Pricing innovative medicines: Tara Raveendran

Challenges and opportunities for UK life science

At first glance the UK life sciences sector is facing many of the same challenges as those encountered by other mature economies: an ageing population, the emergence of new industries and technologies, such as artificial intelligence, and increasing competition from newer market entrants. The life sciences sector is a key pillar of the UK's economy and uniquely positioned to deliver growth on a global scale. However, unlike many other mature economies, the sector is embedded in a national healthcare system that is strongly supported by the population. This brings opportunity but also structural issues that are particular to the UK, and that are currently preventing the country from taking full advantage of its powerful scientific enterprise.

This article examines some of these issues. One of these is pricing and reimbursement, another is market size and growth. Leaders from industry and government are acutely aware of the problems and are mapping out strategies to address them.

One of the leading indicators of the malaise in Britain's growth economy is the departure of companies, including life science enterprises, from the AIM market of the London Stock Exchange. AIM was created in 1995 as a sub-unit of the LSE to give small, high-growth companies an opportunity to raise capital in a more lightly regulated environment. According to the chartered accountants UHY Hacker Young Group, there were 679 companies of all types listed on the AIM market at the end of March. This compares with the exchange's peak of 1,694 companies in 2007.

Among the departures, about 15% were in the life science sector. Table 1 gives a summary of recently delisted biotech companies.

There are many factors at play that affect companies across all sectors. For the pharmaceutical industry however the market shrinkage is especially impactful because of its need for sizeable amounts of capital to finance long periods of drug development, and low success rates. The average time to bring a new drug from discovery to the market is 10 to 15 years, with the probability of a drug making it from Phase 1 through to approval at around 10-15%, according to the US industry group PhRMA.

The UK is at a disadvantage because of the small size of its domestic market. According to a 2024 report by Cambridge Econometrics, the market has shrunk by nearly £140 billion since the country left the EU in 2016. Currently, the UK makes up just 2% to 4% of the $40 to $60 billion global pharmaceutical market by revenue. This compares with a more than 50% share for the US. The UK share is even less when measured by the number of proprietary medicines in development, according to IQVIA, the life science research group.

Like many other developed economies, the UK is facing strong headwinds of macro austerity, and specifically healthcare budgetary constraints. This is a lingering consequence of the Covid pandemic and slower growth domestically. Like many other countries, it is trying to set new priorities for spending across the economy in order to free up fresh funds for investment. One of the most difficult issues on the agenda is its policy for pricing and reimbursing innovative, proprietary pharmaceuticals.

For the past 70 years, the UK has negotiated voluntary pricing agreements with industry that are intended to give the National Health Service access to the newest drugs under an agreed formula which features a price cap for branded, proprietary medicines sold by pharma to the NHS. If the total spend by the NHS for the drugs exceeds the cap, the industry is expected to return a percentage of sales to the health service. The concept is to give the NHS a stable framework for spending on new drugs, while encouraging industry

Table 1. Summary of recently delisted AIM Biotech companies

Company	Delisting Date	Post-Delisting Activity	Comment
e Therapeutics	May 2024	Raised £28.9M from private subscriptions post-delisting; exploring Nasdaq	Raised private capital; planning potential US float
Redx Pharma	April 2024	Opted for private status to access broader capital network	Private; retained UK operations
Destiny Pharma	August 2024	Sought private capital to fund P3 trials	In administration (Aug 2024)
ReNeuron	September 2024	Entered administration; exploring private options	Admin-led, private restructure
C4X Discovery	April 2024	Intention to return to private status; may explore US listings	Likely private; possible US future listing
Synairgen	March 2025	Delisting to save costs (~£650K/ year); backed by £18M from private investor	Private; funding via TFG Asset Management
BiVictriX	Announced	Seeking private capital, citing fundraising hurdles on AIM	Fundraising plans underway
Alliance Pharma	January 2025	Acquisition by private funds (DBAY & Edmond de Rothschild)	Private post-buyout

Source: SSquared Consulting

to invest in research and development. The policy does not involve price controls on individual medicines.

Known as the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG), the scheme is complemented by a statutory scheme. Companies are not required to join VPAG but if they don't, they fall under the statutory scheme. The newest VPAG came into force in January 2024 and runs until the end of 2028. The repayment rate by companies to the NHS was 15.1% in 2024. But this year the rate was set at 22.9%. In January, the industry association ABPI estimated that the higher rate would require repayments by industry to the government of £3.4 billion, which is more than total repayments for the five years from 2014 to 2018.

