief would introduce a stricter test to determine if the shareholder has a true economic interest in a company. The BIA made representations to Treasury that the proposed test would be unworkable in practice. As a result, the Government introduced amendments to the Finance Bill 2018-19 to address the BIA's concerns.

BIA welcomes FCA focus on SME finance

The BIA wrote to the Finance Conduct Authority in January to welcome their efforts to improve regulation to support open-ended investment funds investing in illiquid assets, such as private biotech companies. The regulator's work is part of the wider Patient Capital Review to increase long-term investment in the UK's start-ups and scale-up businesses.

BIA working with Innovate UK to ensure grant schemes remain effective

The BIA is working with Innovate UK and partner trade associations across Europe to ensure that EU State Aid rules do not prevent some biotech companies from receiving R&D grants. The problem emerged over the summer of 2018 and has been experienced by companies in several EU Members States. Experts from the BIA's Finance and Tax Advisory Committee are working on a number of possible solutions that might help companies meet the State Aid requirements. If your company has been affected and you have not yet been in touch with the BIA, please contact Dr Martin Turner at mturner@bioindustry.org.

BIA delegation builds networks in China

In November, the BIA led a delegation of member companies to the BioCentury China Healthcare conference in Shanghai, China. Building on our China Special Interest Group, we are seeking to increase the number of UK biotech companies collaborating with, generating revenue from, and receiving investment from the Chinese market. Five BIA member companies presented in a UK investor track and met with investors at a reception arranged with the British Consulate.

BIA CEO Steve Bates OBE also visited Hong Kong, where he met with key stakeholders to talk about opening up finance and collaboration with the UK. The BIA will work to build on the positive links we have established.

Strategic technologies and areas of scientific focus

BIA takes strategic technologies to investors

In January, we held an event to showcase four strategic technologies: genomics, engineering (synthetic) biology, cell and gene therapies, and antimicrobial resistance (AMR). We heard from companies within each strategic area talk about new developments and investors explaining why they are excited about that particular sub-sector. The event gained a huge amount of interest both from external stakeholders and across the BIA membership.

The event builds on the four explainer documents and videos we recently published to promote the UK's fantastic bioscience to a wider range of audiences.

John Dawson, CEO of Oxford Biomedica, and Clare Terlouw, Head of Corporate Development at Syncona, at the event.

BIA supports work on innovative data hubs for research

In November, the BIA helped Health Data Research UK (HDR UK) organise an industry workshop to discuss the implementation of the Digital Innovation Hubs, which was attended by several BIA members. The Hubs were first recommended in the Life Sciences Industrial Strategy and received multimillion funding through the Industrial Strategy Challenge Fund (ISCF). The purpose of the Hubs is to connect health-related data of populations of around 3-5 million people within a single framework, allowing researchers and scientists to safely and securely use the data to develop new scientific knowledge and emerging technologies.

The BIA will continue to support and engage with HDR UK throughout the implementation process. If you would like to attend future workshops, please contact Eric Johnsson at ejohnsson@bioindustry.org.

Parliamentary group to raise the profile of the UK Life Sciences sector

In November, the BIA relaunched the All-Party Parliamentary Group (APPG) for Life Sciences. Chaired by Daniel Zeichner MP, the APPG will raise awareness of UK life sciences among parliamentarians and explore the challenges and opportunities facing the sector.

At its relaunch, the APPG considered the use of genome-editing technologies in healthcare and how these should be regulated. Leading industry experts from the Nuffield Council for Bioethics, law firm Fieldfisher and Spanish biotech SME, ZeClinics spoke at the meeting, which was attended by members of the European life science community as well as MPs and members of the House of Lords.

APPG Chair Daniel Zeichner MP said:

> *"I am delighted to Chair this APPG which will be an extremely important forum for making parliamentarians aware of the valuable contribution the UK life sciences sector makes to the nation's health and wealth. Over the next year the APPG will consider how we can support the sector and how we can make sure that our constituents, and society more broadly, benefit from the exciting new technologies and treatments being researched and developed by life science companies across the UK."*

The BIA provides the secretariat for the APPG together with the ABPI and the BIVDA.

Left to right: Daniel Zeichner MP (Lab), Dr Albert Pineda (ZeClinics), Lord Warner (Crossbench), and Nunzia Florio (BIVDA).

