Influencing and shaping our sector – BIA update May – July 2021

UK BioIndustry Association

Influence, connect, save

www.bioindustry.org

Introduction

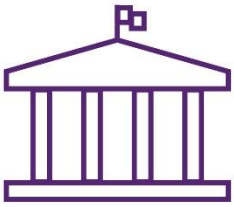
The BioIndustry Association (BIA)'s ongoing engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences sector, from May to July 2021.

The quarter was dominated by the production of the Government's new Life Sciences Vision, launched on 7 July, which the BIA has had a leading role in shaping, supported by a wide range of members who made themselves available to attend government-industry roundtables and deep-dive meetings. The BIA secured a new Life Sciences Scale-Up Taskforce and support for genomics SMEs, among other initiatives.

We published new finance data for the UK biotech sector which showed that 2021 is on track to be another record-breaking fundraising year. This will be complemented by a new £30m Biomedical Catalyst competition in 2021 following the BIA's campaign for a refill. We continued to address ongoing challenges for medicines regulation resulting from the Northern Ireland Protocol, and published an influential report on the public's support for increasing patients' access to innovative medicines for rare diseases through the NHS. Read on for more detail about this and much more.

This quarter in numbers:

15+ influence meetings with 11+ different MPs, Peers and MEPs, including 8 Ministers



8 consultation responses and briefings submitted

4 letters to Ministers

Contents

BIA engagement with the Government and Parliament on life sciences policy

The quarter has seen engagement with the Government reach a new pitch of intensity, following the announcement that it would, in partnership with industry, develop a **Life Sciences Vision.** This is the first of five sectoral visions trailed at the Spring Budget in *Build Back Better: our plan for growth*. The Life Sciences Vision builds on the Life Sciences Industrial Strategy, which is judged to have been a success - it is worth noting that ours is the only sector to have achieved two sector deals as part of the industrial strategy.

An **External Advisory Group (EAG),** co-chaired by Sir John Bell and Sir Jon Symonds of GSK, on which the BIA is represented by Steve Bates, was established in May and has met three times. This group, supported by OLS and the life sciences industry, produced a Vision with the ambition of making the UK a life sciences superpower in 10 years that was launched on 7 July.

Following publication of the high-level Vision, detailed delivery plans will be drawn up, utilizing the network of Life Sciences Council sub-Boards and Expert Groups. The Life Sciences Industrial Strategy Implementation Board (LSISIB) will be re-established to oversee implementation of the Vision. These delivery plans will feed into the **Comprehensive Spending Review** in the Autumn.

In between meetings of the EAG, the BIA has mobilised its community of experts including from the Advisory Committees and worked closely with the team at OLS on areas of key importance to the BIA. We are very pleased to see the outputs of those discussions reflected in the final text. We have held deep-dive meetings and roundtables with officials and commented on sections of the Vision, maintaining a strong focus on **SMEs** throughout.

At the first meeting of EAG, Steve Bates called for a **roundtable for growth companies** to inform the Vision, which we held on 8 June. At the next meeting of the EAG, Steve followed up on the BIA proposal for a **Life Sciences Scale-up Taskforce** which had been made to John Bell and Jon Symonds and endorsed by Business Secretary Kwasi Kwarteng at his Life Sciences Investor Roundtable. This proposal has been adopted and a consortium of UK-based financial institutions, government and life sciences organisations will form the Taskforce to write a plan by the end of 2021 to unlock capital from institutional investors.

The **Life Sciences COVID-19 Response Group (CRG)** continued its collaborative work as a ministerial virtual meeting with industry, led jointly by Department of Health and Social Care (DHSC) Life Sciences Minister, Lord Bethell and Department for Business, Energy and Industrial Strategy (BEIS)/DHSC Vaccines Minister, Nadhim Zahawi.

At the 19 April CRG meeting Steve Bates spoke about on the importance of strategic thinking in manufacturing innovation, as well as traditional lab-based R&D. In the discussion about new DHSC agencies which will replace Public Health England (PHE), he spoke about the importance of new PHE bodies being engaged with the private sector, especially in the field of data.

During the meeting Steve Bates also raised concerns about the risk that the Nagoya Protocol could hamper the ability to do research on samples from overseas with potential consequences for the world-leading work being done in the UK to identify COVID-19 variants. Lord Bethell followed up on these concerns after the meeting.

