UK BioIndustry Association

Influencing and shaping our sector

BIA update: July – October 2017

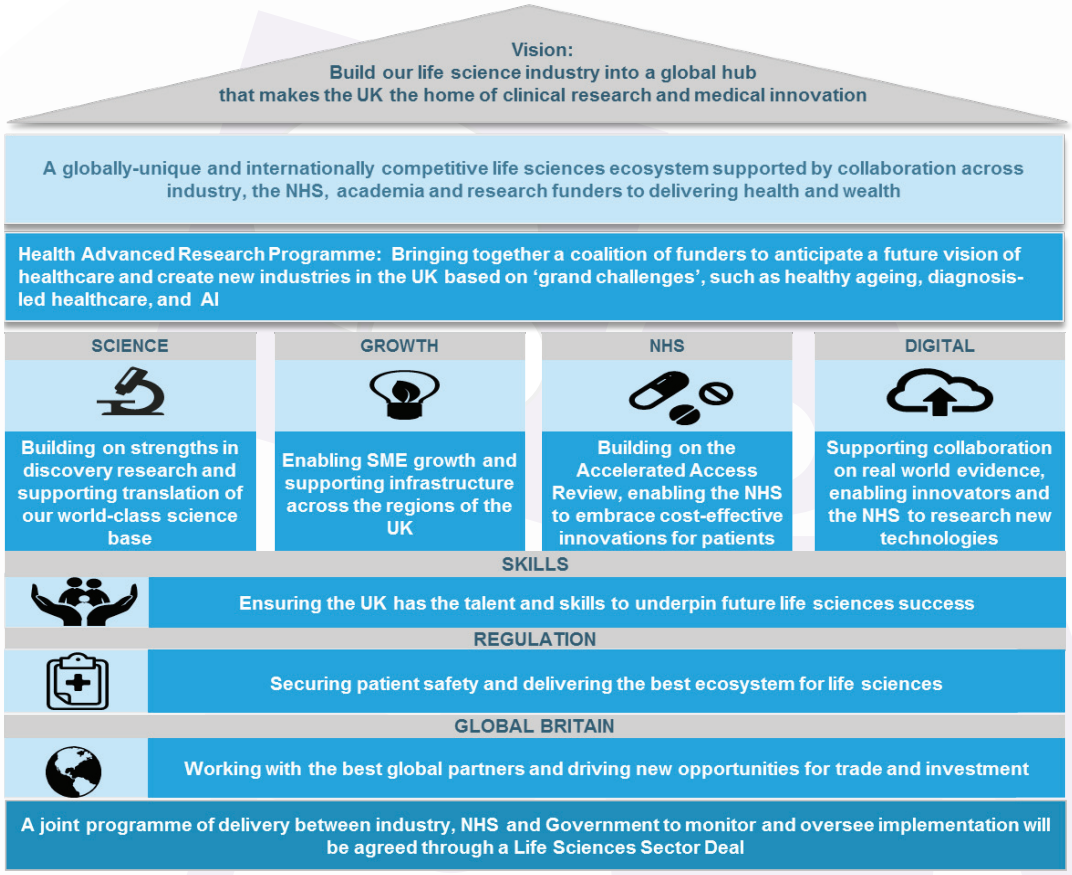
Ongoing BioIndustry Association (BIA) engagement enables our members' voices to be heard at the highest levels. This quarterly update gives an overview of key policy developments and the BIA's continued engagement with policymakers, regulatory authorities and wider stakeholders on behalf of the UK life sciences industry, from July to October 2017.

Brexit, the government's Industrial Strategy and a potential sector deal have been keeping all of us at the BIA very busy this quarter. August saw the publication of Professor Sir John Bell's long-awaited Life Sciences Industrial Strategy while, more recently, we've been making the case for UK bioscience in our submission to the Treasury's Patient Capital Review and through our engagement with politicians at this year's party conferences.

This quarter we also launched our new website and re-branded some of our key communication materials, including our weekly member newsletter, Newscast – make sure you have a look and do let us know what you think!

Read on for more details:

Life Sciences Industrial Strategy



An overview of Sir John Bell's Life Sciences Industrial Strategy

On August 30, the *Life Sciences Industrial Strategy* was launched. Professor Sir John Bell was commissioned by government to report on opportunities for the UK's life science sector in the context of the government's Industrial Strategy. The BIA helped inform the Strategy by providing input into the report via the Life Sciences Industrial Strategy Board.