BIA responds to Wellcome Trust consultation on oversight of emerging technologies

In November, the BIA responded to the Wellcome Trust's consultation on the oversight of emerging science and technology. In our submission, we highlighted the importance of ensuring that the Government's approach to oversight safeguards the UK as an attractive destination for top global talent to conduct their research and for innovative companies to start-up and grow. We said that several areas that should be monitored and considered for reform if innovation and commercial development is being impeded. We also emphasised that it is the shared responsibility of researchers, businesses, and policymakers to contribute to an informed public debate to ensure that the wider society is well-informed of the benefits of emerging areas of science and technology and how any potential risks are mitigated.

Genomics England reaches 100,000 whole genomes sequencing target

The UK continues to break boundaries in life sciences. In December, Genomics England's pioneering 100,000 Genome Project achieved its target of sequencing 100,000 whole genomes – an incredible achievement. The project has forged the way for many similar international efforts and has helped to place the UK as a world-leader in genomics. The project has also delivered life-changing results for patients with rare diseases and cancer. If you would like to learn more about genomics and how UK genomic companies are leading the way globally, see the BIA's *Genomics Explained*.

Given the rapid progress the UK is making in genomics, it is timely that the Royal College of Surgeons published a report on the future of surgery in December. The report predicts that surgery is about to be transformed for millions of patients by a new wave of technologies, including genomics, artificial intelligence (AI), and stem-cell therapies. With input from our Genomics Advisory Committee and Cell and Gene Therapy Advisory Committee, the BIA submitted written evidence to the inquiry.

BIA welcomes UK AMR plan

On 24 January 2019 the Government published it's 5-year action plan and 20-year vision for tackling antimicrobial resistance (AMR). One of the headline goals is to develop and test new funding models in the UK that would de-link the purchase price of new antimicrobials from the volumes of products used in the NHS — a bid to better incentivise the biotech and drugs sector to develop new, effective medicines, although there's little details on how that might work in practise.

BIA CEO Steve Bates OBE said:

> *"It's great to see the UK government and NHS committed to exploring a new payment model for antibiotics in our market. Ensuring these incentives work for innovative small biotech companies and their investors is vital as we continue to see established players divesting from this area."*

Also, in October, the House of Commons Health and Social Care Committee published the findings of their inquiry on antimicrobial resistance (AMR), which the BIA had submitted evidence to in June. Responding to the report, BIA CEO Steve Bates said:

> *"Today's Commons Committee report is right to highlight the need for continued political focus on AMR. The BIA's report and video highlights the great work being done on AMR by smaller UK companies. A key point that Lord Jim O'Neill's evidence overlooks is that, on current trends, more AMR innovation looks set to come from this community than from established pharma."*

The BIA's AMR explainer and video feature case studies from Destiny Pharma, Matoke, Neem Biotech, Novabiotics, and Summit Therapeutics.

Skills, people and talent

Government presents proposals for future immigration system

The Government published their proposals for the future border and immigration system in December. Prime Minister Theresa May said in her foreword that she aims to create a system where "it is workers' skills that matter, not which country they come from".

The White Paper follows a consultation held by the Migration Advisory Committee (MAC), which the BIA submitted views to in collaboration with the ABPI. Significant elements from the Government's proposals include:

- There will be no cap on high skilled migrants, including doctors and scientists
- Skilled migrants will also be free of resident labour market tests
- A consultation with business will take place on what level of salary would act as a minimum threshold; the MAC proposed £30,000 minimum salary

The White Paper is open for consultation and the BIA will continue to engage on the issue and is recruiting a new team member to lead on this important work.

ATAC continues to deliver apprenticeships for the sector

The Advanced Therapies Apprenticeship community (ATAC) programme, sponsored by the Medicines Manufacturing Industry Partnership (MMIP) and delivered by the Cell and Gene Therapy Catapult continues to deliver apprenticeships to support the sector.

The UK's first Advanced Therapy Medicinal Products (ATMP) apprenticeship, a Level 5 Advanced Therapies Scientist standard, was launched in September 2018. In early 2019, the programme is launching a Level 3 Science Manufacturing Technician with 15 apprentices. The programme will next launch a Level 7 Senior Leader Master's Degree Apprenticeship in May 2019, delivered by the Open University and resulting in an MBA qualification. This can be funded through the apprenticeship levy and is ideal for existing employees.

