Regulatory Update Q4 2020 - Special Topic

Post-Brexit Pharmaceutical Regulatory Schemes

UK withdrew from the EU on January 31, 2020, and became a "third country" to the EU, and the transition period after Brexit came to an end in 2020. During the transition period, EU pharmaceutical law was still applicable to the UK. From January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) has been the UK's standalone medicines and medical devices regulator. MHRA issued guidance documents regarding post-transition period information for industry and organizations to follow from January 1, 2021, which includes topics related to clinical trials, licensing, importing and exporting, IT systems, etc.

EMA prepared a series of guidance documents, including guidance on centrally authorized products, nationally authorized products, submission of Brexit-related variations, etc., to help companies take the necessary regulatory steps to enable continued supply of their medicines in the EU for the benefit of patients. As of November 2020, all marketing authorization holders for centrally authorized products are now based in an EU Member State. A small number of centrally authorized products require changes to their marketing authorizations to transfer QPPVs, pharmacovigilance system master files (PSMFs), quality control, batch release and/or import or manufacturing sites from the UK to an EU Member State.

Figure 1 below describes the key milestones for the Brexit process since 2016. Figure 2 describes the key post-Brexit regulatory schemes of EMA and MHRA.

Figure 1. Key Milestones for the Brexit Process Since 2016

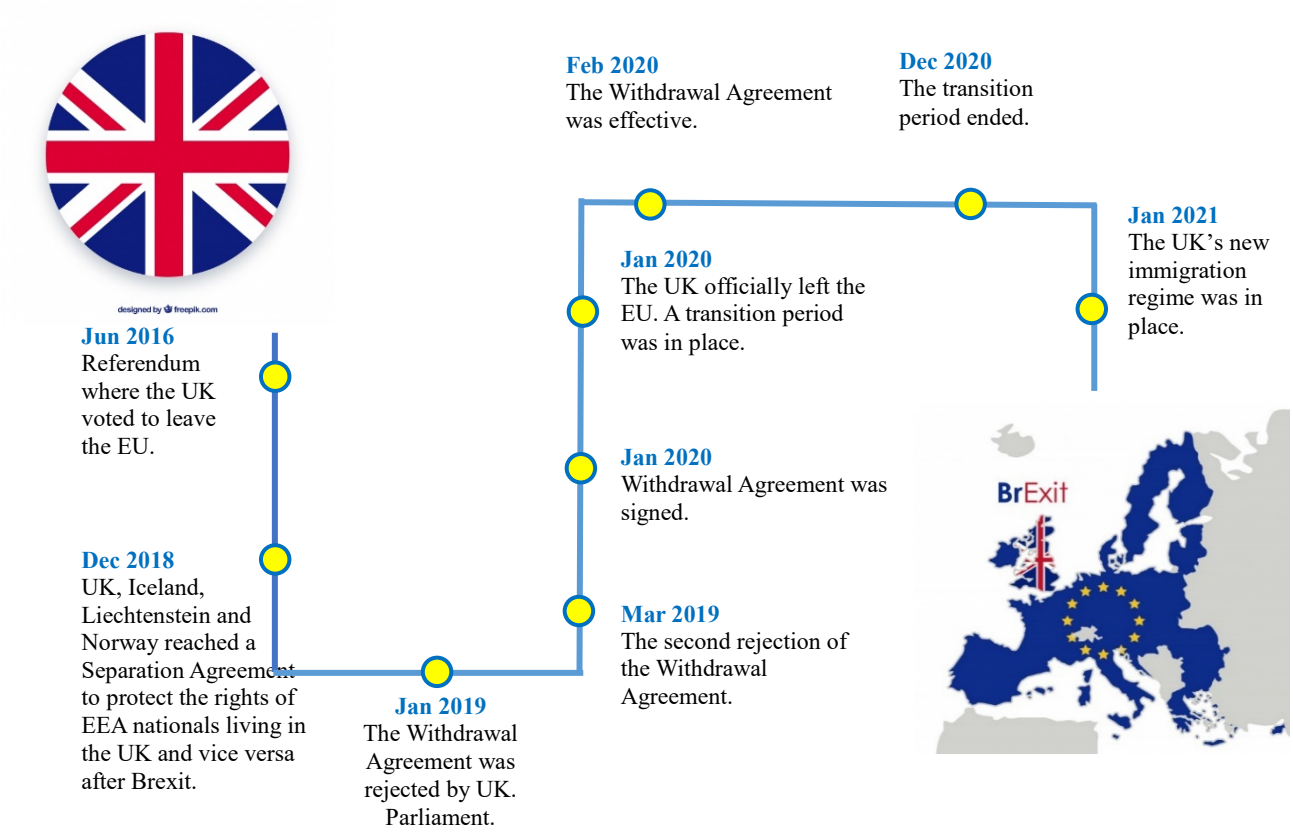

Figure 2. Key Post-Brexit Regulatory Schemes of EMA and MHRA

January 31st, 2020

The UK formally left the EU, and became a "third country."

February 1st, 2020

The Withdrawal Agreement concluded between the EU and the UK entered into force, which established a transition period from 1 February to 31 December 2020. During this period, EU pharmaceutical law continued to apply to the UK.

February 4th, 2020

EMA published a Q&A document regarding European authorities working to avoid shortages of medicines due to Brexit.

March 13th, 2020

The Notice to Stakeholders stated as of the end of the transition period, a MAH currently established in the UK has to have transferred its marketing authorization to a holder established in the EU.

March 16th, 2020

A Practical Guidance that complements the Notice to Stakeholders was published to provide guidance regarding submission of changes and related fees. MAHs and applicants of centrally authorized products for human or veterinary use need to ensure that the necessary changes are made by the end of transition period.

July 9th, 2020

A Joint EC/EMA/HMA Technical Notice document was published to guide the sponsors to continue compliance with the EU legislation for clinical trials following Brexit. It requires that as of July 2020, sponsors of all ongoing trials need to establish a QP in the EU. At the end of the transition period, the sponsor or its legal representative has to be established in the EU for all ongoing trials.

January 1st, 2021

As of January 1st, 2021, EU pharmaceutical law applies to and in the UK in respect of Northern Ireland only, which laid down in the Protocol on Ireland / Northern Ireland. The Q&A addresses issues related to the implementation of this protocol. New MHRA Guidance regarding clinical trials, legislation, licensing, etc. should be followed in the UK from January 1st, 2021.

January 8th, 2021

The EDQM announced mutual recognition of the Official Control Authority Batch Release (OCABR) for human biologicals (vaccines, blood and plasma derivatives) between the EU and the UK is no longer validated.