

Influencing and shaping our sector

October 2023 - January 2024

INTRODUCTION

The BioIndustry Association (BIA) continued to represent the innovative life science sector to Ministers and senior policymakers between October 2023 and January 2024. This quarterly report provides an overview of these engagements.

The Prime Minister's reshuffle in November presented a new ministerial team whom we can expect to take the Conservative Party into the next general election. Remaining at the Exchequer was Jeremy Hunt, whose Autumn Statement in November brought a raft of measures to support our sector, many of which the BIA has been advocating for years.

The BIA continued to set the policy agenda this quarter with new reports on genomics, rare disease treatments, and cell and gene therapies: three emerging sectors powered by UK innovation.



6 consultation responses and briefings submitted



5+ engagement meetings with 8 parliamentarians, incl. 6 ministers

Never attached to our keyboards for long, we also made our influence felt at numerous events this quarter. From internal events like TechBio UK and bioProcess UK to meetings with the Office for Life Sciences, Intellectual Property Office, and MHRA, we at the BIA were out and about making the voice of the innovative life sciences heard.



8 letters to ministers

We are in the process of reforming this report to ensure it is as useful as can be, so look out for some minor changes this quarter.

Read on for further details of all the BIA's important influencing work on behalf of the sector across our key policy areas.

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Engagement with the Government and Parliament on life sciences policy

A **reshuffle in November** brought a new set of ministers for the BIA to engage with. Victoria Atkins moved from the Treasury to become Secretary of State for Health and Social Care, and Andrew Griffiths also departed the Treasury to become Minister for Science, Research and Innovation. Both were already well known to the BIA, having worked closely with the association on R&D tax relief reforms and the rescue of Silicon Valley Bank respectively. Victoria gave BIA CEO Steve Bates a warm welcome at the Life Sciences Council on 21 November. Andrew has been in close contact with us since taking up his new role and is due to speak at the upcoming BIA Gala Dinner on 25 January.



New Science Minister Andrew Griffith MP visiting bit.bio in Cambridge in December. [@griffitha](#)

Science Secretary Michelle Donelan remained in her role following the reshuffle and the BIA attended a lunch with other leading science and technology organisations to discuss with her how the government could improve the business environment. The BIA also joined Shadow Chancellor Rachel Reeves and Shadow Science Secretary Peter Kyle for a breakfast alongside other life science SMEs and investors, providing an excellent opportunity to influence Labour's policy platform, especially on R&D tax relief and pensions investment. The BIA's [Guide to the Government](#) details all of the key ministers following the Prime Minister's reshuffle, as well as shadow ministers.

BIA members were represented at the **Life Sciences Council** by Steve Bates and Kylie Bromley, UK GM at Biogen and member of the BIA's Rare Disease Industry Group. Steve emphasised to ministers and officials around the table that global boardrooms are watching the UK and that the government must have a clear message and demonstrate its progress in implementing the [Life Sciences Vision](#). Kylie expressed concern that UK patients suffering from rare conditions could be missing out on

innovative treatments. The meeting also addressed the NHS Data for R&D programme, with industry raising concerns about the lack of progress.

The BIA also attended the **party conferences** of Labour, the Conservatives and the Liberal Democrats in September and early October. All three events provided excellent opportunity for the BIA to engage with key parliamentarians and policymakers in the run-up to the general election widely expected to fall later this year. The BIA held panel events at the Labour and Conservatives conferences. These panels put innovative companies applying biotech to sustainability challenges in the spotlight and provided a forum for industry and policymakers to discuss how these companies could be supported to grow in the UK and deliver their world-changing innovation.

The **All-Party Parliamentary Group (APPG) for Life Sciences** also saw good engagement at its Q4 event on 'UK leadership in tackling antimicrobial resistance (AMR)'. Run jointly with the ABPI and BIVDA, the event provided a forum for tackling this important but underdiscussed topic. Industry representatives, senior leaders from the AMR Action Fund, and Parliamentarians including Shadow Science Minister Chi Onwurah MP and former Health Minister Will Quince MP joined the discussion, agreeing that the UK could play a key global leadership role on AMR.



Will Quince MP and Maggie Throup MP attending the APPG for Life Science's Q4 roundtable on AMR in November. [Will Quince](#).

