



6 July 2018
EMA/403963/2015 Rev.3
Human Medicines Evaluation

The timetables in this document may be subject to revision

Safety Signal - Assessment of responses to Request for Supplementary Information (RSI)

[30-day](#)

[60-day](#)

[90-day](#)

30-day assessment timetable⁷

| | Deadline for Submission (*) | Start date | PRAC Rapporteur AR | Comments from PRAC/MAH | Updated PRAC Rapporteur AR (#) | PRAC conclusion | CHMP adoption (^) |
|-----|-----------------------------|------------|--------------------|------------------------|--------------------------------|-----------------|-------------------|
| A1 | 08/06/2018 | 13/06/2018 | 27/06/2018 | 02/07/2018 | 05/07/2018 | 12/07/2018 | 26/07/2018 |
| A2 | | | | | | | |
| A3 | 03/08/2018 | 08/08/2018 | 22/08/2018 | 28/08/2018 | 30/08/2018 | 06/09/2018 | 20/09/2018 |
| A4 | 31/08/2018 | 05/09/2018 | 19/09/2018 | 24/09/2018 | 27/09/2018 | 04/10/2018 | 18/10/2018 |
| A5 | 28/09/2018 | 03/10/2018 | 17/10/2018 | 22/10/2018 | 25/10/2018 | 31/10/2018 | 15/11/2018 |
| A6 | 26/10/2018 | 31/10/2018 | 14/11/2018 | 19/11/2018 | 22/11/2018 | 29/11/2018 | 13/12/2018 |
| A7 | 07/12/2018 | 19/12/2018 | 03/01/2019 | 07/01/2019 | 10/01/2019 | 17/01/2019 | 31/01/2019 |
| A8 | 11/01/2019 | 16/01/2019 | 30/01/2019 | 04/02/2019 | 07/02/2019 | 14/02/2019 | 28/02/2019 |
| A9 | 08/02/2019 | 13/02/2019 | 27/02/2019 | 04/03/2019 | 07/03/2019 | 14/03/2019 | 28/03/2019 |
| A10 | 08/03/2019 | 13/03/2019 | 27/03/2019 | 01/04/2019 | 04/04/2019 | 11/04/2019 | 26/04/2019 |
| A11 | 05/04/2019 | 17/04/2019 | 26/04/2019 | 03/05/2019 | 07/05/2019 | 16/05/2019 | 29/05/2019 |
| A12 | 06/05/2019 | 16/05/2019 | 24/05/2019 | 29/05/2019 | 04/06/2019 | 14/06/2019 | 27/06/2019 |
| A13 | 07/06/2019 | 12/06/2019 | 26/06/2019 | 01/07/2019 | 04/07/2019 | 11/07/2019 | 25/07/2019 |
| A14 | | | | | | | |
| A15 | 02/08/2019 | 07/08/2019 | 21/08/2019 | 27/08/2019 | 29/08/2019 | 05/09/2019 | 19/09/2019 |
| A16 | 30/08/2019 | 04/09/2019 | 18/09/2019 | 23/09/2019 | 26/09/2019 | 03/10/2019 | 17/10/2019 |
| A17 | 27/09/2019 | 02/10/2019 | 16/10/2019 | 21/10/2019 | 24/10/2019 | 31/10/2019 | 14/11/2019 |
| A18 | 25/10/2019 | 30/10/2019 | 13/11/2019 | 18/11/2019 | 21/11/2019 | 28/11/2019 | 12/12/2019 |
