



13 July 2021  
EMA/30819/2021  
Human Medicines Division

## Timetable<sup>1</sup> – non safety referral<sup>2</sup>

### 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
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
16/09/2021	28/10/2021	18/11/2021	26/11/2021	03/12/2021	09/12/2021	16/12/2021

<sup>1</sup> This timetable may be subject to revision

<sup>2</sup> 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.

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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
14/10/2021	09/12/2021	30/12/2021	07/01/2022	14/01/2022	20/01/2022	27/01/2022
11/11/2021	06/01/2022	27/01/2022	04/02/2022	11/02/2022	17/02/2022	24/02/2022
16/12/2021	03/02/2022	24/02/2022	04/03/2022	11/03/2022	17/03/2022	24/03/2022
27/01/2022	04/03/2022	25/03/2022	30/03/2022	05/04/2022	11/04/2022	22/04/2022
24/02/2022	31/03/2022	21/04/2022	29/04/2022	06/05/2022	12/05/2022	19/05/2022
24/03/2022	05/05/2022	26/05/2022	03/06/2022	10/06/2022	16/06/2022	23/06/2022
22/04/2022	02/06/2022	23/06/2022	01/07/2022	08/07/2022	14/07/2022	21/07/2022
19/05/2022	01/07/2022	22/07/2022	29/07/2022	05/08/2022	12/08/2022	19/08/2022***
23/06/2022	28/07/2022	18/08/2022	26/08/2022	02/09/2022	08/09/2022	15/09/2022
21/07/2022	25/08/2022	15/09/2022	23/09/2022	30/09/2022	06/10/2022	13/10/2022
19/08/2022***	22/09/2022	13/10/2022	21/10/2022	28/10/2022	03/11/2022	10/11/2022
15/09/2022	27/10/2022	17/11/2022	25/11/2022	02/12/2022	08/12/2022	15/12/2022
13/10/2022	08/12/2022	29/12/2022	06/01/2023	13/01/2023	19/01/2023	26/01/2023
10/11/2022	05/01/2023	26/01/2023	03/02/2023	10/02/2023	16/02/2023	23/02/2023
15/12/2022	09/02/2023	02/03/2023	10/03/2023	17/03/2023	23/03/2023	30/03/2023
26/01/2023	08/03/2023	29/03/2023	05/04/2023	13/04/2023	19/04/2023	26/04/2023
23/02/2023	06/04/2023	27/04/2023	04/05/2023	11/05/2023	17/05/2023	25/05/2023
30/03/2023	04/05/2023	25/05/2023	02/06/2023	09/06/2023	15/06/2023	22/06/2023
26/04/2023	01/06/2023	22/06/2023	30/06/2023	07/07/2023	13/07/2023	20/07/2023
25/05/2023	29/06/2023	20/07/2023	28/07/2023	04/08/2023	10/08/2023	17/08/2023***
22/06/2023	27/07/2023	17/08/2023	25/08/2023	01/09/2023	07/09/2023	14/09/2023
20/07/2023	24/08/2023	14/09/2023	22/09/2023	29/09/2023	05/10/2023	12/10/2023
17/08/2023***	21/09/2023	12/10/2023	18/10/2023	25/10/2023	31/10/2023	09/11/2023
14/09/2023	26/10/2023	16/11/2023	24/11/2023	01/12/2023	07/12/2023	14/12/2023
12/10/2023	07/12/2023	28/12/2023	05/01/2024	12/01/2024	18/01/2024	25/01/2024
09/11/2023	04/01/2024	25/01/2024	02/02/2024	09/02/2024	15/02/2024	22/02/2024

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
14/12/2023	01/02/2024	22/02/2024	01/03/2024	08/03/2024	14/03/2024	21/03/2024
25/01/2024	07/03/2024	28/03/2024	05/04/2024	12/04/2024	18/04/2024	25/04/2024
22/02/2024	11/04/2024	02/05/2024	08/05/2024	17/05/2024	23/05/2024	30/05/2024
21/03/2024	09/05/2024	30/05/2024	07/06/2024	14/06/2024	20/06/2024	27/06/2024
25/04/2024	06/06/2024	27/06/2024	05/07/2024	12/07/2024	18/07/2024	25/07/2024
30/05/2024	04/07/2024	25/07/2024	02/08/2024	09/08/2024	14/08/2024	22/08/2024***
27/06/2024	01/08/2024	22/08/2024	30/08/2024	06/09/2024	12/09/2024	19/09/2024
25/07/2024	29/08/2024	19/09/2024	27/09/2024	04/10/2024	10/10/2024	17/10/2024
22/08/2024***	26/09/2024	17/10/2024	24/10/2024	31/10/2024	07/11/2024	14/11/2024
19/09/2024	24/10/2024	14/11/2024	22/11/2024	29/11/2024	05/12/2024	12/12/2024

## 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
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
14/10/2021	12/11/2021	18/11/2021	03/12/2021	08/12/2021	10/12/2021	16/12/2021
11/11/2021	24/12/2021	30/12/2021	14/01/2022	19/01/2022	21/01/2022	27/01/2022
16/12/2021	21/01/2022	27/01/2022	11/02/2022	16/02/2022	18/02/2022	24/02/2022

