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SCIENCE MEDICINES HEALTH

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An agency of the European Union

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Human Medicines Division

The timetables in this document may be subject to revision

Non-interventional, imposed, Post-Authorisation Safety Study (PASS) protocols, protocol amendments and final study results[1] (CAPs and NAPs[2])

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC (~)	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CHMP/CMD(h) members comments (**) (~)	CHMP Opinion/ CMD(h) position (**)
A1	26/01/2022	08/02/2022	14/03/2022	28/03/2022	31/03/2022	07/04/2022	13/04/2022	22/04/2022
A2	22/02/2022	07/03/2022	11/04/2022	25/04/2022	28/04/2022	05/05/2022	12/05/2022	19/05/2022
A3	29/03/2022	11/04/2022	16/05/2022	30/05/2022	02/06/2022	10/06/2022	16/06/2022	23/06/2022
A4	26/04/2022	09/05/2022	13/06/2022	27/06/2022	30/06/2022	07/07/2022	14/07/2022	21/07/2022
A5								
A6	21/06/2022	04/07/2022	08/08/2022	22/08/2022	25/08/2022	01/09/2022	08/09/2022	15/09/2022
A7	19/07/2022	01/08/2022	05/09/2022	19/09/2022	22/09/2022	29/09/2022	06/10/2022	13/10/2022
A8	16/08/2022	29/08/2022	03/10/2022	17/10/2022	20/10/2022	27/10/2022	03/11/2022	10/11/2022
A9	20/09/2022	03/10/2022	07/11/2022	21/11/2022	24/11/2022	01/12/2022	08/12/2022	15/12/2022
A10	28/10/2022	14/11/2022	19/12/2022	03/01/2023	05/01/2023	12/01/2023	19/01/2023	26/01/2023
A11	29/11/2022	12/12/2022	16/01/2023	30/01/2023	02/02/2023	09/02/2023	16/02/2023	23/02/2023
A12	03/01/2023	16/01/2023	20/02/2023	06/03/2023	09/03/2023	16/03/2023	23/03/2023	30/03/2023
A13	30/01/2023	12/02/2023	20/03/2023	03/04/2023	05/04/2023	14/04/2023	19/04/2023	26/04/2023
A14	28/02/2023	13/03/2023	17/04/2023	02/05/2023	04/05/2023	12/05/2023	17/05/2023	25/05/2023
A15	28/03/2023	10/04/2023	15/05/2023	30/05/2023	01/06/2023	08/06/2023	15/06/2023	22/06/2023

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A16	25/04/2023	08/05/2023	12/06/2023	26/06/2023	29/06/2023	06/07/2023	13/07/2023	20/07/2023
A17								
A18	20/06/2023	03/07/2023	07/08/2023	21/08/2023	24/08/2023	31/08/2023	07/09/2023	14/09/2023
A19	18/07/2023	31/07/2023	04/09/2023	18/09/2023	21/09/2023	28/09/2023	05/10/2023	12/10/2023
A20	14/08/2023	28/08/2023	02/10/2023	16/10/2023	19/10/2023	26/10/2023	31/10/2023	09/11/2023
A21	19/09/2023	02/10/2023	06/11/2023	20/11/2023	23/11/2023	30/11/2023	07/12/2023	14/12/2023
A22	31/10/2023	13/11/2023	18/12/2023	03/01/2024	05/01/2024	11/01/2024	18/01/2024	25/01/2024
A23	28/11/2023	11/12/2023	15/01/2024	29/01/2024	01/02/2024	08/02/2024	15/02/2024	22/02/2024
A24	21/12/2023	08/01/2024	12/02/2024	26/02/2024	29/02/2024	07/03/2024	14/03/2024	21/03/2024
A25	30/01/2024	12/02/2024	18/03/2024	02/04/2024	04/04/2024	11/04/2024	18/04/2024	25/04/2024
A26	05/03/2024	18/03/2024	22/04/2024	06/05/2024	08/05/2024	16/05/2024	23/05/2024	30/05/2024
A27	02/04/2024	15/04/2024	21/05/2024	03/06/2024	06/06/2024	13/06/2024	20/06/2024	27/06/2024
A28	30/04/2024	13/05/2024	17/06/2024	01/07/2024	04/07/2024	11/07/2024	18/07/2024	25/07/2024
A29								
A30	25/06/2024	08/07/2024	12/08/2024	26/08/2024	29/08/2024	05/09/2024	12/09/2024	19/09/2024
A31	23/07/2024	05/08/2024	09/09/2024	23/09/2024	26/09/2024	03/10/2024	10/10/2024	17/10/2024
A32	20/08/2024	02/09/2024	07/10/2024	21/10/2024	24/10/2024	31/10/2024	07/11/2024	14/11/2024
A33	17/09/2024	30/09/2024	04/11/2024	18/11/2024	21/11/2024	28/11/2024	05/12/2024	12/12/2024

(1) Applicable only to the assessment of non-interventional, imposed PASS under Articles 107 n-q of Directive 2001/83/EC, including protocols (article 107n procedure), protocol amendments (article 107o procedure) and final study results (article 107q procedure). For protocols and protocol amendments of non-interventional, non-imposed PASS, the timetable of PAMs assessed by the PRAC applies instead. For the assesment of results from such studies, type II variations should be submitted.

(2) CAPs: Centrally Authorised Products; NAPs: Nationally Authorised Products

(*) The Agency strongly recommends submitting the application before the legally binding 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.

(~) Comments from PRAC, CHMP and CMD(h) members are not made available to Marketing authorisation Holders (MAHs).

(#) An updated AR is optional and dependent on the comments received from PRAC members which create the need for the update.

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(**) Step only applicable in case of proposed changes to the Product Information.