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Question & Answer N. 28/2006
National transfer of MAH

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QUESTION

National transfer of the MA: if a product has been authorised by the mutual recognition procedure in a number of member states is it possible to transfer the several national authorisations to new holders in different countries? These new holders are independent from the MAH of the first authorisation?

ANSWER

The transfer of the national MA is a national responsibility. However, the mutual recognition is based on the principle that the SPC's for products that have undergone the MRP shall be identical and remain identical in all concerned Member States. The transfer of the National MA can occur, but the link with the original Marketing Authorisation in the RMS should remain. These new holders will be linked to the first Marketing Authorisation in the RMS.