BIA CEO and Life Sciences Industrial Strategy Board member, Steve Bates said:

> *"It is fantastic to see the publication of a Life Sciences Industrial Strategy that can act as a springboard to an early sector deal for the life sciences industry. The BIA has long called for a revived industrial strategy to maintain and build investment into the UK and grow and scale the UK's innovative bioscience companies. We stand ready to continue engagement with government to ensure that this strategy can pave the way for an impactful sector deal that can help deliver the BIA's vision to establish the UK as the third global cluster for life sciences."*

The Strategy makes several key recommendations, including:

- Establish a Health Advanced Research Programme (HARP) to ensure the UK life science sector remains at the forefront of medical advances over the next 20 years;
- Support an environment that builds on the UK's current strengths and encourages companies to start and grow;
- Improve NHS collaboration by adopting and building on the Accelerated Access Review;
- Ensure that the sector has access to skills and talent.

Alongside the publication of the Strategy, the government announced a £146m funding package, which is part of the Industrial Strategy Challenge Fund.

Political Party Conferences

Chi Onwurah MP, Thangam Debbonaire MP, and Alex Mayer MEP at our roundtable at the Labour Party Conference.

Kit Malthouse MP, Chair of the APPG for Life Sciences at our roundtable at Conservative Party Conference

This year the BIA attended the conferences of the four major parties in the UK: Conservatives, Labour, Liberal Democrat, and the Scottish National Party.

At the Conservative and Labour Party Conferences, the BIA hosted private roundtables focusing on how data can be harnessed for world-leading healthcare and R&D. As in previous years, the BIA partnered with the Association of Medical Research Charities (AMRC), the British In Vitro Diagnostics Association (BIVDA), and the Association of the British Pharmaceutical Industry (ABPI) to deliver the events. We invited a range of stakeholders from our memberships, academia, and the NHS to meet with MPs and policy makers.

At the Labour Party Conference in Brighton, we were joined by Chi Onwurah MP, Shadow Minister for Industrial Strategy, Science & Innovation, Thangam Debbonaire MP, and Alex Mayer MEP. Attendees discussed the public's perception of data and privacy, access to data in the NHS, and how an Industrial Strategy may support the use of data in innovation.

In Manchester, at the Conservative Party Conference, we were joined by Kit Malthouse MP, Chair of the APPG for Life Sciences, and former Science Minister and BIA Board Member, Lord Willetts. The discussion centred around the Salford Lung Study, a public-private partnership led by GSK, which digitally linked primary and secondary healthcare in the region to allow real-time data collection in clinical trials. Political attendees were impressed to hear how the project is being held up as an exemplar around the world, demonstrating the unique British R&D offering.

Leaving the EU

The BIA's work on Brexit continues, in collaboration with the Association of the British Pharmaceutical Industry (ABPI). Over the Summer we developed further regulatory policy positions and held a number of meetings with government on trade policy. We are currently working with ABPI and BIA member companies to finalise industry trade policy papers on rules of origin, transition, World Trade Organization engagement and Free Trade Agreements (FTAs).

BIA CEO Steve Bates sits on the UK/EU Life Sciences Steering Group, which last met on 17 October. The Group brings together industry and government and provides overarching direction for our Brexit work.

Engagement with EU and UK regulators

The BIA, alongside ABPI, contributed to the latest regulatory deep dive meeting, which took place on 10 October. Chaired by the Medicines and Healthcare products Regulatory Agency (MHRA), the regulation deep dive was set up as a sub-group of the EU/UK Life Sciences Steering Group to consider further the future of medicines regulation post-Brexit. The deep dive allows industry to share their insights and challenges with regulators, and examine the preferred negotiation outcome of ongoing UK partnership with the EU.

The BIA, together with EuropaBio (the European Association for Bioindustries) participated in the Industry Stakeholder meetings with the European Medicines Agency (EMA) and the Heads of Medicines Agencies' Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) on Brexit and operational issues around the centralised and decentralised procedures respectively.

