

Information on the Procedure for Changing the Marketing Authorisation Holder (MAH) Representative

This information sets out the procedure to be followed in the event of a change of MAH representative.

The original MAH representative is obliged to notify Národní organizace pro ověřování pravosti léčiv, z.s. (hereinafter “**CZMVO**”) without undue delay of the termination of its representative authorisation, in writing, indicating the date on which its representative authorisation was terminated. Such written notification must include the termination (i.e. revocation or termination notice) of the Power of Attorney granted to the original MAH.

The new MAH representative is obliged to promptly notify CZMVO of the establishment of its representative authorisation, in writing, indicating the date on which its representative authorisation was established. Such written notification must include a Power of Attorney granted to the new MAH representative.

Should the abovementioned procedure not be followed, CZMVO will proceed in accordance with the established interpretation of the provision of Section 440(1) of Act No. 89/2012 Coll., the Civil Code, as amended, and invoice the user fee according to the Cooperation Agreement concluded between MAH and CZMVO to the original MAH representative.