UK BioIndustry Association

INFLUENCING AND SHAPING OUR SECTOR

April – July 2022

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INTRODUCTION

The BioIndustry Association (BIA) continues to represent our members' voices at the highest levels through our policy and influencing work. This quarterly update gives an overview of key policy developments and BIA's continued involvement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from April to July 2022.

This quarter, BIA continued to work with government partners to realise the ambition of the Life Science Vision by contributing to the production of a roadmap for its delivery, due in the autumn. Our annual Parliament Day in June saw an intense day of influencing and networking for our members with parliamentarians and senior government stakeholders in Westminster, topped by a lunchtime address from then-Minister George Freeman. We launched an Innovation Map to help early-stage life sciences companies find the right support, developed an engineering biology brochure with the Department for International Trade, and our latest quarterly finance report shows investment in the life sciences sector continued despite a global investment slowdown across sectors.

12 influence meetings with 10 MPs, Peers and MEPs, including two Ministers

4 letters to Ministers

The BIA has also represented members' and the sector's interests in numerous government reviews and consultations. Our CEO Steve Bates discussed the need to increase pension funds' investment in our sector with Pensions Minister Guy Opperman. With the Treasury, we voiced our view that a lack of UK venture capital funds poses a threat to the long-term sustainability of the life sciences sector in the UK, continued to call for capital expenditure to be included within R&D tax credits, and represented life sciences SMEs' views on the apprenticeship levy. We engaged with the Home Office to make the new scale-up visa work for our sector, and with the Office for Life Sciences to guide the implementation of the Genome UK strategy.

Read on for all of BIA's influencing work this quarter.

10 consultation responses and briefings submitted

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Engagement with the Government and Parliament on life sciences policy

It has been a tumultuous quarter in government, with Boris Johnson finally standing down at the culmination of a rolling political crisis. Westminster is now gripped by the race to succeed him as Conservative Party leader (and Prime Minister), which will run on to 5 September. Key ministers for our sector who resigned in the last days of the Johnson administration were Chancellor Rishi Sunak, Health Secretary Sajid Javid, Science Minister George Freeman, Pensions Minister Guy Opperman and Trade Minister Lord Grimstone. The caretaker Cabinet for the next couple of months includes Steve Barclay as Secretary of State for Health and Social Care and former COVID-19 vaccines minister Nadhim Zahawi as Chancellor of the Exchequer. Lord Kamall remains in post as Minister for Technology, Innovation and Life Science at the Department of Health and Social Care (DHSC).

In the midst of all the political turmoil, BIA has continued to work with industry and government partners to realise the ambition of the **Life Science Vison**, contributing to the production of a roadmap for delivery.

One of the key elements of the Life Science Vison for BIA was the **Life Sciences Scale-Up Taskforce,** which met on 4 May to finalise recommendations to the Government, including a UK Life Sciences Growth Scheme to secure capital commitments from institutional investors and stimulate growth fund creation in the UK, and on the appointment of a 'Life Sciences Investment Envoy', with the remit and credibility to bring investors, companies, and government together.

Although BIA works with Whitehall and Westminster throughout the year, the pinnacle of our engagement comes on **Parliament Day** which was held on 30 June this year. Over the course of an intense day of influencing and networking, 32 members attended 19 meetings with 7 parliamentarians (including 1 minister and 4 shadow ministers), and 14 senior civil servant stakeholders. At the lunchtime reception on the terrace of the House of Commons, then-Science Minister George Freeman spoke powerfully about the importance of life sciences and biotechnology to the success and wellbeing of the UK and the leading role the BIA plays in representing the interests of SMEs.

BIA members met with key government stakeholders at our annual Parliament Day in June

The **All-Party Parliamentary Group (APPG) for Life Sciences,** for which BIA provides the secretariat jointly with the British In Vitro Diagnostics Association (BIVDA) and the Association of the British Pharmaceutical Industry (ABPI), held a meeting in Parliament on 12 July on 'Data Saves Lives', discussing how industry, government and the NHS can work together to implement the new health data strategy.