On 7 June, CRG heard from the new chair of the Anti-Viral Taskforce, Eddie Gray and Lord Bethell gave an update on plans for long term pandemic response and recovery. The CRG is supported by officials from the

Office for Life Sciences (OLS) and industry representatives in a COVID-19 Industry Group which convenes between the ministerial meetings.

At the Spring meeting of the **Life Sciences Council (LSC)** on 10 May the newly appointed Secretary of State for Business, Energy and Industrial Strategy, Kwasi Kwarteng, was welcomed to his first meeting of the Council, alongside Matt Hancock, Secretary of State for Health and Social Care**,** Innovation Minister Lord Bethell and Vaccines Minister Nadhim Zahawi. The Business Secretary led off on discussion of Innovation for Growth, giving an update on the Life Sciences Vision. Representing the BIA, Olivia Cavlan of Alchemab spoke about the role of government funding in de-risking and validating SMEs to investors, and the Biomedical Catalyst grant as a lifeline for SMEs. She called for the BMC to be re-funded for this year and future years (a call that was heeded only weeks later). Steve Bates drew attention to the BIA's quarterly finance data which shows strong investment into UK life sciences and the opportunity presented by the Life Sciences Vision to drive UK institutional investment into scaling up companies. The Council also discussed the UK operating environment and the Health Innovation Manifesto; trade and international opportunities; and COP26.

At the **Life Sciences Industrial Strategy Implementation Board (LSISIB)** on 27 April, Steve Bates presented the BIA paper proposing the onshoring of flexible biomanufacturing capabilities. Lord Bethel introduced the Pandemic Preparedness Partnership and updated on the life sciences event at the G7. The OLS presented on Life Sciences priorities for 2021 including updates on the Genomics Implementation Plan, the Clinical Research Vision, the Innovation Manifesto and the Medicines and Manufacturing Transformation Fund. The Department for International Trade gave an update on the Sovereign Investment Partnership. The LSISIB is co-chaired by Minister Zahawi and Sir John Bell.

The **Global Opportunities Board (GOB)** (formerly the EU Relationship Group – EURG) met on 1 July and discussed the progress that had been made on the Life Sciences Vision. Steve Bates highlighted the importance of the life sciences as an export industry. There was discussion of the continuing UK negotiations with the European Commission and the operation of the Northern Ireland Protocol and the importance of continued government and industry partnership. MHRA CEO June Raine and Chair Stephen Lightfoot presented the agency's International Vision. The meeting also considered Strategic Supply and Resilience and the G7.

The BIA met **Trade Minister Lord Grimstone** on 4 May to discuss the highlights from the UAE fund and Mubadala's investment criteria.

The **Accelerated Access Collaborative (AAC) Steering Group** met on 2 June. In the discussion of the Patient and Public Involvement strategy, the BIA stressed the importance of patient partners working closely with AAC industry partners, so that people with lived experience can shape research trials and inform the whole development process for new treatments and products. Other discussions at the meeting included: the AAC programme and strategy; an update from Meidnert Boysen of NICE; the Horizon Scanning Vision; Rapid Uptake Products; Digital Regulation and Reimbursement; and the Life Sciences Vision.

There was recognition in the **Queen's Birthday Honours list** for Oxford vaccine developer Professor Sarah Gilbert and former chair of the UK Vaccines Taskforce, Kate Bingham who both received damehoods. Ian McCubbin, manufacturing expert on the Vaccine Taskforce Steering Committee was appointed CBE, with Annette (Netty) England, bioprocessing consultant for the BIA appointed MBE for services to the Vaccines Taskforce.

In June, the BIA held an event together with BIVDA and ABPI for the **All-Party Parliamentary Group on Life Sciences** to look at the role therapeutics play alongside vaccines in tackling COVID-19 variants. The panel included Charlotte Taylor of the UK's Therapeutics Taskforce; Jane Osbourn, Alchemab; Richard Marsden of Synairgen; and Sharon Peacock, Chair of the COVID-19 Genomics UK Consortium.

The BIA continued to be a **voice for industry in the media,** with appearances focussing on the legacy of the UK's Vaccine Taskforce and their work to secure vaccines in the summer of 2020, in the Channel 4 documentary *Jabbed! Inside Britain's Vaccine*. Steve Bates made several appearances on Newsnight, where he made the case against the waiving of intellectual property rights for COVID-19 vaccines and instead emphasised the need for G7 countries to invest and expand global vaccine manufacturing capability, to get doses quicker to patients.

