

Template for cover letter for the submission of the PSUR overview table to P-RMS, when specific MAH product is **not** authorised in P-RMS., Version 18-06-2008

Subject: Submission of the PSUR(s) under the EU PSUR synchronisation scheme for <Product Name(s)>, Procedure Number <../H/PSUR/.../...>

Dear Sir/Madam,

Please be advised that we have submitted (a) PSUR(s) for our product(s) containing <active substance name(s)> in all Member States in which we hold a marketing authorisation. The annexed table contains the full list of authorisations covered by this PSUR.

The relevant product(s) is/are not authorised in <P-RMS name>, but as <P-RMS name> is the PSUR – Reference Member State, we are providing you with this table.

For communication in respect to assessment of this PSUR please contact:

Name:

Email:

Telephone:

Yours sincerely,

<Name>

<Signature>