Finance, tax and investment

Autumn Statement delivers large package of support for life sciences in BIA priority areas

On 22 November, the Chancellor delivered a comprehensive package of investment and support for the UK life sciences industry in his [Autumn Statement](#).

Key announcements by the Treasury spanned the BIA's policy remit, including:

- £520 million in capital grants available for medicine manufacturing that will enable the UK to compete to be the home for next-generation technologies like mRNA and CRISPR.
- Further pension reforms to unlock investment, £50 million for the Future Fund: Breakthrough, and a new VC Fellowship scheme to train the next generation of investors.
- Decreasing the threshold for **the** R&D-intensive SME tax credit from 40% to 30% and introducing flexibility. There will also be no restrictions claims for grant-funded R&D projects.
- Accepting the recommendations of the spin-out review to increase the pace, quality and success of companies coming from UK universities.
- New investment zones, demonstrating the importance of life sciences to the economy across the country.

Steve Bates OBE, CEO of the BIA welcomed the announcements, saying:

‘Life science spin-outs, start-ups and scale-ups are key drivers of the UK’s innovation-based economy and crucial for discovering and developing new medicines to save lives in the NHS. Today’s Autumn Statement by the Chancellor has announced a significant package of investment and support to help turbocharge this innovative industry in the UK.’

BIA’s calls for greater flexibility in R&D tax relief answered in Autumn Statement

Throughout the past quarter, in the run-up to the Autumn Statement, BIA has been engaging heavily across government and parliament to influence the development of the new R&D tax relief regimes.

The Chair of the BIA’s Finance and Tax Committee (FTAC) Colin Hailey [gave evidence](#) to the House of Lords’ Finance Bill Sub-Committee in November. This was an important opportunity ahead of the Autumn Statement to ensure the voice of BIA members was heard at the highest levels, and Colin addressed key issues including rules on sub-contracting, overseas expenditure, and the flexibility of the scheme. On this last point, Colin argued for a ‘period of grace’, allowing companies to remain eligible to claim through the scheme in the event that their R&D intensity drops below the threshold for a single year. This policy was introduced at the Autumn Statement.

The Autumn Statement introduced the grace period and reduced the R&D intensity threshold from 40% down to 30% from April 2024 onwards, increasing the number of innovative companies that are eligible for the enhanced relief rate. Companies will also remain eligible if their R&D intensity drops below the threshold for a single year, providing continuity. This is welcome flexibility that the BIA has called for, as one-off large non-R&D costs can inadvertently hit life science companies.

Following the Statement, the [Autumn Finance Bill 2023](#) was published to give effect to these announcements. The BIA, via FTAC's R&D Sub-Committee, is continuing to work closely with HM Treasury and HMRC to ensure detailed guidance is published urgently, providing certainty for life sciences SMEs so that they can effectively plan and forecast their finances. Guidance on subcontracting and overseas expenditure have been areas of particular focus for the Committee.

The Treasury also confirmed that it will go ahead with a new merged R&D tax relief scheme, which will run alongside the R&D-intensive scheme, ending Government's long-running review. Read this [BIA blog](#) for a rundown of the key features of both regimes.

More recommendations from BIA's Life Sciences Scale-Up Taskforce adopted by government

Momentum continues to build following the Mansion House Compact and the VC Investment Compact, with a large package of reforms published alongside the Autumn Statement in November aiming to help deliver better returns for savers and boost economic growth.

Chief amongst these, the Chancellor announced a [new Growth Fund run by the British Business Bank](#) to facilitate pension fund access to investment opportunities in the UK's most promising businesses. This was a recommendation of the Scale-Up Taskforce and something the BIA has advocated for over a number of years, on the basis that co-investment alongside the government and expert investors will allow pension funds to invest with confidence in the most innovative companies. Further policies to unlock investment with £50 million for the [Future Fund: Breakthrough](#) and a new VC Fellowship scheme to train the next generation of investors completed the package of announcements. Originally proposed by the Life Sciences Scale-Up Taskforce, which the BIA led with the Office for Life Sciences, a fellowship programme will provide structured support for mid-career level VCs, enabling them to share best practice and build the community, similar to the successful Kauffman Fellowship in the US.