| A19 | 06/12/2019 | 18/12/2019 | 03/01/2020 | 07/01/2020 | 09/01/2020 | 16/01/2020 | 30/01/2020 |
| A20 | 10/01/2020 | 15/01/2020 | 29/01/2020 | 03/02/2020 | 06/02/2020 | 13/02/2020 | 27/02/2020 |
| A21 | 07/02/2020 | 12/02/2020 | 26/02/2020 | 02/03/2020 | 05/03/2020 | 12/03/2020 | 26/03/2020 |
| A22 | 16/03/2020 | 19/03/2020 | 01/04/2020 | 06/04/2020 | 08/04/2020 | 17/04/2020 | 30/04/2020 |
| A23 | 08/04/2020 | 15/04/2020 | 29/04/2020 | 04/05/2020 | 07/05/2020 | 14/05/2020 | 28/05/2020 |
| A24 | 08/05/2020 | 13/05/2020 | 27/05/2020 | 02/06/2020 | 04/06/2020 | 11/06/2020 | 25/06/2020 |
| A25 | 05/06/2020 | 10/06/2020 | 24/06/2020 | 29/06/2020 | 02/07/2020 | 09/07/2020 | 23/07/2020 |
| A26 | | | | | | | |
| A27 | 03/08/2020 | 06/08/2020 | 19/08/2020 | 24/08/2020 | 27/08/2020 | 04/09/2020 | 17/09/2020 |
| A28 | 28/08/2020 | 02/09/2020 | 16/09/2020 | 21/09/2020 | 24/09/2020 | 01/10/2020 | 15/10/2020 |
| A29 | 25/09/2020 | 30/09/2020 | 14/10/2020 | 19/10/2020 | 22/10/2020 | 29/10/2020 | 12/11/2020 |
| A30 | 23/10/2020 | 28/10/2020 | 11/11/2020 | 16/11/2020 | 19/11/2020 | 26/11/2020 | 10/12/2020 |
| A31 | 04/12/2020 | 16/12/2020 | 04/01/2021 | 06/01/2021 | 07/01/2021 | 14/01/2021 | 28/01/2021 |
| A32 | 08/01/2021 | 13/01/2021 | 27/01/2021 | 01/02/2021 | 04/02/2021 | 11/02/2021 | 25/02/2021 |
| A33 | 05/02/2021 | 10/02/2021 | 24/02/2021 | 01/03/2021 | 04/03/2021 | 11/03/2021 | 25/03/2021 |
| A34 | 08/03/2021 | 11/03/2021 | 24/03/2021 | 29/03/2021 | 31/03/2021 | 09/04/2021 | 22/04/2021 |
| A35 | 30/03/2021 | 07/04/2021 | 21/04/2021 | 26/04/2021 | 29/04/2021 | 06/05/2021 | 20/05/2021 |
| A36 | 07/05/2021 | 12/05/2021 | 26/05/2021 | 31/05/2021 | 03/06/2021 | 10/06/2021 | 24/06/2021 |
| A37 | 04/06/2021 | 09/06/2021 | 23/06/2021 | 28/06/2021 | 01/07/2021 | 08/07/2021 | 22/07/2021 |
| A38 | | | | | | | |
| A39 | 02/08/2021 | 05/08/2021 | 18/08/2021 | 23/08/2021 | 26/08/2021 | 03/09/2021 | 16/09/2021 |
| A40 | 27/08/2021 | 01/09/2021 | 15/09/2021 | 20/09/2021 | 23/09/2021 | 30/09/2021 | 14/10/2021 |
| A41 | 24/09/2021 | 29/09/2021 | 13/10/2021 | 18/10/2021 | 21/10/2021 | 28/10/2021 | 11/11/2021 |
| A42 | 27/10/2021 | 03/11/2021 | 17/11/2021 | 22/11/2021 | 25/11/2021 | 02/12/2021 | 16/12/2021 |