Full details of all of these can be found on the ATAC website. The apprenticeships will be discussed at the second Advanced Therapies Apprenticeship Community (ATAC) Event on Tuesday 5 March 2019, as part of National Apprenticeship Week, at Oxford BioMedica. To learn more or join the MMIP AT Apprentice LinkedIn Group, please contact Netty England at aengland@bioindustry.org.

Intellectual property and technology transfer

Obvious issues raised by the BIA discussed in Supreme Court

On 19 and 20 November, the Supreme Court heard from parties in *ICOS v Actavis*. The BIA intervened in this case to present the sector's concerns regarding the test for "obviousness" in the context of assessing the validity of a pharmaceutical patent. The Court heard from ICOS representatives who argued, as the BIA said in its submission, that discoveries made during dosing regime experiments in the clinical trial process are not obvious and should therefore be patentable. The IP Advisory Committee (IPAC), which led on the BIA's submission, will monitor the case and report the outcome to members when it is delivered.

BIA welcomes Supreme Court ruling but questions remain

On 14 November, the Supreme Court handed down its judgment in the case of *Warner Lambert v Generics*. The BIA intervened in this case on the issue of plausibility, requesting that a balance be struck that neither unfairly penalises bioscience companies in requiring an unwarranted level of information in order to demonstrate plausibility of an invention (e.g. clinical trial data) nor permits applicants to unfairly close down areas of research through the filing of speculative patent applications. The Court provided some welcome guidance on the issue but there remains a lack of clarity. See here for more information.

BIA provides views to IPO on SPC waiver

Legislation to introduce an EU manufacturing waiver that would allow generic pharmaceutical companies to produce medicines protected by a Supplementary Protection Certificate (SPC) continues to be negotiated by the European Council and Parliament. The BIA submitted views to the UK Intellectual Property Office in the summer of 2018 and continued to meet with officials throughout the autumn to discuss their ongoing negotiating position.

IPAC Committee member Andrew Hutchinson of Simmons & Simmons has been leading on this work and has written a useful update on the Regulation's progress.

BIA raises concerns in House of Lords about no-deal legislation

The BIA has raised concerns in the House of Lords that the sector was not consulted on The Patents (Amendment) (EU Exit) Regulations 2018 and that the legislation will result in shorter effective Supplementary Protection Certificate (SPC) terms in the UK in a no-deal scenario.

On 4 December, The Patents (Amendment) (EU Exit) Regulations 2018 were laid before Parliament. These set the SPC term in the UK to run from the earliest Market Authorisation in the UK or EEA, despite the BIA having raised concerns with ministers and civil servants that weakening IP protection would harm the UK's standing in the global pharmaceutical industry. Ahead of it being debated by the Lords Grand Committee, the BIA briefed Lord Warner (a former Labour Health Minister, 2003-2007, and Department of Health civil servant, 1974-1985), highlighting our concern about the impact the policy will have on the UK SPC term – and thus R&D investment – and the lack of industry consultation. Peers raised a number of objections to the Statutory Instrument and rejected the bill, sending it back to the House of Commons. Following the debate, the BIA held several meetings with government officials and the minister Lord Henley, who appreciated the BIA's concerns and agreed that the BIA and other industry representative bodies were not consulted in the way that would usually happen and that there would be further consultation.

At the time of writing, the Statutory Instrument is waiting to be considered again by the House of Lords.

Pre-clinical and clinical research

DHSC deep-dive survey on clinical trials

The Department of Health and Social Care (DHSC) is conducting a 'deep-dive' survey to understand in more detail the number of clinical trials that might be impacted by any possible disruption to clinical trial supplies in the event of border delays if there is a no deal Brexit. On 14 January, DHSC wrote to clinical trial sponsors to obtain this information and provided a link to the online survey together with a list of trials for which they sponsor.

We would like to encourage our member companies to take part in this survey which closes on 4 February though returns will continue to be accepted after the deadline. All information received from this survey will assist the DHSC's planning for the UK's exit from the EU. For any queries regarding this survey, please contact ctcontingencyplanning@dhsc.gov.uk.

Manufacturing

BIA MAC launches third leadership programme

In January 2017, the BIA's Manufacturing Advisory Committee (MAC) launched the Leadership Programme (LeaP) to support development of managers in the biopharmaceutical and cell and gene therapy industries. The first programme is now nearing completion and at the request of the participants, an alumni group is being set up to enable them to continue sharing best practice and develop relationships to encourage future collaborations.

