Brexit: Rumours and Realities for Pharmaceutical and Medical Device Companies to Consider

15 March 2016
Hogan Lovells

How would Brexit impact the UK pharmaceutical industry?

A fundamental obligation related to the marketing of medicinal products in the EU is the requirement of a valid marketing authorisation. Only entities established within the EEA, most commonly within the EU, may apply for and hold a valid marketing authorisation. Brexit would mean that entities in the UK could no longer either apply for or hold EU marketing authorizations for medicinal products.

How would Brexit impact the UK medical device industry?

The right for medical device manufacturers to affix a CE mark to their products is based on demonstration of compliance with the obligations laid down in the EU medical device directives and related guidance documents that are currently the basis of related UK law. Brexit would mean that UK medical device manufacturers would no longer be permitted to claim automatic entitlement to market medical devices throughout the EU on the grounds that they have conducted a conformity assessment on the basis of EU device rules and affixed the CE mark to their devices.

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