Life Sciences Council and other government-industry engagement

The BIA continues to support government-industry engagement through its membership of the **Life Sciences Council (LSC)** and the joint government-industry secretariat that coordinates the work of the Council and its sub-Councils and expert groups.

After the additional meeting of the LSC on 4 April to discuss **Net Zero and Sustainability**, there have been two follow-up meetings, with the trade associations discussing the dissemination of Net Zero information to industry and possible funding streams on 6 May, and a deep-dive working group on R&D on 16 June at which BIA was represented by four member companies who were able to bring the SME perspective to the fore, at the particular request of Minister Kamall.

The LSC's **Patient Access to Medicines Partnership** (PAMP) met on 9 May. It was Lord Kamall's first time in the chair at this government-industry meeting. The BIA was represented by Charlie Galvin, chair of our Rare Disease Industry Group (RDIG). PAMP discussed the future of life sciences in the NHS; early access pathways, including the Early Access to Medicines Scheme (EAMS); the Innovative Licencing and Access Pathway (ILAP); the Innovative Medicines Fund (IMF) and Project Orbis; and the NICE methods and process review.

The **Accelerated Access Collaborative** (AAC) Board, on which BIA is represented by our Chair, Dan Mahony, met on 29 June to discuss the AAC's support for innovators and ambition for clinical research, the adoption and spread of proven innovation, and the Life Science Vison, one year on. The Board is supported by the AAC Steering Group which met on 1 June.

The **National Genomics Board** (NGB) met on 21 June and heard an offer of support from David Atkins, who is BIA's SME representative on the Board, to capture the recommendation of the Scale-up Task Force and SME training requirements, as part of a discussion of the implementation of Genome UK.

At the BIA and Medicines and Healthcare products Regulatory Agency (MHRA) bilateral meeting on 5 May, CEO June Raine and Chair Stephen Lightfoot introduced the new executive team of Chief Officers who have joined the Agency as part of the MHRA transformation programme. The MHRA also held a meeting with BIA's ILAP working group on 24 June. The ILAP working group brings together members from our Regulatory Affairs, Cell and Gene Therapy and Rare Disease communities to put forward constructive proposals for the development of the programme.

We attended the BIO conference in San Diego and hosted the official UK reception in collaboration with the Department for International Trade (DIT). Working with international partners, BIA took part in the EuropaBio SME forum on Advanced Therapy Medicinal Products (ATMPs) on 31 May, and in the National Associations Council in Brussels on 22 June. We were also represented at BioEquity Europe in Milan from 16-18 May, with our Head of Policy and Public Affairs, Dr Martin Turner, appearing on a panel to discuss the impact of the NASDAQ downturn.

BIA has continued this quarter to promote sector developments to the **media**. We continued to make the case to the Government and World Trade Orgnisation that an IP TRIPS Waiver for COVID-19 vaccines would not lead to greater global access to vaccines. BIA CEO Steve Bates was covered several times in Politico and in industry magazine Pink Sheet on the issue.

Martin Turner was interviewed by the Sunday Telegraph where he explained the strong economic headwinds companies are facing particularly on public markets, and our Q2 report on investments was covered by the Scotsman. BIA celebrated RQ BIO signing a licencing deal with AstraZeneca for its monoclonal antibodies against COVID-19 which was covered in PM Live and The Times.

Finance, tax and investment

New report shows investment in biotech continues despite headwinds

New data published by BIA and Clarivate in June showed that the UK biotech sector has continued to attract investment despite global economic headwinds impacting all sectors.

The report, which focuses on equity investment in the UK biotech and life sciences sector between March and May 2022, showed £450 million was raised, compared to £481 million in the first quarter of 2022. This included £277 million in venture capital, down 39% from £453 million in Q1 2022; £173m in public follow-on financings, up 4666% from £3.55 million in Q1 2022; but just £4.5 million in initial public offerings (IPOs), down 81% from £24 million in Q1 2022.

