



12 October 2018
EMA/480430/2012 Rev 2
Human Medicines Evaluation Division

Timetable¹ – non safety referral²

1. Standard Timetable for CHMP List of Questions/List of Outstanding Issues

CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
18/10/2018	13/12/2018	03/01/2019	11/01/2019	18/01/2019	24/01/2019	31/01/2019
15/11/2018	10/01/2019	31/01/2019	08/02/2019	15/02/2019	21/02/2019	28/02/2019
13/12/2018	07/02/2019	28/02/2019	08/03/2019	15/03/2019	21/03/2019	28/03/2019
31/01/2019	08/03/2019	29/03/2019	05/04/2019	12/04/2019	17/04/2019	26/04/2019
28/02/2019	10/04/2019	01/05/2019	08/05/2019	15/05/2019	22/05/2019	29/05/2019
28/03/2019	09/05/2019	30/05/2019	07/06/2019	14/06/2019	20/06/2019	27/06/2019

¹ This timetable may be subject to revision

² This timetable is applicable to referrals under Articles 29(4), 30 and 31 of the Directive 2001/83/EC, Article 13 of Regulation (EC) No 1234/2008 as well as procedures under Article 20 of Regulation (EC) No 726/2004.



CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
26/04/2019	06/06/2019	27/06/2019	05/07/2019	12/07/2019	18/07/2019	25/07/2019
29/05/2019	04/07/2019	25/07/2019	02/08/2019	09/08/2019	15/08/2019	22/08/2019
27/06/2019	01/08/2019	22/08/2019	30/08/2019	06/09/2019	12/09/2019	19/09/2019
25/07/2019	29/08/2019	19/09/2019	27/09/2019	04/10/2019	10/10/2019	17/10/2019
22/08/2019	26/09/2019	17/10/2019	25/10/2019	31/10/2019	07/11/2019	14/11/2019
19/09/2019	24/10/2019	14/11/2019	22/11/2019	29/11/2019	05/12/2019	12/12/2019
17/10/2019	12/12/2019	02/01/2020	10/01/2020	17/01/2020	23/01/2020	30/01/2020
14/11/2019	09/01/2020	30/01/2020	07/02/2020	14/02/2020	20/02/2020	27/02/2020
12/12/2019	06/02/2020	27/02/2020	06/03/2020	13/03/2020	19/03/2020	26/03/2020
30/01/2020	12/03/2020	02/04/2020	08/04/2020	15/04/2020	23/04/2020	30/04/2020
27/02/2020	09/04/2020	30/04/2020	08/05/2020	15/05/2020	20/05/2020	28/05/2020
26/03/2020	07/05/2020	28/05/2020	05/06/2020	12/06/2020	18/06/2020	25/06/2020
30/04/2020	04/06/2020	25/06/2020	03/07/2020	10/07/2020	16/07/2020	23/07/2020
28/05/2020	02/07/2020	23/07/2020	31/07/2020	07/08/2020	13/08/2020	20/08/2020
25/06/2020	30/07/2020	20/08/2020	28/08/2020	04/09/2020	10/09/2020	17/09/2020
23/07/2020	27/08/2020	17/09/2020	25/09/2020	02/10/2020	08/10/2020	15/10/2020
20/08/2020	24/09/2020	15/10/2020	23/10/2020	30/10/2020	05/11/2020	12/11/2020
17/09/2020	22/10/2020	12/11/2020	20/11/2020	27/11/2020	03/12/2020	10/12/2020
15/10/2020	10/12/2020	31/12/2020	08/01/2021	15/01/2021	21/01/2021	28/01/2021
12/11/2020	07/01/2021	28/01/2021	05/02/2021	12/02/2021	18/02/2021	25/02/2021
10/12/2020	04/02/2021	25/02/2021	05/03/2021	12/03/2021	18/03/2021	25/03/2021
28/01/2021	04/03/2021	25/03/2021	31/03/2021	07/04/2021	15/04/2021	22/04/2021
25/02/2021	01/04/2021	22/04/2021	30/04/2021	07/05/2021	12/05/2021	20/05/2021
25/03/2021	06/05/2021	27/05/2021	04/06/2021	11/06/2021	17/06/2021	24/06/2021

CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
22/04/2021	03/06/2021	24/06/2021	02/07/2021	09/07/2021	15/07/2021	22/07/2021
20/05/2021	01/07/2021	22/07/2021	30/07/2021	06/08/2021	12/08/2021	19/08/2021
24/06/2021	29/07/2021	19/08/2021	27/08/2021	03/09/2021	09/09/2021	16/09/2021
22/07/2021	26/08/2021	16/09/2021	24/09/2021	01/10/2021	07/10/2021	14/10/2021
19/08/2021	23/09/2021	14/10/2021	22/10/2021	29/10/2021	04/11/2021	11/11/2021