Government policy papers

In August and September, government published a number of policy papers that reflected BIA and ABPI policy work around regulatory cooperation. In September the Collaboration on Science and Innovation Partnership Paper stated that:

> *"the UK is fully committed to continuing the close working relationship with our European partners, in the interests of public health and safety. Drug development and clinical trials are a global business, and the UK believes a deep and special relationship with the EU remains the best way to promote improved patient and animal health outcomes, both in Europe and globally. The UK will therefore look to continue to work closely with the EMA and other international partners."*

The paper also sought for continued engagement for the UK in Horizon2020.

In August, the Continuity in the availability of goods for the EU and the UK position paper also reflected positions developed by ABPI and the BIA. The paper focused on the availability of goods, seeking agreement that:

- Goods which are placed on the market before exit day can continue to be sold in the UK and EU, without any additional requirements or restrictions.
- Where products have gone through an authorisation process prior to exit this approval should remain valid in both markets after exit.
- Continued oversight of products to ensure the necessary action can be taken for non-compliant or unsafe goods to safeguard patients.
- Where goods are supplied with services, we believe there should be no restriction to the provision of these services.

Movement of talent

'Britain's got talent' – BIA's panel session at Conservative Party Conference

The Migration Advisory Committee has been commissioned by government to advise on the "economic and social impacts of the UK's exit from the European Union and also on how the UK's immigration system should be aligned with a modern industrial strategy". The Committee has published a consultation and the BIA is working with ABPI to produce a joint response.

The BIA also focused on movement of talent at Conservative Party Conference this year. With support from UCB Pharma, we held a fringe event entitled "Britain's got talent: what happens to innovation as we leave the EU?" Ranil Jayawardena MP, member of the House of Commons International Trade Committee (and former member of the Home Affairs Select Committee), Dr Sarah Main, Executive Director of CaSE and Steve Turley, Managing Director of UCB UK & Ireland joined BIA's Steve Bates on a panel chaired by Kevin Schofield, Editor of PoliticsHome. The panel discussed how people are the key element that drives innovation in the UK and how, as we leave the EU, we can ensure that the UK has the people that are able to help it remain a global innovation leader – both through development of talent via industrial strategy and the movement of skilled people. The panel also answered questions from the audience and touched on issues including Brexit, trade and regulation.

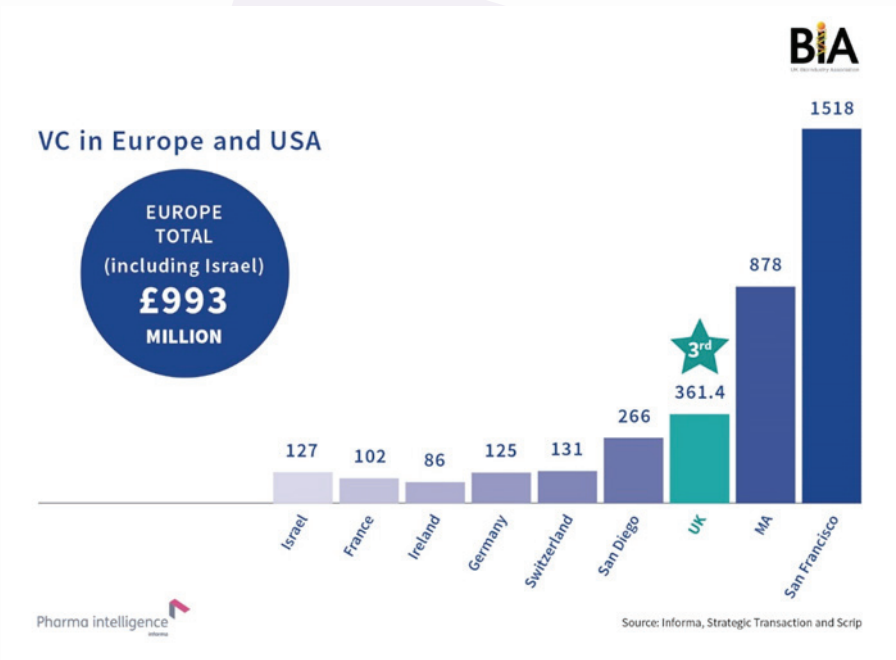
Member events

The BIA will be holding a series of member seminars to inform, guide and facilitate discussion for members on Brexit and how to mitigate against its impacts. These will start this year with seminars focusing on regulation and movement of people before turning to trade, research collaboration and funding in 2018.

For more information regarding our work on Brexit please register for our Brexit webinars.

