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**At the time of writing of this report and following the "No" to the Brexit deal vote, the outcome of the Brexit drama is still unknown. Regardless of whether the UK's exit from the EU is negotiated or "hard", the impact on the Pharmaceutical industry will be profound. In a report published in May 2018, the UK's House of Commons assesses the impact Brexit will have on the pharmaceutical sector and the UK economy; stringent regulations in the sector may result in restricted restrained access to medicines, the UK could become less attractive as a Pharma market and medicines could become more expensive in the UK. However, the impact of Brexit actually goes far beyond the frontiers between the UK and the EU.**

# Brexit – Uncertainty for the Pharma Industry

**What's at stake?**

The pharmaceutical industry is one of the most productive sectors in the UK. With a turnover of approximately £42bn, it accounts for over 8% of the UK's export goods, employing over 113,000 people. The turnover for the broader life sciences sector alone totals nearly £63.5bn, accounting for over 230,000 jobs. Beyond its impact on the economy, of all the trade barriers analyzed, it is regulatory divergence which is causing the most concern and has the greatest potential impact on access to medicines, particularly the most innovative ones. Increasing costs resulting from import/export policies (customs processing, logistics and duties), could put patients at risk on both sides of the Channel. Other uncertainties relate to the country's ability to remain attractive and maintain employment, along with leadership in clinical trials.

The pharmaceutical industry supply chain is complex, tightly integrated and relies on the smooth transfer of ingredients and finished products; roughly 1 billion packs into and out of the UK annually. Any physical restriction imposed on the exchange of goods is particularly challenging for time- or temperature-sensitive products, which cannot endure border delays resulting from new customs procedures.

In 2016, the UK had a £6.3bn trade deficit with the European Union, with the EU representing close to half of its pharmaceutical exports and close to three quarters of its imports. Following Brexit, the UK will still be able to trade Pharmaceuticals with the EU, the USA, Canada and other countries, benefiting from zero tariffs based on the World Trade Organization (WTO) Pharmaceutical Tariff Elimination Agreement. However, not all active pharmaceutical ingredients (APIs), excipients or finished pharmaceutical products, are currently covered by the WTO agreement and therefore, some could face duties of between

4.0-6.5%. The Imposing of tariffs between the UK and EU would lead to higher costs to the NHS, due to a "double charge" being placed on imports and exports, disproportionately affecting companies that use the UK as a hub within their global supply chain, consequently putting jobs at risk.

Such a high dependency on EU imports could also reduce access to pharmaceutical products. Furthermore, the UK may become a less attractive market to launch new medicines in comparison to other EU countries. Similarly, Brexit will bring uncertainty regarding continued EU funding of R&D projects, from which up until now, the UK has disproportionately benefited. This again makes the UK a less attractive location for running clinical trials, which in turn may cause the country to lose its status as a global leader in research.

**What's gone is gone**

Adding to the pain, the European Medicines Agency (EMA) is relocating from London to Amsterdam in 2019. In addition to many highly qualified jobs leaving, the UK will also lose considerable influence on centralized drug-approvals, along with the supervision and safety monitoring of medicines in the EU for which the EMA is responsible. The EMA works with local regulators – "rapporteurs" – to perform this duty and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) have till now, made a disproportionate contribution, thereby shaping the EMA's policies. Further aggravating the issue, Brexit may also result in a substantially increased workload for the MHRA which previously benefited from shared expertise and funding with the EMA.

The lack of specific details laid out in the draft Brexit deal provides no comfort to the pharmaceutical industry. The UK government has provided some information and guidance in an effort to address increasing concerns, but the terms of a future relationship based on cooperation and in the interest of protecting patients, have yet to be agreed. On the advice of the EMA, most companies have already initiated plans based on regulatory requirements assuming a "no deal" scenario. Marketing authorizations (MAs) and licenses are being transferred to other EU member states, along with safety testing and batch release activities, including the relocation of Qualified Persons (QPs and QPPVs). We estimate that circa 400 MA holders are currently registered in the UK, with thousands of products being affected. Beyond the changes to the license holders, the packaging artwork and leaflet must be updated for each SKU, incurring significant costs.

Another area of uncertainty is related to IP rights and the expected EU Unitary Patent system and specifically what will happen to the London branch of the Unified Patent Court, devised to deal with cases in the chemical, pharmaceutical and life sciences sectors.

When all is said and done, the impact of Brexit clearly goes far beyond the issues addressed in the UK's report and the borders between the UK and the EU, and many questions still remain. What will be the UK's future status with regards to the mutual recognition agreements (MRAs) between the EU and third-country authorities (e.g. Switzerland or Japan) or concerning the good manufacturing practice (GMP) conformity assessment and inspections? What about the authorization process with countries such as Turkey that currently recognize EMA approvals? Which countries will continue to include UK prices in their baskets of comparator countries for external reference pricing and what will be the impact for pricing in countries such as Austria and Belgium using an average EU price?

Whichever way you look at it, Brexit puts the spotlight on the complexity generated in a highly regulated industry if a leading economy decides to exit bilateral or multilateral agreements.

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