On the back of the success of the first LeaP, a second cohort started in January 2018 and is now half way through, and a third cohort kicked-off in January 2019. Due to massive oversubscription, two parallel cohorts will run this year, resulting in a total of over 40 next-generation leaders being trained through LeaP. Please contact Netty England at aengland@bioindustry.org if you would like to hear further details of this programme, which is free to BIA members.

One of the cohorts of this year's MAC LeaP programme.

Manufacturing community gather in Edinburgh for BIA's annual bioProcessUK Conference

In November, we held our 15th Annual bioProcessUK conference in Edinburgh. Almost 300 delegates from the manufacturing and bioprocessing communities caught up to discuss challenges of producing medicines and the strides being made in the production of new and innovative therapies.

The pre-party at Edinburgh Castle kicked off proceedings in style, followed by two days of outstanding presentations and panels focusing on bioprocess intensification to drive down the cost of medicines. A bagpiper led delegates into a Scottish-themed conference dinner, where delegates enjoyed networking in a relaxed environment. As always, the conference was a roaring success and plans are already underway for putting together this year's conference, which will be held in Liverpool in November.

Medicines regulation

BIA input to MHRA consultation on EU exit no-deal legislative proposals

The BIA has together with the ABPI responded to the MHRA's consultation on EU Exit no-deal contingency legislation for the regulation of medicines and medical devices The full consultation response submitted on 1 November 2018 can be found here.

The consultation sought views on how the UK's legislation and MHRA regulatory processes would have to be modified in the event of the UK not securing a deal with the EU after the UK's exit, with no implementation period. Our discussions with regulators over the last year around contingency planning for the regulation of medicines, clinical trials, and medical devices fed into the consultation documents.

While we continue to advocate for the avoidance of a no deal Brexit, this consultation and the proposed statutory instruments address many of the regulatory consequences of a no deal Brexit. The BIA is generally supportive of the proposals made in the consultation. That said, our consultation response is clear that we do have some key concerns about the suggested approach in the following areas, as described in more detail in our submission:

- The lack of incentives linked to research and development of orphan medicines
- The proposal for UK paediatric investigation plans
- The practical details of the proposed new targeted assessment route
- The proposed requirements for data provision for grandfathered centrally-authorised products
- The challenges of the proposed approach on packaging and
- The potential impact on public safety of removing certain legal obligations under the Falsified Medicines Directive.

In addition, we are also concerned that the proposal for data and market exclusivity for marketing authorisations is not being consulted on. Data exclusivity is a critical incentive for innovation and therefore highly important to the life sciences industry. For this protection to fulfil its intended function in recognising the enormous investment behind clinical trials for new medicines, it is vital that the term should be connected to the actual date of grant of a marketing authorisation in the UK which enables its holder to place the medicine on the UK market.

MHRA updates no-deal Brexit guidance on medicines and clinical trials regulation

On 3 January 2019, the MHRA issued a further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal. This guidance provides the MHRA response to their consultation on EU exit no-deal legislative proposals (see above) and is an updated and more comprehensive version of the relevant technical notice published in August 2018.

On 9 January, we circulated a BIA Member Briefing providing a summary of the proposed arrangements for medicines and clinical trials if the UK leaves the EU on 29 March 2019 with no deal. The briefing also highlighted our ongoing work to address some of the concerns we had, including giving feedback on the MHRA guidance on converting centrally authorised products to UK marketing authorisations. If you have any further questions, please contact Dr Christiane Abouzeid at cabouzeid@bioindustry.org.

Following BIA activity, we are pleased that the MHRA has now agreed to provide free scientific advice to UK-based SMEs to support innovative biotech companies and help retain R&D activities in the UK. We are also glad to see that on orphan medicines, the MHRA proposed that the initial marketing authorisation application fee will be refunded at 100% for UK SMEs and 10% for all other manufacturers where a medicine receives orphan status.

BIA continues engagement with EU regulators on Brexit

In November, the BIA participated in the Heads of Medicines Agencies' Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) meeting with Interested Parties, hosted at the EMA offices. The discussion focused on operational issues around the Mutual Recognition and Decentralised procedures for marketing authorisation of a medicinal product in two or more EU Member States.

