

AN ISLAND, BREXIT & A MOST PERFECT STORM

On 29 March 2017, the European Council received the notification by the UK of its intention to withdraw from the EU. This set in motion a chain of events within the pharmaceutical industry, amongst other things. Contingency plans by industry, academia and specific member states have kicked in with a view to address any foreseeable regulatory challenges, primarily medicine shortages together with any associated price hikes. An unexpected twist in the Brexit drama is the expected significant loss of 30% in the European Medicines Agency's workforce owing to its relocation to Amsterdam by 29 March 2019, when the United Kingdom withdraws from the EU. Although this may well mean a golden career opportunity for some, as from 1 August 2018 it has also resulted in a reduction of regulatory services offered by the Agency. Interestingly, the European Medicines Agency's lease of its London headquarters, 30 Churchill Place in Canary Wharf, does not expire until 2039 and there is no early break clause. It is understood that EMA pays around €14m each year for rent and has an outstanding liability for the remainder of the term of approximately €400m (including service charges).

As highlighted in a recent article, *Can Registration Procedures of Pharmaceuticals Inadvertently Contribute to Off-Label Prescribing in Children?*¹ published in 2016, one of the regulatory challenges faced by Malta is that a high number of medicine registrations rely on article 126(a) of Directive 2001/83/EC. Article 126a states that "in the absence of a marketing authorisation or of a pending application for a medicinal product authorized in another Member State in accordance with this Directive, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product." The authors found that as of 2016, 1877 out of 5025 medicines (37%) available on the Maltese market had a valid article 126a licence. Further to this, 1705 out of 5025 medicines (34%) authorized in Malta had a marketing authorization holder registered in the UK. In keeping with this, the Maltese Medicines Authority is currently advising suppliers to identify alternative source countries in the EU in lieu of the UK; repackaging of the medicinal product should be performed if the pack is not available in English/Maltese language. Obviously this could lead to rising costs of medicines because of any added costs for those UK-registered products which

are retained on the local market, but also possibly due to decreased market competition for specific active ingredients following any UK registration cancellations.

In order for medicines to be imported and distributed within the EU, medicinal products need to be quality control-tested and released by a qualified person [QP] inside the EU [with the exception of products from Switzerland, where the testing done in Switzerland can be accepted; in this case you still need a QP release inside the EU]. Following Brexit, for those UK products remaining on our market, these will now need, as a minimum and assuming that the UK can negotiate an MRA similar to Switzerland's, an additional QP release inside the EU. Indeed, at least in the few months succeeding Brexit, this scenario can impact the access to UK medicines within the EU, including Malta, because of the additional quality control steps needed for release. Having said this, last August the UK Government officially reassured stakeholders that if there is a no-deal, the UK will continue to accept batch tests carried out in the EU, EEA countries and those third countries with which the EU has an MRA.

Further to this, Sanofi, AstraZeneca, Novo Nordisk, Novartis & MSD [as well as the UK's NHS] have stated that they will stockpile medicines for a number of weeks in preparation for a hard Brexit. This follows a call from EMA, the Association of the British Pharmaceutical Industry, and the BioIndustry Association who advocated preparedness for the possibility of an interruption in medication supplies. In keeping with this, one must also mention the fact that the perception that access to UK medicines may be affected, as well that their price may increase, could lead to a scenario where Maltese patients start to stockpile medicines sourced from the UK. It would be reassuring and appreciated if stakeholders within the pharma industry are continuously kept updated on the matter by local authorities in a timely manner to mitigate any shooting from the hip. 🇬🇧

Jan Ellul

REFERENCE

1. Ellul J, Grech V, Attard-Montalto S. Can Registration Procedures of Pharmaceuticals Inadvertently Contribute to Off-Label Prescribing in Children? *Therapeutic Innovation & Regulatory Science* 2016;50(6): 808-816.

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