The sector looks unlikely to reach the heady heights of 2021, but a total of £931m for all equity investment for the first half of the year is strong by historical standards. BIA will continue to follow the flow of investment into the biotech sector over the next quarter.

BIA secures support from pensions minister for increasing investment in life sciences

In May, the BIA responded to the Department for Work and Pensions (DWP) consultation on facilitating investment from pension funds into illiquid assets, such as venture capital (VC). In our response, we expressed disappointment at the apparent delay in amending regulations.

Following our submission, BIA CEO Steve Bates was invited to meet with the Pensions Minister, Guy Opperman. The two discussed the need to increase pension funds' investment in the sector and how the French Tibi Scheme could be adopted in the UK to facilitate this.

The Minister said: "The UK life sciences sector has many fantastic start-ups but too few domestic investors support them as they scale-up. I would welcome the UK's life sciences sector and pensions industry coming together to form a partnership that would benefit both parties, and I will continue to look at ways to remove barriers to support long term investment in innovative assets and projects such as life sciences."

Guy Opperman MP resigned from the Government on 7 July but BIA will continue to work with all parliamentarians on this agenda.

BIA's response to the Treasury Select Committee inquiry on venture capital, submitted in June, warned that a lack of UK VC funds poses a threat to the long-term sustainability of the life sciences sector in the UK. We recommended the Tibi Scheme as a model for the UK to bring together UK institutional investors, such as pension schemes, and VC funds to facilitate growth fund creation and greater levels of investment.

BIA calls for capex to be included in R&D tax credits

At his Spring Statement, the then-Chancellor Rishi Sunak launched a wide-ranging review of taxes. As part of this, HM Treasury launched a call for views on potential reforms to the UK's capital allowance regime in May. The BIA's response repeated our long-standing call for capital expenditure (capex) to be included within the eligible costs for R&D tax credits. This would create an incentive for loss-making companies to invest in capital equipment and buildings by providing a cash payment. This message was repeated in a

meeting with Treasury officials on the BIA's Parliament Day, in which officials were broadly receptive to the proposal.

BIA continues to call for essential overseas activity not to be penalised in R&D tax credits changes

Members of the BIA's Finance and Tax Advisory Committee (FTAC) have continued to meet with Treasury officials to discuss the design of an exemption to new rules limiting R&D tax relief claims for overseas activity. This follows the former Chancellor's decision to end claims for R&D conducted overseas unless it was necessary for regulatory, legal or "material" purposes. FTAC have engaged constructively with officials on how this could be formalised in legislation and now await the publication of the draft text for further public comment.

A BIA webinar featuring HMRC officials has also been arranged to help members understand the changes once the legislation has been published.

BIA launches Innovation Map to support early-stage companies

In June, the BIA launched the Innovation Map as part of our work to support early-stage companies in the UK. For several years, we have run our PULSE programme, a three-day entrepreneurship boot camp giving early-stage companies and up and coming life sciences entrepreneurs an introduction to the sector and helping them to address the challenges involved.

It can be difficult for new entrepreneurs to find the right support and to identify whether a given organisation offers the help they need for the stage they are at. This is especially true given the large number of organisations in the UK devoted to helping early-stage companies launch and scale, including incubators, funders, accelerators and training programmes. To address this, the BIA used its unique position in the sector to build the Innovation Map as a guide to the supporting organisations in the UK.

The BIA Innovation Map collects all programmes in a single place and provides an at-a-glance summary of what each of them provides, enabling innovators to make direct comparisons and find the programme and support that is right for them. The map aims to provide a jumping-off point to allow innovators to shortlist those organisations that are most relevant to their needs.