Finance, tax and investment

UK life sciences on the cusp of a golden age as £1.6 billion raised in just three months

New data from the BIA and Clarivate shows that the UK's biotech and life sciences sector is on the cusp of a golden age driven by strong demand from global investors for UK innovation, with £1.56bn invested in the last quarter (March 2021 – May 2021). This is the highest total amount ever recorded for a quarter since the trade association began recording this data.

The stellar performance means £2.39bn has been raised in the year to date, compared to £2.81bn in the whole of 2020, which itself was a record year for investment.

Breakdown of investments:

- £1,068m was raised in venture capital by UK biotech and life science companies
- There were thirteen deals worth over £20m, including four over £100m
- UK companies accounted for 60% of the total biotech venture capital invested in Europe
- £431m was raised through three NASDAQ IPOs and £58m in follow-on public financings

Steve Bates said: "Biotech and life science companies have demonstrated their value in the greatest global public health crisis of recent times by finding the vaccines, therapies and diagnostics needed to end the COVID-19 pandemic. The sector will be crucial in addressing future healthcare needs as well as being a crucial economic driver as the UK economy builds back from the impact of the pandemic."

The Secretary of State for Business, Energy and Industrial Strategy tweeted his support for the BIA's finance update.

Biomedical Catalyst for 2021 secured by BIA

On 18 May, the Government announced that £18m will be invested in innovative UK life science companies through a relaunched Innovate UK Biomedical Catalyst competition.

The news follows a major campaign by the BIA to secure fresh funding for the programme. In addition to the £18m competition that opened for applications on 7 June, the BIA understands a second round is planned for the Autumn focused on feasibility and proof of concept studies, bringing the 2021 Biomedical Catalyst total value to £30m.

BIA presses HM Treasury for more support for the sector ahead of the Spending Review

Ahead of the upcoming Comprehensive Spending Review (CSR) the BIA held a private meeting on 6 July with key officials from HM Treasury and representatives from member companies Autolus and Alchemab to put forward our recommendations for the Treasury to strengthen and support the life sciences sector.

Highlighting the effectiveness of government grants, particularly forn SMEs in the life science sector, the BIA pressed for the refilling and long-term funding of the Biomedical Catalyst ,along with an increase in funding for Innovate UK, and urged the Government to double down on efforts to increase access to scale-up capital. As part of a broader campaign over the summer ahead of the CSR, the BIA will be preparing a new report that will make additional recommendations and emphasise the successes in the sector enabled by government support.

'Undertaking in Difficulty' scrapped in new UK subsidy control regime following BIA campaign

In late June the Government published its planned legislation for the UK's new subsidy control regime (previously known as State aid), which will govern support for our sector, such as Innovate UK grants and R&D tax credits. The new regime will not include the EU's State aid rule known as Undertakings in Difficulty, which the BIA has campaigned for the UK not to use now that it has left the EU.

The BIA's Finance and Tax Advisory Committee is now looking in detail at the proposed new rule that is intended to identify ailing companies that should not receive State subsidies and will engage with the legislation as it passes through Parliament.

BIA supports UK life science companies and investors with National Security and Investment Act

The National Security and Investment Act became law on 29 April, with the BIA working with Parliamentarians to scrutinise the Bill through its Parliamentary passage. Since then, we have been working with Ministers and civil servants refining the sector definitions under this new regime, focusing on the definition of Synthetic Biology, which the BIA has been lobbying to narrow further to limit the impact on the life sciences sector. BEIS has consulted the BIA regularly through our appointment to its **Expert Panel** on the guidance being developed to help companies navigate the new regime, and the operation of the new notification system.

Supporting our members in adapting their business practices to comply with the new investment regime, we launched a new resource hub on our website which includes a resource repository of literature and guidance related to the new regime, an overview of the regime and how it will work in practice, and an FAQs page.

To ensure businesses and investors are aware of their obligations under the new regime, we presented at the Anglonordic Life Sciences Conference to explain how the new regime will work and answer questions

from attendees. We also held a workshop at our Life Sciences Leadership Summit on 28 June, where we were joined by Jacqui Ward, Director of National Security and Investment at BEIS; Katherine Kingsbury, associate at Covington & Burling LLP; and Kate O'Brien, Head of Legal at Oxford Sciences Innovation. This session was an opportunity for BIA members to hear from key individuals operating the regime and working with companies going through the process, as well as to have their views on the new arrangements heard and their questions answered by a government official.

