Towards Brexit: how MAHs can prepare for the UK's EU exit

EMA and EC have published documents relating to Brexit, to help pharmaceutical companies prepare for the UK's exit from the EU: a Q&A for Centralised Procedures, and two documents from CMDh .

MHRA has yet to release its position, and it is anticipated this will be happen sooner rather than later. As the UK is timetabled to leave the EU on 30th March 2019, it is in the MHRA's interest to publish its position for companies as soon as possible, especially those based in the UK who will need to be prepared for the new relationships and requirements.

A recent meeting hosted by the UK's Drug Safety Research Unit suggests that one possible outcome is that UK-based pharmacovigilance may not be acceptable moving forward. There are still a lot of uncertainties as to how Brexit will ultimately play out, but preparing for the different scenario is a prudent option.

What are the EMA requirements related to Pharmacovigilance?

a. Marketing authorisation holders must be established in EU.
b. Pharmacovigilance activities are required to be conducted within EU.

Marketing Authorisation Holder Options

a. MAH in the EU; If the UK were to have third-country status at the end of the Brexit process, this would mean that MAHs currently in the UK would have to consider establishing themselves in the EU (or at least within the EEA).
b. Appointing an EU QPPV; The current QPPV will therefore need to relocate to within the EEA, or a new EEA-based QPPV should be appointed.
c. PSMF location in EU; If the PSMF is located in the UK, this would have to be transferred to a legal entity in EU by submitting a variation.

How ELC Group can help

Our fully compliant pharmacovigilance (PV) solutions enable biotech and pharmaceutical companies to meet PV obligations in a robust, cost-effective and compliant manner, in accordance with the requirements of the EMA/CMDh in the EU.

ELC Group can provide advice and practical support to MAHs throughout the Brexit transition period and beyond. Leveraging our experience, expertise and intimate knowledge of the internal workings of PV, regulatory agencies and workgroups, we are able to help pharmaceutical companies ensure continuing compliance and best practice.

For more information please visit our website or contact Fionna Tan at ftan@elc-group.com