



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

Part 2: What will happen before and after
Brexit? - 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 considers 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 looks 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.

PRE-BREXIT IMPACT OF LEAVING THE EU

Pricing repercussions

The most immediate effect of the referendum outcome on market access has been the sharp depreciation of the pound sterling against the euro and the US dollar, as well as other currencies. As a result, imported medicines have become more expensive in the UK, while exports have become cheaper. Exchange rate movements also have potentially significant implications for parallel trade across Europe. Historically, the UK was always a substantial net parallel importer, but relatively low prices for many drugs in the UK have complicated patterns of parallel trade in recent years. The UK remains a net parallel importer of certain drug classes, but is conversely a significant source of parallel exports for some other drug classes.¹ The recent sharp decline in the value of sterling is likely to boost the overall volume of parallel exports from the UK and curb demand for parallel imports. An additional concern is the risk of supply shortages of drugs that are subject to substantial parallel exportation.

Lower prices in the UK, relative to other countries, could also have significant repercussions for external reference pricing in the EU and beyond. The UK is a comparator country for more than 20 countries around the world, including 17 EU member states,² Australia, Canada, Japan, Saudi Arabia, South Korea and Taiwan. Countries might cut their prices for certain drugs in line with the relative decline in UK prices, potentially triggering a domino effect that will also have an impact on countries that indirectly reference UK prices.

Potential for increased financial pressure on the National Health Service (NHS)

A further consequence of the referendum outcome in the short term is an increased risk of a significant economic slowdown. The Bank of England reports “no clear evidence” of a slump in the first month following the referendum³, but the International Monetary Fund recently downgraded its forecasts for gross domestic product (GDP) growth in the UK from 1.9% to 1.7% in 2016, and from 2.2% to 1.3% in 2017⁴. A recent Reuters survey of economists found a median 60% likelihood of recession in the coming year.⁵ A recession would inevitably increase financial pressure on all government departments, including the NHS, which recorded a £2.45 billion budget deficit in the 2015–16 financial year.⁶

Prescription drug spending would likely be a prime target for any economies that the government considered necessary.

Relocation of the European Medicines Agency (EMA)

Once Article 50 is triggered and the countdown to Brexit begins, the EU will almost certainly have to take a fairly urgent decision regarding the relocation of the EMA from London, which has been the organization’s home since its creation in 1995. There appears to be a clear consensus that the EMA could not remain based in a country that is no longer a member state of the EU. The loss of the EMA would arguably contribute to a perception that the UK was becoming a less attractive market for the life sciences industry.

POST-BREXIT IMPACT OF LEAVING THE EU

Forecasting the consequences of Brexit in the years after the UK leaves the EU is fraught with uncertainty at this very early stage in the process. However, it is possible to identify some appreciable risks.

Promise of increased funding for the NHS

The campaign to leave the EU argued that the UK’s contributions to the EU could be better used to fund essential services at home: most notably, the official campaign bus was emblazoned with the slogan, “We send the EU £350 million a week—let’s fund our NHS instead.”⁷ The Remain campaign robustly and repeatedly challenged this figure, and warned that a likely contraction of the economy might actually lead to an overall reduction in spending on the NHS. It remains unclear how much of the money saved from EU contributions will be allocated to healthcare, and whether spending on prescription drugs might grow as a result of increased investment in the NHS.

Future regulatory environment

The long-term shape of the UK market access environment will depend, to a significant degree, on whether, or to what extent, the country retains access to the Single Market. If the UK negotiates a deal similar to the Norwegian model, based on membership of the European Economic Area (EEA), the degree of change that will be required of the life sciences industry could be relatively modest. Although the EMA would have relocated to an EU member state, the regulatory status quo might otherwise remain largely unchallenged.

