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Group Briefing

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Brexit Guidance for the Pharmaceutical Industry

The European Medicines Agency ("**EMA**") and the European Commission have released the first in a series of guidance notes to prepare the pharmaceutical industry for the UK's withdrawal from the EU.

Further information, including access to the guidance notes, is published on the website of the EMA. Companies and other interested stakeholders should keep an eye on this website as it is anticipated that further guidance will be issued over the coming months and possibly years, as Brexit takes effect.

On 2 and 31 May, the following two guidance documents were issued:

1. Notice to marketing authorisation holders of centrally authorised medicinal products for human and veterinary use ("**Notice**"); and

2. Questions and answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure ("**Q&A**").

1. NOTICE

The Notice reminds marketing authorisation holders ("**MAHs**") of obligations under EU law that may prompt a re-consideration of:

(i) the entity that holds the marketing authorisation; (ii) ("**MA**"),a change to their current processes or; (iii) a variation to the MA in light of Brexit. These are as follows:

- MAHs must be established in the EEA;
- and certain activates must be performed in the EEA such as batch release and pharmacovigilance; and
- the location of PSMF must be in the EEA.

The Notice essentially calls for MAHs to conduct a scoping exercise of all MAs that may be held by UK entities with a view to their transfer or variation and to review current activities that are currently taking place in the UK to take account of the above rules.

2. Q&A

As a follow up to the Notice, the Q&A provides more detailed and practical direction for MAHs based in the UK and for those individuals or entities involved in certain activities that take place in the UK. While we would expect that most of these should not come as a surprise, some of the key takeaways are as follows:

2.1 UK MAHS OF CENTRALISED PRODUCTS

These MAs will likely need to be transferred to an entity in the EEA using the EMA transfer procedure.

2.2 UK HOLDERS OF ORPHAN DESIGNATION

Holders of orphan medicinal product designations will need to transfer designation to a holder established in the EEA or change its place of establishment to a Member State of the EEA via notification to the EMA of a change of name and/or address (provided the legal entity remains the same).

2.3 QPPV RESIDES AND CARRIES OUT TASKS IN UK

Under EU law, the QPPV must reside and carry out their tasks in the EEA. The QPPV will therefore need

to change his/her place of residence and carry out his/her tasks in the EEA or a new QPPV in the EEA will need to be appointed. Except for veterinary products, changes to the contact details of the QPPV may be updated through the Article 57 database only without the need for a formal variation to the EMA.

2.4 PSMF LOCATED IN THE UK

The location of the PMSF must be within the EEA. Following Brexit, where those files are held in the UK, they must be transferred to an EEA Member State. Notification of this change can also be made through the Article 57 database.

2.5 MANUFACTURING SITES OF ACTIVE SUBSTANCES IN THE UK

Following Brexit, active substances manufactured in the UK will be considered imported active substances for the purposes of bringing these into the EEA. This means that the MHRA will have to provide written confirmation to the EEA competent authorities that the relevant manufacturing plant meets equivalent standards of good manufacturing practice and control to those in the EEA.

2.6 MANUFACTURING SITES OF FINISHED PRODUCTS IN THE UK

Medicinal products manufactured in the UK for placing on the market in the EEA will require an import authorisation which demonstrates that they have been manufactured in accordance with EU GMP.

There must be an authorised importer within the EEA and the products must undergo batch control and testing at a site in the EEA before they can be placed on the EEA market. In both instances, the MA's can be updated using the EMA variation procedure.

2.7 BATCH RELEASE SITES IN THE UK

As above, the MAH will need to transfer its site of batch release to a location within the EEA if this site is currently situated in the UK.

2.8 FINANCIAL AND ADMINISTRATIVE ASSITANCE FOR SMEs

UK companies may no longer automatically benefit from the EU financial and administrative assistance for SMEs.

Essentially, either the company will have to establish a subsidiary in the EEA for the purposes of availing of SME assistance in the normal way or else they can seek to indirectly benefit from the SME incentives through a SME regulatory consultancy established in the EEA. In the latter case, both the regulatory consultancy and the UK based company must meet the SME criteria i.e. fall below the headcount and financial thresholds.

3. GUIDANCE FOR NATIONAL, MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

Please note that the guidance on the EMA website primarily concerns centralised products and that guidance for products authorised via national, decentralised or mutual recognition procedures is provided on the website of the Heads of Medicines Agencies.

On this website, the CMDh also published a corresponding Q&A document and notice for MAHs of nationally authorised products for human use.

The responses were essentially quite similar to the above except for one aspect in relation to having the UK as a Reference Member State ("**RMS**") for a mutual recognition or decentralised Procedure. The guidance makes it clear that a UK RMS will need to be changed to a competent authority of a Member State of the EEA.

If you require advice or further information on how to transfer or vary these authorisations, designations or activities to involve Irish entities, please contact Colin Kavanagh or Ciara Farrell:

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