Following an update on Brexit related Reference Member State (RMS) changes and ongoing procedures with the UK as RMS, the CMDh noted that there are sufficient resources within the European medicines network to take over UK procedures and cope with the additional workload for future procedures. The UK advised that they will apply a transitional period after 29 March 2019 for Market Authorisation Holders in the event of a no deal Brexit to avoid disruption to supply of medicines. The presentations from this meeting are available on the CMDh website. A further guidance was published in December complementing the CMDh Q&As to provide procedural and practical guidance regarding the submission of Brexit related changes.

EMA consults on Regulatory Science strategy

In December, the EMA launched a six-month consultation on its draft Regulatory Science to 2025 strategy. The strategy aims to build a more adaptive regulatory system that will encourage innovation in medicines and help shape the vision for the next EU Medicines Agencies Network strategy. It seeks to offer informed guidance on modern medicines development, facilitate the optimisation of regulatory science, and critically assess the benefits and risks of innovative therapies and diagnostics based on new technologies. The BIA will respond to the EMA consultation working with our members and in partnership with EuropaBio. Please contact Dr Christiane Abouzeid at cabouzeid@bioindustry.org if you would like to contribute to the consultation response.

BIA responds to Serious Shortages Protocol consultation

In December, the BIA responded to a short informal consultation by the Department of Health and Social Care on urgent changes to the Human Medicines Regulation 2012 to ensure the continuity of supply of medicines. The consultation covered both deal and no deal Brexit scenarios. The BIA sought further clarification in subsequent meetings around what constitutes a shortage and the process around shortages, as well as highlighting that biosimilars cannot be automatically substituted. The Statutory Instrument has now been laid before Parliament and is working its way through the parliamentary process.

Access to medicines

Accelerated Access Collaborative announces rapid uptake products

In October, the Accelerated Access Collaborative (AAC) announced seven "rapid uptake" products. These products will be spread through the Academic Health Science Network's (AHSN) Innovation Exchanges, which match solutions to the needs of their local health and care systems. The selected products include treatments for cancer, heart disease, and multiple sclerosis. In line with the AAC's stated initial focus, the selected products are all approved treatments but are not widely used across the NHS.

The BIA hopes that the AAC will now ramp up its activity both in terms of ambition and volume of work. We would like to see the AAC delivering accelerated patient access to truly innovative products in our members' pipelines. BIA CEO Steve Bates OBE met the Chair of the AAC, Lord Darzi, in January 2019 and shared these messages with him.

New Voluntary Scheme for Branded Medicines Pricing and Access launched

On 1 January 2019, a new voluntary and statutory medicine pricing schemes came in to force in the UK. The voluntary scheme replaces the previous Pharmaceutical Pricing Regulation Scheme (PPRS) and was negotiated by the Department of Health and Social Care and the ABPI. It includes:

- A payment mechanism based on an allowed growth rate of 2.0% each year
- A taper for companies with sales between £5 million and £25 million
- An exemption for small companies with sales less than £5 million

The health department consulted on the statutory pricing scheme in September 2018. The BIA responded asking the Government to consider the combined impact of the proposals and broader developments affecting UK life sciences, including the uncertainty caused by Brexit. We highlighted the importance of an internationally competitive industrial environment for bioscience companies as the UK leaves the EU and argued that allowable growth in medicine spend should reflect the 5-year funding settlement for the NHS.

BIA group hosts workshop focused on rare diseases

In November, the BIA's Rare Disease Industry Group (RDIG) held a workshop with patient organisations, medical research charities, health economists, and clinicians to explore the current challenges for rare disease medicines trying to navigate the access and reimbursement landscape and to discuss how these can be addressed.

The group will continue their work in 2019, building on the outcomes of the workshop. If you would like to join the group, or learn more, please contact Nicky Edwards at nedwards@bioindustry.org.

Long term plan for the NHS published

In January, the Government published the NHS Long Term Plan. The Plan sets out how the Government seeks to guarantee the NHS for the future and strengthen it over the next decade. It focuses on prevention, and the promotion of good health, but also places emphasis on new treatments and more rapid diagnostics to improve care. As an example of the latter, the Plan seeks to save 55,000 more lives a year by diagnosing cancers early.

The Long Term Plan will be complemented by the Social Care Green Paper in the coming weeks and by local NHS plans for 2019/20 in April. Local five-year plans are expected to be published in Autumn 2019.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Eric Johnsson, Senior 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 life science sector, contact Michael McGivern, Membership and Business Development Manager, on 0207 630 2194 or mmcgivern@bioindustry.org

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