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Preparing for Brexit and its impact on the life sciences industries

The Kinapse view

Pharma and Biotech executives have a duty to prepare for the exit of the UK from the EU

The UK declaration of article 50, in response to the UK referendum result, has triggered the process for departing the EU. This departure is very likely to have an impact on the pharmaceutical and biotech industries and the patients they serve.

Irrespective of any individual executive's views on the rights or wrongs of either the Leave or Remain positions and campaigns, the most likely outcome now is that the UK will cease to be a member of the EU either at, or soon after, 29th March 2019 – so a responsible executive must prepare their organisation, their investors and the patients they serve for what is to come afterwards.

Regulatory licencing, supply chain and talent are three areas most likely to be impacted

Complicating such executive planning is the great uncertainty as to what "Leave" means. Significant impact is possible in three business critical areas for our industries:

- **Regulatory approval and licence maintenance** of drug, vaccine and medical device products in the UK
- **Supply chain management** ie movement of drug, vaccine and device products between the UK and the EU
- **Talent acquisition and management** between the UK and the EU.

Kinapse recommends taking a structured approach to planning and risk management

With significant impact possible but great uncertainty as to what the outcome can be, what can industry executives do to prepare for Brexit?

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The Kinapse view...continued

1. Build scenarios

a. Establish a team, of internal SMEs, expert facilitators and professional project management, supplemented by insightful and objective external support, to identify and describe scenarios based on possible Brexit deal outcomes (e.g. “Switzerland style deal”; “Transitional period”; “No deal scenario”) and tailored to your company strategy, portfolio and footprint.

2. Identify risk across scenarios

a. Through table-top-gaming or other risk identification methodologies, identify, assess and prioritise risk for each selected scenario.

3. Build and test plans for prioritised outcomes

a. Assign business owners to each risk or group of risks and, with core team support and structure, define and test (e.g. through gaming) plans for managing prioritised risks.

4. Engage routinely with appropriate influencer groups either direct or via trade associations etc and clear internal communications with employees

a. Maintain currency of insight into likelihood of scenarios and associated risks, to dynamically manage planning and mitigation activity, as well as keeping colleagues reassured and appropriately informed.

5. Identify and execute preparatory activities based on scenario risk assessments

a. Where identified through risk assessment and lean business case development, execute targeted risk mitigation activities to get ahead of the curve on prioritised, high probability scenarios.

Kinapse can support you with each of the steps outlined above, thanks to our:

- **Life sciences expertise**, in particular public health, regulatory and pharmacovigilance insight
- External **objectivity and professional services rigour**
- **Advise-Build-Operate service spectrum**, taking you from strategic analysis through managed change to high quality and timely execution.

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The Kinapse view...continued

US biotech acts smartly to avoid both stock outs impacting patient safety and millions of Euros of lost revenues

An illustrative case study

Haruspex Inc., a US-headquartered global biopharma, formed a Brexit Task Force with sponsorship from the CEO. Leadership of this initiative was assigned to a rising star from the European Market Access group – knowledgeable about European markets and policy-makers but without the bias of functions closest to key risk areas.

The Core Team included senior experts from Commercial, Portfolio Analytics, Government Affairs, Regulatory Affairs, Manufacturing/Supply Chain and Security as well as external facilitation, objectivity and project rigour from a professional services firm with deep life sciences expertise.

One prioritised scenario was 'No Deal'. As the Core Team drilled into the related risks, it became clear that, with:

1. The company's EMEA headquarters and QPPV based in Berkshire, England, and

2. A significant portion of their marketed products registered in the UK

Action needed to be taken to ensure the continued validity of the European marketing authorisations.

The Regulatory Affairs rep from the core team took these findings back into the GRA function and, with continued support from the external facilitators, swiftly conducted a deep dive into the extent of the risk and the effort required to mitigate in modelled timeframes.

As 29th March 2019 loomed ever closer, continued divergence of views between the UK and EU negotiating teams was compounded by unhelpful politicking from Remain and Leave factions in the UK and a federalist vs free market split between member states in the EU 27. The Haruspex Inc. Brexit Task Force Steering Committee therefore decided to design and execute a major licence transfer programme – structured as a time-limited bolus of work to their existing specialist Regulatory licence maintenance partner – and recruit a back-up QPPV in its largest EU market.

This decision was based on a clear business case, created by the Regulatory sub-team of the Brexit Task Force, showing the high impact and high likelihood of stock outs impacting patient safety and millions of Euros of lost revenues.

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Kinapse, a Syneos Health Comapny, 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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