Government consultations seek to improve R&D tax credits and EMI share options

In March, the Treasury launched two important consultations for our sector, both of which sought to improve the functioning of tax incentives that support R&D-intensive SMEs.

The first was a wide-ranging review R&D tax reliefs. Notably, it specifically explored the possibility of including data and cloud computing costs within the relief regime, as well as capital expenditure, all of which the BIA has campaigned for. But it also sought views on merging the SME and large company schemes. In our response, we recommended maintaining the current structure of the SME and Research and Development Expenditure Credit (RDEC) regimes, including maintaining the alignment of the SME regime to the life sciences business model where essential aspects of R&D need to be contracted out.

The BIA also responded to the call for evidence on Enterprise Management Incentive (EMI) share options.In our submission, we recommend increasing the limits on eligibility criteria that prevent some SMEs from properly benefitting from the scheme. We also said that in the event of any changes to Capital Gains Tax rate or Business Asset Disposal Relief, the tax benefits of the EMI scheme should be retained, but the Knowledge Intensive Company definition could be used to better target the scheme and reduce costs to the taxpayer.

Strategic technologies and areas of scientific focus

SMEs championed as the key drivers of the genomics industry by the BIA

On 19 May, the Government launched the Genome UK implementation plan for 2021/22 to build on *Genome UK: the future of healthcare strategy*, its vision published in 2020 to create the most advanced genomic healthcare system in the world. The BIA welcomed the Government's commitment to a series of actions to build on our global competitive advantage, emphasising the important role SMEs play in the delivery of the vision as the key drivers of the genomic industry's growth. Through our seat on the National Genomics Board, the BIA is working closely with the Government to make the UK the most attractive location globally for genomic start-ups and SMEs.

MPs back BIA's call for better regulation of direct-to-consumer genomic testing

The House of Commons Science and Technology Select Committee has supported the BIA's recommendation to establish regulatory standards for direct-to-consumer (DTC) genomic testing so that both patients wishing to have these tests and health services can be confident that commercial tests are clinically accurate and of a high value.

Submitting evidence to the committee's inquiry into DTC genomic testing, the BIA used this as an opportunity to highlight the successes of the UK's genomic capability and make a series of recommendations to further bolster research, innovation and commercialisation in the sector. Whilst this inquiry did not look at the UK's genomic landscape more broadly, the report did echo the BIA's recommendation that the UK Government should continue to support genomics.

BIA urges the Government to provide clear and pragmatic guidance on the Nagoya Protocol

In an informal consultation with the Department for Environment, Food and Rural Affairs (Defra), the BIA has urged the Government to improve upon the EU guidance for the Access and Benefit Sharing Regulation and Nagoya Protocol, which the BIA holds to be an incorrect interpretation of the obligations, as it develops the UK guidance. The BIA's sub-committee on access and benefit sharing is leading on the ongoing engagement.

The BIA has also been working to ensure members are aware of their obligations, which the Government is actively enforcing.

Steve Bates raised concerns about the risk that the Nagoya Protocol could hamper the ability to do research on COVID-19 samples from overseas with potential consequences for the world-leading work being done in the UK to identify variants with Health Minister, Lord Bethell..

People, skills and talent

BIA Skills Working Party gets to work

Under the leadership of Oliver Hardwick and Charlotte Casebourne the BIA's new Skills Working Party, founded in February 2021, has been key in engaging companies and influencing skills policy, highlighting important areas of concern, including development of technical expertise and commercial talent for organisational success.

Over the second quarter of 2021, successes include: launch of the new skills website to connect BIA members with key skills policy; delivery of monthly leadership webinars to our BIA LeaP early career leaders community learning from key entrepreneurs in the sector; leading skills panel discussions at the annual Medicines Manufacturing Industry Partnership conference, recognising the role BIA is playing in shaping the skills landscape in the UK; and leading important conversations on equality, diversity and inclusion across the medicines manufacturing community, as a founding member of UKRI ED&I focus group.

BIA submits evidence to MAC call on intra-company visa system

At the end of 2020, the Home Secretary asked the Migration Advisory Committee (MAC) for a report on the Intra-Company transfer (ICT) immigration route. ICT currently exists alongside the skilled worked route to facilitate UK employers in moving existing senior employees and specialists from offices overseas to roles in the UK. There are some significant differences between the routes, and it is several years since a review was completed on ICT, so it is not in line with the new points-based immigration system launched in January 2021.