It was also confirmed that £250 million would be allocated to the winners of the Long-term Investment For Technology and Science (LIFTS) competition, launched at Autumn Statement 2022 and run by the BBB. This competition invited pension funds and venture capital firms to form consortiums and bid for £250 million to unlock new investment from pension funds into innovative tech and science companies. The BIA supported Dan Mahony as BIA Chair and Life Science Investment Envoy in providing [detailed feedback](#).

BIA convenes investors for an audience with CEO of British Patient Capital in preparation for next phase of pension funds deployment

In December, the BIA supported Chair and UK Government Life Sciences Investment Envoy Dr Dan Mahony in hosting a lunch discussion with key members of the UK's life sciences investment community at the Royal Society of Medicine. Following the announcement of the [Venture Capital Investment Compact](#), which saw 20 leading VC firms commit to working to boost pension fund investment in high-growth companies, this was an opportunity to continue the fruitful discussions begun in September. Attendees heard from Catherine Lewis La Torre, outgoing CEO of British Patient Capital, who shared her reflections on her time at BPC, and on the opportunities and challenges for our sector. All raised a glass to Catherine, and thanked her for the tireless role she has played in [supporting our ecosystem over the last seven years](#).

Genomics, data & AI

Genomics Nation report takes the pulse of a growing sector

The BIA [published](#) Genomics Nation 2023 in December in collaboration with the Wellcome Sanger Institute and Medicines Discovery Catapult. The report analyses the various types of genomic companies currently operating in the UK and considers the ways they interact with national research and data assets. Examples include data assets such as the British BioBank, Our Future Health, Genomics England, and the network of Secure Data Environments ([SDEs](#)), in addition to academia, investors, and the NHS. The report also considers the SDE network currently being built in England and what this means for genomic companies looking to access this data.

Genomics Nation also delves into collaboration between genomic companies and the different parts of the ecosystem, often using data and AI, and the success stories that have emerged from these collaborations. Sixteen UK genomic companies are showcased, highlighting the cutting-edge collaborations that have taken place within the ecosystem and the positive health outcomes they have generated. Please contact Senior Policy and Public Affairs Manager [Dr Emma Lawrence](#) if you have any questions about the BIA's work on genomics.

BIA amends Value Sharing Framework on access to health data

The BIA has worked with the ABPI and the ABHI to amend the NHS's Value Sharing Framework, which sets out the commercial principles that should be applied when the NHS works with commercial partners who want to access its data. In our contributions, the BIA sought to clarify the kinds of commercial models that could best be applied and to remove references to commercial arrangements that would be unfeasible for companies. [A new iteration of the framework](#) is now available via the NHS website.

BIA contributes to two OLS workshops on the future of genomics

The BIA was invited to attend two workshops run by the Office for Life Sciences (OLS) this quarter. The first, regarding the future of genomic databases focused on ownership of genomic data, how it might evolve over the next few years, and what the implications might be. The discussions also touched upon the gaps in genomic data currently being held, how we can ensure there is diversity of genomic data and accurate representation of the diversity of the UK population.

The second workshop focused on identifying high-level metrics to monitor the 3-year [Genome UK](#) implementation plan. Genome UK is a UK-wide, decade-long plan to create the most advanced genomics healthcare system in the world. The [implementation plan](#) is specific to England and covers the period 2022-2025. OLS intend to have a template for a 'baseline report' around Winter 2023/24

BIA members helped OLS find metrics to measure the level of testing activity within the NHS, to ensure patients are getting definitive diagnoses. BIA members also suggested metrics to measure the volume of genomic research using data in UK assets and ensuring the public and patients are offered opportunities to be involved in genomic and clinical research.

Cell & gene therapies

BIA report highlights the strength of the UK cell and gene therapy sector

In January, the BIA published a [report](#), in collaboration with Citeline, which presented new data showing the strength of the UK cell and gene therapy sector. The report shows that UK companies are continuing to attract significant investment, having secured 55% of Europe's cell and gene therapy VC funding in 2023. The data also demonstrates that the UK is the leading destination in Europe for clinical trials in cell and gene therapy, with 84 drugs currently in clinical development. Additionally, the report presents a series of case studies on the UK companies driving innovation in this space. These include Orchard Therapeutics, a spinout from UCL whose gene therapy for the treatment of the rare inherited disease metachromatic leukodystrophy (MLD) is now being used to treat newborns in the NHS.