The map will be continually updated to reflect changes in the landscape, and feedback on the functionality of the map and information on organisations that should be included is welcome. Please contact Programme Manager, Sam Cruickshank, with questions, suggestions and feedback.

Strategic technologies and areas of scientific focus

Impact of NSI regime on life sciences appears low in first three months of operation

The Government unit responsible for the UK's National Security and Investment (NSI) regime published its first Annual Report in June, covering the first three months of the system since it began operating on 4 January 2022.

The NSI Act requires the notification to government of any deals involving synthetic biology. The definition of synthetic biology was originally drafted very broadly with the potential to capture the whole life sciences sector but was substantially narrowed following BIA intervention throughout 2021.

The Annual Report shows that synthetic biology accounted for the fewest mandatory notifications (approximately 2% of total) and only made up 5% of voluntary notifications. This suggests that the narrow definition is providing some certainty to companies. However, deals involving companies classed in the Professional, Scientific, And Technical Activities (PSTA) sector, which will include life sciences companies which do not fit the synthetic biology definition, was the top-ranking sector for voluntary notifications (17.5% of total).

No synthetic biology notifications were "called in" for further scrutiny by government. Although the scrutiny of the majority of called-in deals was still ongoing at the time of the report, no deals have been blocked under the NSI powers to date.

The BIA will continue to monitor the implementation of the NSI regime to ensure it does not adversely affect the UK biotech and life sciences sector. Please contact Head of Policy and Public Affairs, Dr Martin Turner, with any questions or concerns.

BIA hosts Genome UK workshop with the Office for Life Sciences and ABPI

In April, the BIA co-hosted a workshop with the Office for Life Sciences (OLS) and the ABPI. The event gathered industry feedback on genomics to contribute to the Government's 'Genome UK: the future of healthcare' strategy implementation plan. Genome UK was published in 2020 and sets out the ambition of making the UK the best place globally to start and scale up new genomics companies. This will be the first full three-year implementation plan since publication of the strategy.

The BIA's Genomics Advisory Committee (GAC) collectively advised on policy priorities for the implementation plan. The workshop was attended by five BIA members who discussed the key topics of data access, functional genomics and standardising referral pathways in the NHS Genomic Medicine Service. This feedback will be instrumental in forming an implementation plan that works for industry.

The BIA continues to liaise with OLS on the implementation plan, with a particular focus on skills and finance. To find out more, please contact Senior Policy and Public Affairs Manager, Dr Emma Lawrence.

BIA engages with NHS Transformation directorate on 'Data saves lives' strategy

In April, the Government published its strategy for reshaping health and social care with data, 'Data Saves Lives'. This landmark strategy seeks to reset the conversation on data and has key impacts for the life sciences sector. The BIA is engaging with various teams within the NHS Transformation directorate (NHST) to ensure that the adoption of trusted research environments (TREs) and the value-sharing framework do not present barriers to SMEs which use health data.

The APPG for Life Sciences hosted Jen Boon, Deputy Director for Data Policy at NHST, at a roundtable discussion in July. Co-chaired by Daniel Zeichner MP and Anthony Browne MP, the discussion centred on how the new UK health data strategy could transform healthcare. The event was attended by industry representatives who discussed how we can best support the implementation of the new strategy in a way that delivers for the NHS, patients and the wider life science sector securely, safely and transparently.

Senior Policy and Public Affairs Manager, Dr Emma Lawrence, is hosting a workshop for members on our current data policy interests on 20 July. Contact Emma to find out more.

BIA continues to engage with government on the Nagoya Protocol

Throughout this quarter, the BIA continued to engage with the Office for Product Safety and Standards (OPSS) on the scope of their activities to enforce the Nagoya Protocol (Compliance) Regulations 2015 in our sector. After multiple letters seeking clarification on OPSS' broad request for information that went beyond the scope of the Nagoya Protocol, we unfortunately did not receive a clarifying answer from OPSS.

