image: Science Photo Library - TEK IMAGE / Brand X Pictures / Getty Images

Paul Ranson Consultant
paul.ranson@morganlewis.com
Morgan Lewis, London

An industrial strategy for the life sciences sector in a post-Brexit world

Professor Sir John Bell's industry-led industrial strategy for the UK's life sciences sector was published on 30 August 2017 and puts forward proposals to be considered by the Government and used to work towards a sector deal between Government and the life sciences sector, particularly in light of the imminent changes to be brought about by Britain's exit from the European Union. Paul Ranson, Consultant at Morgan Lewis, dissects Sir John Bell's industrial strategy in the context of the UK's departure from the European Union.

Introduction

The concept of industrial strategies in Britain will forever be linked to the Labour governments of the 1970s with industrial rescue attempts losing billions of pounds for taxpayers. Apparently killed off by Margaret Thatcher's free market economic liberalism, they were resuscitated by Theresa May in a green paper in July last year in the immediate wake of the EU referendum, with May promising "a proper industrial strategy to get the whole economy firing," although its supposed vagueness elicited a somewhat lukewarm reception from some sections of industry.

Life sciences which employs more than 235,000 people in the UK and has sales of some £64 billion last year, was one of the first five sectors that the Government requested in its January 2017 green paper 'Building our Industrial Strategy' to come up with an industry-led, multi-stakeholder vision and indeed was the first to benefit from the launch of such an initiative. The strategy developed by Professor Sir John Bell and published on 30 August 2017 (the '2017 Strategy') was independent of the Government, but the Government has encouraged the initiative and expressed its support particularly through Business Secretary Greg Clark and Health Secretary Jeremy Hunt.

We have also arguably been here before with the 2011 'Strategy for UK Life Sciences.' The proposed initiatives, which have met with varying success, included encouraging the use of genomics, improved NHS management of clinical trials, a Clinical Practice Research Datalink, the Earlier Access to Medicines Scheme[1], the formation of Academic Health Science Networks[2] ('AHSNs'), the NICE Implementation Collaborative ('NIC') and programmes such as the biomedical catalyst and catapults.

The 2017 Strategy

The 2017 Strategy has six key themes - science, growth, NHS, data, and skills and the Healthcare Advanced Research Programme:

- Science - Increased funding for basic science and enhanced UK clinical trial capabilities. The EU currently provides opportunities for international research consortia to compete for funding through programmes such as Horizon 2020, a rolling seven year programme with €80 billion to fund research and innovation, a source the UK has vowed to replace.

1. http://webarchive.nationalarchives.gov.uk/20100709153055/http://www.mhra.gov.uk/Howweregulate/Medicines/MISGNewTechnologiesAdvisoryPanel/Earlieraccesstonewmedicinesintheuk/CON065736
2. https://www.england.nhs.uk/ourwork/part-rel/ahsn/

continued

- Growth - Improved national growth and infrastructure through a tax environment that supports growth and encourages investment to manufacture and export. There is much debate on the extent to which Brexit should be exploited to push for a low tax economy.
- NHS - Greater NHS collaboration through the Accelerated Access Review with streamlined national routes to market, particularly for digital products which would most benefit the NHS.
- Data - Improved use of data through regional innovation hubs that would provide data across regions of three to five million people.
- Skills - Ensuring that the sector has access to a pool of talented people to support its aims through a strong skills strategy. The potential loss of talent would require an immigration policy that ensures that non-UK staff can come to, and remain in, the UK, enables intra company transfers, and responds to employer needs. It also suggests the creation of a high-level recruitment fund that would pay the real cost of bringing successful scientists from abroad to work in major UK university institutions.
- The Healthcare Advanced Research Program ('HARP') - A programme through which industry, the NHS and other stakeholders can collaborate on long-term transformative UK-based projects or 'moon shots' such as artificial intelligence, genomics, the early detection of diseases such as cancer and cognitive diseases and understanding the biology of healthy ageing, initiatives that could help create entirely new industries in healthcare.

