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SPC improvement of generic product

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QUESTION

A generic product (A) has been subjected to the Mutual Recognition procedure and two Repeat Use procedures in a number of Member States. All these procedures have been conducted before the implementation of Directive 2004/28/EC amending Directive 2001/82/EC. During those procedures the SPC of product A was cutting down because of the local SPCs of the Reference Product in those Member States. (The SPC of the generic Product A was harmonised with the lowest common denominator of the SPC's of the Reference Product) Is it possible now to make a Type 2 variation to get back all those e.g. indications which were approved in the first SPC of the Product A in the RMS, just referring to the Reference Product approved in RMS (using as European Reference Product)?

ANSWER

It is not possible to update the SPC with the lost indications by a type II variation where only a reference is made to the originator product in the RMS. The MAH can apply for the previously deleted indications by means of a type II variation. However the marketing authorisation holder would need to comply with the NTA Volume 6C Guidance on the Assessment of environmental risks of veterinary medicinal products. If the addition is to include a food producing species then an extension application would be required as it is not possible under legislation to submit such a change as a variation.

The concept of European Reference Product (originator approved in RMS) cannot be taken into account in cases where the originator is authorised in a CMS. Nevertheless, the SPC of the reference product should be followed.

It may also be necessary for National Competent Authorities to exchange the minimum data as detailed in CMD(v)/GUI/006.