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In compliance with the Act No 378/2007 on Pharmaceuticals, veterinary medicinal products are subject to the marketing authorisation in the Istitute for State Control of Veterinary Biologicals and Medicaments (national, mutual recognition and decentralised procedures) or subject to the Community marketing authorisation according to the Regulation (EC) No 726/2004.

ISCVBM grants a marketing authorisation if requirements for the marketing authorisation specified in the Act on Pharmaceuticals and the Regulation No 228/2008 which are in compliance with the EU legislation (Directive 2004/28/EC) are fulfilled. A marketing authorisation is granted for a period of 5 years and is renewable upon application three months before expiry.Once renewed, the marketing authorisation shall normally be valid for an unlimited period oftime. However, on justified grounds relating to pharmacovigilance, the ISCVBM may decide to proceed with one additional five-year renewal, after which the authorisationwill become valid for unlimited period of time.

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Throughout the life of a veterinary medicinal product, the marketing authorisation holder is responsible for the product which is placed on the market and is also requiredto take into account technical and scientific progress, and to make anyamendments that may be required to enable the veterinary medicinal product to bemanufactured and checked by means of generally accepted scientific methods.Such amendments may involve administrative or more substantial changes. The marketing authorisation holder shall submit a notification or an application for the approval of a variation to the terms of a marketing authorisation to the ISCVBM before its implementation.

USKVBL Information on the Impact of "Brexit" on the Marketing Authorisation of Veterinary Medicinal Products

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that unless the withdrawal agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'.

In this context, the USKVBL informs the applicant / MAH of nationally authorised veterinary medicinal products (including via MRP / DCP authorised products) on the certain legal repercussions of this step which need to be considered:

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EU law requires that marketing authorisation holders are established in the EU (or EEA);

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Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, manufacturing, import etc.

We recommend that marketing authorisation holders affected by the situation consider as soon as possible measures and necessary changes to the terms of marketing authorisations to ensure a validity of the marketing authorisations. once the UK leaves the Union (transfer of the MA to another holder, change of the MA holder's address, manufacturing and pharmacovigilance, generic and hybrid application issues, etc ...).
The necessary steps need to be taken in advance to avoid any impact on the validity of the marketing authorisations and a related availability of veterinary medicinal products within the European Union.
Necessary applications for MAH transfers or variations to the marketing authorisations should be submitted in due time, taking into account the timetables of the particular procedures, so that the procedures are closed by 29 March 2019 at the latest.

Practical information, including a document containing questions and answers on the issue, can be found on the CMDv Coordination Group website.
For veterinary medicinal products authorised by a centralised procedure, information
is available through the Commission's and the European Medicines Agency’s (EMA) website.