2. Shortened Timetable for CHMP List of Questions/List of Outstanding Issues (as applicable)

CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
18/10/2018	09/11/2018	15/11/2018	30/11/2018	05/12/2018	07/12/2018	13/12/2018
15/11/2018	28/12/2018	03/01/2019	18/01/2019	23/01/2019	25/01/2019	31/01/2019
13/12/2018	25/01/2019	31/01/2019	15/02/2019	20/02/2019	22/02/2019	28/02/2019
31/01/2019	22/02/2019	28/02/2019	15/03/2019	20/03/2019	22/03/2019	28/03/2019
28/02/2019	22/03/2019	29/03/2019	08/04/2019	12/04/2019	17/04/2019	26/04/2019
28/03/2019	25/04/2019	01/05/2019	16/05/2019	21/05/2019	23/05/2019	29/05/2019
26/04/2019	24/05/2019	30/05/2019	14/06/2019	19/06/2019	21/06/2019	27/06/2019
29/05/2019	21/06/2019	27/06/2019	12/07/2019	17/07/2019	19/07/2019	25/07/2019
27/06/2019	19/07/2019	25/07/2019	09/08/2019	14/08/2019	16/08/2019	22/08/2019
25/07/2019	16/08/2019	22/08/2019	06/09/2019	11/09/2019	13/09/2019	19/09/2019
22/08/2019	13/09/2019	19/09/2019	04/10/2019	09/10/2019	11/10/2019	17/10/2019
19/09/2019	11/10/2019	17/10/2019	31/10/2019	06/11/2019	08/11/2019	14/11/2019

CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
17/10/2019	08/11/2019	14/11/2020	29/11/2019	04/12/2019	06/12/2019	12/12/2019
14/11/2019	27/12/2019	02/01/2020	17/01/2020	22/01/2020	24/01/2020	30/01/2020
12/12/2019	24/01/2020	30/01/2020	14/02/2020	19/02/2020	21/02/2020	27/02/2020
30/01/2020	21/02/2020	27/02/2020	13/03/2020	18/03/2020	20/03/2020	26/03/2020
27/02/2020	27/03/2020	02/04/2020	17/04/2020	22/04/2020	24/04/2020	30/04/2020
26/03/2020	24/04/2020	30/04/2020	15/05/2020	20/05/2020	22/05/2020	28/05/2020
30/04/2020	22/05/2020	28/05/2020	12/06/2020	17/06/2020	19/06/2020	25/06/2020
28/05/2020	19/06/2020	25/06/2020	10/07/2020	15/07/2020	17/07/2020	23/07/2020
25/06/2020	17/07/2020	23/07/2020	07/08/2020	12/08/2020	14/08/2020	20/08/2020
23/07/2020	14/08/2020	20/08/2020	04/09/2020	09/09/2020	11/09/2020	17/09/2020
20/08/2020	11/09/2020	17/09/2020	02/10/2020	07/10/2020	09/10/2020	15/10/2020
17/09/2020	09/10/2020	15/10/2020	30/10/2020	04/11/2020	06/11/2020	12/11/2020
15/10/2020	06/11/2020	12/11/2020	27/11/2020	02/12/2020	04/12/2020	10/12/2020
12/11/2020	25/12/2020	31/12/2020	15/01/2021	20/01/2021	22/01/2021	28/01/2021
10/12/2020	22/01/2021	28/01/2021	12/02/2021	17/02/2021	19/02/2021	25/02/2021
28/01/2021	19/02/2021	25/02/2021	12/03/2021	17/03/2021	19/03/2021	25/03/2021
25/02/2021	19/03/2021	25/03/2021	09/04/2021	14/04/2021	16/04/2021	22/04/2021
25/03/2021	16/04/2021	22/04/2021	07/05/2021	12/05/2021	14/05/2021	20/05/2021
22/04/2021	21/05/2021	27/05/2021	11/06/2021	16/06/2021	18/06/2021	24/06/2021
20/05/2021	18/06/2021	24/06/2021	09/07/2021	14/07/2021	16/07/2021	22/07/2021
24/06/2021	16/07/2021	22/07/2021	06/08/2021	11/08/2021	13/08/2021	19/08/2021
22/07/2021	13/08/2021	19/08/2021	03/09/2021	08/09/2021	10/09/2021	16/09/2021
19/08/2021	10/09/2021	16/09/2021	01/10/2021	06/10/2021	08/10/2021	14/10/2021
16/09/2021	08/10/2021	14/10/2021	29/10/2021	03/11/2021	05/11/2021	11/11/2021