Finance, tax and investment

BIA report shows UK biotech venture capital fundraising on track to beat 2016 figures



Source: Informa, Strategic Transaction and Scrip

On 28 September, the BIA published its Biotech financing update for January-June 2017, produced in conjunction with Informa Pharma Intelligence. The data is very encouraging, revealing that life science venture capital funding and secondary offerings are on track to meet or surpass 2016 figures.

At the halfway point in 2017, the UK is dominating venture capital funding in Europe, having raised £361.4 million. This places the UK 3rd globally, behind only the biotech powerhouses of San Francisco and Boston.

Other headline statistics from the report include:

- Seed, second round and later funding are all on track to meet or surpass last year's figures, with only first round currently behind on 2016
- There was one UK IPO in the first half of 2017 from Skin Biotherapeutics who raised £4.5 million on AIM
- Secondary public funding rounds are on track to meet or surpass 2016 figures with £261 million raised in 16 offerings across AIM and Nasdaq
- The emergence of Biopharma Credit, which raised over £600 million on the LSE through initial placements and secondary placements, could be a novel source of debt finance for UK life science

Despite the current political uncertainty, these figures show that the UK sector is continuing to attract investment from around the world and is well on its way to establishing itself as the third global cluster for life sciences.

The updated data was launched at the BIA's latest Investor Breakfast event – an initiative launched earlier this year to reach out into the investor community to make them more aware of the opportunities presented by UK bioscience and engage them in the work of the

BIA. Held on 29 September at investment bank Stifel, the event brought together specialist and generalist investors for a panel discussion on the Patient Capital Review. Former Science Minister and BIA Board Member, Lord David Willetts joined the panel along with hVIVO CEO, Kym Denny and Stifel Managing Director, Max Herrmann.

The BIA calls for greater support for bioscience in Patient Capital Review

The BIA responded to the government's Patient Capital Review consultation on 22 September, welcoming the proposal to establish a new National Investment Fund to support the growth of innovative UK companies. The fund could potentially invest billions of pounds alongside private investors over the coming years to provide long-term finance for new and scaling bioscience companies.

Since its launch in November 2016, the BIA has engaged with the Patient Capital Review at all levels to ensure bioscience benefits from the Treasury initiative. The sector is singled out as a key interest in the public consultation, published in August.

In its submission to the consultation, the BIA called for:

- The National Innovation Fund to support a diversity of privately-managed sector-specific investment funds
- Incentives, regulatory changes and a communications campaign to encourage pension funds to back the UK's innovative industries
- Support to expand the number of UK-based fund managers with expertise in the life sciences
- Support for bio-incubators
- Tax incentives to encourage greater investment in scaling businesses
- A new Investor Visa Fund to channel money from high-net worth individuals emigrating to the UK into innovative growing companies

BIA CEO Steve Bates said:

> *"UK bioscience companies have global ambitions but have long-lacked the domestic financial support they need to scale and take on their US and Asian rivals. It's great to see the government taking this issue seriously and willing to work with industry to address it through the Patient Capital Review. Critically, we need to open up opportunities for pension funds and other large investors to support the growth of innovative UK businesses. The proposed National Innovation Fund is an exciting and promising action that the government should take forward."*

The government is expected to announce the findings of the review at the end of November.

BIA's FTAC meets the Office for Tax Simplification

On 2 August, the BIA's Finance and Tax Advisory Committee (FTAC) met with the Treasury's Office for Tax Simplification. The Committee helped the government officials understand how a range of tax incentives benefit bioscience companies at different stages of their development and made recommendations to reduce bureaucracy and streamline tax accounting for SMEs. A number of enhancements to the Enterprise Innovation Scheme (EIS) and other tax incentive schemes were also proposed. The Committee will continue to engage with the Office.

Strategic technologies and areas of scientific focus

BIA responds to international consultation on the inclusion of digital sequence information in the Nagoya Protocol

In September, the BIA responded to a consultation held by the international secretariat for the Nagoya Protocol on whether Digital Sequence Information (DSI) should be included in the scope of the Protocol. In its response, the BIA stressed that DSI is essential throughout the bioscience sector and argued against the inclusion of DSI by highlighting three main points:

- The incorporation of DSI into the Protocol will lead to further legal uncertainty and compliance difficulties, particularly for SMEs;
- DSI regulation in the Protocol will hinder R&D in all biological fields, including medical, agricultural, and industrial biotechnologies;
- The incorporation of DSI into the Protocol poses serious public health concerns.

