Protecting Europe's Patients, Public Health and Life Sciences Ecosystem during Brexit

June 2019

UK BioIndustry Association

Post Brexit referendum result the life sciences sector across Europe, including the UK BioIndustry Association, considered how Brexit might impact patients, public health and the life sciences sector. The sector agreed a number of priorities. As UK MEPs head to Brussels post European elections, BIA would like to take the opportunity to set out these priorities. These positions are best for patients, public health and the sector both in the UK and EU, during withdrawal and in the future relationship.

The BioIndustry Association

- The BIA is the trade association for biotech and pharma in the UK.
- We have about 370 members including large UK, US, European and Japanese multinationals, scaling and SME UK companies, science parks, funders/venture capital and institutes.
- Over 150 of our members have at least one R&D and/or manufacturing sites in the UK. Numerous members are also currently expanding existing R&D/manufacturing sites or opening new sites.
- Many of our members manufacture in the UK and export to both the EU and global markets from the UK.

The Sector

The biotech/pharmaceutical industry is a global industry that discovers, researches, develops and manufactures life-saving and enhancing medicines for patients. The UK has one of the strongest and most productive Life Sciences industries in the world. Despite Brexit uncertainty, the UK biotech sector continues to deliver world-leading life science which continues to attract finance and talent from around the globe.

- In 2016, the UK exported approximately £30.7bn of life science goods (84% pharmaceutical products and 16% medtech products) - 48% of life science exports were to the EU.
- The UK is the world's 3rd largest bioscience cluster (after east and west coast US)
- The UK has the strongest R&D pipeline in Europe, with 479 products in pre-clinical development and clinical trials. France is second with 265.

Key Policy Areas

There are four key areas for our sector:

- **Medicines Regulatory Partnership** - participation of the UK medicines regulator, MHRA, in the European regulatory system and the European Medicines Agency to protect patients and public health in both the UK and EU.
- **Research collaboration** - Inclusion of the UK in EU research and development initiatives, including Horizon Europe, the Innovative Medicines Initiative (IMI), European Reference Networks (ERNs).
- **Brain circulation** - Ability for continued circulation of talent between UK and EU, and vice-versa, to drive innovation.
- **Frictionless trade** - Frictionless borders to maintain the flow of the medicines and clinical trial supplies that patients rely on.

The positions have been reflected in the EU/UK Political Declaration, and by UK Government, Parliament and by Political Parties.

Medicines Regulatory Partnership

A close regulatory partnership between the UK's MHRA and the European Medicines Agency on medicines and vaccines will ensure that the health and safety of citizens and patients in the UK and EU is not put at risk by Brexit. There is no standalone UK medicines agency option that would not adversely impact patients and citizens in the UK. At the same time the inclusion of the UK's MHRA within the European regulatory network increases the attractiveness of Europe, at a time of increasing pressure from other markets such as China, US and India.

This partnership should allow for the UK's MHRA to continue to participate in the European system and provide its expertise and competence in centralised authorisations[1], decentralised[2] and mutual recognition[3] procedures. This also requires membership of EMA committees[4].UK-EU mutual recognition of manufacturing inspections and medicines testing[5] and batch release processes should be maintained. Precedent exists in the Swiss model.

Pharmacovigilance systems monitor medicines and vaccines safety post-authorisation to ensure they are the safest that they can be and provide early warning and interpretation of any potential issues. The UK is a key contributor of data – both in terms of volume (about 30%) and quality. OHE Consulting's report *Public Health and Economic Implications of the United Kingdom Exiting the EU and the Single Market* found that if the UK does not achieve regulatory cooperation with the European Medicines Agency and has a standalone regulatory agency, it is estimated that there will be delays of two to five months for detection, and two to five months for publication of recommendations relating to safety signals. The UK has more to lose in terms of safety monitoring, however the EU would also lose valuable data to enable and support decisions that safeguard public health.

Without a regulatory partnership there will likely be delays in NHS patients getting new medicines and vaccines as the UK will move down priority lists for the launch of a medicine/vaccine, as on its own the UK is not a significant world market (it constitutes 3% of the global medicines market).