BIA responded to the call for evidence, launched 23 March, following engagement with member organisations. We highlighted the importance of the visa route for senior staff in particular and also problems with the clarity of requirements. MAC is due to report back to the Government in October 2021.

Official launch of the UK-wide Advanced Therapy National Training Centres

The BIA attended the official launch of the National Training Centres (NTCs) which took place at a special event with representatives from the three centres: National Horizons Centre; RoslinCT and their training partners; and the University of Birmingham.

Held as a blended event at the National Horizons Centre in Darlington and online, attendees heard how these NTCs bring a wealth of experience across manufacturing, bioprocessing and immersive training technologies which address the growing need in the UK for specialist skills in vaccine and advanced therapy manufacturing. This initiative was built on a foundation of industry collaboration and backed by £4.7m in funding from BEIS through UK Research and Innovation (UKRI). The ATSTN programme will help grow the sector by creating economic opportunities for new jobs and industry-driven learning.

Intellectual property and technology transfer

BIA works with UK Government and international coalition to improve vaccine equity and protect IP

Following the announcement by the US Government in support of proposals to waive IP protections for COVID-19 on 5 May, the BIA attended a quickly-convened industry roundtable with the International Trade Secretary, Liz Truss, on 7 May. The BIA stressed the importance of increasing vaccine supply through voluntary licencing and collaborations – the fastest way to get more people vaccinated – rather than attacking IP protections, and appeared on BBC's Newsnight twice to explain this position.

Steve Bates also chaired an emergency Board meeting of the International Council of Biotech Associations (ICBA) on what more the life sciences sector could do to help the global vaccination effort. Continuing to work with global colleagues, the BIA supported ICBA in a joint letter to champion the importance of protecting IP, with CEOs of 50 UK biotech companies joining the long list of signatories from across the world.

BIA guide to the SPC manufacturing waiver updated

The BIA's IP Advisory Committee (IPAC) has published an updated guide to the Supplementary Protection Certificate (SPC) manufacturing waiver, which came into force on 1 July 2019 but was amended in UK law following the UK's departure from the EU.

In August 2019, the Government consulted to amend the law for the SPC waiver to permit the production of SPC-protected medicinal products for export to the EU, which the innovative life sciences industry objected to on the grounds that it could erode their IP rights in some EU Member States. Following the BIA's formal response and meetings between members of IPAC and officials, the Government changed its approach to restrict the export market under the making for export waiver to countries outside the EU and UK.

The updated guide will help companies assess what the impact of the waiver might be on their business and how to protect their IP rights.

Pre-clinical and clinical research

BIA discusses proposed legislative changes to clinical trial regulations with MHRA

In May, the BIA and member company representatives on the Regulatory Affairs Advisory Committee (RAAC) participated in two engagement sessions with MHRA and Health Research Authority (HRA) officials to discuss the legislative changes to clinical trial regulations that are being proposed under the Medicines and Medical Devices (MMD) Act 2021. The Act gained Royal Assent in February and provides the MHRA with the opportunity to design a regulatory environment for clinical trials that will support the development of innovative medicines and ensure that the UK remains a favourable base for life sciences, in line with the Government's future of clinical research vision.

The proposals are informed by global best practice and will support international harmonisation of trials to minimise burdens for multinational trials. The proposed changes also aim to align with the EU Clinical Trials Regulation (CTR) where that makes sense, and to streamline processes that will support quicker timelines for overall trial approvals. This was supported by BIA representatives, noting that alignment with CTR was desirable to conduct clinical trials in the EU and UK, and that it was important not to raise any additional requirements or have different requirements from other jurisdictions.

Members who wish to contribute to the BIA submission to the public consultation which is expected to be issued over the summer should contact Dr Christiane Abouzeid (cabouzeid@bioindsutry.org).

BIA input into Life Sciences Vision on regulation and clinical research

In June, the BIA gave feedback on the proposed ambitions for the regulatory environment and the future of clinical research delivery for inclusion in the Life Sciences Vision.

The regulation section has taken on board our contributions to the OLS-MHRA workshops on the future of regulation which were held last summer; in particular, the need to support innovation, to have a joined up regulatory and access approval system, international leadership and ensuring international standards are maintained. Companies will continue to invest in R&D if the UK provides value to their global strategy. The BIA supports the Vision's ambition for the clinical research environment to maintain the UK's world leading position but also increase the capacity for trial conduct and patient recruitment.