The Nagoya Protocol is an international agreement that entered into force in 2014. The Protocol aims to enable the fair and equitable sharing of benefits arising from the utilisation of genetic resources. This means that researchers accessing genetic resources in countries signed up to the Protocol must share the benefits arising from the research according to the regulatory framework established by the Protocol.

At the moment, the Protocol covers physical genetic resources from plants, animals, microbials, and hereditary materials. Some countries are pushing for the expansion of the scope of the Protocol to include DSI. This prompted the international secretariat to hold the consultation on the possible implications of including DSI into the Protocol. The secretariat will set up an expert working-group in January 2018 and parties to the Protocol will meet to discuss DSI next autumn.

BIA comments on Chief Medical Officer's Generation Genome report for House of Commons inquiry

The newly formed House of Commons Science and Technology Committee recently announced that they will continue the former Committee's inquiry on genomics and genome-editing, with a slightly revised focus on the use of these technologies in the NHS. We submitted our position on human gene editing as written evidence to the former inquiry, and we have now submitted further evidence to the revised inquiry, commenting on the Chief Medical Officer's recently published annual report, *Generation Genome*.

Our submission highlights the number of SMEs developing capability across the various stages of genomics, including sampling, sequencing, analysis, interpretation, and application, and it asks that the National Genomics Board, recommended by Dame Sally Davies in her report, includes SME representation.

Skills, people and talent

BIA Manufacturing Advisory Committee (MAC) bioproduction leadership skills initiative interim review

Participants of the BIA MAC bioproduction leadership skills initiative visiting AstraZeneca

The development of managers in the biopharmaceutical and cell and gene therapy industries is an important part of the training landscape to deliver senior leaders of the future. An initiative, led by BIA's Manufacturing Advisory Committee (MAC), to support this development, kicked off with a group of 11 people from UK BIA member companies in January 2017 and is now almost half way through. Members visit each participating company to build a network, gain an insight into the work of other companies in the sector, share best practice and develop relationships to encourage potential future collaborations.

Discussing their experience, one participant said:

> *"The BIA Skills Tour has been a great experience, seeing how other companies and institutes operate whilst managing various projects has helped develop my understanding of the industry considerably. The group discussions have been of a particular interest as it allows the group to share good working practices and how technical challenges have been overcome, which may be applicable to other representatives within the group.*
>
> *An amazing way to meet like-minded people, explore common problems and issues and come up with mutually beneficial resolutions."*

Current members include next generation leaders from Allergan, Cell & Gene Therapy Catapult, F-star, FUJIFILM Diosynth Biotechnologies, GE Healthcare, Lonza Biologics, MedImmune/AstraZeneca, Oxford BioMedica, Pall, Porton Biopharma and UCL.

Feedback from both participants and their managers has been very positive, resulting in the decision to launch a second cohort in January 2018.
If you would like to take part in this, please contact Netty England at aengland@bioindustry.org

Developing technician skills for the emerging advanced therapies sector in the UK

Catalysed by the introduction of the apprenticeship levy, The Gatsby Charitable Foundation funded a short piece of work, led by Bradshaw TM and Paul Lewis of King's College London, earlier this year to determine barriers to apprenticeship uptake in the Advanced Therapy Medicinal Products (ATMP) sector. This work was initiated as part of a recommendation contained in a wider skills assessment for the ATMP sector conducted by the Advanced Therapies Manufacturing Taskforce, led by industry and chaired by Jim Faulkner at Autolus - a leading ATMP company.

Feedback from the organisations that took part was that they are not accustomed to taking on apprentices and support is required to embed apprenticeship thinking in the sector. Partnership working between the relevant employers would enable them to amalgamate demand and coordinate activity.

Gatsby is catalysing an initiative to overcome these barriers, with longer term funding anticipated through the Industrial Strategy Challenge Fund (ISCF). Meanwhile, Tony Bradshaw and his team are engaging with the community to put high quality apprenticeships on the map.

Apprenticeships are obviously only part of the solution and the follow on ISCF funding will work with the ATMP community on a wider talent management plan to ensure that we capture the value presented by these cutting-edge therapies and achieve the government's aim of becoming a centre of excellence for both the research and manufacturing of ATMPs. Find out more on the BIA blog.

