PHARMSOL NEWS

ARE YOU BREXIT READY?

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The United Kingdom (UK) formally left the European Union (EU) on 31 January 2020. A transition period began on 01 February 2020, during which EU pharmaceutical law remains applicable to the UK. This is due to end on 31 December 2020.

The European Medicines Agency (EMA) has made preparations to ensure it continues to deliver on its mission to protect public and animal health throughout the Brexit process.

One of the consequences of Brexit was that EMA relocated to Amsterdam, the Netherlands, in March 2019. This is in line with Regulation (EU) 2018/1718, which covers EMA's location and seat.

EMA continues to operate in accordance with the timelines set by its rules and regulations throughout the Brexit process. The UK notified the EU of its intention to leave the EU on 29 March 2017.

TRANSITION PERIOD

The withdrawal agreement establishes the terms of the UK's withdrawal from the EU, including a transition period. This began on 01 February 2020 and is due to end on 31 December 2020.

During the transition period, EU pharmaceutical law as laid out in the ‘acquis communautaire’ will be applicable to the UK. This means that pharmaceutical companies can continue to carry out activities in the UK until the end of 2020.

However, the UK no longer participates in EU institutions after its withdrawal from the EU on 31 January 2020.

For EMA, this means that as of 01 February 2020, no one who represents the UK, or is appointed or nominated by the UK can participate in any EMA scientific committee meeting, working party meeting or in the Agency’s Management Board.

IMPACT ON EMA ACTIVITIES

EMA developed a business continuity plan to ensure operational continuity during its physical relocation and readiness for Brexit. This enabled EMA to deliver its highest priority activities, temporarily scaling back or suspending lower priority activities as required.

The Agency is reinitiating its activities in 2020 and is no longer under business continuity measures.

In defining its work programme for 2020 and beyond, EMA focused on the core activities identified in phase four of its business continuity plan as a basis and added prioritized tasks taking into account available resources.

The Agency is still in the process of rebuilding its workforce after its relocation. It will continue to monitor staff levels and review in 2020 whether it can relaunch additional activities.

REGULATORY PREPAREDNESS

In preparation for Brexit, the EU27 Member States and EMA redistributed the UK's portfolio of medicines to other EU Member States. This involved transferring over 370 centrally authorized products to rapporteurs (One of the two members of a committee or working party who leads the evaluation of an application) and co-rapporteurs from the EU27 plus Iceland and Norway.

EMA informed the relevant marketing authorization holders of the new (co)-rapporteurships at the end of April 2018.

In September 2018, the new (co)-rapporteurs received a knowledge transfer package for each product. This contained background on the regulatory and evaluation history of each product, including the most recent benefit-risk assessment. The transfer package also helps each national competent authority forecast upcoming workload and support the planning of resources, particularly for complex products in the portfolio.

The new rapporteurs and co-rapporteurs have been fully responsible for these medicines since 01 July 2019.

WHAT ARE PHARMSOL’S BREXIT SOLUTIONS?

- ⇒ Trigger EUGMP inspection without filing a dossier if you are MHRA approved
- ⇒ Legal entity representation in EU
- ⇒ Holding MAH rights on your behalf
- ⇒ Reference Member State (RMS) Switching from UK to EU Member State
- ⇒ Batch Import, Batch Control, Batch Release Support in EU Member State
- ⇒ EU QP & QPPV Support in EU Member State
- ⇒ PSMF Summary variation updates
- ⇒ Annex your orphan designation to PharmSol amidst establishment of your own legal entity in EU

You may contact us info@pharm-sol.com