We also highlighted the resources needed to support this. Significant investment will be required across MHRA, NICE and other partner organisations to ensure success.

Concordat on openness in animal research annual BIA progress update

In early June the Concordat on Openness in Animal Research held its annual review, with the BIA submitting an update on its progress on the commitments to enhance animal research communications, as a signatory of the Declaration on Openness in Animal Research. The BIA proactively shares information publicly about animal research news and plans trips for staff to visit animal facilities to better understand the important role animals play in research. In addition, we have shared the news of positive preclinical trials for COVID-19 vaccines and therapeutics and the important role animals played in this.

Manufacturing

BIA continues to provide advice and support to the Vaccines Taskforce

The UK government has appointed Sir Richard Sykes as the new chair of the Vaccine Taskforce. Sir Richard will use his extensive experience in biotechnology and pharmaceuticals to lead the significant programme of work to find, procure and deliver vaccines to support the largest vaccination programme in British history, which continues at unprecedented pace. This includes helping with preparations for any potential booster programmes and working to make the UK a global centre of excellence for the next generation of vaccines.

The BIA continues to support the Vaccines Taskforce through the Expert Advisory Group, assisting with the ongoing delivery of new vaccines such as Novavax, Valneva, Janssen and CureVac; helping to develop a national capability for manufacturing and vaccine formulation and delivery; and supporting manufacturing onshoring work.

As part of this onshoring work, in June the Government conducted a pre-market engagement exercise to help them develop a strategy to strengthen the UK's onshore capacity and capability in vaccine development, manufacturing and supply chain to provide resilience for this and future pandemics. Thanks are due to all BIA members who contributed. We will continue to monitor and share next steps.

MMIP Conference

The Medicines Manufacturing Industry Partnership (MMIP) annual conference took place online in June. Vaccines Deployment Minister Nadhim Zahawi kicked off the event talking about the importance of medicines manufacturing in the Government's Life Sciences Vision and set out the Government's commitment to support a sustainable UK sector.

Ian McCubbin OBE of the Vaccine Taskforce and colleagues presented the practical lessons from their experience in the pandemic, where the 'holy trinity' of academia, industry and government in close collaboration allowed the UK to punch well above its weight on COVID-19 vaccines.

Mary Jones of the Office for Life Sciences shared the Government's intention to move forward with the Life Sciences Vision and Medicines Manufacturing Strategy to improve the health, wealth and resilience of the UK. With the development of a skilled workforce a key theme in the strategy, it was good to hear once again from apprentices on the skills panel. The final session on delivering an adaptable and scalable ecosystem saw Martin Wallace from GSK set out the grand challenges for future innovation in manufacturing.
A recording of the event is available to download, and the next MMIP update will take place at BIA's bioProcessUK conference in Cardiff in November, with registration going live shortly.

Medicines regulation

BIA continues to engage with Government on NI protocol implementation

The BIA has continued working closely with DHSC and MHRA to ensure continuity of supply of medicines from Great Britain to Northern Ireland. We understand that the UK has received a proposal from the European Commission in June. This may involve the EU changing its own rules so that regulatory compliance functions for medicines authorised by the UK regulators for the Northern Ireland market may be located in Great Britain, subject to specific conditions that these medicines are not further distributed in the EU Internal Market.

The BIA welcomes this important development, which, if confirmed, would provide a practical solution to an outstanding challenge and ensure the continued long-term supply of medicines to Northern Ireland. The UK Government is currently analysing the Commission's proposal, and we hope that a suitable agreement can be reached soon.

Innovative regulatory milestone for MHRA issuing its first authorisation under Project Orbis and joining ICH

The BIA welcomed the MHRA granting its first authorisation under the Project Orbis scheme since joining in January 2021. This international collaboration with global regulatory authorities, including the US FDA, Australia's Therapeutic Goods Administration, Health Canada, Singapore's Health Sciences Authority, Swissmedic and Brazil's ANVISA, signals the flexibility enabled by the UK's departure from the EU and aims to deliver faster patient access to innovative cancer treatments.

The BIA was also pleased that the MHRA joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as an ICH Observer, paving the way to apply for ICH membership. ICH brings together regulatory authorities and the pharmaceutical industry around the world to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines. It now includes 18 Members and 33 Observers.

