"Brexit means Brexit"— but what will it mean for pharmaceutical market access?

Part 3: Is there a silver lining to this cloud? - a guest article from Neil Grubert

On 23 June 2016, the UK electorate stunned politicians, pundits and business communities right around the world by voting to leave the European Union (EU). While the impact will naturally be greatest for the UK, the repercussions of the vote will be felt across Europe and beyond. In the weeks since the referendum, there have been countless assessments of the potential consequences of the UK's decision to leave the EU. This three-part analysis focuses specifically on what Brexit will mean for pharmaceutical market access. Part 1 considered the current uncertainty surrounding the UK's departure from the EU, the importance of the life sciences industry to the UK, and the importance of the UK to the international life sciences industry. Part 2 looked ahead to the potential consequences of Brexit both before and after the UK actually leaves the EU. Part 3 reflects on how the challenges associated with Brexit could be turned into opportunities.

TURNING CHALLENGES INTO OPPORTUNITIES FOR THE UK PHARMACEUTICAL MARKET

An uncertain outlook, even without Brexit

Even if the outcome of the referendum had been to remain in the EU, the UK pharmaceutical market would have faced exceptionally challenging times in the coming years. This is because:

- The NHS is struggling to meet growing demand for its services: the House of Commons Select Committee on Health recently described the scale of the funding challenge as "colossal."[1]
- The Accelerated Access Review, which is scheduled to publish its final report in September, is expected to recommend new, flexible methods of pricing and reimbursement, including price–volume agreements, multi-year outcomes-related agreements, patient cost caps and free or discounted treatment initiation, as well as measures to encourage local drug and therapeutics committees to pursue medicine optimization and cost reduction.[2]
- NHS England is implementing a prioritization framework for specialized services to review the status of approximately 80 drugs over the next year.[3]
- The reformed Cancer Drugs Fund will require all new oncology drugs to undergo a pre-launch assessment by the National Institute for Health and Care Excellence (NICE); manufacturers of drugs covered by the £340 million fund will have two years to gather real-world evidence of effectiveness and cost-effectiveness as a condition of general NHS reimbursement in England.[4]

- To minimize the amount of HTA activity at a local level, drugs that are not appraised by NICE will in future be evaluated by one of four new regional medicines optimization committees on behalf of the NHS in England.[5]

- Fifty vanguard sites have been established to explore the potential of new models of care, including integrated primary and acute care, multi-specialty community providers and acute care collaborations.[6]

These reforms, alongside the changes that may accompany Brexit, could deter companies from doing business in the UK. Alternatively, the life sciences industry could see the forthcoming period of unprecedented change as an opportunity to engage with the government to help shape the future evolution of the NHS in general, and the UK pharmaceutical market in particular.

Urgent need for the life sciences industry to set out its stall

One of the highest priorities will surely be to make a strong case to the government for the regulatory environment life sciences companies will need in the UK, not just for the benefit of their own businesses and the national economy, but also to ensure that patients are not denied timely access to innovative medicines. The UK-EU Life Sciences Transition Steering Group will play a crucial role in communicating the industry's needs and aspirations.

The negotiations with the EU will be central to defining how medicines are regulated in the UK in the coming decades, but national policy will also be a major factor in shaping the regulatory environment. Sir Andrew Witty, CEO of GlaxoSmithKline, has posed the following question: "To what extent are we prepared to give up being a rule shaper in a space that we've dominated historically as a country? ... If we remain engaged, it really needs to be on the terms of us having a strong voice at the table on the rule set."[7]

Faced with an uncertain future, this may be an opportune time to undertake a publicity campaign to highlight the life sciences industry's importance to the economy and to the healthcare system.

Capitalize on the Accelerated Access Review

The expected publication of the final report of the Accelerated Access Review this autumn will require the industry to respond promptly, in order to ensure that recommendations intended to improve access to medicines are widely disseminated and, most importantly, effectively implemented. Drug manufacturers might also have to embrace new pricing and reimbursement arrangements for some new medicines.

Manage the impact of the Pharmaceutical Price Regulation Scheme (PPRS)

It is likely that the vast majority of branded drugs on the UK market will continue to be priced under the terms of the PPRS, until at least the end of 2018, when the current contract expires. Given that the government will be preoccupied with Brexit negotiations for at least the next couple of years, a radical overhaul of the UK pricing system for branded medicines in 2019 seems unlikely. Nevertheless, the industry needs to begin planning now—taking full account of the implications of Brexit—for negotiations with the government regarding the arrangements that will replace the existing PPRS.

In the meantime, the PPRS will require manufacturers to pay rebates if NHS spending on branded medicines exceeds specified growth limits each quarter: as of March 2016, the cumulative total for these payments amounted to £1.296 billion.[8] The industry might consider lobbying for the government to allocate the money from rebates to a fund to cover the reimbursement of innovative drugs.

Seek opportunities for closer collaboration with the NHS

Forthcoming changes to the organization of the NHS present opportunities for life sciences companies to forge new partnerships within the healthcare system. The move towards accountable care, the integration of healthcare and social care, and the increased focus on outcomes all call

for drug manufacturers to reinvent themselves—focusing on delivering healthcare solutions, rather than simply selling pills. Pharmaceutical companies can play a valuable role in providing a range of support services to the NHS. Experience gained in the UK could be exported to other countries.

Promote the value of innovative medicines and a successful life sciences sector

In the long term, the life sciences industry in the UK will need to address what 'value' really means within a changing healthcare environment. A key element of this challenge will be to promote a wider societal perspective on the evaluation of medicines. Pharmaceutical companies must also work with the NHS to recognize long-term value—looking beyond the horizon of the current financial year. Above all, the industry must broaden the debate around value, moving from a narrow focus on cost to take full account of the benefits innovative medicines—as well as a flourishing research-based life sciences sector—will bring the UK in the coming decades.

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[1] Spending review does not meet funding commitment for NHS's vision

[2] Accelerated Access Review: Interim report

[3] Investing in specialized services

[4] NHS England approves Cancer Drugs Fund plans

[5] Regional medicines optimization committees—workshop outputs from 20 April 2016

[6] New care models—vanguard sites

[7] GSK says Britain is still an attractive place to invest

[8] UK pharma contributes £1.3bn to NHS meds bill