In May, the Department for Environment, Food and Rural Affairs (Defra) published the long-awaited guidance on the UK Access and Benefits Sharing (ABS) regulations to help guide UK users of non-human genetic resources on how to comply with Nagoya in the UK. While some of the recommendations BIA made towards the development of the guidance last year were taken on board, it fails to adequately reflect the scope of the UK regulations, making it difficult for UK businesses in our sector to comply.

On the international level, discussions are ongoing at the Convention on Biological Diversity (CBD) to include Digital Sequence Information (DSI) in an ABS mechanism under the Nagoya Protocol. The BIA has previously lobbied against the inclusion of DSI under the Nagoya Protocol. The inclusion of DSI in an ABS mechanism now looks likely, so international discussions are focused on the different options for its inclusion. In July, the BIA attended an ABS Forum meeting hosted by Defra which informed stakeholders of the upcoming CBD negotiations on DSI.

The BIA continues to engage with government on the OPSS enforcement activities, UK ABS guidance and DSI, in order to minimise the impacts of the Nagoya protocol on innovative R&D in the life sciences sector.

BIA join forces with DIT on engineering biology and One Health

Together with the Department for International Trade (DIT), the BIA published 'Power of Biology: The UK is engineering biology for global good', a brochure on the opportunities in engineering biology, an area identified as one of the seven key technologies of strength for the UK in the 2021 Innovation Strategy.

The brochure explains the impact of engineering biology across healthcare, agriculture and industry, provides an overview of the policy landscape as well as trade and investment opportunities in the field, and includes member cases studies from the BIA's Engineering Biology Advisory Committee (EBAC). The brochure is accompanied by a directory of UK engineering biology companies.

The BIA has been invited by DIT to be part of a new One Health think tank that brings different government departments together with industry to promote UK companies' expertise. In the coming months, the BIA will support the think tank in producing a One Health report. To find out more, please contact Policy and Public Affairs Manager, Linda Bedenik.

People, skills and talent

BIA represents views of life sciences SMEs on apprenticeship levy and training

In the 2022 Spring Statement, then-Chancellor Rishi Sunak recognised employers' frustrations with the way apprenticeship levy funds can be spent. In his Mais Lecture, he prioritised three focus areas to accelerate UK growth, including exploring whether the current tax system is doing enough to incentivise businesses to invest in high quality training.

In June, the BIA consulted life science employers on how to bring new talent into the sector and upskill existing employees through apprenticeships. We made recommendations about financial adjustments that could support SMEs, which were welcomed in direct discussions with HM Treasury. BIA's insights also fed into a coordinated response from the Life Sciences Future Skills Team, a sector-wide group including OLS, ABPI, Association of British HealthTech Industries (ABHI), Science Industry Partnership (SIP) and BIA.

BIA voices challenges over access to international talent in UK life sciences industry

In February, the UK's points-based immigration system, originally introduced in 2021 to provide a flexible arrangement for UK employers to recruit skilled global talent, was updated. Visa routes to work in the UK now include the skilled-worker-visa, global-talent, innovator-visa, start-up-visa, global-business-mobility-routes, and a recently introduced high-potential-individual-visa.

As access to global talent is critical for the success of UK life sciences, the BIA collected feedback from across the sector on current challenges in the immigration system and made proposals for improvements. These include reducing complexity in the system particularly for SMEs without dedicated immigration support, reducing the extensive timelines that are inhibiting recruitment and increasing transparency of costs across visa routes. The BIA also influenced the new scale-up visa to be launched later this summer, aimed at making it easier and quicker for companies experiencing rapid growth to hire international talent. The BIA will continue to promote the sector and ensure the suitable application of the immigration system across the life sciences industry.

