

The UK Life Sciences Sector in Election Year

By Ralph Cox and Nii-Lante Bannerman

The next general election in the UK has to take place before 28 January 2025, but the Prime Minister, the Right Honourable Rishi Sunak MP, can decide to call it for an earlier date of his choosing. Current indications are that it will be in October or, more likely, November 2024.

But, whatever the date, after 13 years in power, opinion polls suggest that Mr Sunak's Conservative Party will lose power and be replaced by Sir Keir Starmer KC's Labour as the governing party. This article, therefore, considers the Conservative Government's approach to the UK's life sciences sector over recent years and how that might change under Labour.



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The Conservative's Life Sciences Strategy

The Conservative Party has consistently recognised the importance of the life sciences sector to the UK economy and has sought to support and further develop it through various policy initiatives and commitments as well as through new legislation and regulation. For example, the Government commissioned the report "Life Sciences Industrial Strategy", issued in August 2017, and produced its own strategy document "Life Sciences Vision" in July 2021. The Conservative's main aims from these documents are to:

- improve the tax environment to encourage research and development and capital investment in the UK life sciences industry;
- support the growth of life sciences clusters around the UK;
- attract skilled workers in the sector to the UK;
- establish data innovation hubs;
- improve the UK as a venue for clinical trials; and
- speed up regulatory approvals by the Medicines and Healthcare products Regulatory Agency (MHRA) and also assist overseas trade in medicines through mutual recognition agreements with other regulatory agencies.

These strategic aims respond to long-term concerns in the sector that the lack of manufacturing capabilities and investment capital means that small to mid-sized UK biopharma and medical devices companies are limited in the growth they can achieve here in the UK before they need to move their centre of operations to the US or enter into a deal with a deeper-pocketed multinational (often an acquisition of the company or its lead candidate(s)). The aims also recognise the continuing shortage of skilled workers and the regulatory issues affecting the sector, both of which, in part, result from Brexit.

A further Conservative strategy document is the "Genome UK" Report of 2020. It sets out a 10-year strategy to "create the most advanced genomic healthcare system in the world, underpinned by the latest scientific advances, to deliver better health outcomes at lower cost". Data from genome sequencing is the key underlying the strategy's three "pillars" of improving diagnosis and increased use of personalised medicine; improving predictive and preventative care through expanded and targeted screening programmes; and, supporting research, particularly through the availability of high quality genomic data.

Developments Made

(i) *The Windsor Framework*

Despite significant issues such as the Covid pandemic, the invasion of Ukraine and the return of high inflation that have understandably taken up much of the Government's time over the last few years, there have been some notable achievements in, or that affect, the life sciences sector – some as a result of Government policy, one or two notwithstanding it.

One of the most significant from an industry perspective is the Windsor Framework published in February 2023. While its primary concern is to ease the post-Brexit barriers to trade between Northern Ireland and the rest of the UK (i.e. Great Britain or "GB") contained in the Northern Ireland Protocol to the EU-UK Withdrawal Agreement, it has wider implications.

The main issue with the Protocol is that, under it, EU law has continued to apply in Northern Ireland whereas it ceased applying in GB from 1 January 2021⁽¹⁾. This had various consequences in the life sciences field, including from a life sciences regulatory perspective:

- the MHRA having to issue different types of marketing authorisations for different parts of the UK;
- the European Medicines Agency's centralised authorisations continuing to apply to Northern Ireland but not to GB (where they are invalid); and
- medical devices and in vitro diagnostic medical devices being regulated under the EU's 2017 Regulations in Northern Ireland but under the older medical devices Directives in GB⁽²⁾.

The movement of medicines from GB to Northern Ireland was also made difficult by the medicines being treated as imports into Northern Ireland, with the regulatory burdens that entailed.

The Windsor Framework addresses certain of these difficulties by providing that:

- the MHRA will regulate and authorise all medicines in Northern Ireland in accordance with UK law and through UK-wide marketing authorisations;
- medicines can be transported from GB to Northern Ireland without need for the importation site to hold an EU manufacturer/importer authorisation; and
- separate customs channels (or lanes) will be introduced – a "green" lane, with lesser requirements and checks, for goods (including medicines) from GB and intended for the Northern Irish market only, and a "red" lane for goods for onward supply to the EU market through the Republic of Ireland.

