



Type II Variations (60 day procedure) and Worksharing

Submission	Start	(Co)- Rapporteurs AR	Comments from CHMP Members	Opinion or Request for supplementary information
28/09/2007	14/10/2007	16/11/2007	03/12/2007	13/12/2007
09/11/2007	25/11/2007	28/12/2007	14/01/2008	24/01/2008
07/12/2007	23/12/2007	25/01/2008	11/02/2008	21/02/2008
04/01/2008	20/01/2008	22/02/2008	10/03/2008	20/03/2008
08/02/2008	24/02/2008	28/03/2008	14/04/2008	24/04/2008
14/03/2008	30/03/2008	02/05/2008	19/05/2008	29/05/2008
11/04/2008	27/04/2008	30/05/2008	16/06/2008	26/06/2008
09/05/2008	25/05/2008	27/06/2008	14/07/2008	24/07/2008
N/A	N/A	N/A	N/A	N/A
11/07/2008	27/07/2008	29/08/2008	15/09/2008	25/09/2008
08/08/2008	24/08/2008	26/09/2008	13/10/2008	23/10/2008
05/09/2008	21/09/2008	24/10/2008	10/11/2008	20/11/2008
03/10/2008	19/10/2008	21/11/2008	08/12/2008	18/12/2008
07/11/2008	23/11/2008	26/12/2008	12/01/2009	22/01/2009
05/12/2008	21/12/2008	23/01/2009	09/02/2009	19/02/2009
02/01/2009	18/01/2009	20/02/2009	09/03/2009	19/03/2009
06/02/2009	22/02/2009	27/03/2009	13/04/2009	23/04/2009
13/03/2009	29/03/2009	01/05/2009	18/05/2009	28/05/2009
10/04/2009	26/04/2009	29/05/2009	15/06/2009	25/06/2009
08/05/2009	24/05/2009	26/06/2009	13/07/2009	23/07/2009
N/A	N/A	N/A	N/A	N/A
10/07/2009	26/07/2009	28/08/2009	14/09/2009	24/09/2009
07/08/2009	23/08/2009	25/09/2009	12/10/2009	22/10/2009
04/09/2009	20/09/2009	23/10/2009	09/11/2009	19/11/2009
02/10/2009	18/10/2009	20/11/2009	07/12/2009	17/12/2009
06/11/2009	22/11/2009	25/12/2009	11/01/2010	21/01/2010
04/12/2009	20/12/2009	22/01/2010	08/02/2010	18/02/2010
05/01/2010*	19/01/2010	19/02/2010	08/03/2010	18/03/2010
05/02/2010	21/02/2010	26/03/2010	12/04/2010	22/04/2010
05/03/2010	21/03/2010	23/04/2010	10/05/2010	20/05/2010
09/04/2010	25/04/2010	28/05/2010	14/06/2010	24/06/2010
07/05/2010	23/05/2010	25/06/2010	12/07/2010	22/07/2010
N/A	N/A	N/A	N/A	N/A
09/07/2010	25/07/2010	27/08/2010	13/09/2010	23/09/2010
06/08/2010	22/08/2010	24/09/2010	11/10/2010	21/10/2010
03/09/2010	19/09/2010	22/10/2010	08/11/2010	18/11/2010
01/10/2010	17/10/2010	19/11/2010	06/12/2010	16/12/2010
05/11/2010	21/11/2010	24/12/2010	10/01/2011	20/01/2011
03/12/2010	19/12/2010	21/01/2011	07/02/2011	17/02/2011
31/12/2010	16/01/2011	18/02/2011	07/03/2011	17/03/2011
28/01/2011	13/02/2011	18/03/2011	04/04/2011	14/04/2011
04/03/2011	20/03/2011	22/04/2011	09/05/2011	19/05/2011
08/04/2011	24/04/2011	27/05/2011	13/06/2011	23/06/2011
06/05/2011	22/05/2011	24/06/2011	11/07/2011	21/07/2011

Submission	Start	(Co)- Rapporteurs AR	Comments from CHMP Members	Opinion or Request for supplementary information
N/A	N/A	N/A	N/A	N/A
08/07/2011	24/07/2011	26/08/2011	12/09/2011	22/09/2011
05/08/2011	21/08/2011	23/09/2011	10/10/2011	20/10/2011
02/09/2011	18/09/2011	21/10/2011	07/11/2011	17/11/2011
30/09/2011	16/10/2011	18/11/2011	05/12/2011	15/12/2011
04/11/2011	20/11/2011	23/12/2011	09/01/2012	19/01/2012
02/12/2011	18/12/2011	20/01/2012	06/02/2012	16/02/2012
30/12/2011	15/01/2012	17/02/2012	05/03/2012	15/03/2012
03/02/2012	19/02/2012	23/03/2012	09/04/2012	19/04/2012
09/03/2012	25/03/2012	27/04/2012	14/05/2012	24/05/2012
06/04/2012	22/04/2012	25/05/2012	11/06/2012	21/06/2012
04/05/2012	20/05/2012	22/06/2012	09/07/2012	19/07/2012
N/A	N/A	N/A	N/A	N/A
06/07/2012	22/07/2012	24/08/2012	10/09/2012	20/09/2012
03/08/2012	19/08/2012	21/09/2012	08/10/2012	18/10/2012
31/08/2012	16/09/2012	19/10/2012	05/11/2012	15/11/2012
28/09/2012	14/10/2012	16/11/2012	03/12/2012	13/12/2012

In case issues are identified which prevent the adoption of an Opinion, the CHMP will adopt a request for supplementary information together with the date by when the MAH must submit the requested data ([Responses to List of questions/List of outstanding issues or Request for Supplementary Information](#)). The CHMP assessment of responses will take up to 30 or 60 days depending on the complexity and amount of data provided by the MAH.

Comments from CHMP members are not made available to applicants. Moreover, it is not intended that applicants directly contact CHMP members in the context of an ongoing CHMP assessment of an application.

* For information on the Regulatory framework for processing the application, please refer to the transitional provisions for implementation of Variation Regulation (EC) No 1234/2008, EMEA/709668/2009