The 2017 Strategy celebrates some of the strengths of the UK including the promise of the 'Golden Triangle' between Oxford, Cambridge and London, the productivity of the UK's R&D capability, the 10% effective corporate tax rates for patented products once the patent box had been factored in and the potential of the NHS one-stop-shop for collection of real world data.

Conversely it acknowledges the limited attraction of the UK as a market that makes up just 3% of the global pharma market and the NHS being the single payer, one that is strapped for cash. Significantly the 2017 Strategy states that "The issues of pricing were explicitly not included in the scope of the report" and for many in the life sciences sector, especially those involved in the development of high technology products, that is the proverbial 'elephant in the room.'

Moreover, the 2017 Strategy acknowledges that the UK has never scaled a company to mid-size, in contrast with the US's successes such as Biogen and Amgen and notes the UK's loss of some manufacturing sites, such as Pfizer's Sandwich plant.

The 2017 Strategy and the Accelerated Access Review

The challenge will be whether the funding and support will be there to implement this vision. The first test may be the 2017 Strategy recommendation that the findings of the Accelerated Access Review ('AAR'), chaired by Sir Hugh Taylor, which was published just over a year ago in October 2016, be implemented. The AAR proposed:

- optimising use of existing and emerging regulatory approval pathways;
- generation and use of patient data to establish and define the benefits of innovations; and
- a much more streamlined approach to new product reimbursement including conditional licensing and new tools for pricing individual products.

The 2017 Strategy insists that the Government should implement the AAR, emphasising the need for closer collaboration between industry and the National Health Service, seeking to shift the relationship from being "essentially confrontational to one where they can work constructively together." This seemed to provoke an early Government reaction when it finally did respond to the AAR just a few weeks later, "broadly" accepting the AAR proposals. The response promises from April 2018 a new Accelerated Access Pathway, a fast-track route into the NHS for 'breakthrough' selected medicines and technologies selected by the 'Accelerated Access Collaborative,' which would benefit from a support package to accelerate clinical development through a more frequent and creative use of existing procedures and a fast-track route through the NHS's approval and reimbursement processes.

While the news has been welcomed in pharma and biotech circles it is clear that the £86 million in funding is intended mainly for small-to-medium sized enterprises in the digital health field with products able to help the NHS budget go further, and to help the 15 regional Academic Health Science Networks ('AHSNs') in the task of "encouraging grassroots adoption and uptake of new medical technologies." Only £6 million will support medtech, diagnostics and pharmaceutical products. Moreover, this attempt to encourage innovation in the NHS is only the latest of some half dozen efforts over the last decade or so including Innovation Health and Wealth (2012). Additionally, the budget constraints imposed by the Pharmaceutical Price Regulation Scheme ('PPRS'), the National Institute for Health and Care Excellence ('NICE') and NHS England (through the Strategic Commercial Unit) on new products will be unaffected as will the Budget Impact Test under which NHS England can negotiate with companies whose products have been approved by NICE, but could have an annual cost to the NHS of more than £20 million a year.

The 2017 Strategy and post-Brexit regulation

The 2017 Strategy also briefly addresses regulatory issues and acknowledges the impact on the future of regulation in the life sciences sector of the UK

Whilst the Government acknowledges the key Brexit challenges of skills access and friction free EU/UK regulation, whilst it can control the former, the latter depends wholly on a good trade deal.

leaving the European Union. As the UK has announced that it does not intend to remain in the European Economic Area ('EEA') or be part of the European Free Trade Association ('EFTA'), the effects on the life sciences sector are likely to be substantial. This is because the UK would no longer keep access to many of the benefits of the EU system, such as the centralised procedure for marketing authorisations, the EU portal for clinical trials and the pharmacovigilance database.

Assuming an outcome other than a 'hard Brexit,' the 2017 Strategy reflects the industry's hope that such a deal allows the UK and the Medicines and Healthcare Products Regulatory Agency ('MHRA'), using its strong global reputation for innovation and leadership in the field of regulation, to seek to continue to work closely with the European Medicines Agency ('EMA'), now to be situated in Amsterdam. For medicines licensing, continued involvement of the MHRA in the review of dossiers and joint scientific deliberations would enable patients across the UK and EU to benefit from the UK's high quality regulatory expertise.

The UK could make a 'sovereign decision' based on the shared information, should it not wish to seek to be part of the EU voting system. This would be the preferred solution given the impracticability, attractiveness and cost of a wholly free-standing system. In addition it points to the benefits of scale in areas such as pharmacovigilance and clinical trials where greater patient numbers will improve the evidence for decision making. Similarly, given recent agreements across the FDA and EMA for mutual recognition of manufacturing inspections, the UK should continue to share expertise and collaborate with the EMA system as in the past, and seek to share in these mutual recognition agreements. Medical device assessment through CE marking currently works across a wider than EU footprint so it is similarly recommended that the UK seeks to continue to operate within this wider framework.

IP and Brexit

The 2017 Strategy does not particularly address free movement and intellectual property ('IP') and it is hoped, as the nature of the UK's departure becomes clear, that these issues will be clarified. The UK's departure from the EEA means that EU exhaustion of rights rules will cease and it is unclear what the UK Government will replace them with.

Moreover with an industry as dependent on IP rights, in particular patent rights, as the pharmaceutical and life sciences industry, Brexit causes considerable uncertainty regarding the geographical validity of patents. Additionally, the EU is close to creating a 'Unitary Patent' ('UP') and a 'Unitary Patent Court' ('UPC') which offers patent protection across the EU. The UK has been committed to implementing the UPC agreement, but with Brexit approaching it is possible that the UPC system will proceed without the UK.

There is further doubt as to how the protection afforded to patentees by Supplementary Protection Certificates ('SPCs') would be treated under UK law. These extensions to patent protection of up to five years are available in various forms in many countries (e.g. the US and Japan). It is possible that the EU Repeal Bill will preserve any SPCs that have been previously applied for and equivalent regulations may then be enacted by the UK Government for future SPCs but it is unclear what the nature of these will be and how far SPC rights will extend in the UK in the future.

Conclusions

Sir John indicated that he was confident that most of the recommendations in the 2017 Strategy will be accepted, and Greg Clark has stated that "We will be engaging with Sir John in the coming months to work towards a sector deal that helps us seize the opportunities in this field." The national Industrial Strategy just published on 27 November confirms what is termed a 'Sector Deal' with the life sciences sector which the Government indicates is to be built on the 2017 Strategy. We await specifics of what the 'deal' will comprise.

However, the uncertainty surrounding Brexit pervades despite the 2017 Strategy including the degree of preparation and knowledge of central Government in relation to the future of the industry outside the EU. There are three life sciences reports within the 58 sector analyses of the economic impact of EU withdrawal which the Government initially refused to publish, with the Government arguing that disclosure of the studies would undermine the UK's negotiating position.

However, critics claim the information is being hidden out of fear the findings might embarrass the Government over a lack of planning - the Government finally agreed to their publication at the end of November, but at the time of writing the concern is that only redacted versions have been released and the Exiting the European Union Select Committee is vigorously pursuing full disclosure. Whilst the Government acknowledges the key Brexit challenges of skills access and friction free EU/UK regulation, whilst it can control the former, the latter depends wholly on a good trade deal.

Additionally, any attempt to attract life sciences investment into the UK has to be considered against what has been described as the currently "essentially confrontational" Department of Health/NHS England interactions with the industry, driven by tight reimbursement and pricing policies and the need for a change to a more constructive relationship. Hopefully such a change will form part of the promised life sciences 'deal.'