COGENT HEALTHCARE

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Brexit Consequences for EU Marketing Authorization

A considerable debate has surrounded the consequences of Britain leaving the EU regarding international trade, given the largely unclear situation concerning border controls, tariffs, need for compliance with WTO guidelines. Pharmaceuticals were part of the debate and European countries, as well as the UK, have already begun stockpiling medicines in anticipation of possible supply chain disruptions after March 29th, the official Brexit date.

Compared to the supply side, regulatory issues have not been top priority but are far more problematic - for consumers, but in particular for pharmaceutical industry. British regulatory authorities have already signaled that they will continue to comply with EU jurisdiction.

However, given different regulatory approval paths - the centralized and the decentralized procedure – the UK and the EU will face mutual recognition issues: All 1200 products that were approved via the centralized procedure will maintain their approval within the UK (and the EU). In contrast, for pharmaceuticals approved via the decentralized procedure that used the UK as rapporteur, there will be a major regulatory issue. This is particularly noteworthy, since more than one quarter of all pharmaceuticals approved via the decentralized process were evaluated by British authorities.

In order to maintain their approval within the EU, pharmaceuticals that were evaluated by British authorities need to be transferred to a different member state authority for future pharmacovigilance monitoring and change requests. Since April 2018, more than 200 rapporteur switches per month have occurred. And, given that roughly only half of the pharmaceuticals have been switched so far, many more will follow. The German BfArM, for example, has already absorbed more than 450 new pharmaceuticals, formerly evaluated by British authorities.

British regulatory authorities have been always on top of the priority list for US companies. Even before the official Brexit, pharmaceutical companies need to re-evaluate their EU approval and marketing strategies.

First, the formerly favorable and preferred UK rapporteur system for decentralized approval will no longer be available. Second, the depreciation of the British pound following the Brexit vote has resulted in comparatively lower drug prices that may have an impact on countries that reference UK prices. Given those have and price decline following Brexit, the UK may no longer be a priority country for drug launch by international companies.

Given the multitude of healthcare systems, and, the reverberation prior to and expected after the official Brexit, the European landscape has become increasingly difficult to navigate.

Given our presence in Germany, Switzerland and the US, Cogent Healthcare may help you better navigate the diverse European healthcare systems and help you avoid pitfalls while entering and competing in the European markets.

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