The departure of the United Kingdom from the European Union - known as BREXIT - on 29 March 2019 implies that EU rules will no longer apply to the United Kingdom unless, in the meantime, a specific agreement is signed between the two parties. As details of such an agreement are not known and there is no certainty to its signature, the European Commission requests that the measures be taken in accordance with the assumption of the total absence of an agreement, thus several documents on the subject have been published (link to the CMDv website http://www.hma.eu/542.html

Based upon this worst-case assumption, the DGAV recommends the following measures.

EU legislation requires that marketing authorization holders (MAHs) are established in the EU (or the EEA). Other activities should also be located in the EU (or EEA) such as pharmacovigilance and batch release.

The preparation for BREXIT is therefore not only the responsibility of the EU and national authorities, but also of the veterinary medicinal industry.

MAHs shall proactively prepare and control the authorizations they hold and identify any necessary changes. Requests for transfer of ownership or amendments to the marketing authorization should be submitted in time to be finalized before 30 March 2019, taking into account the procedural deadlines provided for in the regulatory framework.

MAA procedures:

For new MA requests in which the UK is the Reference Member State (RMS), if the procedure is not completed before March 30, 2019, the procedure will be discontinued. The applicant shall submit a new application to a new Reference Member State. Applicants should take this into account when submitting any new application for marketing authorization.

In the case of existing marketing authorizations where the UK is the RMS, MAHs shall amend their Reference Member State as soon as possible before 30 March 2019.

Other Procedures:

Since the holder of a marketing authorization for veterinary medicinal products must be located in the EU / EEA, MAA holders located in the United Kingdom should therefore transfer their authorizations to another entity within the EU / EEA.

- The MA transfer must be terminated and implemented before 3/30/2019.

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For pharmacovigilance of veterinary medicinal products, the person qualified for pharmacovigilance (QPPV) must be located in the EU / EEA.

• Change of QPPV must be made before 03/30/2019.

In the absence of a mutual recognition agreement between the European Union (EU) and a third country, veterinary medicinal products manufactured in this third country should be re-examined and released by an authorized EU / EEA site for import and marketing purposes in the EU. The MAH may choose to keep the place of control of the finished product and the place of release of the consignment in the United Kingdom, provided that an import control site and a batch release site in the EU / EEA are secured in the AIM.

• All such changes must be notified by 3/30/2019.

The document "***Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products***", which can be found at the link below, infroms taht, with regard to the quality control testing there may be objective reasons beyond control of the marketing authorisation holders that may prevent timely transfer of such testing activities to the Union by the withdrawal date. In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC provide that competent authorities may allow importers of medicinal products coming from third countries to have in justifiable cases certain of the controls carried out by third parties.
https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf

All batches of veterinary medicines registered in Portugal that are properly released and placed in the EU market before 30 March 2019 may be commercialized in Portugal until their expiry date, even if the PT marketing authorisation is being subject to a variation to include a batch control site and/or batch release site in the EU.

The assessment of potential issues related to the availability of veterinary medicinal products on the national market is carried out by the competent national authorities of the Member States. Marketing authorization holders shall ensure a continuous supply covering the need of wholesalers and retailers of veterinary medicinal products and the also the general public.

If there is any question or irregular situation related to BREXIT, we kindly ask the MAH to inform DGAV to the email: national@dgav.pt

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