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The regulatory impact of Brexit on the Life Sciences Industry

The time to act is now

Over the past four months there has been a change in the mood regarding when the Pharma Industry should move forward on their plans for Brexit. In July the guidance from the MHRA appeared to be one of Keep Calm and Carry on. But now the overriding guidance from not only the MHRA but also the EMA and ABPI is one of yes keep calm but act now if you are to meet the timelines required. The impact of Medical Device Regulations makes Brexit timings and planning even more of a challenge.

If the UK is to continue with its ambitions to be one of the largest biotech clusters in the world then there are a number of changes internal taskforce teams must now act on if we are to continue to secure the growth of the life sciences sector in the UK and Worldwide.

1. **Regulatory updates on product registrations and MAHs1**
   For EU/EEA licences there will be an impact on the Marketing Authorisation Holder (MAH) and pharmacovigilance activities that must be conducted within the EU/EEA. Where these are currently held or conducted in the UK they will need to be transferred to a country within the EU. In addition, there will be implications for the import of Drug Substance and Product into the EU from the UK.

2. **Maintaining patient access and company revenues**
   As of 30 March 2019 it is assumed that the UK will be considered a 3rd country. If you are significantly exposed by these changes, then proactive planning ahead of the 30 March 2019 timeline is recommended. Preparing for Brexit now will help minimise the impact to you.

   Kinapse has the expertise and proven delivery model to develop a company specific solution and execute this one-off, business critical licence maintenance activity, so MAHs can focus on new product development.

   Transfer of the MAH to an EU legal entity or changing the setting of API and finished product manufacturing and import into the EU will require variations to be filed and new import licences to be obtained. With significant experience of managing administration and site transfer changes Kinapse are well placed to support you with the strategy and execution of these variations. Via our K-NET (Kinapse Expert Network) we can also support the need for EU batch release and a EU based QP for batch release. Kinapse are Thought Leaders and can help in your decision making process on batch release, importation and distribution considerations. We understand the challenges that managing the volumes and complexities associated with variations can pose and we can support you in mitigating risk and ensure continued compliance and Licence to Operate.

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The time to act is now...continued

Our experience of managing administration and site transfer changes for clients is extensive, having successfully completed more than 6000 submissions over the last 4 years for multiple Top 10 pharmaceutical companies.

3. Impact on Pharmacovigilance Services

Pharmacovigilance Aspects such as the partnership with the Pharmacovigilance Risk Assessment Committee (PRAC), mutual recognition of pharmacovigilance studies by the MHRA and the EMA and the location of the Qualified Person responsible for PV (QPPV) will need to be closely assessed for potential impacts by MAHs. Currently the majority of EU QPPVs are based in the UK. Kinapse can support you in providing a suitable QPPV based in the EU and can manage the associated updates to the Article 57 database. The short-term impact to PV services could be significant and without continued access to these systems, companies may face duplicative requirements and greater workload. Kinapse is well placed with deep expertise in all Pharmacovigilance activities to manage activities associated to Brexit including those connected with updates to the Eudravigilance database (for example, updates to the location of the Pharmacovigilance System Master File, continual monitoring and evaluation of the safety profile of products, as well as activities associated with the QPPV).

Managing the Regulatory Impact of Brexit – June 2017

Kinapse can provide you with End-to-End fully integrated services to manage the potential Regulatory and PV impact of Brexit including:

- Collaborating with you to design a thoughtful, balanced and strategic plan for impacted products and the transfer to another MAH
- Planning, authoring and submission of high quality, timely variations with limited oversight from your strategically-focused internal regulatory staff
- Provision of EU based QPPV and QP batch release
- On-going support if duplicate requirements for data entry become reality

References

1. Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use (May 2017) (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf)
2. EMEA specific web-site – United Kingdom's Withdrawal from the European Union (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/general/general_content_001707.jsp&mid=WC0b01ac0580a809a7)
3. Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human Brexit website: http://www.hma.eu/535.html

Footnote

1. Products licensed under the Centralised Procedure, MRP and DCP procedures involving the MHRA as Rapporteur or Reference Member State and products licenced nationally in UK. MAHs located in UK and all non EU companies whose EU MAH is a UK affiliate.

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Kinapse is a global technology-enabled services firm, providing expert advisory, capability building and operational solutions to life sciences organisations across the R&D and Commercialisation life cycle.

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