Intellectual Property and Technology Transfer

Supreme Court modifies test for IP equivalence following BIA calls

The UK Supreme Court has reformulated the UK Improver questions on equivalence, which allow patents to cover molecules similar to those described in the patent, even if they themselves are not described.

The new guidance was provided in the Supreme Court's ruling in favour of Lilly in its case against Actavis, finding that Actavis' products directly infringe Lilly's Alimta vitamin regimen patent. The judgement provides a two-step process to determine if a patent infringes another due to equivalence and thus provides welcome greater certainty to patent applicants and owners. Other national courts in Europe can also refer to this test, improving consistency across the continent.

With the support of the IP Advisory Committee, the BIA had previously written to the Supreme Court urging it to take up the case as members reported that national courts across Europe were approaching the question of equivalents differently, which was leading to legal uncertainty and expense for biotech companies.

BIA urges the Intellectual Property Office to support supplementary protection certificates for innovative new formulations of existing medicines

With the support of the IP Advisory Committee, the BIA has urged the Intellectual Property Office to make representations to the Court of Justice of the EU (CJEU) in support of allowing supplementary protection certificates (SPCs) for new, inventive formulations of existing medicines (where these are separate innovations protected by patent rights). Such an approach encourages important research in the pharmaceutical industry but courts have generally opposed it, with a few notable exceptions.

The BIA's request has been made in relation to the case Abraxis Bioscience vs The General Patent Comptroller, which has been referred by the UK High Court to the CJEU. The SPC has been granted to Abraxis in a number of other countries but not in the UK. The BIA is keen that the CJEU clarifies the law in favour of Abraxis, which will bring the UK into line with other European countries and support further innovation in reformulation.

BIA guide to the UPC updated following new developments

In March 2017, a constitutional complaint was filed against both the German Bill for ratifying the Unified Patent Court (UPC) Agreement and the UPC Agreement itself with the German Federal Constitutional Court. The complaint is being taken forward by the authorities and so the ratification of the Agreement is being delayed. It is unknown when the new court will now be formally established but it is likely to be considerably later than the previous January 2018 expected date. The UK continues to progress its ratification process despite Brexit.

The BIA's IP Advisory Committee has updated its guide on the UPC following the announced delay. BIA members are still recommended to consult their advisers to determine the best course of action for their IP protection strategies.

Manufacturing

MMIP calls on government to invest in cutting-edge R&D centres

The Medicines Manufacturing Industry Partnership (MMIP) have published their *Manufacturing Vision for UK Pharma*, which asks the government for support in building three new Centres of Excellence for medicines manufacturing across the UK.

The report details how the centres would help plug gaps in the UK's capabilities in areas like diagnostics and packaging, advanced therapy production and small molecule processing. It sets out a practical plan of action for how the government and the pharmaceutical industry can work together to build up the UK's medicine manufacturing sector and asks for government funding for three new Centres of Excellence including:

- A Medicines Manufacturing Innovation Centre (MMIC) in Scotland capable of providing a clinical supply of medicines and further develop manufacturing capabilities at EPSRC Centre for Innovative Manufacturing in Continuous Manufacturing and Crystallisation – already a world-class international hub for manufacturing research and training
- An open-access facility to allow the manufacturing of complex medicines and handling of high-potency materials
- A centre to support the development of the next generation of packaging technology and smart devices required for new types of medicines, such as specialised packs

The investment of £140m over three years would be paid back in the long-term by pharmaceutical companies both in fees to access the research hubs and through indirect investment as global companies choose the UK as a base to research and launch their medicines.

Medicines Regulation

BIA and MHRA publish *Innovation in life sciences in a changing and dynamic environment*

