Hogan Lovells

Brexit

First Aid for Pharma

Should the UK choose to leave the EU, there will be a substantial impact for the UK pharmaceutical industry. Crucially, these implications will not just be limited to the regulatory issues governing medicinal products.

"First Aid for Pharma" is intended for UK pharmaceutical companies that wish to continue to operate within the EU structure should the UK choose to leave the EU. It is intended to assist UK pharmaceutical clients in identifying issues that must be addressed.

1. Marketing Authorisation

The pharmaceutical sector is the most highly regulated sector in the EU.

A valid marketing authorisation for a medicinal product in the EU can be held only by an entity that is established within the EU. Should the UK choose to leave the EU, UK pharmaceutical companies will no longer have an EU establishment at which a valid marketing authorisation can be held.

i. Basic questions to be addressed concerning transfer of the marketing authorisation:

- Should the UK entity establish a presence in another EU Member State to which the marketing authorisation is transferred; or should the UK entity conclude a licensing agreement with an entity in another EU Member State?
- Would a transfer of marketing authorisation constitute a new marketing authorisation for a medicinal product; is a variation to an existing marketing authorisation an option?
- Is it necessary to change manufacturing facility?
- Is a new GMP audit required?
- Can the name and address of the UK entity remain on the packaging?
- Does the transfer procedure vary between EU Member States?
- How long does a transfer procedure take?

ii. Pharmacovigilance

What are the consequences for UK-based marketing authorisation holders concerning their regulatory obligations to report adverse events occurring with their products in the UK or in the EU?

Will UK pharmaceutical companies be required to appoint a new qualified person responsible for pharmacovigilance (QPPV) in an EU Member State?

2. Corporate Issues

Should a UK entity decide to establish a presence in another EU Member State, what would be the related corporate issues to be considered? These would include:

- Investigation of the national rules of individual EU Member States governing establishment of an entity;
- Determination of which EU Member State presents the most attractive alternatives to the UK.

3. Clinical Trials

Applications for marketing authorisation for medicinal products through the centralised marketing authorisation process must be supported by clinical data generated during clinical trials conducted in the EU. Data generated in third countries is considered "ancillary clinical data".

What is the validity of clinical data generated in clinical trials conducted in the UK, both pre and post UK departure, and intended to support marketing authorisation application for a medicinal product or the CE marking of a medical device?

4. Data Protection Issues

What would be the consequence of a UK departure for UK-based companies when they process personal data within the meaning of the Data Protection Directive and the future Data Protection Regulation? The UK could become an "adequate" third country in the medium term following a related decision of the European Commission but what would be the position in the short term, particularly in relation to data generated in on-going long term clinical trials?

5. Intellectual Property Issues

If a UK marketing authorisation holder either establishes a presence in another EU Member State to which the marketing authorisation is transferred or concludes a licensing agreement with an entity in another EU Member State which entity owns the marketing authorisation?

In a similar vein, who owns the patent in such circumstances? What consequences will there be for current European Patents that include the UK and for existing SPCs?

6. Contractual Issues

Changes in marketing authorisation holder will lead to a revision of contracts such as supply contracts governing APIs and final products. Where the UK marketing authorisation holder contracts out activities such as pharmacovigilance obligations related contracts will also require revision.

Will changes in national law governing related contracts be necessary?

What will the consequences be for supply contracts to competent authorities, hospitals, physicians within the EU?

7. Pricing and Reimbursement

Following a UK departure, competent authorities in EU Member States responsible for pricing and reimbursement may question the on-going suitability of sourcing supplies of medicinal products from a non-EU country. What are the related pricing and reimbursement issues?

What are the related issues concerning supplies based on previous public procurement activities in the EU Member States?

8. Employment Issues

Should a UK entity decide to establish a presence in another EU Member State, what would be the consequences of transfer for existing UK employees?

Which EU Member State presents the least employment challenges?

9. Tax Issues

Should a UK entity decide to establish a presence in another EU Member State, what would be the tax consequences of transfer for the existing UK entity?

Which EU Member State presents the least tax challenges and the most beneficial tax environment?

10. Trade Issues

Should a UK entity decide to establish a presence in another EU Member State, what would be the consequences from an international trade perspective?

Will the UK become a third country from an EU trade perspective?

What are the consequences for products/raw material, imported from the EU into the UK and exported from the UK towards the EU in terms of custom duties and controls?

Will the UK be required to renegotiate all trade agreements concluded directly by the EU with third countries?

11. EU Funding and Public-Private Partnerships

What are the consequences of a UK departure for UK-based companies participating in EU funding programmes such as Horizon 2020?

What are the consequences for UK-based companies participating in public-private partnerships such as the Innovative Medicines Initiative?

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