BIA chairs panel on attracting talent into medicines manufacturing at MMIP conference

The skills workstream of the Medicines Manufacturing Industry Partnership (MMIP) is under the new leadership of Liz Collins from Pfizer, with key objectives on attracting diverse talent, increasing numbers of apprentices, promoting engineering roles, scaling skills, and inspiring the next generation. The MMIP Annual Conference on 21 June focused on further development of the UK's manufacturing capabilities and featured panel discussions with senior stakeholders from government and industry.

MMIP skills panel joined by Elizabeth Collins (Pfizer), Kate Barclay (BIA), Ben Mosley (Cell and Gene Therapy Catapult), Andrew Matthews (Siemens), and apprentice Daniele Acquisto.

The BIA chaired an engaging skills panel with representatives from Siemens, Pfizer, the Cell and Gene Therapy Catapult and an early career scientist completing their degree apprenticeship, discussing approaches to attracting and retaining talent into medicines manufacturing. The panelists discussed how to make the most of the current landscape in the UK to attract talent, how to ensure investors know highly skilled talent is available, and highlighted that there are financial incentives and diverse pathways for growing organisations.

Intellectual property and technology transfer

BIA reacts to IP TRIPS waiver agreed to at WTO Ministerial Conference

Throughout the past year, the BIA has urged government to oppose intellectual property (IP) waiver proposals on COVID-related products that have been part of the WTO discussions on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The BIA highlighted that an IP waiver is not the solution to increasing vaccination rates or facilitating the distribution of COVID-19 vaccines, therapies or diagnostics. Instead, we argued that it makes it harder for smaller companies to develop innovative solutions to current and future pandemics.

In a letter exchange between BIA and the DIT in May, the ministry reiterated that the UK's position stands firm in opposition to a TRIPS waiver on COVID-related products. However, in June the UK agreed to a TRIPS waiver for COVID-19 vaccines at the WTO Ministerial Conference in Geneva following international pressures to come to an agreement. The agreement implements a 5-year IP waiver for COVID-19 vaccines for all developing countries. An IP waiver on other COVID-19 diagnostics and treatments will be discussed internationally in the next six months.

The new waiver agreement incorrectly points to intellectual property as a barrier to the pandemic response rather than an enabler that brings healthcare solutions safely and quickly to patients. The BIA will continue to highlight the importance of IP to our sector and monitor the implications of the waiver.

BIA responds to UKIPO consultation on Substantive Patent law Harmonisation

For several decades, there has been an ongoing effort to secure the international harmonisation of substantive patent law. In June, the UK Intellectual Property Office (IPO) sought the views of UK intellectual property and industry associations on three different substantial proposals to harmonisation as part of a Europe-wide coordinated consultation by the European Patent Office (EPO). The consultation specifically sought views on grace periods, prior user rights and conflicting applications.

BIA responded to the consultation, highlighting the desirability of having greater global harmonisation of the patent process, as well as the need for any new globally harmonised system to be simple and accessible for smaller companies with limited resources for legal and patent functions. We argued that while the introduction of a harmonised grace period could complicate both daily operation and global freedom to operate projects for SMEs, there are attractive benefits of one common global rule within which to operate.

The BIA met with the UKIPO on 15 July to discuss the consultation and the importance of making any harmonised system work for all players in the patent system, including SMEs.

BIA writes amicus curiae brief to EPO

In April, our Intellectual Property Advisory Committee (IPAC) sent an amicus curiae brief to the EPO's Enlarged Board of Appeal (EBA) regarding referral G2/21 on 'plausibility', which could impact the information required in patent filings and how they are judged. Being heavily dependent on patents, the life sciences sector needs clarity and certainty in patent law.

In the amicus brief, we argued against the introduction of a particularly high or low bar for plausibility on datasets in patent filings and instead argued for a middle ground, but purposefully did not specify where that middle ground should be as views across our membership, from small start-ups and SMEs to large pharmaceutical companies, vary. We asked for an approach to plausibility which lies between the two extremes of excluding post-filed data completely and not taking plausibility into account at all in deciding whether to admit such post-filed data.