3. Swift Timetable for final CHMP List of Outstanding Issues (as applicable)

CHMP meeting: Start/LoQ, clock start and stop	Submission of responses (*)	Clock restart	(Co-) Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	CHMP meeting: Opinion or LoOI
18/10/2018	24/10/2018	29/10/2018	31/10/2018	06/11/2018	09/11/2018	15/11/2018
15/11/2018	21/11/2018	26/11/2018	30/11/2018	05/12/2018	07/12/2018	13/12/2018
13/12/2018	09/01/2019	14/01/2019	18/01/2019	23/01/2019	25/01/2019	31/01/2019
31/01/2019	06/02/2019	11/02/2019	15/02/2019	20/02/2019	22/02/2019	28/02/2019
28/02/2019	06/03/2019	11/03/2019	15/03/2019	20/03/2019	22/03/2019	28/03/2019
28/03/2019	04/04/2019	09/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
26/04/2019	07/05/2019	12/05/2019	16/05/2019	21/05/2019	23/05/2019	29/05/2019
29/05/2019	05/06/2019	10/06/2019	14/06/2019	19/06/2019	21/06/2019	27/06/2019
27/06/2019	03/07/2019	08/07/2019	12/07/2019	17/07/2019	19/07/2019	25/07/2019
25/07/2019	31/07/2019	05/08/2019	09/08/2019	14/08/2019	16/08/2019	22/08/2019
22/08/2019	28/08/2019	02/09/2019	06/09/2019	11/09/2019	13/09/2019	19/09/2019
19/09/2019	25/09/2019	30/09/2019	04/10/2019	09/10/2019	11/10/2019	17/10/2019
17/10/2019	23/10/2019	28/10/2019	31/10/2019	06/11/2019	08/11/2019	14/11/2019
14/11/2019	05/02/2020	10/02/2020	14/02/2020	19/02/2020	21/02/2020	27/02/2020
12/12/2019	08/01/2020	13/01/2020	17/01/2020	22/01/2020	24/01/2020	30/01/2020
30/01/2020	05/02/2020	10/02/2020	14/02/2020	19/02/2020	21/02/2020	27/02/2020
27/02/2020	04/03/2020	09/03/2020	13/03/2020	18/03/2020	20/03/2020	26/03/2020
26/03/2020	08/04/2020	13/04/2020	17/04/2020	22/04/2020	24/04/2020	30/04/2020
30/04/2020	06/05/2020	11/05/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
28/05/2020	03/06/2020	08/06/2020	12/06/2020	17/06/2020	19/06/2020	25/06/2020
25/06/2020	01/07/2020	06/07/2020	10/07/2020	15/07/2020	17/07/2020	23/07/2020

23/07/2020	29/07/2020	03/08/2020	07/08/2020	12/08/2020	14/08/2020	20/08/2020
20/08/2020	26/08/2020	31/08/2020	04/09/2020	09/09/2020	11/09/2020	17/09/2020
17/09/2020	23/09/2020	28/09/2020	02/10/2020	07/10/2020	09/10/2020	15/10/2020
15/10/2020	21/10/2020	26/10/2020	30/10/2020	04/11/2020	06/11/2020	12/11/2020
12/11/2020	18/11/2020	23/11/2020	27/11/2020	02/12/2020	04/12/2020	10/12/2020
10/12/2020	06/01/2021	11/01/2021	15/01/2021	20/01/2021	22/01/2021	28/01/2021
28/01/2021	03/02/2021	08/02/2021	12/02/2021	17/02/2021	19/02/2021	25/02/2021
25/02/2021	03/03/2021	08/03/2021	12/03/2021	17/03/2021	19/03/2021	25/03/2021
25/03/2021	31/03/2021	05/04/2021	09/04/2021	14/04/2021	16/04/2021	22/04/2021
22/04/2021	28/04/2021	03/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
20/05/2021	02/06/2021	07/06/2021	11/06/2021	16/06/2021	18/06/2021	24/06/2021
24/06/2021	30/06/2021	05/07/2021	09/07/2021	14/07/2021	16/07/2021	22/07/2021
22/07/2021	28/07/2021	02/08/2021	06/08/2021	11/08/2021	13/08/2021	19/08/2021
19/08/2021	25/08/2021	30/08/2021	03/09/2021	08/09/2021	10/09/2021	16/09/2021
16/09/2021	22/09/2021	27/09/2021	01/10/2021	06/10/2021	08/10/2021	14/10/2021
14/10/2021	20/10/2021	25/10/2021	29/10/2021	03/11/2021	05/11/2021	11/11/2021
11/11/2021	24/11/2021	29/11/2021	03/12/2021	08/12/2021	10/12/2021	16/12/2021

ⁱ(*) 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.
(**)Comments from members are not made available to Marketing Authorisation Holder(s) or Applicant, as applicable