VAN BAEL & BELLIS

CLIENT ALERT MEMORANDUM

6 June 2017

European Commission and European Medicines Agency Publish First Set of Questions and Answers Addressing Establishment Requirements Resulting From Brexit

In a notice published at the end of April 2017, the European Medicines Agency ("EMA") stated that "*although negotiations on the terms of the UK's departure have not yet officially commenced and one cannot prejudge their outcome, work will now start on the basis of the scenario that foresees that the UK will no longer participate in the work of EMA and the European medicines regulatory system as of 30 March 2019*" (see press release in separate attachment).

In other words, the EMA is proceeding on the basis that there will be no agreement on the many complex matters involving medicines that are associated with a withdrawal of the UK from the European Union. In that scenario the UK will become a 'third country' in Spring 2019.

Last week, the European Commission and the EMA published a first set of questions and answers to deal with the implications of this scenario for medicinal products for human and veterinary use within the framework of the Centralised Procedure (see Q&A in separate attachment). They stem from a double establishment requirement for marketing authorisation holders of centrally authorised medicinal products for human and veterinary use:

- EU law requires that marketing authorisation holders be established in the EU (or EEA);
- Specific activities must be performed in the EU (or EEA). These relate to issues such as pharmacovigilance, batch release and so forth.

The Q&A thus starts with the straightforward question what to do if the marketing authorisation holder of a centrally authorised medicine is established in the UK. The equally straightforward answer is that a firm in that position will have to transfer its marketing authorisation to a holder established in the EU (or EEA).

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The Q&A addresses further such issues with regard to a UK based orphan designation holder; a UK based holder of a “minor use minor species/limited marketing” status for a veterinary product; a UK based qualified person for pharmacovigilance; a UK located pharmacovigilance system master file; a UK based manufacturing site of an active substance or finished product; a UK based batch release site; and UK based SMEs that until now qualified for financial and administrative assistance.

The European Commission and the EMA will publish additional Q&A’s addressing Brexit-related issues on a page of the EMA’s website dedicated to Brexit which can be retrieved here.

Lawyers to contact

If you have any questions concerning this memorandum, please contact

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