The BIA's report also acknowledges some of the challenges facing companies in the cell and gene therapy sector, including ensuring sustainable patient access, attracting skilled talent, manufacturing at scale, and accessing sufficient capital. These challenges are not unique to the UK, and the BIA is engaged in a number of initiatives to address them. To find out more about the BIA's work in the cell and gene therapy space, please contact Policy and Public Affairs Manager [Rosie Lindup](#).

Engineering biology

BIA submits views on precision bred organisms for food and feed to the FSA

In January 2024, the BIA responded to the Food Standards Authority's (FSA) [consultation](#) on proposals for a new framework in England for the regulation of precision bred organisms (PBOs) used for food and animal feed. The aim of the consultation is to establish a regulatory framework under the [Genetic Technology \(Precision Breeding\) Act 2023](#), which passed in March 2023, allowing products derived from precision breeding to be sold in the UK.

The BIA has engaged with the government throughout the lifecycle of this legislation, including the Department of Environment, Food and Rural Affairs' (Defra's) 2021 [consultation](#) on the regulation of genetic technologies, which informed the development of the Act.

The BIA [supports](#) the intentions of the precision breeding act and welcomes the FSA's consultation. Gene editing can help society tackle environmental challenges and enable the transition towards a sustainable bioeconomy. In order to transform and sustainably grow the economy through scientific and technological progress, the UK needs an innovation-friendly regulatory framework that enables the biotechnology industry. Critical to this is having a framework that fosters commercialisation by regulating the product instead of the process of its creation.

To get involved with the BIA's work in this area, please contact Senior Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA calls for pro-innovation regulatory landscape for life sciences and biotech

The BIA [has responded](#) to the Department for Business and Trade's [call for evidence](#) on smarter regulation and the regulatory landscape, highlighting that the life sciences and biotech sector, with applications in health and beyond, including food and the environment, has extensive interactions with many regulators.

We raised concerns that divergence from international regulatory regimes, constantly changing regulatory requirements, and resourcing issues within regulators have negatively impacted industry and the UK as an investment destination. Regulation can have significant impact on innovation and innovative businesses, we said, and government and regulators have on occasion shown a lack of appreciation for the interlink of regulation and innovation, resulting in unintended negative consequences.

The BIA also met with the Government's Regulatory Horizons Council, which is currently conducting a review of regulation for engineering biology. We discussed the principles and approach regulators should take when interacting with innovative new sectors and technologies, and the specific challenges surrounding the regulation of genetic resources under the Nagoya Protocol as well as future challenges regarding digital sequence information.

BIA joins bilateral discussion on UK-South Korea opportunities in engineering biology

In October, the BIA joined a UK-South Korea dialogue on technology security and international cooperation in Seoul. Representatives from across the UK's Department for Science, Innovation and

Technology (DSIT), Department for Business and Trade (DBT), and Foreign and Commonwealth Development Office (FCDO) met with South Korean ministerial officials to discuss existing and emerging technology areas of cooperation between the two countries, including quantum, AI, semiconductors, telecommunications, and engineering biology.

The BIA accompanied colleagues from DSIT to present on the UK's engineering biology sector and discuss opportunities for stronger collaboration between the two countries, as well as shared challenges.

A few weeks later in November, the South Korean President Yoon Suk Yeol, joined by his Science Minister Lee Jong-ho, made a [state visit](#) to the UK to cement closer collaboration and trade between the two countries.

Intellectual property and technology transfer

IPO and BIA meet in bilateral to discuss series of life sciences IP developments

In November, the BIA held a bilateral meeting with the UK Intellectual Property Office (IPO) to discuss a series of IP policy developments pertinent to the life sciences sector.

Topics covered during the meeting included the IPO's current development of a code of practice on copyright and AI in the context of Text and Data Mining (TDM), how SPC term duration is calculated in the UK, the EU's proposal on compulsory licensing in crisis management, and ongoing discussions at the World Intellectual Property Office (WIPO) on implementing a disclosure requirement for the source of genetic resources in patent applications.

The BIA has engaged with the IPO on all four topics over the past few years and will continue to do so over the coming months as the code of practice will be published, SPC regulations are being reviewed, and WIPO moves towards a diplomatic conference in May 2024.