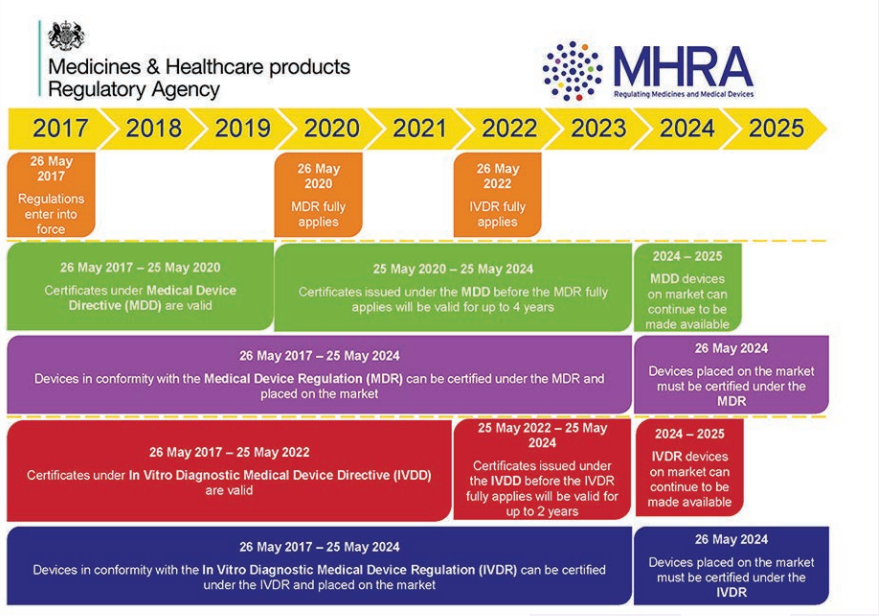
Following their seventh annual joint conference, the BIA and the MHRA have published a report, *Innovation in life sciences in a changing and dynamic environment.*

MHRA and the BIA brought together experts from across the sector to discuss important developments that are having an impact on the changing and dynamic UK life sciences ecosystem. Through a series of presentations, panel discussions and Q&As, key topics were debated and analysed including the Accelerated Access Review and the Life Sciences Industrial Strategy, personalised medicines and companion diagnostics, the Priority Medicines (PRIME) scheme and the challenges posed to medicines regulation by Brexit.

Keynote speaker Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, provided the UK government's position on medicines regulation post-Brexit. He explained that the government wants to retain a close working partnership in respect of medicines regulation after the UK leaves the EU, in the interests of public health and safety. Chief Executive of NHS England, Simon Stevens, also gave a keynote speech outlining the challenges faced by the NHS, the opportunities for industry in the NHS Five Year Forward View and the patient's role in promoting access to new medicines.

The report summarises the presentations and perspectives from senior experts and leading speakers from MHRA, government, NHS England, the National Institute for Health and Care Excellence (NICE), the life science industry, academia, research charities and patient organisations. The full programme and slide presentations are available on the conference website.

MHRA launch guide to new EU medical device regulations



MHRA timeline for the implementation of the MDR and IVDR

On 29 August, the MHRA issued an interactive guide to the new EU Regulations for medical devices (MDR) and in vitro diagnostic medical devices (IVDR). The guidance is designed for all users – to help experienced manufacturers navigate the changes in the new EU regulations and requirements for devices and diagnostics, as well as those manufacturers who need to meet their obligations as a result of the broader scope of the new legislation.

Entered into force on 25 May 2017, the three and five-year transition periods of the new regulations are now underway. This means the MDR and IVDR will fully apply in EU Member States from 26 May 2020 and 2022 respectively.

It is important to note the IVDR will bring in some key changes, in particular:

- changes to classification rules for IVDs will mean that 80-90% of IVDs will require a notified body to conduct a conformity assessment
- manufacturers of IVDs will be required to produce significantly more performance evidence, which will need to be updated throughout the life cycle of the device
- the performance and testing of Class D devices, for example HIV blood diagnostic tests, will need to be verified by reference laboratories

There will also be a new consultation procedure for companion diagnostics.

EMA consults on concept paper on development and lifecycle of personalised medicines and companion diagnostics

On 28 July, the EMA released for public consultation a concept paper on the development and lifecycle of personalised medicines and companion diagnostics that measure predictive biomarkers, helping to assess the most likely response to a particular treatment. The proposed concept paper is intended to be developed into a guideline which will provide recommendations on the interface between predictive biomarker-based assays including companion diagnostics, and the development and lifecycle of medicines. It will help with compliance with the new IVDR which envisages cooperation between medicines regulators and notified bodies in the evaluation of new companion diagnostics to obtain a CE mark. The future guideline will replace the existing reflection paper on co-development of pharmacogenomics markers and assays in the context of drug development.

The choice of a personalised medicine relies on the use of a companion diagnostic medical device to identify patients who are most likely to benefit from a specific medicine, but also those patients who are likely to be at increased risk of serious adverse reactions as a result of treatment with the associated medicine.