The duplication of medicines regulatory certifications and procedures will impact patients and industry both in UK and EU. Europe, including the UK, benefits from significant investment from industry, patient groups and research institutes – investment in R&D delivers economic and patient benefit. Investment funds are limited, and duplicating spending and red tape, takes away from the investment that will deliver new medicines to patients and economic benefit.

A regulatory partnership would also be beneficial for multinational clinical trials taking place across the UK and EU. This would allow continued access to and collaboration with Member States on the existing clinical trials database (EudraCT) and the new EU Clinical Trials Information System. UK companies, institutes and

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[1] "Centralised procedure" used for licensing novel and innovative drugs, including treatments for cancer. Member states take lead for performing assessments of individual medicines, for adoption of opinions on licensing by all Member States at an EMA committee.

[2] "Decentralised procedure" Applications sent to the lead Member State and others that the company wishes to sell in. Lead member state carries out assessment, then peer-reviewed by the others. Once agreed on assessment – drug is licenced for all of those countries.

[3] "Mutual recognition": One member state carries out assessment and authorises it for use in their country. Other member states can choose to mutually recognise that assessment and adopt for their country.

[4] Scientific sub-committees; EMA management board; and Coordination Group for Mutual Recognition & Decentralised Procedures.

[5] Good Manufacturing Practice (GMP) regulations

patient organisations make significant investment in running clinical trials, many across Europe, at the same time the UK provides a conducive environment for clinical trials to derive quality data. There is global competition for conducting clinical trials, and the UK and Europe is facing increasingly strong and competitive offers from locations such as South America and China.

UK/EU Research Collaboration

The UK should seek to become an associate member (or equivalent) of research and innovation framework programs including Horizon Europe and the Innovative Medicines Initiative. Precedents exist for this in Switzerland, Norway & others.

The UK has much to offer Horizon Europe members as a research partner – the UK's life sciences ecosystem is a global leader with world leading universities, institutes (Crick and the Wellcome Trust) and a mass of innovative companies. More finance is raised by companies in the UK than anywhere else in Europe – the upwards trend of UK companies raising finance has continued in 2017 and 2018 despite uncertainty, and the first quarter of 2019 has also continued the trend.

UK membership of the European Reference Networks[6] (ERNs), including the ability to lead ERNs, is important. Scarcity of expertise and patients in any single country means that rare disease policy strongly benefits from international collaboration. Additionally, continued access to membership on international EU expert panels in health research and public health is needed. Without access, the UK would not be able to access expert panels to peer review research. Peer review is an important part of research, allowing for benchmarking and quality assurance and without it, UK institutions could become less prevalent among leading academics.

The UK should have continued participation as a funder, investor and recipient of support from the European Investment Bank (EIB) and European Investment Fund. It is estimated that the EIB has provided loans for research and innovation-related activities to UK organisations for a value of €5.9bn in the period 2007-2016,[7] including €2.8bn for UK universities and knowledge transfer services. The UK investments are known to be vibrant and profitable.

Circulation of Talent

The circulation of talent within Europe is important to enable scientific collaborations for companies and research institutes. The UK benefits from attracting scientific talent from Europe, and scientists benefit from the ability to work in different European countries.

Frictionless Trade

Whilst borders and frictionless trade is a key issue for industry sectors beyond the life sciences sector, we would like to reiterate how important it is for our sector given that patients are at the end of our complex supply-chains which span Europe.

A close regulatory partnership could help with the continued supply of medicines and clinical trial materials, but further action is required around customs and borders to reduce friction.

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[6] ERNs offer doctors across the EU access to a highly specialised pool of over 900 healthcare units working together on 24 thematic networks.

[7] Technopolis Report (2017): The role of EU funding in UK research and innovation: https://royalsociety.org/~/media/policy/Publications/2017/2017-05-technopolis-role-of-EU-funding-report.PDF

Brussels event – September

BIA will be holding an event in Brussels. If you would be interested in hearing further information please contact Laura Collister, Brexit Lead, lcollister@bioindustry.org

Further Information

The BIA recently published a series of explainers on strategic technologies coming out of the biotech sector – these can be downloaded by clicking on the images below: