The Life Sciences Industrial Strategy

The Life Sciences Industrial Strategy was published on 31st August. The report, written by life sciences champion, Professor Sir John Bell, provides recommendations to the Government on the long-term success of the life sciences sector from an industry perspective. The strategy has been developed in collaboration with industry, academia, charity, and research organisations.

The report acknowledges that the life sciences industry represents one of the dominant economic sectors in the UK and includes biopharmaceuticals, medical technology, genomics, diagnostics and digital health, and has a very high productivity compared to other sectors. The industry generates a wide range of products including drugs, medical technology, diagnostics and digital tools, as well as products for consumer health. The industry is widely distributed geographically and brings growth and jobs to almost every region of the UK.

In the light of this, it was recognised in the strategy that the UK should continue to excel in the sectors that have dramatically improved patient outcomes.

Manufacturing

One of the key goals of the strategy was to attract substantial investment to manufacture and export high-value life science products. This will involve accepting the recommendations of the Advanced Therapies Manufacturing Action Plan and applying its principles to other life science manufacturing sectors, including a partnership programme with Industry that will address scale-up challenges and drive up productivity.

NHS Collaboration

The report recommends that the Accelerated Access Review (AAR) is adopted with national routes to market streamlined and clarified, and welcomed the recently announced £86 million joint funding by the Department for Business, Energy and Industrial Strategy (BEIS) and the Department of Health (DH) to support the implementation of the AAR.

The strategy outlines how industry has expressed a willingness to collaborate with the NHS to enable service transformation and support the continued improvement in patient outcomes by building on the recommendations of the AAR. It was suggested that a forum for early engagement between industry, the NHS and other bodies such as the National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare products Regulatory Agency (MHRA), should be created in order to agree commercial access agreements.

Some of the other proposed collaborative activities included:

• Risk-sharing in development of tools and therapies using NHS infrastructure to run evaluative studies and delivering benefit sharing from proven technologies
• Collecting real-world data and linking this in a closed system to assess clinical and cost-effectiveness
• Modernisation of clinical trials including digitisation and regulatory innovation.

As a means of measuring the success of the NHS in collaborating with Industry it was also outlined that in the next five years, the NHS should engage in 50 collaborative programmes in late-stage clinical trials, real world data collection, or in the evaluation of diagnostics or devices.

Improving Patient Access

The report sets out that evidence demonstrates that access to and diffusion of products in the NHS
is often slower than in some comparable countries. The strategy outlines the ambition for the UK to be in the top quartile in comparator countries, both for the speed of adoption and the overall uptake of innovative, cost effective products by the end of 2023.

One proposed strategy to achieve this is to deliver a conditional reimbursement approval for implementation as soon as licensing and value milestones are delivered so that patients can benefit sooner. Other suggestions were that value assessments should evolve in the long-term with improved patient outcome measures, affordability and cost management data extending beyond one-year timeframes and that NICE’s funding model for technology evaluation should be set up in a way that does not stifle small and medium enterprise SME engagement.

Regulation

The MHRA regulates medicines and medical devices for the UK, and having been instrumental in shaping the European regulatory systems, now has a strong global reputation for innovation and leadership in the field.

In light of the UK leaving the European Union, the future of regulation in the life sciences will need to be considered. Given the UK market size at around 3% of global pharmaceutical sales, a wholly free-standing system would likely be high cost. Industry has therefore expressed that the UK and MHRA should seek to continue to work closely with the EMA.

Pharmaceuticals – Marketing Authorisation

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.

The report outlined, that as it stands, the UK market is too small even with the fastest and most innovative regulatory system in the world, to stand alone from a larger decision-making bloc.

Implementing the recommendations

It is believed that if implemented, the recommendations of the report will deliver economic growth through the projects and programmes outlined. However, there is a need for oversight of the execution of the strategy over the next five years with accountability for the relevant programmes being assigned. It is also recommended in the strategy that both Industry and Government should regularly review progress against the objectives of the strategy to ensure the most desirable outcomes for the economy, Industry and the NHS.

Industry Response

In response the ABPI said “We want the UK to be one of the best places in the world for discovering, developing and adopting new medicines and this Strategy provides the focus for all life science partners to work together to deliver exciting medical innovations for patients. The NHS is rightly at the heart of the strategy: if it can build on its unique capability to use health data in research and development and address the UK’s long-standing challenge of adopting new treatments, it will create a virtuous circle for all and deliver massive health and economic benefits to the UK”.

MAP insights

Although this is an industry led document rather than Government policy its development will have been shaped by Government thinking. Sir John Bell is highly regarded and the recommendations will be taken very seriously by Ministers who have already identified the life science industry and central to the nation’s industrial strategy. Industry should continue to reiterate these messages to ensure that the Government’s response which will include a response to the AAR will reflect these recommendations.