The BIA is planning to input together with EuropaBio to this consultation, which ends on 15 November. If members wish to comment on the concept paper, please contact Christiane Abouzeid, BIA Head of Regulatory Affairs at cabouzeid@bioindustry.org.

EMA revised guideline on first-in-human clinical trials

On 25 July, the EMA published its revised guidance on first-in-human clinical trials that outlines strategies to further help stakeholders identify and mitigate risks for trial participants in first-in-human and early clinical trials. This guideline applies to all new chemical and biological investigational medicinal products except gene and cell therapy medicinal products. It covers non-clinical issues for consideration prior to the first administration in humans and the design and conduct of trials in the initial phase of single and ascending doses during the clinical development.

In May 2016, the EMA began reviewing the 2007 guideline following a patient death and several hospitalisations that occurred during a Phase I trial in France in January 2016. The revision takes into account the fact that first-in-human trials now use more complex protocols that combine different designs. This was carried out in cooperation with the European Commission and the representatives of EU Member States through the EU Clinical Trials Facilitation Group.

This guideline updates and replaces the 2007 guideline, and will come into effect on 1 February 2018.

Access to Medicines

BIA polling signals that leadership, alignment and buy-in key to deliver accelerated access in the UK

In September, the BIA published data which reveals that the majority of health care professionals are not aware of the Accelerated Access Review or previous government-led initiatives aimed at improving the adoption of innovation across the NHS.

Polling of NHS staff, commissioned by the BIA in March 2017, reveals that:

- Only 11% of health care professionals are aware of the Accelerated Access Review, a government-commissioned report that makes recommendations for speeding up patient access to innovative treatments.
- Many of the report's recommendations build upon initiatives introduced by a previous government report, *Innovation Health and Wealth: Accelerating adoption and diffusion in the NHS*. However, when asked about these initiatives, almost half (46%) of those surveyed said they were not aware of any of them.
- The data also shows that only 20% of NHS staff are aware of the Early Access to Medicines Scheme, introduced in the 2011 Life Sciences Strategy.

Earlier this year, the BIA published *Now More Than Ever: Seizing the opportunity to make the UK a world leader in the life sciences*, which finds that despite the efforts of successive governments to support the UK life science sector and encourage uptake of innovation, policies have not been fully implemented or led to lasting change. In the report, we call for greater cross-sectoral buy-in, ministerial buy-in and NHS buy-in and implementation as well as more clearly defined targets to measure improvement in uptake.

Commenting on the data, BIA CEO, Steve Bates, said:

> *"The UK has been great at talking the talk on driving innovation into the NHS but now is the time to walk the walk. This data highlights what many of us in the life sciences sector have long suspected – that great policy is meaningless without effective implementation."*

The government are expected to publish their response to the Accelerated Access Review at the end of October. We are keen to hear how the government will ensure the Review's recommendations are implemented fully and effectively.

BIA member workshop on financial support for SMEs applying for the Early Access to Medicines Scheme

At the BIA and MHRA conference earlier this year, Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, announced an £86M package of support for innovation in medicine and technology. £6 million of this has been set aside, over the next three years, to support SMEs to gather evidence about how their products perform in the real world, thereby reducing their barriers to market entry.

In line with the recommendations of the Accelerated Access Review, it is proposed that for medicines the support will be available to SMEs with products participating in the existing Early Access to Medicines Scheme (EAMS), allowing patients and the healthcare system to benefit from earlier access to evaluated innovative products.

The Office for Life Sciences (OLS) is currently working with stakeholders to develop the support scheme for SMEs. In September, the BIA held a workshop for members where they could find out more about OLS's current thinking and share their views on the practicalities and costs of participation and data collection in EAMS for an SME.

For more information please contact BIA's Policy and Public Affairs Manager, Rachael Mann at rmann@bioindustry.org.

For more information on the BIA's activities in policy and regulatory affairs please call 020 7639 2187 or email rmann@bioindustry.org

Please also email us with any comments on the content and usefulness of these updates. We would welcome your feedback.

Not a BIA member? If you want to have a say on policy areas key to the sector, contact Jane Wall on jwall@bioindustry.org now to find out about BIA membership.

We are at the forefront of UK bioscience, connecting individuals and organisations, helping to shape the future of the UK sector

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