(-) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(*) 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.

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

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

60-day assessment timetable⁷

| | Deadline for Submission (*) | Start date | PRAC Rapporteur AR | Comments from PRAC/MAH | Updated PRAC Rapporteur AR (#) | PRAC conclusion | CHMP adoption (^) |
|-----|-----------------------------|------------|--------------------|------------------------|--------------------------------|-----------------|-------------------|
| B1 | 08/05/2018 | 14/05/2018 | 18/06/2018 | 02/07/2018 | 05/07/2018 | 12/07/2018 | 26/07/2018 |
| B2 | | | | | | | |
| B3 | 04/07/2018 | 09/07/2018 | 13/08/2018 | 28/08/2018 | 30/08/2018 | 06/09/2018 | 20/09/2018 |
| B4 | 01/08/2018 | 06/08/2018 | 10/09/2018 | 24/09/2018 | 27/09/2018 | 04/10/2018 | 18/10/2018 |
| B5 | 29/08/2018 | 03/09/2018 | 08/10/2018 | 22/10/2018 | 25/10/2018 | 31/10/2018 | 15/11/2018 |
| B6 | 26/09/2018 | 01/10/2018 | 05/11/2018 | 19/11/2018 | 22/11/2018 | 29/11/2018 | 13/12/2018 |
| B7 | 07/11/2018 | 19/11/2018 | 14/12/2018 | 07/01/2019 | 10/01/2019 | 17/01/2019 | 31/01/2019 |
| B8 | 12/12/2018 | 17/12/2018 | 21/01/2019 | 04/02/2019 | 07/02/2019 | 14/02/2019 | 28/02/2019 |
| B9 | 09/01/2019 | 14/01/2019 | 18/02/2019 | 04/03/2019 | 07/03/2019 | 14/03/2019 | 28/03/2019 |
| B10 | 06/02/2019 | 11/02/2019 | 18/03/2019 | 01/04/2019 | 04/04/2019 | 11/04/2019 | 26/04/2019 |
| B11 | 06/03/2019 | 18/03/2019 | 16/04/2019 | 29/04/2019 | 06/05/2019 | 16/05/2019 | 29/05/2019 |
| B12 | 11/04/2019 | 16/04/2019 | 20/05/2019 | 03/06/2019 | 06/06/2019 | 14/06/2019 | 27/06/2019 |
| B13 | 07/05/2019 | 13/05/2019 | 17/06/2019 | 01/07/2019 | 04/07/2019 | 11/07/2019 | 25/07/2019 |
| B14 | | | | | | | |
| B15 | 03/07/2019 | 08/07/2019 | 12/08/2019 | 27/08/2019 | 29/08/2019 | 05/09/2019 | 19/09/2019 |
| B16 | 31/07/2019 | 05/08/2019 | 09/09/2019 | 23/09/2019 | 26/09/2019 | 03/10/2019 | 17/10/2019 |
| B17 | 28/08/2019 | 02/09/2019 | 07/10/2019 | 21/10/2019 | 24/10/2019 | 31/10/2019 | 14/11/2019 |
| B18 | 25/09/2019 | 30/09/2019 | 04/11/2019 | 18/11/2019 | 21/11/2019 | 28/11/2019 | 12/12/2019 |
