Brexit and the Pharmaceutical Industry

Introduction

On 23 June 2016, the UK voted to leave the EU. This has a number of significant potential implications for the pharmaceuticals industry. In this note we shall investigate a few of these. Specifically, we shall consider:

- drug budgets;
- parallel trade and intellectual property;
- Brexit and TTIP;
- R&D staffing and research funding;
- access to finance and financial services; and
- regulatory governance in Europe.

Brexit and the drugs budget

Even amongst the minority of economists that believe the economy will benefit in the longer term, there is widespread agreement that the run-up to Brexit and the immediate period thereafter are likely to be associated with some reduction in GDP growth. Estimates differ. One mainstream example is that of the OECD, which projects a 3 per cent loss in GDP growth by 2020 for the UK and a 1 per cent loss for the rest of the EU.¹

Slower macroeconomic growth could have implications for drugs budgets. In the UK, NHS spending is ringfenced from the budget cuts that have applied, and will be extended, in other departments. However, if UK growth had continued and the deficit cleared, NHS spending would have been expected to start rising in real terms, rather than being broadly flat. That may not now happen for some years.

Extended tightness in drugs budgets may also mean that EU authorities become more nervous of authorising expenditure on drugs that could have large budgetary impacts, even if those drugs come with large therapeutic benefits. Pharmaceuticals companies seeking expenditure authorisation for drugs with large potential costs may increasingly need to demonstrate positive macroeconomic benefits (e.g. extended working lives or higher work productivity) as well as therapeutic benefits.

Brexit, parallel trade and intellectual property

A patent is exhausted across the EU when a product is placed on the market in any Member State. This means that those with parallel importing licences are able to obtain drugs sold at lower prices in some parts of the EU and import them into other higher-priced Member States. Such trade constitutes a significant share of total pharmaceutical sales in several Member States, as we see in Figure 1.

One significant issue for the pharmaceutical industry and the NHS is whether the UK will remain part of the EU’s patent exhaustion zone post-Brexit. If it does not, both parallel imports into and (of increasing importance in recent years) parallel exports from the UK will cease. That could mean a rise in the drugs budget (as the NHS is no longer able to source drugs so cheaply via parallel importing) and greater scope for differential pricing between the UK and the remainder of the EU.

**Other intellectual property rights issues**

Parallel trade would not be the only important intellectual property issue arising from Brexit. Another fairly immediate question would be whether the UK would still be part of the new unitary patent (the “European patent with unitary effect”) and Unified Patent Court, due to come into operation next year. All 24 members of the unitary patent are members of the EU. It is therefore natural to assume that Brexit will mean the UK withdrawing from the unitary patent.

There are a number of complex issues arising from this. If the unitary patent were to come into full effect, with the UK included, before Brexit but the UK then left the unitary patent area, what would be the status in the UK of unitary patents taken out whilst the UK was still a member? Perhaps that complication means that part of the Brexit transition process will include the UK withdrawing from the unitary patent process immediately? If the UK were to withdraw, could that potentially mean a delay to implementation of the whole scheme?

If the UK were to remain within the unitary patent despite leaving the EU, might that mean that patents taken out under the unitary patent would be subject to patent exhaustion (and thus parallel trade) but those taken out as UK patents would not?

Another set of questions — though perhaps in this case more straightforward to answer — concern the UK’s involvement in the European Patent Organisation. Brexit might be a moment to review the UK’s involvement in that body. A number of the European Patent Organisation’s members are not members of the EU, but all are countries that are candidates for EU membership (e.g. Serbia, Albania, Turkey), members of the European Economic Area (e.g. Iceland, Liechtenstein), or nested European mini-states (e.g. San
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Marino).² It seems fairly likely that the UK would continue to be part of the European Patent Organisation despite falling in none of these categories — but by no means certain.

One reason the UK might cease to be part of the European Patent Organisation could be if doing so proved incompatible with whatever new geopolitical arrangements the UK comes to after it leaves the EU. For example, the UK might establish a new trade agreement with the US that would include new patenting arrangements that were incompatible with continued involvement in the European Patent Organisation. Or it might establish some new regulatory and intellectual property convergence treaty with Canada and Australia that established a new unitary patent for those countries — again, incompatible with continued involvement in the European Patent Organisation.³ A further possibility is that the UK and Japan could enter into a new trade agreement, building on the EU-Japan trade talks that have become delayed but that the UK might find easier to pursue on a bilateral basis. That might include significant pharmaceutical-relevant elements.