On 22 August, the ABPI announced that meetings with the government during the spring to find a mutually agreed solution didn't reach a conclusion. "Specifically, industry and government have not been able to reach agreement on the changes needed to rapidly return the UK to single-digit, internationally competitive payment rates on medicine sales to the NHS, nor address the way in which NICE (the National Institute for Health and Care Excellence) fundamentally values innovation, for which the standard decision-making parameters have not changed for almost a quarter of a century," the ABPI said in a statement.

The elephant in the room

The elephant in the room is the UK's policy for assessing the cost-effectiveness of new medicines, which is the basis for deciding whether they will be funded by the NHS or not. Drugs not funded by the NHS can still go on the market, but for commercially related prices. A recommendation by NICE carries weight, both for enabling access to the NHS but also for the stringency of its evaluations.

NICE assesses value according to cost-effectiveness thresholds. The goal is to align a drug's price with the value it provides in quality-adjusted life years (QALYs) and benefits compared with existing treatments. Generally medicines costing between £20,000 and £30,000 per additional QALY achieved is considered good value for the NHS, according to Jacoline Bouvy, NICE's programme director for medicines evaluation. But this threshold is often misunderstood as meaning the NHS cannot spend more than £20,000 to £30,000 per patient per year. "A medicine's yearly treatment costs can be much higher than £30,000 per person and still be considered cost effective because we focus on the difference in costs between the new medicine and the current standard of care," she wrote in a blog on 13 December 2024.

There are caveats however. One is an apparent misalignment between NICE's current cost-effectiveness thresholds and the evolution of the NHS budget. NHS spending has increased in recent years while the QALY thresholds have remained largely unchanged, according to industry observers. But the biggest, and most widely publicised controversy surrounds a NICE decision in March 2024 to deny financial support to AstraZeneca Plc for a new indication for its breast cancer treatment Enhertu. Enhertu was first approved by the US Food and Drug Administration to treat breast cancer in 2019. It was first recommended by NICE for reimbursement by the NHS in 2021 and again in December 2022. Since its first approval, Enhertu has gained six new indications from the FDA. However, the company was unable to get a recommendation from NICE in 2024 for an indication of advanced HER2-low metastatic breast cancer. According to the *Financial Times*, the two parties could not agree on a price.

This incident has resonated throughout the financial community. Investors, including Gareth Powell, head of healthcare at Polar Capital, have warned that countries can lose investment if they cannot offer an attractive end market considering the cost and risk of developing new drugs. He went on to note that early-stage technologies and products are likely to see their development moved to places where there is an attractive opportunity like the US.

The UK government is aware of the problems. In July, it published a plan for the life sciences with the goal of becoming Europe's leading location for the sector by 2030. The industry already supports 300,000 jobs and generates £100 billion for the economy. The plan is to lighten regulation and provide incentives for clinical trials and manufacturing. The stakes are high. If current trends continue, the UK could lose up to £11 billion in R&D investment by 2033. This estimate is based on the assumption that VPAG rebates remain high, which is a risk, but not a certainty.

Kate Bingham, managing partner of SV Health Investors, has expressed concern that pharma companies will not run clinical trials in the UK if there is no prospect for patients in these trials to get access to these drugs once they have been approved. This could happen if the drugs were not reimbursed under the NICE and VPAG rules. An encouraging sign is that the NHS has expressed interest in new payment schemes that could lead to differentiated pricing for drugs with multiple indications. These prices would be based on a cost-effectiveness evaluation per use case. Innovative access agreements are already being tested across the country including one for Mounjaro, the weight loss drug recommended by NICE for weight management in December 2024. Under the trial access scheme, Eli Lilly & Co, the drug's developer, is helping pay for weight management care, including access to Mounjaro, through pharmacies.

The strength of science and technology

According to the US research group, Foundation for Research on Equal Opportunity, the UK was in the eleventh position in 2024 for its contribution to healthcare innovation globally. It secured fourth place for excellence in science and technology. This was based on strong contributions to global health from its scientists and universities. The UK showed above average performance in quality of life and choice for its citizens. However it fell to 29th place in the category for fiscal sustainability. This will be a marker of success going forward.

This article was prepared by Tara Raveendran, PhD. She is founder and manager of SSquared Consulting, a life sciences consultancy focusing on healthcare-focused start-ups. She has worked in equity research for over 15 years.