⁽¹⁾ Following an 11-month transition period from 31 January 2020, when the UK formally left the EU. Certain EU laws have been retained in the UK, "assimilated" law since 1 January 2024, but supremacy of EU law and single market rules no longer apply. There has also been divergence as new domestic UK law is made.

⁽²⁾ These Directives having been implemented through UK domestic regulations prior to Brexit whereas the Regulations came into force too late to form part of the EU law retained as part of UK law following Brexit.

A further point worth noting is that medicines for the UK market (including Northern Ireland) will now need to be labelled “UK-only”⁽³⁾.

These changes under the Windsor Framework are being brought into effect in stages: the new green custom lane will take effect from September 2024 and the changes on the authorisation and labelling of medicines from 1 January 2025.

(ii) Horizon Europe

An important consequence of the Framework Agreement was that it cleared the way for the UK to re-enter the Horizon Europe research and innovation programme.

Although R&D groups based in the UK were encouraged by the Conservative Government to continue to apply for Horizon funding post-Brexit, with the Government underwriting applications, the funding received had fallen dramatically from €959 million (£829 million) across 1,364 grants in 2019 to around €22 million (£19 million) through 192 grants in 2023⁽⁴⁾. This fall-off in funding, as well as reduced collaboration with EU teams and participation on long-running programmes, had unsurprisingly become a major issue for UK-based researchers.

From January 2024, under a bespoke deal negotiated by the EU Commission and the Conservative Government, the UK will become a full associate member of Horizon Europe until the end of its 7 year term in 2027, with UK researchers and research organisations being eligible for funding under the programme’s €95.5 billion (£82.5 billion) budget on equal terms with counterparts in EU member states.

(iii) Medical Devices & CE Marking

While the disparity discussed above in the regulatory framework for medical devices between GB on the one hand and the EU and Northern Ireland on the other will continue, following a 2021 consultation, the Government is intending to update the UK regulations including by aligning them with the EU framework in some respects as well as with international initiatives (examples of the latter being amendments to IVD classifications and a framework for international recognition).

Regarding EU alignment, the main point relates to CE marking. Upon Brexit, the UK introduced UKCA marks, overseen by the MHRA, as a replacement for CE marking but with a transitional period in which CE marking would continue to be accepted. The transitional period will now be extended to 30 June 2028 for implantable medical devices and to 30 June 2030 for general medical devices and IVDs. The Government’s most recent update on the area (dated 9 January 2024) also says that it will “Bring the essential requirements for medical devices being placed on the market in GB into greater alignment with those of the EU. This will include cybersecurity requirements for software as a medical device including for artificial intelligence”. The Government will be discussing the detail of the changes with stakeholders during 2024.

(iv) Other Points

Similarly to the reprieve for CE marking, the Government has pragmatically retreated from its intended bonfire of the numerous EU regulations that remained part of UK law following Brexit. Instead what was “retained” EU law has, from 1 January 2024, become “assimilated” law, which is no longer supreme over UK law. This means that, although many EU regulations will in effect continue to apply in the UK, ministers now have wide powers to revoke, amend or update EU-derived laws (with limited scrutiny by Parliament) and appeal courts can more readily depart from EU case law (and its own EU-related case law)⁽⁵⁾.

More positively, the Government can point to a number of notable achievements:

- In 2019 a national action plan for tackling antimicrobial resistance was issued, under which NHS England ran a pilot scheme for a new reimbursement model. This involved paying two drugs companies a fixed-fee irrespective of the amount of their antimicrobial drugs actually used and instead based mainly on the value of the medicines to the NHS. Following the success of the pilot, the NHS is now in the process of adopting the scheme more widely in the expectation that this “subscription fee” model will remove incentives to overprescribe antimicrobials and that the extra money paid to the drug companies through the scheme will encourage research into new antimicrobial medicines⁽⁶⁾.

⁽³⁾ The EU’s Falsified Medicines Directive will not apply to UK-only medicines, but the MHRA has said that it expects anti-tamper devices to remain on all medicine packaging.

⁽⁴⁾ Up to September 2023 when re-entry into the programme was agreed.

⁽⁵⁾ In deciding whether to depart from the existing case law, the courts should consider whether there is a relevant change of circumstance and the extent to which the case law restricts the proper development of domestic UK law.

⁽⁶⁾ This is the first scheme of its type in the world and has generated considerable interest in other countries.