A test for plausibility that is uncertain or places an increased burden on life sciences companies to disclose data at an early stage in the research process could make it more difficult to obtain patents in the sector. Developments in the life sciences field require a great deal of research and the BIA is keen to ensure that any test for plausibility does not impact this sector more than others, leading to differing standards for patenting across sectors, and making it more difficult for life science companies to attract investment to their R&D programme.

Manufacturing

MMIP Conference places focus on implementation of Life Sciences Vision

In June, the Medicines Manufacturing Industry Partnership (MMIP) annual conference hosted by the ABPI and supported by the BIA moved online due to the rail strikes. Fleet of foot organisation ensured delegates continued to enjoy a range of interesting panels and presentations, virtual tours of the Centre for Process Innovation (CPI) and Fujifilm, and a positive keynote speech from then-Science Minister George Freeman.

The focus of the conference was the implementation of the Life Sciences Vision and further development of UK manufacturing capability that is currently energised, partly due to the UK success on the global stage in mobilising to manufacture COVID-19 vaccines. Steve Bates joined Roz Campion (OLS), Richard Torbett (ABPI), Stephen Ward (Cell and Gene Therapy Catapult) and Aphrodite Spanou (DIT) on a panel to discuss the delivery of the Vision, including the launch of the Life Sciences Innovative Manufacturing Fund, the importance of supporting scale up of companies, and investing in the development of a skilled workforce.

Other sessions included the support of the regulator for the Vision, how the medicines manufacturing sector is playing its part in greener healthcare, and approaches to attracting diverse talent into medicines manufacturing. The latter was covered in a panel discussion facilitated by BIA skills consultant, Dr Kate Barclay. Delegates also heard from CPI on their expanding portfolio to support innovation, including the emerging RNA vaccines/therapies; from the Cell and Gene Therapy Catapult on their programmes to help unblock the potential skills bottleneck; and finally, from Reef Capital Partners on their investment in real estate for life sciences, showcasing their recent venture in the Stevenage life sciences cluster.

The next opportunity for this community to come together will be the BIA's annual bioProcess UK conference taking place in Edinburgh in November.

Medicines regulation

Government responds to MHRA consultation on clinical trials legislative proposals

In July, the Government published its response to the Medicines and Healthcare products Regulatory Agency (MHRA) consultation on proposals to update the clinical trials legislation following the UK's departure from the European Union. Shaping the future UK legislation for clinical trials is a priority for our members. The BIA response to the consultation was developed with input from our Regulatory Affairs Advisory Committee (RAAC).

Stakeholder engagement with the consultation was high, with over 2000 respondents from across the UK and internationally. A legislative reform of the UK clinical trials regulatory framework will be taken forward to ensure patients and their safety are at the heart of the legislation for clinical trials; to create a proportionate and flexible regulatory environment; to ensure the UK is a preferred global destination to conduct clinical trials and develop innovative medicines; and to provide a framework that is streamlined, agile and responsive to innovation.

Clear guidance will be essential to help achieve the desired goal of not introducing granular legislation where best practice guidance would be more appropriate. The BIA has offered to help with the co-creation of this guidance together with the research community and patients.

Government introduces Northern Ireland Protocol Bill

On 13 June, the Government introduced the Northern Ireland Protocol Bill to Parliament, which aims to amend parts of the Northern Ireland Protocol and protect the Belfast (Good Friday) Agreement. Though the Department for Health and Social Care (DHSC) indicated to the BIA that industry does not yet need to make any changes to the way that medicines are supplied, it is important to note that the Bill gives substantive powers to ministers to make, by secondary legislation, 'any provision about regulation of goods which the Minister considers appropriate in connection with the Northern Ireland Protocol'. The Bill will also enable a 'dual regulatory' model for goods, including medicines and medical devices, to choose between UK or EU rules.

