Insight

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Brexit—an update from MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) has, on 6th August 2018, published technical guidance for industry on the impact of the UK's decision to withdraw from the European Union (EU) on the life sciences industry.

https://www.gov.uk/guidance/technical-information-on-what-the-implementation-period-means-for-the-life-science-sector

This important communication sets out how the EU Withdrawal Agreement will impact the Life Sciences industry between March 2019 and December 2020, the so-called "implementation period". The key messages for each sector are discussed below:

Medicines - GMP inspections and batch release

Currently, medicines manufactured outside the EU must be release from an EU based batch release site, by an EU resident QP with the exception of those countries (e.g. but not exclusively USA, Japan, Israel) for which Mutual Recognition Agreements (MRAs) exist. These MRAs enable the inspection performed by a non-EU authority for which an MRA is in force to be recognised by EU regulatory authorities. There had been initial concern within the pharmaceutical industry that following the UK's departure from the EU, it would be considered a "third country" with respect to Qualified Person (QP) and Qualified Person for Pharmacovigilance (QPPV) activities thus requiring an EU batch release site to be registered on the product license.

- During the implementation period, there will be no changes to the QP and batch release arrangements for marketed or investigational medicinal products released to the EU market.
- QPs and QPPVs may continue to be located in the UK.
- Inspections and Marketing Authorisations (MAs) will continue to be recognised mutually by EU and UK.

Notwithstanding the risk mitigation associated with registering an additional batch release site within a post-Brexit EU country, the implementation period arrangements highlighted above now create a little additional time for industry to respond.

Medicines - Licensing procedures

UK based companies can continue to apply for MAs using the Decentralised and Centralised procedures as usual. The MHRA will continue to support MAA procedures, but will not be able to vote or act as Rapporteur or Reference Member State (RMS). This is consistent with the recent move by EMA to transfer all RMS and Rapporteur-ships to other EU member states. Whilst this appears to potentially diminish the influence of MHRA in assessment decisions, the continued support and involvement of MHRA indicates that a close working relationship and harmonisation of approaches is likely to continue post Brexit.

Centrally authorised product licenses will remain valid in the UK throughout the implementation period.

Devices - CE marking

CE marking will be recognised in both EU and UK markets.

Mutual Recognition Agreements

The relationship will not change.

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- The decision of the UK to leave the EU is unprecedented, however both EMA and MHRA are generally pragmatic and work to support the pharmaceutical industry, not just regulate it.
- The MHRA includes leading Experts in both assessment and inspection activities who have worked to develop and harmonise EU guidance . It is therefore thought unlikely that significant divergence will ensue following Brexit.
- Given the approach adopted to practical arrangements such as batch release and inspections, it can be anticipated that even after the implementation period ends in December 2020, the impact of Brexit on industry is likely to be minimal from a Regulatory viewpoint.