efpia
European Federation of Pharmaceutical Industries and Associations

To:
EFPIA BOARD MEMBERS

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February 22, 2018

Dear Colleagues,

Following the 30 January EFPIA Board meeting, I am writing to you regarding the progress of the Article 50 negotiations on the future relationship between the EU and the UK, and the preparations that your company is making for the UK's withdrawal from the EU.

As you will be aware, in December the President of the European Council, Donald Tusk, announced that there had been 'sufficient progress' on the first phase of the negotiations. Preliminary discussions on the second phase have now begun, which will focus on the future trading relationship between the EU and the UK, as well as negotiating a transition period. From the moment article 50 was triggered, EFPIA has been clear in stating that in the interest of patients and public health, the second phase should include an agreement to cooperate on the regulation, trade and supply of medicines to patients in the EU and the UK.

I am aware that your company is likely to be planning for a range of outcomes from the negotiations including the 'No Deal scenario', which guidance from the EMA currently assumes. The political uncertainty presents a number of difficulties in making business continuity decisions and the potential costs that individual companies may incur depends on the nature of your specific portfolio and business locations. Whilst it would be entirely inappropriate for EFPIA to direct any such business decision, the EFPIA Board recommended that I share with you a range of considerations that may be helpful as you put in place all necessary business continuity plans. This should be seen as part of our ongoing dialogue regarding Brexit preparations.


EFPIA Brussels Office
Leopold Plaza Building * Rue du Trône 108
B-1050 Brussels * Belgium
Tel: + 32 (0)2 626 25 55 *
www.efpia.eu * info@efpia.eu

For your internal considerations, below are a number of areas you may wish to check when planning for the impact of the UK leaving the EU.

Considerations for regulatory continuity planning

- For centrally approved products and products approved non-centrally in EU27 countries, consider the location of the Marketing Authorisation Holder (MAH). If based in the UK, determine which EU/EEA member state entity(ies) may be best placed to replace the UK MAH in holding Mas. Alternatively, consider the need to establish a new entity for this purpose. In addition, consider the need for submissions to transfer the MAH for the impacted MAs.
- Consider the Regulatory Authority currently acting as Reference Member State (RMS) for products approved via the Mutual Recognition (MRP) or Decentralised Procedure (DCP).
- Consider the location of required contact points and staff performing associated regulatory activities.
- Consider the necessary variations for centralised and non-centralised MAs to support changes to manufacturing/supply activities and artwork/labelling changes.
- Consider the location of the EU qualified person for Pharmacovigilance (EU QPPV).
- Consider the location of the named individual responsible for batch recalls and product complaints.
- Consider the location of the holder of any Orphan Designations for orphan medicinal products.

Considerations for trade and supply continuity planning

- Assessment of impact on current supply chain and trade flows. Mapping of trade flows and manufacturing operations, including a review of stock holding and resilience of contingency arrangements.
- Consider location of importation point of entry to the EU for goods from the UK. This to include reviewing UK manufactured medicines imported into the EU/EEA and batch testing for products exported from the UK to EU/EEA and batch testing of products in the UK exported from the EU/EEA to the UK.
- Evaluation of third party services. Ensure third party supplier network (e.g. CMOs) have the correct footprint and resilience.
- Review customer and supplier contracts. Assessment of the need to renegotiate contracts with customers and suppliers once details from Brexit trade negotiations emerge.


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Considerations for clinical trials continuity planning

- Consider the location of the sponsor and/or legal representative for clinical trials being conducted in the EU27, if based in the UK.
- Assess the impact on current supply chain and flows of investigational medicinal products for clinical trials, in particular the location of certification of IMPs by a qualified person.

Considerations for workforce continuity planning

- Assessment of potential employee impact and working visas. Assess business-critical roles and assist with residency applications.
- Understand minimum requirements for potential new MAH entity.
- Consider staffing investments in order to adhere to requirements.
- Consider location of EU QPPV if currently based in the UK.
- Consideration of regulatory presence in relation to new EMA location.

EFPIA continues to advocate that, in the interest of patients and public health, securing future cooperation on the regulation, trade and supply of medicines must be a priority for both the UK Government and EU Commission. I would like to thank the work of the EFPIA Brexit Taskforce for the significant progress we have made over the past year, and I am grateful for your company's support in this work.

I hope that this letter is useful to you, and please do not hesitate to contact me if you have any further questions.

Yours sincerely,

Stefan Oschmann
EFPIA President

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