Evaluate Vantage

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Vantage point – What Brexit means for drug regulation

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The pharmaceutical sector is one of the most tightly regulated industries, and most of the rules that govern the daily lives of UK drug companies are enshrined in EU law. With the shape of the UK's exit from the EU still unknown it is hard to predict what the future holds for medicine regulation.

But it seems certain that keeping the cogs of drug development and regulation turning for the UK's many life science companies will be a huge legislative task. Under some circumstances EU frameworks could largely remain in place; however, last weekend the government gave the clearest signals yet that that the UK will abandon these frameworks. "A hard Brexit is very much the mood music of the moment. Which means no EEA and no EFTA – and no EU law," says Paul England, a partner at law firm Taylor Wessing.

At her Conservative Party conference speech at the weekend the UK prime minister, Theresa May, explicitly ruled out following the Norway and Switzerland models. This would seem to imply that the UK is set to plough its own unique furrow in the world.

In terms of pharmaceutical regulation, EU laws and guidelines govern everything in the drug development process from authorising clinical trials to the procedures for securing new drug approvals and the movement of goods through supply chains. The 10 years of marketing exclusivity for orphan drugs and the six-month supplementary protection certificates (SPCs) are also part of EU legislation.

After a hard Brexit the UK would be left with no laws in place to govern any of these activities. According to Mr England, mirroring these legislations would be an immediate fix.

"The Government has announced that there will be a Great Repeal Act, which is expected to enact much EU law into domestic law upon Brexit. This will be important for the immediate continuity of those rights that are important to the life sciences sector.

"So the status quo could be maintained at least for the time being. They could be tweaked later on – the SPC regulation has been heavily criticised, for example – one judge said it risked being not fit for purpose – so this could provide an opportunity for the UK to improve on legislation," he says.

The possible Brexit options	
The EEA model (European Economic Area, eg, Norway)	
Features	**Implications**
Allows full participation in the EU internal market, with free movement of goods, services, capital and persons. However, a country has very little influence, with no MEPs, no vote in the EU Council, and only observer status in EU procedures.	Full implementation of all EU pharma laws; supply chains unaffected. Companies able to apply for and hold marketing authorisations, orphan drug designations etc. But MHRA demoted to observer status.
The EFTA Model (European Free Trade Association, eg, Switzerland)	
Features	**Implications**
Bilateral free-trade relations can be negotiated with the EU and EEA on a case-by-base basis. Some flexibility to restrict free labour movement.	EU pharma rules no longer apply, unless bilateral treaty negotiated. Companies would need a legal presence in the EU to hold marketing authorisations, orphan designations etc.
The WTO Model (World Trade Organisation)	
Features	**Implications**
The UK would need to negotiate a multilateral trade relationship with the WTO and separate bilateral trade agreements with the EU and EEA.	Even greater separation from EU pharma regulation.
Source: Covington & Burling presentation.	

The route for seeking regulatory approval of new medicines is one of the biggest legislative quagmires the sector will have to navigate. Ultimately the UK needs to consider whether it wants to force companies to make a completely separate marketing application from the European process.

While the country has size on its side – representing the second-biggest European economy the UK is likely to remain an important target market for new drugs and devices – adding to a company's administrative and cost burden could be harmful in the long term.

And, on the other side of the fence, the MHRA will have to be beefed up if it is to be tasked with repeating every assessment already done elsewhere in Europe.

Currently the MHRA is one of Europe's dominant drugs regulators, and is used more often than any other as reference member state when the decentralised procedure is followed. As a result it is widely respected, and there could be far-reaching implications if the institution's key role in Europen drug regulation disappears.

"Even if we enter into a close free-trade agreement, the UK will lose influence in the development of pharmaceutical legislation and policy, and will also lose influence in the pharmaceutical regulatory procedures," says Grant Castle, a regulatory lawyer for Covington & Burling. "And that must inevitably mean that companies shift their focus to more influential jurisdictions."

Routes to the European market
Centralised authorisation procedure
A single marketing application is submitted to the EMA; approval allows a drug to be sold throughout the EU and EEA. The great majority of novel molecules pass through this route.
Mutual-recognition procedure
A marketing application is submitted to regulators in one member state, and once approved it can then be recognised in other EU countries.
Decentralised procedure
Marketing applications are submitted simultaneously to relevant member states.
All require at least a legal entity to be present in an EU member state.

Many regulatory experts believe that patients, payers and applicants would benefit if a way can be found for the MHRA to remain a cog in the European drug approval process, not only for the future but for products already on the market in Europe and on which UK regulators have passed judgement.

Tim Worden, a lawyer with Taylor Wessing, says: “We believe that there is reason to be optimistic that a negotiated solution will be reached in which the efficiencies of the current systems are maintained, not only because such a scenario would benefit the EU and the users of the system as well as the UK, but also because the UK life sciences sector enjoys an excellent reputation globally. So it is hoped that its continued pre-eminence, and easy accessibility, will be a priority for the UK government.”

No doubt many companies, regulatory experts and indeed regulators are hoping that this comes to pass.

Location location

One of the first repercussions to be raised after the result of the referendum was announced was the location of the European Medicines Agency. This is currently in London, and, while there are no legal reasons why it must move, logic states that it will have to, particularly if a hard Brexit renders all EU law void.

“If you have a body dealing with marketing applications that are governed by EU law, what argument could we make to keep it?” says Mr England.

Ultimately its location is likely to be decided around the negotiating table, he believes, as politicians hammer out the finer details of the UK’s exit. Countries including Denmark, Spain and Sweden have already offered to host the agency.

However, also located in London is the life sciences division of the Unified Patent Court. It is equally unthinkable that this could remain where it is, according to Mr England.

40 years in the genesis, the Unified Patent Court was on the eve of being ratified when the Brexit vote threw up yet another roadblock in its long journey. Its formation was intended to enable a single patent to be enforced – or revoked – throughout the region of its jurisdiction, with obvious cost implications for the applicant (*Vantage point – What Brexit means for medtech patents, October 4, 2016*).

Given that the UK is in no position to ratify its formation – an essential step before it can go ahead – the process is essentially in limbo. This has not stopped Milan pitching a bid to host the life science courts instead of London.

“My gut feeling is this will go ahead as so much been invested in it. But they can’t do anything until they know the UK’s situation. Estimates are, with or without us, this court probably won’t start in the next five years,” Mr England says.

As it stands he believes that it is unlikely that the UK will ever be a part of it. “If we are in a situation where we are cutting ties with any kind of European law and judgement then it’s not possible to see how we could participate,” Mr England says.

Which means that if in the long term the UPC does go ahead and comes to represent a large, patent-efficient region, the UK faces a future as a smaller, single-patent market with its unique administrative burdens.

Feeling the impact

Despite predictions that the UK would grind to a halt in the wake of a Brexit vote, the country continues to generate encouraging signs of economic activity.

“People are still doing deals, recognising that there has been no big economic shock and there is a need to press on. It is interesting how little impact it has had,” Mr England says.

This could easily shift once negotiations begin in earnest, and the shape of the UK’s relationship with Europe and the rest of the world begins to emerge. Companies in the business of developing new drugs will want to see the UK remain closely allied to the well-established systems of Europe, giving them easy access to a huge drugs market and the regulatory systems that they know so well.

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