BIA meet with DBT to discuss WHO pandemic accord

The UK Government continues to engage in negotiations for an [international treaty on pandemic preparedness, prevention and response](#) at the World Health Organisation (WHO). After sharing a [position statement](#) with the UK Department for Business and Trade (DBT) and the Department for Health and Social Care (DHSC), the BIA met with both departments in November.

We reiterated the importance of IP in the life sciences, including the role of strong IP rights in enabling technology transfer and the sharing of know-how. We warned of the pitfalls of implementing an access and benefit sharing mechanism for pathogens and the impact it could have on innovation, collaboration, and achieving the [100 Days Mission](#).

A final draft of the accord will be presented at the 77th World Health Assembly in May 2024. BIA has formed a temporary subgroup under our Intellectual property Advisory Committee ([IPAC](#)) to support our continued efforts to ensure any formal treaty will not negatively impact UK biotech. To learn more or get involved, please contact Senior Policy and Public Affairs Manager, [Linda Bedenik](#).

BIA urge UK Government to oppose extension of IP TRIPS waiver

In parallel to the discussions of an international treaty on pandemic preparedness, the decision on whether to extend the 2022 TRIPS waiver to COVID-19 therapeutics and diagnostics is rapidly approaching.

On 9 November, the BIA sent a letter to then-Minister for International Trade Nigel Huddleston urging the UK government to continue to champion why extending the TRIPS waiver to therapeutics and diagnostics damages the life sciences sector and will not result in any practical effects on advancing equitable access to vaccines and treatments.

The 13th WTO Ministerial Conference ([MC13](#)) will take place from 26-29 February 2024 in Abu Dhabi, with a decision to be expected. The BIA continue to urge the Government to safeguard strong IP protection and oppose a waiver extension.

People, skills and talent

BIA flying the flag for diversity in biotech

The BIA has had the opportunity to highlight the skills challenges and opportunities within our sector at several conferences following the successful launch of our pioneering [Diversity in Biotech report](#) in March 2023.

The [Skills Forward](#) conference at Discovery Park in Sandwich provided an overview of the skills landscape, proposed education forms, and employment pathways. BIA presented the keynote on ‘navigating diversity across innovative life sciences and biotech within the UK’, with Dr Kate Barclay providing a fireside interview with Chairman Martino Picardo and chairing an interactive panel session on addressing sector skills gaps.



(L) The BIA's Dr Kate Barclay speaking at the Skills Forward conference in Sandwich. (R) A BIA-run DEI workshop on linking workplace inclusion to company strategy and the role of ERGs, kindly hosted by Cooley

The BIA also held the second in the series of engaging member workshops focussed on linking workplace inclusion to workplace strategy and the important role of ERGs (employee resource groups). The workshop provided a forum to share best practices for member organisations across the sector, including charity partners, and was well attended by a range of people leaders and human resource professionals, with contributions from RNID, Imperial College London, Illumina, and Autolus, among others.

Nurturing the next generation of TechBio talent

Attracting early career researchers to motivating careers in UK biotech is essential if the sector is to continue to grow, as has been identified by feedback from the BIA's member companies in the TechBio space. For this reason, skills featured heavily at this year's [TechBio UK conference](#). In particular, postgraduate scientific talent was given a central platform to engage with industry experts through the early career poster session, which was well attended by students from universities across the UK including Oxford, Ulster, Edinburgh London, and Bath.

Our #BIGIMPACT campaign also showcased the sector at TechBio via case studies and motivational career stories to attract early career computational talent. To engage further please see the website [here](#).

BIA helps life science professionals reskill to boost innovative growth sectors

The BIA hosted a webinar in December focussed on ‘Reskilling for future growth technologies’ in support of colleagues across the sector who have been impacted by recent news on organisational changes in both large pharma and small biotechs. Presenters focussed on the current investment landscape, advances in manufacturing, and opportunities within TechBio as well as how to apply existing experience and skills and where to find up-skilling, training, and development opportunities. The webinar was very well attended with excellent feedback giving existing employees food for thought on the importance of UK biotech, practical advice, and alternative career insights which will help retain talent within the sector. A recording of the event can be found [here](#).

Inaugural Women in Biotech mentoring programme draws to a close

The first pilot cohort of the BIA’s groundbreaking Women in Biotech mentoring programme concluded this quarter with 35 pairs of mentees and mentors supporting career development and leadership growth opportunities within the sector. Multiple case studies have demonstrated the qualitative benefits of this programme, whether applicants are in the early stages of their career or operating at C-suite level. In celebration of the support from incredible mentors across the sector, the BIA held two lunches in parallel with sold-out Women in Biotech events in Oxford and London.