BIA joins EuropaBio-EMA bilateral meeting

On 5 May, Christiane Abouzeid, as Chair of EuropaBio's Regulatory Policy Working Group, participated in the EMA-EuropaBio bilateral meeting. After an introduction by EuropaBio on the biotechnology pipeline and key trends, there was a good exchange with MHRA senior officials led by EMA Executive Director Emer Cooke on a range of topics including:

- more global convergence between regulators through the International Coalition of Medicines Regulatory Authorities (ICMRA)
- OPEN pilot for international collaboration on COVID-19 treatments and vaccines
- future collaboration with MHRA
- innovative clinical trial designs, decentralised trials

Access to medicines

Ongoing contribution to the NICE Methods Review

The NICE Methods Review advanced into its latest phase following its consultation on the process guide and the Highly Specialised Technology (HST) programme. We have continued to support our representatives from the BIA Rare Disease Industry Group (RDIG) sitting on the both the Working Group and the two task and finish groups on the process guide and benefits realisation. In addition, NICE convened a workshop to discuss its proposal for the HST programme in more detail, recognising the feedback from across industry and patient group stakeholders that the original proposals were insufficient. The discussion was productive, and we look forward to seeing the feedback from attendees incorporated in future versions.

The BIA also contributed to the launch of NICE's interim statement on commercial and managed access, which sets out its role in commercial negotiations pending the finalisation of the NICE Methods and Process guide, which is expected to published for consultation later this summer. We will be working with RDIG members and other BIA members to respond.

BIA study finds strong public support for equal access to rare disease medicines

The BIA published Public attitudes to Rare Diseases: The case for equal access in June, which presents the findings of a survey commissioned by the BIA on public attitudes towards rare diseases and access to medicine.

The survey, conducted by YouGov, revealed that the public strongly believe that patients living with a rare disease should be able to access medicines through the NHS on the same basis as people living with more common conditions. Further, the majority agreed that the NHS should ensure access on the basis of clinical need to these patients, even if it would be more costly to the NHS. The findings follow recent assertions made by NICE during a review of their methods and processes that there isn't appetite or interest among the general public for specific measures to tackle rarity as an issue.

The key findings include:

- 79% of respondents agreed that patients living with a rare disease should be able to access medicines on the same basis as people living with more common conditions.
- 78% of respondents agreed that the NHS should ensure access on the basis of clinical need even if this would be more costly to the NHS.
- 46% agreed that the cost threshold for medicines for rare diseases should be raised to ensure equitable access to medicines for all.

The report recommends that NICE revise their position on this issue and considers the value of a rarity modifier as part of the HTA process to people with rare diseases and the general public.

The report was covered in Politico and in the specialist press and was also sent to all MPs. We are continuing to follow up with Parliamentarians and have secured a number of meetings to discuss the findings of the report.

BIA hosts roundtable on patient values and access to rare disease medicines

As part of its ongoing commitment to raise awareness of the impact of rare diseases on patients and carers, the RDIG hosted a roundtable with a range of patient groups in the rare disease community.

The roundtable facilitated an important discussion around the value of rare disease medicines to the patient community and how RDIG can continue to engage with NICE through their Methods Review to overcome the key barriers patients face in accessing these innovative medicines. The event provided the BIA with invaluable insight into patient's key priorities and concerns that will inform RDIG's work going forward.

The event was also successful in securing buy-in from patient groups on the need for NICE to adopt specific considerations to address rarity in its HTA processes as recommended in the BIA's report *A Rare Chance for Reform*.

BIA joins the Rare Disease Forum

The BIA is pleased to have accepted an invitation to join the UK Rare Disease Forum as an industry representative. The Forum was set up by the DHSC following the publication of the UK Strategy for Rare Diseases in 2013 to monitor the strategy's implementation. The Forum now monitors the implementation of the UK Rare Disease Framework and is also tasked with supporting the development of the action plan for England.

As a member of the Forum, the BIA will be able to provide industry perspective to the biennial report to Ministers, ensuring it represents the views of both patients and industry. In addition, the BIA will contribute to the development of policy through participation in issue-focused task and finish groups.

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.

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

www.bioindustry.org

BIA Supporters

AstraZeneca

cytiva

Deloitte.

Gallagher
Insurance | Risk Management | Consulting

BIA
UK BioIndustry Association

Johnson & Johnson
INNOVATION

LifeArc

avantor™
delivered by VWR™