Diamond BioPharm Limited
REGULATORY CONSULTANTS

HARLOW, UK., 5th May 2017

DIAMOND BIOPHARM'S RESPONSE TO THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION

On 2nd May 2017 the EMA and European Commission published a notice alerting Marketing Authorisation Holders of centrally authorised medicines of their obligations in relation to Brexit.[1] Although the final deal between the UK and the EU is unknown, the notice assumes a complete regulatory break between both parties as of 30th March 2019. According to this notice, centralised marketing authorisations held by UK entities would need to be transferred to an entity within another EU member state prior to the UK exit from the EU, in order to ensure continuity of supply in the EU. Obligations such as batch release and pharmacovigilance must also continue to take place in an EU member state.

What does this mean for Diamond BioPharm and our clients?

Diamond BioPharm are first and foremost a regulatory affairs consultancy with extensive expertise in European regulatory affairs. This will not change regardless of the ongoing Brexit negotiations. Diamond BioPharm also has a physical presence in continental Europe. We will continue to monitor negotiations on the exit of the UK from the EU and act as needed to maintain the high levels of service and expertise for our clients on European regulatory matters.

As a UK-based consultancy we have a long history of interaction with the UK's Medicines and Healthcare products Regulatory Agency (MHRA). As UK-specific regulatory requirements evolve, we will be well placed to spot opportunities and risks for our clients and contribute further to their global regulatory portfolio.

While the final relationship between the UK and the EU is currently unclear, the team at Diamond BioPharm are committed to ensuring that we continue to excel in providing regulatory support and strategic advice for both the UK and European regulatory frameworks.

1) http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

About Diamond BioPharm Ltd

Diamond BioPharm Ltd was founded in 2005 by Dr Maureen Graham. The company is part of the Diamond Pharma Services group of companies, a leading technical and scientific consulting group serving the biotechnology and pharmaceutical industry, with an emphasis on:

- Regulatory Affairs: from product concept to registration and beyond
- Product Development: Chemistry manufacturing and control (CMC), non-clinical and clinical
- Pharmacovigilance: Clinical trial (phase I-IV), post marketing and QPPV services
- Compliance: GLP, GMP, GCP and QP services

For more information, please visit the Diamond Pharma Services website www.diamondpharmaservices.com or contact us on 0845 070 4336