How to submit a transfer of a Marketing Authorisation Holder (MAH)

The Marketing Authorisation Holder (MAH) transfer procedure must be applied in case the medicinal product holdership is transferred from the currently approved MAH to a new MAH which is a different person/legal entity.

If the change refers only to the name and/or address of the MAH and the holder remains the same person/legal entity, a MAH transfer procedure is not requested and the change should be submitted as a Type $IA_{IN,}$ category A.1 variation (according to Commission Regulation (EC) No 1234/2008).

For products which are submitted through a National procedure a Transfer of the Marketing Authorization (MA) Holdership can only be initiated once the MA has been granted.

For products which are submitted through a European procedure (Mutual Recognition/Decentralised Procedure) the MAH can be changed during the on-going procedure (in this case the request can be only submitted on Day 106 and day 160 along with the official response document) or during the national phase (after day 210) or after the MA is granted When the MAH changes during the national implementation phase, or after granting of the MA (both for National and European MR/DC procedures), the new MAH should submit in parallel a type IA_{IN} variation procedure (category C.I.8.a) to change the Summary of the Pharmacovigilance System (sPhVS) (See CMDh Q&A 2.8 on variations). A type IB variation (category A.2) with the aim to change the name of the medicinal product, if any, should also be submitted in parallel.

The request should be submitted as local submission/notification (the responsibility of the submission depends on the agreements between the parties) in paper original copy. The request must be readable and preferably shall be printed on a headed paper, that includes the following information and/or documentation:

- The name of the medicinal product concerned, the Italian authorisation number(s) (AIC) and the Marketing Authorization date;
- Dee of transfer of MAH from Transferor (old MAH) (XXX) to Transferee (new MAH) (XXX) in which {Title, name, position} of the Transferor and of the Transferee are indicated with legalized signatures;
- The relevant fee must be paid for each medicinal product (see table of fees at at the following link http://www.aifa.gov.it/content/informazioni-sul-sistema-di-versamento-tariffe fee code B.3.1). Please note that the payment should be made through the on-line AIFA POL system. Proof of documentation for POL number (in paper copy) must be submitted with documentation. The cover letter should bear a € 16.00 revenue stamp.
- List of batches, if any, for which the new MAH requests a delay to update product information (see also the AIFA communication, published on 21/07/2015.

The Marketing Authorisation transfer will be finalized within 90 days from the submission's receipt , if valid.

The stock already manufactured and released may be sold until expiry date indicated on the label.