| B19 | 06/11/2019 | 18/11/2019 | 13/12/2019 | 06/01/2020 | 09/01/2020 | 16/01/2020 | 30/01/2020 |
| B20 | 11/12/2019 | 16/12/2019 | 20/01/2020 | 03/02/2020 | 06/02/2020 | 13/02/2020 | 27/02/2020 |
| B21 | 08/01/2020 | 13/01/2020 | 17/02/2020 | 02/03/2020 | 05/03/2020 | 12/03/2020 | 26/03/2020 |
| B22 | 10/02/2020 | 18/02/2020 | 20/03/2020 | 03/04/2020 | 06/04/2020 | 17/04/2020 | 30/04/2020 |
| B23 | 11/03/2020 | 16/03/2020 | 20/04/2020 | 04/05/2020 | 07/05/2020 | 14/05/2020 | 28/05/2020 |
| B24 | 06/04/2020 | 13/04/2020 | 18/05/2020 | 28/05/2020 | 04/06/2020 | 11/06/2020 | 25/06/2020 |
| B25 | 06/05/2020 | 11/05/2020 | 15/06/2020 | 29/06/2020 | 02/07/2020 | 09/07/2020 | 23/07/2020 |
| B26 | | | | | | | |
| B27 | 02/07/2020 | 07/07/2020 | 10/08/2020 | 24/08/2020 | 27/08/2020 | 04/09/2020 | 17/09/2020 |
| B28 | 29/07/2020 | 03/08/2020 | 07/09/2020 | 21/09/2020 | 24/09/2020 | 01/10/2020 | 15/10/2020 |
| B29 | 26/08/2020 | 31/08/2020 | 05/10/2020 | 19/10/2020 | 22/10/2020 | 29/10/2020 | 12/11/2020 |
| B30 | 23/09/2020 | 28/09/2020 | 04/11/2020 | 16/11/2020 | 19/11/2020 | 26/11/2020 | 10/12/2020 |
| B31 | 11/11/2020 | 16/11/2020 | 21/12/2020 | 04/01/2021 | 07/01/2021 | 14/01/2021 | 28/01/2021 |
| B32 | 09/12/2020 | 14/12/2020 | 18/01/2021 | 01/02/2021 | 04/02/2021 | 11/02/2021 | 25/02/2021 |
| B33 | 06/01/2021 | 11/01/2021 | 15/02/2021 | 01/03/2021 | 04/03/2021 | 11/03/2021 | 25/03/2021 |
| B34 | 04/02/2021 | 09/02/2021 | 15/03/2021 | 29/03/2021 | 31/03/2021 | 09/04/2021 | 22/04/2021 |
| B35 | 03/03/2021 | 08/03/2021 | 12/04/2021 | 26/04/2021 | 29/04/2021 | 06/05/2021 | 20/05/2021 |
| B36 | 07/04/2021 | 12/04/2021 | 17/05/2021 | 31/05/2021 | 03/06/2021 | 10/06/2021 | 24/06/2021 |
| B37 | 05/05/2021 | 10/05/2021 | 14/06/2021 | 28/06/2021 | 01/07/2021 | 08/07/2021 | 22/07/2021 |
| B38 | | | | | | | |
| B39 | 01/07/2021 | 06/07/2021 | 09/08/2021 | 23/08/2021 | 26/08/2021 | 03/09/2021 | 16/09/2021 |
| B40 | 28/07/2021 | 02/08/2021 | 06/09/2021 | 20/09/2021 | 23/09/2021 | 30/09/2021 | 14/10/2021 |
| B41 | 25/08/2021 | 30/08/2021 | 04/10/2021 | 18/10/2021 | 21/10/2021 | 28/10/2021 | 11/11/2021 |
| B42 | 29/09/2021 | 04/10/2021 | 08/11/2021 | 22/11/2021 | 25/11/2021 | 02/12/2021 | 16/12/2021 |

