19 April 2013
EMA/170043/2013

Guideline on good pharmacovigilance practices (GVP)

Annex II – Templates: Cover page of Periodic Safety Update Report (PSUR) (Rev 1)

Draft of first version finalised by the Agency in collaboration with Member States and submitted to ERMS FG (as part of GVP M VII)	19 January 2012
Draft agreed by ERMS FG	24 January 2012
Draft adopted by Executive Director	20 February 2012
Released for public consultation	21 February 2012
End of consultation (deadline for comments)	18 April 2012
Revised draft of first version finalised by the Agency in collaboration with Member States	20 June 2012
Revised draft agreed by ERMS FG	21 June 2012
Revised draft adopted by Executive Director as final (as part of GVP M VII)	22 June 2012
Date for coming into effect	2 July 2012
Draft Revision 1* finalised by the Agency in collaboration with Member States	21 March 2013
Draft Revision 1 agreed by ERMS FG	27 March 2013
Draft Revision 1 adopted by Executive Director as final	19 April 2013
Date for coming into effect of Revision 1	25 April 2013

*Note: Revision 1 contains the following:

- correcting "*(Underline (Harmonised) EU Birth Date)*" to "*(Underline the International Birth Date)*".

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PERIODIC SAFETY UPDATE REPORT

for

ACTIVE SUBSTANCE(S): <INN>

ATC CODE(S): <Code(s)>

MEDICINAL PRODUCTS COVERED:

Invented name of the medicinal product(s)	Marketing authorisation number(s)	Date(s) of authorisation *(Underline the International Birth Date)*	Marketing authorisation holder
<>	<>	<>	<>
<>	<>	<>	<>

AUTHORISATION PROCEDURE in the EU:
<Centralised/Mutual Recognition/Decentralised/Purely National>

INTERNATIONAL BIRTH DATE (IBD): <Date>

EUROPEAN UNION REFERENCE DATE (EURD): <Date>

INTERVAL COVERED BY THIS REPORT:
From <date> to <date (i.e. data lock point)>
DATE OF THIS REPORT:
<Date>

OTHER INFORMATION:
<Other identifying or clarifying information if necessary>

MARKETING AUTHORISATION HOLDER'S NAME AND ADDRESS:
<Name>
<Address>

<E-mail address> **(contact person for the PSUR procedure)**

NAME AND CONTACT DETAILS OF THE QPPV:
<Name>
<Address>
<Telephone number>
<Fax number>
<E-mail address>

SIGNATURE (QPPV or designated person): <Signature>

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