Brexit, TTIP and a future US-UK trade agreement

The EU-US Transatlantic Trade and Investment Partnership (TTIP) was already at serious risk of being vetoed within the EU even before Brexit. With Brexit, the TTIP is now likely to fall, with a number of implications for the pharmaceuticals sector. These include:

- the maintaining of separate Good Manufacturing Practices inspections for the US and EU;
- non-convergence of approvals processes for pharmaceuticals and in particular biosimilars, generics and paediatrics; and
- the continued rejection of the Anti-Counterfeiting Trade Agreement by the European Parliament (which declined its consent in 2012, by a huge majority).

On the other hand, Brexit may mean a separate US-UK trade deal becomes more likely. This might include a number of the above elements. Alternatively, perhaps the UK agreement might become included in the Trans Pacific Partnership deal.

R&D, free movement and research budgets

A central issue of the UK’s referendum debate was free movement of persons within the EU. It is very unlikely that any post-Brexit arrangement with the EU would preserve free movement. One important issue for the pharmaceuticals sector would therefore concern its ability to secure appropriately skilled staff for research facilities or to move staff between such facilities when located in the UK and the remaining EU.

Our view is that this is more likely to be an administrative than substantive issue for the pharmaceuticals research sector. The UK will have a very high appetite to access highly skill staff of the sort used in pharmaceuticals research and will not seek to place any material impediments in the way of such staff coming to work in the UK. Indeed, it is even plausible that Brexit results in it becoming marginally easier to source highly skilled research staff in the UK, as it might be easier to recruit non-EU staff if the UK government is perceived as having more control of EU immigration (and thus does not need to compensate by being more restrictive with non-EU immigration).

² See the list here: https://www.epo.org/about-us/organisation/member-states.html.
³ The Comprehensive Economic and Trade Agreement between the EU and Canada, which was at risk of being vetoed at EU level, requiring ratification by each individual Member State, may now be replaced by a dedicated bilateral agreement between the UK and Canada.

In the case of Australia, talks about a new trade agreement were offered by the Australian government, following the Brexit referendum result, on 17 July 2016 — see: http://www.bbc.co.uk/news/uk-politics-36818055.
One version of this could be if the UK established a new free movement zone with new geopolitical partners. For example, it is quite likely that the UK will establish free movement with Canada and Australia. A more significant (though less likely) development might be free movement with the US. A more limited variant could be countries where easy-access immigration quotas are introduced. For example, forms of that have been proposed as part of a new UK-India agreement.

Research funding and the Innovative Medicines Initiative

The EU is an important source of funding for various forms of academic research, including in areas relevant to pharmaceuticals. It is possible that the EU itself would continue to fund some such research within the UK. Of more significance however, would be the replacement of EU funding with new UK government direct funding streams.

It is possible that there is actually a greater impact on R&D funding in the remaining EU than in the UK, because the UK is a very significant net contributor to the EU, meaning that the UK’s withdrawal is likely to mean a drop in available EU funds per citizen in the remaining EU. The EU might seek to compensate for this by increasing the EU contribution of remaining Member States, but that could have significant political ramifications.

One of the most important European R&D funding sources for the pharmaceutical industry is the Innovative Medicines Initiative (IMI-1), a private partnership programme funded jointly by the EU and the European pharmaceutical industry. IMI-1 disbursed over €2bn between 2007 and 2014, with UK institutions winning the largest proportion of funding by 2012 (€140mn). IMI-2 will run from 2014-2024 with funding of €3.3bn. The EU’s funding for IMI comes from the Horizon 2020 Framework Programme. Once the UK leaves the EU, funding to UK institutions and companies would change, probably via some process whereby the UK would substitute domestic funding for IMI, though it is possible that the UK could negotiate to continue involvement in IMI-2 out to 2024 (with some equivalent financial contribution).

Access to finance

The pharmaceuticals sector across Europe uses finance and financial services provided by the UK in general and the City of London in particular. As well as the raising of finance, such needs include:

- When pharmaceutical companies operate in multiple markets they hold foreign currency to conduct their activities. The exposure of overseas operating subsidiaries to transaction risk is minimised by matching local currency income with local currency costs. For this purpose, internal trading transactions are matched centrally and the company manages inter-company payment terms to reduce foreign currency risk.
- Some large firms have a range of liquidity requirements and means of managing these requirements. Some pharmaceutical companies manage their borrowing requirements through a sophisticated portfolio of long-term bonds and short-term financing to meet liquidity requirements.
- Some pharmaceutical companies manage credit risk by assigning global counterparty limits to each of the firm’s banking and investment counterparties based on long-term credit ratings from ratings agencies.