(–) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(*) 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.

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

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

90-day assessment timetable ⁷

| | Deadline for Submission (*) | Start date | Individual PRAC Rapporteurs/ Lead MSs AR (~) | Preliminary PRAC Rapporteur (Joint) AR | Comments from PRAC/MAH | Updated PRAC Rapporteur Joint AR (#) | PRAC conclusion | CHMP adoption (^) |
|-----|-----------------------------|------------|--|--|------------------------|--------------------------------------|-----------------|-------------------|
| C1 | 11/04/2018 | 14/04/2018 | 14/05/2018 | 12/06/2018 | 27/06/2018 | 05/07/2018 | 12/07/2018 | 26/07/2018 |
| C2 | | | | | | | | |
| C3 | 06/06/2018 | 09/06/2018 | 09/07/2018 | 07/08/2018 | 22/08/2018 | 30/08/2018 | 06/09/2018 | 20/09/2018 |
| C4 | 04/07/2018 | 07/07/2018 | 06/08/2018 | 04/09/2018 | 19/09/2018 | 27/09/2018 | 04/10/2018 | 18/10/2018 |
| C5 | 31/07/2018 | 03/08/2018 | 03/09/2018 | 01/10/2018 | 16/10/2018 | 24/10/2018 | 31/10/2018 | 15/11/2018 |
| C6 | 29/08/2018 | 01/09/2018 | 01/10/2018 | 30/10/2018 | 14/11/2018 | 22/11/2018 | 29/11/2018 | 13/12/2018 |
| C7 | 08/10/2018 | 20/10/2018 | 12/11/2018 | 11/12/2018 | 03/01/2019 | 10/01/2019 | 17/01/2019 | 31/01/2019 |
| C8 | 14/11/2018 | 17/11/2018 | 17/12/2018 | 15/01/2019 | 30/01/2019 | 07/02/2019 | 14/02/2019 | 28/02/2019 |
| C9 | 12/12/2018 | 15/12/2018 | 14/01/2019 | 12/02/2019 | 27/02/2019 | 07/03/2019 | 14/03/2019 | 28/03/2019 |
| C10 | 09/01/2019 | 12/01/2019 | 11/02/2019 | 12/03/2019 | 27/03/2019 | 04/04/2019 | 11/04/2019 | 26/04/2019 |
| C11 | 13/02/2019 | 16/02/2019 | 15/03/2019 | 15/04/2019 | 30/04/2019 | 08/05/2019 | 16/05/2019 | 29/05/2019 |
| C12 | 12/03/2019 | 17/03/2019 | 15/04/2019 | 14/05/2019 | 28/05/2019 | 06/06/2019 | 14/06/2019 | 27/06/2019 |
| C13 | 10/04/2019 | 13/04/2019 | 13/05/2019 | 11/06/2019 | 26/06/2019 | 04/07/2019 | 11/07/2019 | 25/07/2019 |
| C14 | | | | | | | | |
| C15 | 05/06/2019 | 08/06/2019 | 08/07/2019 | 06/08/2019 | 21/08/2019 | 29/08/2019 | 05/09/2019 | 19/09/2019 |
| C16 | 03/07/2019 | 06/07/2019 | 05/08/2019 | 03/09/2019 | 18/09/2019 | 26/09/2019 | 03/10/2019 | 17/10/2019 |
| C17 | 31/07/2019 | 03/08/2019 | 02/09/2019 | 01/10/2019 | 16/10/2019 | 24/10/2019 | 31/10/2019 | 14/11/2019 |
| C18 | 28/08/2019 | 31/08/2019 | 30/09/2019 | 29/10/2019 | 13/11/2019 | 21/11/2019 | 28/11/2019 | 12/12/2019 |
| C19 | 09/10/2019 | 19/10/2019 | 11/11/2019 | 11/12/2019 | 03/01/2020 | 09/01/2020 | 16/01/2020 | 30/01/2020 |
| C20 | 13/11/2019 | 16/11/2019 | 16/12/2019 | 14/01/2020 | 29/01/2020 | 06/02/2020 | 13/02/2020 | 27/02/2020 |
| C21 | 11/12/2019 | 14/12/2019 | 13/01/2020 | 11/02/2020 | 26/02/2020 | 05/03/2020 | 12/03/2020 | 26/03/2020 |
| C22 | 10/01/2020 | 19/01/2020 | 14/02/2020 | 13/03/2020 | 27/03/2020 | 06/04/2020 | 17/04/2020 | 30/04/2020 |
| C23 | 12/02/2020 | 15/02/2020 | 16/03/2020 | 14/04/2020 | 29/04/2020 | 07/05/2020 | 14/05/2020 | 28/05/2020 |
| C24 | 06/03/2020 | 14/03/2020 | 15/04/2020 | 13/05/2020 | 27/05/2020 | 04/06/2020 | 11/06/2020 | 25/06/2020 |