If, however, the UK ends up outside the EEA, the future shape of the country’s market access environment will be much more uncertain – a prospect that worries the life sciences industry. In the worst-case scenario, the UK would have to establish a completely independent regulatory system, a development that could substantially increase the workload and costs for drug manufacturers. The industry is also concerned that the UK might not be covered by the EU Clinical Trials Regulation, which is expected to streamline access to trials across the EU when it begins operation in 2018. Furthermore, London is currently due to become the home of the new European Unified Patent Court’s pharmaceutical unit in autumn 2016. If the UK were to be excluded from all of these arrangements, it would probably become a significantly less attractive market for the international life sciences industry. As a result, the country might no longer be a priority market for multinationals: manufacturers might delay the introduction of new medicines in the UK, or even decide to forgo a UK launch of certain drugs altogether. Companies have already shown their willingness to avoid marketing their products in major markets that they consider are offering them unfavorable terms: 25 medicines have been



withdrawn in Germany in response to pricing reforms introduced in that country in 2011.

Diminished international influence in health technology assessment

As noted earlier, the UK is generally considered a world leader in the field of health technology assessment, largely on account of the international reputation and influence of the National Institute for Health and Care Excellence and the Scottish Medicines Consortium. It remains to be seen, however, whether the UK will be in a position in the long term to play an active role in the work of the European Network for Health Technology Assessment (EUnetHTA), and whatever body succeeds it after 2020. In the absence of a UK contribution to international HTA collaboration, agencies from other EU member states would need to fill the breach.

Implications for parallel trade and external reference pricing

In the event that the UK leaves the Single Market, the legal basis for parallel trade with EU member states would presumably cease to apply. It would be interesting to see if EU countries that take account of UK prices for external reference pricing would continue to include the UK in their baskets of comparator countries.

In Part 3 of this article we will reflect on how the challenges associated with Brexit could be turned into opportunities.

¹ [Parallel trade: Which factors determine the flow of goods in Europe?](#)

² [Study on enhanced cross-country coordination in the area of pharmaceutical product pricing](#)

³ [Business as usual: Bank reports no slump](#)

⁴ [Uncertainty in the aftermath of the UK referendum](#)

⁵ [British slide into recession to force BoE's hand next month – Reuters poll](#)

⁶ [Deficits in the NHS 2016](#)

⁷ [EU referendum: Statistics regulator loses patience with Leave campaign over '£350m a week' EU cost figure](#)



	IMPACT IN THE UK	IMPACT IN THE EU
POTENTIAL PRE-BREXIT IMPACT		
NHS funding	Recession (forecast by many economists) would increase financial pressure on the NHS, including the prescription drug budget	-
Drug prices	Depreciation of the pound sterling will make UK imports more expensive, and exports cheaper	
Parallel trade	Parallel importation into the UK is likely to decline	Parallel exportation from the UK is likely to increase
Supply stability	Increase in parallel exports could lead to shortages of some drugs	-
External reference pricing	-	Lower UK prices, relative to other European markets, could trigger price cuts in countries that reference the UK
Relocation of the European Medicines Agency (EMA)	Loss of the EMA from London would contribute to a broader erosion of the attractiveness of the UK market	The new home of the EMA would become a more attractive market to manufacturers than previously
POTENTIAL POST-BREXIT IMPACT		
NHS funding	Referendum pledges of increased NHS funding could boost pharmaceutical spending directly or indirectly	-
Clinical trials	If excluded from the EU Clinical Trials Regulation, the UK would likely become a less attractive center for clinical trials	Other European countries could host trials that would otherwise have been conducted in the UK
Patents	The prospect that London will not be the home of the European Unified Patent Court's pharmaceutical unit could further erode the attractiveness of the UK market	-
Drug registration	If the UK is excluded from the EMA and has to establish a completely independent regulatory system, the administrative burden on manufacturers would likely grow	-
Pricing	Increased financial pressure on the NHS might deter the government from exploring radical alternatives to the Pharmaceutical Price Regulation Scheme (PPRS)	-
Health technology assessment (HTA)	The UK's international influence on HTA could be substantially diminished	Other HTA bodies would need to take on the responsibilities previously fulfilled by UK agencies
Launch sequencing	The UK might no longer be a priority market for multinationals	-
Parallel trading	Parallel trade between the UK and the EU could cease if the UK is excluded from the Single Market	
External reference pricing	-	Some countries might decide to stop using the UK as a comparator country



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