

**Question & Answer N. 130/2011**

**Changes to the invented name during mutual recognition or decentralised procedures**

<b>Status</b>	<b>Public</b>
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## QUESTION

How to deal with changes to the invented name during mutual recognition or decentralised procedures?

## ANSWER

The product name as proposed by the applicant in the application for a Marketing Authorisation (MA) is assessed by the National Competent Authorities (NCAs). Issues related to the name of the Veterinary Medicinal Products (VMPs) should whenever possible be solved and an agreement on the name reached during the procedure. An updated application form and annex 5.19 should be submitted when a new name is agreed.

In case the applicant wishes to have a common name in a number of Member States to facilitate multi-lingual packs, any naming issues should be clearly communicated in a separate mailing to the relevant Member States, i.e. changes to the proposed product name initiated by the applicant or by a Concerned Member State during the procedure should be notified immediately to the NCA affected by the proposed change, copying the Reference Member State.

If agreement on the product name is not reached at the end of the EU procedure, the agreement can be sought in the national phase or in a subsequent variation procedure where the MA has already been granted with the previous product name. The MAHs are reminded that in all cases of changes to the product name, the mutually recognized English Package Leaflet needs to be updated so that Section 15 of the Package Leaflet lists all the marketed names for the product in the EEA, as follows:

This medicinal product is authorised in the Member States of the EEA under the following names:

For example,

Spain, Portugal, Italy: <Name 1>

UK and Ireland: <Name 2>