| | Deadline for Submission (*) | Start date | Individual PRAC Rapporteurs/ Lead MSs AR (~) | Preliminary PRAC Rapporteur (Joint) AR | Comments from PRAC/MAH | Updated PRAC Rapporteur Joint AR (#) | PRAC conclusion | CHMP adoption (^) |
|-----|-----------------------------|------------|--|--|------------------------|--------------------------------------|-----------------|-------------------|
| C25 | 08/04/2020 | 11/04/2020 | 11/05/2020 | 09/06/2020 | 24/06/2020 | 02/07/2020 | 09/07/2020 | 23/07/2020 |
| C26 | | | | | | | | |
| C27 | 04/06/2020 | 07/06/2020 | 06/07/2020 | 04/08/2020 | 19/08/2020 | 27/08/2020 | 04/09/2020 | 17/09/2020 |
| C28 | 01/07/2020 | 04/07/2020 | 03/08/2020 | 01/09/2020 | 16/09/2020 | 24/09/2020 | 01/10/2020 | 15/10/2020 |
| C29 | 29/07/2020 | 01/08/2020 | 01/09/2020 | 29/09/2020 | 14/10/2020 | 22/10/2020 | 29/10/2020 | 12/11/2020 |
| C30 | 26/08/2020 | 29/08/2020 | 28/09/2020 | 27/10/2020 | 11/11/2020 | 19/11/2020 | 26/11/2020 | 10/12/2020 |
| C31 | 14/10/2020 | 17/10/2020 | 16/11/2020 | 15/12/2020 | 04/01/2021 | 07/01/2021 | 14/01/2021 | 28/01/2021 |
| C32 | 11/11/2020 | 14/11/2020 | 14/12/2020 | 12/01/2021 | 27/01/2021 | 04/02/2021 | 11/02/2021 | 25/02/2021 |
| C33 | 09/12/2020 | 12/12/2020 | 11/01/2021 | 09/02/2021 | 24/02/2021 | 04/03/2021 | 11/03/2021 | 25/03/2021 |
| C34 | 07/01/2021 | 10/01/2021 | 08/02/2021 | 09/03/2021 | 24/03/2021 | 31/03/2021 | 09/04/2021 | 22/04/2021 |
| C35 | 03/02/2021 | 06/02/2021 | 08/03/2021 | 06/04/2021 | 21/04/2021 | 29/04/2021 | 06/05/2021 | 20/05/2021 |
| C36 | 10/03/2021 | 13/03/2021 | 12/04/2021 | 11/05/2021 | 26/05/2021 | 03/06/2021 | 10/06/2021 | 24/06/2021 |
| C37 | 07/04/2021 | 10/04/2021 | 10/05/2021 | 08/06/2021 | 23/06/2021 | 01/07/2021 | 08/07/2021 | 22/07/2021 |
| C38 | | | | | | | | |
| C39 | 03/06/2021 | 06/06/2021 | 05/07/2021 | 03/08/2021 | 18/08/2021 | 26/08/2021 | 03/09/2021 | 16/09/2021 |
| C40 | 30/06/2021 | 03/07/2021 | 02/08/2021 | 31/08/2021 | 15/09/2021 | 23/09/2021 | 30/09/2021 | 14/10/2021 |
| C41 | 28/07/2021 | 31/07/2021 | 31/08/2021 | 28/09/2021 | 13/10/2021 | 21/10/2021 | 28/10/2021 | 11/11/2021 |
| C42 | 01/09/2021 | 04/09/2021 | 04/10/2021 | 03/11/2021 | 17/11/2021 | 25/11/2021 | 02/12/2021 | 16/12/2021 |

(-) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(-) This step may apply in case the signal involves several active substances/products (e.g. class issues). In such cases, individual assessments may be carried out by the relevant Lead Member State(s) according to [the List of substances and products subject to worksharing for signal management](#) (for nationally authorised products – NAPs) and/or the relevant PRAC Rapporteurs (for centrally authorised products - CAPs), before a joint assessment report is prepared by the PRAC-appointed Rapporteur for the evaluation of the signal.

(*) 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.

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

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of CAPs.