Brexit and Pharma

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On 23 June 2016, the British people voted "yes" to exiting the 28-member EU bloc in the move that has become known as "Brexit". Although this referendum is not legally binding, the British government is moving ahead with the complicated 2-year process of "extracting" Britain from Europe. Before the event, the pharmaceutical industry [lead by UK-based Astra Zeneca and GSK] were vocal in their opposition to the vote warning that it would bring uncertainity to the sector (1); it is estimated that drugmakers account for 25% of all UK business research spending (2). But what does it mean for those of us involved in life sciences, and especially drug development?

There are 3 main areas that could be impacted:

Regulatory approvals: From a drug development viewpoint, the biggest question is, if the UK is NOT a member of the EU, would the approval of drugs in the UK still fall under the EMA? (3). There could be two main consequences if this was not the case – increased regulatory burden to drug companies and potential loss of early access programmes for patients. This issue is further complicated by the fact that EMA headquarters are in London and houses >900 staff. However, it is instructive to note that Switzerland operates outside the EU bloc with its own regulatory system yet has a strong pharmaceutical presence (Novartis and Roche).

Clinical trials: Currently, each country regulates its own clinical trials; however, there have been plans in Europe to harmonize this procedure allowing for a single application for different countries by 2018. Being outside this centralized review system could potentially exclude Britain from participation in future clinical trials. However, in an article entitled "Brexit offers opportunities for UK scientists" in September 2016 (4), Professor Sir John Bell (Regius Professor of Medicine, Oxford University) argues that "Britain is inclined towards a relatively liberal risk-based regulatory environment that allows fields to move quickly – to reflect on ethical issues but not to over-regulate them". He gives the example of clinical trials in the early 1990s when "Britain was recognized as one of the best places in the world to test new drugs on patients", but this all changed with the European Directive in 2004. He maintains that the EU regulatory constraints pertain not just to clinical trials, but also to use of data, stem cell research and application of genetically modified materials.

Life sciences funding: The UK receives a huge amount of funding from the EU - it is estimated that up to £8.5 billion of funding and investment in UK science could be threatened over the next 4 years by exiting the EU (3). However, Swiss companies (as noted above) currently participate in collaborations such as DDMoRe as members of EFPIA, as opposed to members of the EU (5). Sir John Bell again lays out the case that with appropriate government support, enabling "light touch regulatory support", that "this small country could ..succeed in converting science and innovation into economic growth" (4).

So what has happened since the vote? Amongst the many advances, drug industry leaders and government officials have set up a task force to address regulatory and other problems facing the pharmaceutical sector, Europe's largest biomedical centre (The Crick Institute) has recently opened in London, and (as reported in The Guardian on 21 September 2016) "fears that Britain will slide into a post-referendum recession have been allayed after a Guardian analysis showed the latest news on the economy has confounded analysts' gloomy expectations, with consumer spending strong, unemployment low and the housing market holding steady" (6). The actual impact on the life sciences sector will be dependent on "how far" Britain moves from Europe – there may be options to remain part

of the European Economic Area or the European Free Trade Association which would allow for continued close association with Europe, then the effects may be less severe (7).

(1) http://belsconnector.org/bels-brexit-nice/
(2) Reuters, July 2016 http://www.reuters.com/article/us-britain-eu-pharmaceuticals-idUSKCN0ZN1W0
(3) PharmExec, June 2016 http://www.pharmexec.com/brexit-and-uk-pharma-industry
(4) Posted on the University of Oxford's web-site (5 September 2016) but originally published in the Financial Times http://www.ox.ac.uk/news-and-events/eu-referendum-latest-university-statements/analysis-brexit-opportunities#
(5) http://www.ddmore.eu/
(6) https://www.theguardian.com/business/2016/sep/21/post-referendum-gloom-fears-confounded-economic-evidence
(7) Lexology http://www.lexology.com/library/detail.aspx?g=00bac58e-ca77-47b0-99d6-dc239c2c9095

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