

27 July 2015
EMA/518452/2011 Rev. 3
Procedure Management and Committees Support

Timetable¹: Multiple applications² starting at day 121 of the related ongoing full Marketing Authorisation Application

Submission date (*)	Start date (Day 121)	PRAC Rapporteur's RMP Assessment Report	CHMP (Co-) Rapporteur Assessment Report	Comments on RMP AR from CHMP and PRAC	Updated PRAC Rapporteur RMP AR	PRAC Output (■) Adoption	Comments on CHMP (Co-) Rapporteur AR (**)	Opinion or adoption of LoOI (***)
26/10/2012	18/11/2012	17/12/2012	17/12/2012	21/12/2012	24/12/2012	10/01/2013	07/01/2013	17/01/2013
04/12/2012	23/12/2012	21/01/2013	21/01/2013	25/01/2013	28/01/2013	07/02/2013	11/02/2013	21/02/2013
20/12/2012	20/01/2013	18/02/2013	18/02/2013	22/02/2013	25/02/2013	07/03/2013	11/03/2013	21/03/2013
05/02/2013	24/02/2013	25/03/2013	25/03/2013	29/03/2013	01/04/2013	11/04/2013	15/04/2013	25/04/2013

¹ This timetable may be subject to revision

² For a product identical to the one for which the full Marketing Authorisation Application is ongoing

Submission date (*)	Start date (Day 121)	PRAC Rapporteur's RMP Assessment Report	CHMP (Co-) Rapporteur Assessment Report	Comments on RMP AR from CHMP and PRAC	Updated PRAC Rapporteur RMP AR	PRAC Output (■) Adoption	Comments on CHMP (Co-) Rapporteur AR (**)	Opinion or adoption of LoOI (***)
11/03/2013	31/03/2013	29/04/2013	29/04/2013	03/05/2013	06/05/2013	16/05/2013	20/05/2013	30/05/2013
09/04/2013	28/04/2013	27/05/2013	27/05/2013	31/05/2013	03/06/2013	13/06/2013	17/06/2013	27/06/2013
02/05/2013	26/05/2013	24/06/2013	24/06/2013	28/06/2013	01/07/2013	11/07/2013	15/07/2013	25/07/2013
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
02/07/2013	21/07/2013	19/08/2013	25/08/2013	25/08/2013	28/08/2013	05/09/2013	09/09/2013	19/09/2013
06/08/2013	25/08/2013	23/09/2013	29/09/2013	29/09/2013	02/10/2013	10/10/2013	14/10/2013	24/10/2013
03/09/2013	22/09/2013	21/10/2013	27/10/2013	27/10/2013	30/10/2013	07/11/2013	11/11/2013	21/11/2013
01/10/2013	20/10/2013	18/11/2013	24/11/2013	24/11/2013	27/11/2013	05/12/2013	09/12/2013	19/12/2013
05/11/2013	24/11/2013	23/12/2013	29/12/2013	29/12/2013	01/01/2014	09/01/2014	13/01/2014	23/01/2014
03/12/2013	22/12/2013	20/01/2014	26/01/2014	26/01/2014	29/01/2014	05/02/2014	10/02/2014	20/02/2014
19/12/2013	19/01/2014	17/02/2014	23/02/2014	23/02/2014	26/02/2014	06/03/2014	10/03/2014	20/03/2014
05/02/2014	24/02/2014	25/03/2014	31/03/2014	31/03/2014	03/04/2014	10/04/2014	15/04/2014	25/04/2014
04/03/2014	23/03/2014	21/04/2014	27/04/2014	27/04/2014	30/04/2014	08/05/2014	12/05/2014	22/05/2014
03/04/2014	27/04/2014	26/05/2014	01/06/2014	01/06/2014	04/06/2014	12/06/2014	16/06/2014	26/06/2014
05/05/2014	25/05/2014	23/06/2014	29/06/2014	29/06/2014	02/07/2014	10/07/2014	14/07/2014	24/07/2014
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
08/07/2014	27/07/2014	25/08/2014	31/08/2014	31/08/2014	03/09/2014	11/09/2014	15/09/2014	25/09/2014
05/08/2014	24/08/2014	22/09/2014	28/09/2014	28/09/2014	01/10/2014	09/10/2014	13/10/2014	23/10/2014
02/09/2014	21/09/2014	20/10/2014	26/10/2014	26/10/2014	29/10/2014	06/11/2014	10/11/2014	20/11/2014
30/09/2014	19/10/2014	17/11/2014	23/11/2014	23/11/2014	26/11/2014	04/12/2014	08/12/2014	18/12/2014
04/11/2014	23/11/2014	22/12/2014	28/12/2014	28/12/2014	31/12/2014	08/01/2015	12/01/2015	22/01/2015
04/12/2014	28/12/2014	26/01/2015	01/02/2015	01/02/2015	04/02/2015	12/02/2015	16/02/2015	26/02/2015
06/01/2015	25/01/2015	23/02/2015	01/03/2015	01/03/2015	04/03/2015	12/03/2015	16/03/2015	26/03/2015

Submission date (*)	Start date (Day 121)	PRAC Rapporteur's RMP Assessment Report	CHMP (Co-) Rapporteur Assessment Report	Comments on RMP AR from CHMP and PRAC	Updated PRAC Rapporteur RMP AR	PRAC Output (■) Adoption	Comments on CHMP (Co-) Rapporteur AR (**)	Opinion or adoption of LoOI (***)
03/02/2015	22/02/2015	23/03/2015	29/03/2015	29/03/2015	01/04/2015	09/04/2015	13/04/2015	23/04/2015
03/03/2015	22/03/2015	20/04/2015	26/04/2015	26/04/2015	29/04/2015	07/05/2015	11/05/2015	21/05/2015
07/04/2015	26/04/2015	25/05/2015	31/05/2015	31/05/2015	03/06/2015	11/06/2015	15/06/2015	25/06/2015
30/04/2015	24/05/2015	22/06/2015	28/06/2015	28/06/2015	01/07/2015	09/07/2015	13/07/2015	23/07/2015
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

The CHMP and PRAC timeframe for assessment of responses is depending on the complexity and amount of data provided by the Marketing Authorisation Holder/Applicant.

(*) The validation period between submission date and start date is thirteen EMA working days. For further information about the dates on which the Agency will be closed during the current year, please refer to the business hours and holidays page on the website.

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched. Integrated Responses to list of Questions to which the multiple application is related to need to be despatched before the end of validation as a separate sequence.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

(■) PRAC RMP Assessment Overview and Advice – A teleconference between Rapporteurs may be held two days before

(***) After adoption of a List of Outstanding Issues (LoOI), the multiple application follows the same timetable as for the full Marketing Authorisation Application to which the multiple application is related to.