This Bill is of major concern to our member companies, given the adoption of EU legislative changes on medicines to address the supply chain challenges caused by the Protocol. This development may also impact on investment in R&D in the UK as a result of the uncertainty caused, and legal action launched by the EU against the UK Government over the Bill. The BIA will track the passing of the Bill through Parliament, though it is not expected to go through all its Parliamentary stages before the summer recess.

BIA develops Reflection Paper on regulatory reliance

The BIA developed a Reflection Paper on the role and value of reliance in the UK medicines regulatory framework with input from our Regulatory Affairs Advisory Committee (RAAC). Reliance-based regulatory procedures can be utilised across all stages of the product lifecycle. The COVID-19 pandemic has stressed the importance of reliance to address the significant workloads of regulators as well as the urgent need to deliver new and established treatments for patients globally.

The paper will make a useful contribution to our continuous dialogue and engagement with MHRA and DHSC on the future of medicine regulation for the benefits of UK life sciences and patients.

BIA welcomes MHRA re-joining the International Council for Harmonisation

On 16 June, the MHRA announced that it has joined three international partnerships to set global standards for medicines and medical devices regulation. These memberships are critical to the MHRA's international strategy post-Brexit.

The BIA is delighted to see the MHRA rejoin the International Council for Harmonisation of Technical Requirements for Pharmaceuticals (ICH) as a full sovereign member with voting rights. The MHRA also joined the International Medical Device Regulatory Forum and the Medical Device Innovation Consortium. Through these partnerships, the MHRA will share expertise with other leading organisations, support the development of regulatory guidelines and drive greater harmonisation and convergence of regulation globally.

Access to medicines

BIA continues to engage with NICE following conclusion of NICE Methods Review

Following the conclusion of the National Institute for Health and Care Excellence (NICE) Methods Review in January, BIA has continued to engage closely with NICE to achieve broader and quicker patient access to innovative medicines.

In April, General Managers of BIA's Rare Disease Industry Group (RDIG) hosted a roundtable with the new CEO of NICE, Sam Roberts. The roundtable provided an opportunity to consider how to maintain the positive working relationship that has been built between NICE and industry throughout the Methods Review. Members were keen to discuss some of the key outputs of the Review as well as the topics that are likely to feature as part of NICE's new modular approach to updating its methods and processes.

In May, the BIA's Innovative Licensing and Access Pathway (ILAP) Working Group was delighted to meet with colleagues from NICE to discuss the experience of the UK flagship initiative to date. The new Working Group is composed of a cross-committee group of members who will be involved in the development of a white paper that can inform the impact of ILAP on patient access. Members were keen to articulate what success would look like from an industry persp ective, citing the importance of reducing the gap between marketing authorisation and patient access. The whitepaper will make recommendations to improve the pathway with greater clarity and efficiency.

BIA advocates for alternative reimbursement solutions for cell and gene therapies

Following the publication of the BIA's report on the case for an innovative payment model in November 2021, the BIA has continued to advocate for alternative reimbursement solutions for Advanced Therapy Medicinal Products (ATMPs), including cell and gene therapies.

The BIA sent a letter to DHSC on this issue and was pleased to receive a written response from the Minister for Technology, Innovation and Life Sciences, Lord Kamall, in May, recognising that the procedures in place for the reimbursement of treatments must be appropriate for new and emerging technologies, including cell and gene therapies.

On 30 June, the BIA met with a representative from the NHSE Commercial Medicines Directorate at the annual BIA Parliament Day. During the meeting, members were keen to understand the Directorate's plans for coping with the large pipeline of ATMPs and there was recognition that a new approach is likely to be needed in the future.

High-level discussions about the need to adopt a new approach to ensure system preparedness are ongoing, including at the Accelerated Access Collaborative Board, on which BIA is represented.

For more information on the BIA's activities in policy and regulatory affairs, or to share feedback on this report, please contact Martin Turner, Head of Policy and Public Affairs, at mturner@bioindustry.org.

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