Applications have now closed for the second Women in Biotech mentoring cohort for 2024, with over 55 mentees matched with fantastic mentors from across the sector.



(L) Attendees at a lunch celebrating the completion of the inaugural Women in Biotech (WiB) mentoring programme. (R) The BIA's WiB event at the Oxford University Museum of Natural History on 1 November.

Manufacturing

20th Annual bioProcessUK Conference is the biggest yet

With over 400 attendees and 55 exhibitors, the 20th anniversary bioProcessUK conference, which took place on 28-30 November 2023 in Brighton, broke all records, emerging as the largest and most successful edition to date. The purpose of the event is to connect, inspire, and celebrate the thriving bioprocessing sector, and this tone was set with the welcome party at the Brighton Museum.

During day one of the conference, an interactive Question Time-styled expert panel session stimulated an informative discussion around establishing the manufacturing of medicines of the future in the UK. This segued into a session entitled Back to the future, looking at new developments in traditional biotherapeutics including continuous manufacturing, ADCs and mRNA vaccines and therapeutics. The afternoon's workshops focused on "New frontiers in workforce planning" and "Advances in therapies for bowel cancer".

The event was also an opportunity to [recognise](#) exceptional individuals who have made groundbreaking contributions to the life sciences and biotech sector. Kate Barclay, a champion of skills development and DEI initiatives, was bestowed with the Richard Wilson Impact Award, while Ian McCubbin CBE, a beacon of pharmaceutical industry excellence, received the prestigious Peter Dunnill Award.

Day two kicked off with a Medicines Manufacturing Industry Partnership update, followed by a Next Generation Analytics themed Dragon's Den style technology showcase that saw Abselion receive the most votes and win tickets to the [BIA's Summer Party at The Langham](#) in London in July. The conference finale, looking at Building a strategy for a sustainable future, had speakers from AstraZeneca, Ipsen and Cytiva who are making bold moves in sustainability whilst also advancing patient care.

This year we return to Liverpool, on 19-21 November 2024, for the [21st bioProcessUK Conference](#).



(L) Ruizhi Wang, Co-Founder and CEO of Abselion, winners of the Dragon's Den challenge, speaking at BPUK. (R) PhD students who took part in the BPUK23 bursary competition.

Regulatory affairs

BIA maintains strong relationship with MHRA in bilateral meeting

In January, the BIA held its biannual bilateral meeting with the senior leadership of the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA gave an update on the measures it is taking to shape itself as a world leading, sovereign regulator and as a driver for innovation in the UK and beyond. Discussion focused on a number of topics of relevance to our member companies, including the agency's performance, international recognition, refreshing the Innovative Licensing and Access Pathway (ILAP), and the use of AI in medicines regulation.

We shared the excellent feedback received from delegates who attended the 2023 BIA [Conference on the Future of UK Regulation](#), and discussed potential themes for the next conference in 2024.

BIA continues to input into MHRA's new International Recognition Procedure

The new international recognition procedure (IRP) went live on 1 January 2024 meaning that developers of new medicines can now submit applications in accordance with the [MHRA Guidance](#). The IRP, which is expected to speed up the licensing process and bring life-saving medicines to UK patients, has been developed by the MHRA with input from industry including the BIA. It allows the agency to take into account the expertise of trusted regulatory partners in other countries, including Australia, Canada, the EU, Japan, Switzerland, Singapore and the US, when authorising medicines.

In addition, the BIA provided feedback on the MHRA's [Eligibility Checker](#) prior to its launch in November 2023. Applicants should use this new tool to determine whether their marketing authorisation application is suitable for IRP and to identify Route A or B as appropriate before submitting an IRP application. Members may find [the recording of the MHRA webinar](#) useful when planning their applications.

If members wish to share their view on the IRP, please contact the BIA's Head of Regulatory Affairs, [Dr Christiane Abouzeid](#).

Change to Project Orbis guidance welcomed by BIA

In January, the MHRA updated its guidance in relation to [Project Orbis](#) and the [Innovative Licensing and Access Pathway](#) to remove the requirement to obtain an Innovation Passport. Project Orbis provides a framework to review and approve oncology products so as to deliver faster patient access to innovative treatments.