- In response to industry criticism that the UK was out of line with other major markets in how little it was paying for medicines, a new pricing scheme for the NHS's drug purchases was announced in November 2023. Under the scheme the level of annual allowed growth in sales of branded medicines will double from 2% in 2024 to 4% by 2027. As part of the deal, the pharmaceutical industry will invest £400 million (€463 million) over the next 5 years to support innovation in the UK, including by improving the capacity for clinical trials within the NHS, boosting sustainable manufacturing and supporting innovative therapies such as personalised cancer therapies and one-time gene therapies.
- During 2023, the MHRA cleared the backlog of nearly 1,000 clinical trial applications resulting from the Covid pandemic and introduced streamlining measures to speed up new applications⁽⁷⁾.
- Also during 2023, the Government announced the creation of two investment zones for life sciences. These are in Liverpool and West Yorkshire, based around local universities and the pre-existing clusters of life sciences businesses in those areas.

Next steps for the Conservative Party?

The Conservative Government's commitment to life sciences has continued in recent months despite increasingly speculation about the forthcoming election and tax give-aways that it may make in its Spring and Autumn budgets in order to boost its electoral prospects. Examples have been the creation of a £100 million (€116 million) fund aimed at exploring ways in which the use of AI in life sciences can be accelerated (announced in late October 2023) and the "Landmark National Vision for Engineering Biology", a £2 billion (€231 billion) plan to boost the use of biological techniques in the development of new medical therapies, crop varieties, eco-friendly fuels and chemicals over the next decade (announced in December 2023).

To this extent it also seems that the resignation of George Freeman MP, the long serving Minister for Science, Research and Innovation who, for example, oversaw negotiations on the UK re-joining Horizon Europe, has not led to a loss of focus on the life sciences sector. That said, as the election approaches, attention will inevitably be diverted from day-to-day Government business to electioneering.

⁽⁷⁾ The MHRA is now comfortably meeting the statutory timescales of producing initial assessments of a trial application within 30 days and of assessing amendments within 35 days. A new notification scheme has also been reduced, which will further reduce the approval time for low-risk trials by more than 50%.



Labour's Life Sciences Strategy

The UK's Labour Party last held government in 2010 and its leading figures have all changed in recent years. Its front bench therefore has little track record that it can point to regarding the life sciences sector. Labour has also been careful over the last year or so not to give much detail on its policy intentions before the election campaign starts in earnest. Accordingly, in its Industrial Strategy, published in September 2023, Labour had said little that was specific to life sciences, focussing instead on general cross-sector intentions such as to address supply chain issues, boost R&D spending to 3% of GDP and improve long-term investment through public/private partnerships.

The Party had, though, made it clear that it supports the life sciences industry as an important driver of economic growth and been quietly engaged in discussions with industry bodies. This has now resulted, on 30 January 2024, in the announcement of Labour's plans for the sector. These include a pledge to increase R&D investment in the pharmaceutical sector by £10 billion a year if elected. Other plans include moving from three-year to ten-year funding cycles, so as to create a more certain funding environment and avoid short-termism, generally improving access to funding (including by creating a UK version of France's Tibi fund), cutting red-tape and improving the regulatory process. These plans are in line with comments from Rachel Reeves, the Shadow Chancellor of the Exchequer, at the Party's October 2023 conference that Labour would fast-track reforms in the life sciences industry.

Another factor likely to be important in Labour's approach to life sciences (and policies generally as they develop in the lead up to the election) is its more pro-EU stance compared to the Conservatives. The Labour Party leader, Sir Kier Starmer, has said that he would like the UK to re-set its relationship with the EU and to renegotiate the current Brexit deal. It therefore seems likely that Labour will seek to maintain regulatory harmonisation with the EU and strengthen the relationship between UK and EU regulators, leading towards a mutual recognition of standards. Labour has also said that it will aim to boost the number of clinical trials being conducted by the NHS, quicken the uptake of new medicines by the NHS and create more biotech clusters.

Conclusion

It is encouraging for the life sciences industry that both the Conservative and Labour Parties acknowledge its importance to the UK economy. Both Parties' strategies also share similar aims to encourage funding, increase research & development and improve the regulatory environment in the sector. While it can be expected that the Conservative Party will provide more of the same if it remains in power following the election, Labour's plans should develop in the details of how its now stated aims are to be achieved as the election process gets underway. The industry will ultimately be hoping for a period of political stability following the election, after the volatility of the last few years, so that it can build lasting relationships with ministers and work with whichever party is in power in constructively critiquing and implementing its policies.

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