If Brexit were to result in restrictions on the ability of the UK to offer finance or financial services to firms located in the remainder of the EU, that could make it more expensive for pharmaceutical companies to secure and use such services or even, in some cases, mean they lose the ability to access such services (at least for practical purposes) altogether.

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The question of the status of the City, post-Brexit, is one of the most widely discussed ramifications of the UK’s referendum result. Some commentators envisage London financial services relocating, under regulatory pressure, elsewhere within the EU — e.g. perhaps to Paris or Frankfurt. This seems unlikely. If financial services activities were going to relocate, wholesale, to elsewhere in the EU that probably would have happened when the UK declined to join the euro. Furthermore, it is easy to exaggerate the ability of regulatory pressure to trigger significant geographic relocations. Governments go to great expense with regional policies, attempting to encourage firms to relocate even within countries, to relatively little effect.

It is perhaps plausible that sufficient regulatory impediments imposed upon the City could remove the advantages of certain activities being conducted in London relative to New York — that seems more plausible than encouraging relocation to Paris (where staff would have to accept much higher taxes) or Frankfurt (where the pace of life might seem very different to those used to London). It might be important for pharmaceutical companies located within the remainder of the EU to communicate to their governments the importance to them of continued access to the City.

Regulatory governance

Two EU institutions in London important for the pharmaceutical industry are the European Medicines Agency (EMA) and the Unified Patent Court (UPC). London is set to be the location of one of the three branches of the Central Division of the UPC, set to specialise in chemistry (including pharmaceutical) cases. If the UK will not now be part of the unitary patent, that would almost certainly mean the UPC branch in London will be moved.

The EMA has been based in London since 1995, approving medicines for all EU countries. The UK has its own national Medicines & Healthcare Products Regulatory Agency (MHRA) and at the moment, companies can choose to either submit drug approvals to the EMA for EU-wide rulings, or separately to the MHRA for UK approvals. For drugs that are to be marketed across the EU, it is likely that pharmaceutical companies would prefer a central route for approval, rather than submitting to each member state separately.

Once the UK exits the EU, it seems likely that the EMA will be relocated (though it is not totally implausible that the UK’s new arrangements with the EU could be such that ongoing involvement in the EMA might allow its continued location in London).

If the UK were to have fully third-country status with respect to the EMA, it could materially affect timetables for drug approvals. For example, in Switzerland and Canada - which have their own drug approval processes - on average approval comes, respectively, 157 and 144 days after EMA approval.5

A new EU-wide regulatory policy on clinical trials will take effect from 2018 that aims to increase the efficiency of clinical trials taking place in multiple member states. This will replace regulations that were criticised for excessive red-tape.6 Brexit may mean that multi-country clinical trials will have less incentive to choose the UK as a location, although all clinical trial authorisations and oversight will still be done by Member States.7 If the UK continues to mirror EU regulations on medicines and the MHRA coordinates closely with the EMA, this may be less of an issue.

Good manufacturing practices, which assure the quality of medicinal products, are managed at the national level on UK laws based on EU directives. As with clinical trials, if the UK maintains equivalent regulation as

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5 Source: Charles River Associates (2016) “Assessing the impact of a change in the UK relationship with the EU on the life sciences industry”.
the EU, this is not expected to affect the pharmaceutical industry. It is very likely that the UK would maintain this, given that the current set of rules is similar to those within other developed countries such as the United States.\(^8\)

If the UK enters into new geopolitical partnerships and new trade deals with non-EU countries, these could involve the establishment of their own new regulatory governance mechanisms and institutions. Some of these might relate to the pharmaceuticals sector and involve institutions located in the UK in future.

**Conclusion**

Brexit has the potential to be a highly significant event for the pharmaceuticals sector. There are both positive and negative aspects, as one would expect. Some of the points raised here will be subjects of negotiation as part of the Article 50 process, and it will be of interest to understand which points the pharmaceuticals sector chooses to prioritise in its lobbying efforts.

Other important issues concern what new arrangements the UK enters into with non-EU countries and their potential implications for the pharmaceuticals sector. We have seen that these could include new arrangements with the US, Japan, Australia and Canada.

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