It has been the BIA's view that a positive Innovation Passport designation should not be a prerequisite for inclusion of a product in Project Orbis, which was created separately by the US Food and Drug Administration (FDA) as an international collaboration to facilitate approval of cancer treatments. Such a requirement creates disproportionate administrative burden on biotech SMEs and international biopharmaceutical companies.

MHRA updates guidance under the Windsor Framework

In December, several guidance documents in relation to labelling and packaging of medicines were updated to address some issues resulting from the implementation of the Windsor Framework that industry bodies including the BIA raised with the MHRA and DHSC.

With regards to the [guidance](#) on ‘labelling and packaging of medicinal products for human use following agreement of the Windsor Framework’, the updates include the decision to allow early release to the GB market before 1 January 2025 of PLGB products that have had ‘UK Only’ added, and the addition to the notification process of a third option for submitting new artwork changes without an electronic Common Technical Document (eCTD). The Q&A will also be updated to reflect the latest changes.

BIA thanked as MHRA Clinical Trials Task and Finish Group reaches its conclusion

The BIA continued engagement with the MHRA Clinical Trials Task and Finish Group, which was set up in March 2023 to help with the MHRA’s work to improve performance for the assessment of clinical trial applications until the conclusion of this group in October. We provided feedback on documents to improve the clinical trials service and input on questions to support effective communications.

The Chair of the group thanked members for their tremendous effort and support over the past few months, having cleared backlogs in processing applications and keeping to the statutory timelines from 1 September for initial clinical trial authorisation (CTA) applications and substantial amendments.

The BIA will continue to pursue opportunities to collaborate linked to the MHRA clinical trials service and to the implementation of Lord O’Shaughnessy’s [recommendations](#) for UK commercial clinical trials which were accepted by Government as part of November’s [Autumn Statement](#).

Access to medicines

New BIA report urges UK leadership in supporting access to rare disease treatments

In November, the BIA published a [report](#) assessing the progress made in the UK on improving access to rare disease medicines since 2021. The report, with research provided by PwC, also compares and evaluates the processes and schemes adopted in six comparable countries to reveal insights and establish international best practice.

Drawing on focus groups, interviews, and extensive research with key stakeholders, the report highlights the importance of effective implementation of recent changes and initiatives that could improve patient access. These changes include the greater acceptance of uncertain evidence bases in National Institute for Health and Care Excellence (NICE) technology appraisals and the impact of the Innovative Medicines Fund (IMF) in providing a consistent managed access process. Analysing [data](#) from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the report also identifies that the UK lags behind comparator countries, including France and Germany, on the availability of rare disease treatments.

To celebrate the launch of the report, the BIA hosted a [webinar](#) on 6 November during which a panel of experts shared their reflections on the report and the next steps for securing UK leadership in faster and broader patient access to new medicines. Following the report's publication, the BIA is calling for the Government to improve access to rare diseases treatments by increasing collaboration between system stakeholders and encouraging the uptake of best practice at home and abroad. We will continue to engage with stakeholders on the opportunities to drive improvements in this space, including a parliamentary event in February. Please get in touch with Policy and Public Affairs Manager [Rosie Lindup](#) to find out more about the BIA's work on rare diseases.

BIA calls on NICE to demonstrate increased value for higher fees for technology appraisals

In December, the BIA responded to a NICE [consultation](#) on changes to charging for Technology Appraisals (TA) and the Highly Specialised Technology (HST) programme. The changes include a 23% increase in fees for technology appraisals from 1 April 2024, as well as the introduction of additional charges, including a change fee in the event of regulatory delays or company requests to change the timelines.

The [BIA response](#) calls on NICE to provide greater transparency in the justification for the proposed increase in charges, and to demonstrate increased value to companies for the higher fees by delivering continual improvements to its processes. Our recommended improvements include the introduction of 'after-action reviews' after each appraisal, and changes to committee meetings to make them less adversarial for patients and clinicians. The BIA looks forward to continuing to engage with NICE on these recommendations over the coming months.

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.



BIA Supporters



Not a BIA member?

If you want to have a say on policy areas key to the life science sector, contact Michael McGivern, Head of Membership and Business Development, on 079 2029 3171 or mmcgivern@bioindustry.org

bioindustry.org