

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

**Changes to the invented name during mutual recognition**

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

How to deal with changes to the invented name during mutual recognition 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.

The NCAs may request the applicant to update relevant sections of the application (e.g. annex 5.18) 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 MR 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 previously agreed product name.

For naming issues in DCP please see the *Clarification Paper- Agreeing Product Name during the Decentralised Procedure*, published at the CMDv website:

[http://www.hma.eu/uploads/media/100315\\_Note\\_for\\_publication\\_on\\_agreeing\\_product\\_name\\_in\\_DCP.pdf](http://www.hma.eu/uploads/media/100315_Note_for_publication_on_agreeing_product_name_in_DCP.pdf)