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
27/01/2022	18/02/2022	24/02/2022	11/03/2022	16/03/2022	18/03/2022	24/03/2022
24/02/2022	19/03/2022	25/03/2022	01/04/2022	08/04/2022	13/04/2022	22/04/2022
24/03/2022	15/04/2022	21/04/2022	06/05/2022	11/05/2022	13/05/2022	19/05/2022
22/04/2022	20/05/2022	26/05/2022	10/06/2022	15/06/2022	17/06/2022	23/06/2022
19/05/2022	17/06/2022	23/06/2022	08/07/2022	13/07/2022	15/07/2022	21/07/2022
23/06/2022	15/07/2022	22/07/2022	05/08/2022	11/08/2022	12/08/2022	19/08/2022***
21/07/2022	12/08/2022	18/08/2022	02/09/2022	07/09/2022	09/09/2022	15/09/2022
19/08/2022***	09/09/2022	15/09/2022	30/09/2022	05/10/2022	07/10/2022	13/10/2022
15/09/2022	07/10/2022	13/10/2022	26/10/2022	31/10/2022	04/11/2022	10/11/2022
13/10/2022	11/11/2022	17/11/2022	02/12/2022	07/12/2022	09/12/2022	15/12/2022
10/11/2022	23/12/2022	29/12/2022	13/01/2023	18/01/2023	20/01/2023	26/01/2023
15/12/2022	20/01/2023	26/01/2023	10/02/2023	15/02/2023	17/02/2023	23/02/2023
26/01/2023	24/02/2023	02/03/2023	17/03/2023	22/03/2023	24/03/2023	30/03/2023
23/02/2023	23/03/2023	29/03/2023	13/04/2023	18/04/2023	20/04/2023	26/04/2023
30/03/2023	21/04/2023	27/04/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
26/04/2023	19/05/2023	25/05/2023	09/06/2023	14/06/2023	16/06/2023	22/06/2023
25/05/2023	16/06/2023	22/06/2023	07/07/2023	12/07/2023	14/07/2023	20/07/2023
22/06/2023	14/07/2023	20/07/2023	04/08/2023	09/08/2023	11/08/2023	17/08/2023***
20/07/2023	11/08/2023	17/08/2023	01/09/2023	06/09/2023	08/09/2023	14/09/2023
17/08/2023***	08/09/2023	14/09/2023	29/09/2023	04/10/2023	06/10/2023	12/10/2023
14/09/2023	06/10/2023	12/10/2023	26/10/2023	31/10/2023	03/11/2023	09/11/2023
12/10/2023	10/11/2023	16/11/2023	01/12/2023	06/12/2023	08/12/2023	14/12/2023
09/11/2023	22/12/2023	28/12/2023	12/01/2024	17/01/2024	19/01/2024	25/01/2024
14/12/2023	19/01/2024	25/01/2024	09/02/2024	14/02/2024	16/02/2024	22/02/2024
25/01/2024	16/02/2024	22/02/2024	08/03/2024	13/03/2024	15/03/2024	21/03/2024
22/02/2024	22/03/2024	28/03/2024	12/04/2024	17/04/2024	19/04/2024	25/04/2024

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
21/03/2024	26/04/2024	02/05/2024	17/05/2024	22/05/2024	24/05/2024	30/05/2024
25/04/2024	24/05/2024	30/05/2024	14/06/2024	19/06/2024	21/06/2024	27/06/2024
30/05/2024	21/06/2024	27/06/2024	12/07/2024	17/07/2024	19/07/2024	25/07/2024
27/06/2024	19/07/2024	25/07/2024	09/08/2024	14/08/2024	16/08/2024	22/08/2024***
25/07/2024	16/08/2024	22/08/2024	06/09/2024	11/09/2024	13/09/2024	19/09/2024
22/08/2024***	13/09/2024	19/09/2024	04/10/2024	09/10/2024	11/10/2024	17/10/2024
19/09/2024	11/10/2024	17/10/2024	31/10/2024	06/11/2024	08/11/2024	14/11/2024
17/10/2024	08/11/2024	14/11/2024	29/11/2024	04/12/2024	06/12/2024	12/12/2024

### 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
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
16/12/2021	05/01/2022	10/01/2022	14/01/2022	19/01/2022	21/01/2022	27/01/2022
27/01/2022	02/02/2022	07/02/2022	11/02/2022	16/02/2022	18/02/2022	24/02/2022
24/02/2022	02/03/2022	07/03/2022	11/03/2022	16/03/2022	18/03/2022	24/03/2022
24/03/2022	30/03/2022	04/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022

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
22/04/2022	27/04/2022	02/05/2022	06/05/2022	11/05/2022	13/05/2022	19/05/2022
19/05/2022	01/06/2022	06/06/2022	10/06/2022	15/06/2022	17/06/2022	23/06/2022
23/06/2022	29/06/2022	04/07/2022	08/07/2022	13/07/2022	15/07/2022	21/07/2022
21/07/2022	28/07/2022	02/08/2022	05/08/2022	11/08/2022	12/08/2022	19/08/2022***
19/08/2022***	24/08/2022	29/08/2022	02/09/2022	07/09/2022	09/09/2022	15/09/2022
15/09/2022	21/09/2022	26/09/2022	30/09/2022	05/10/2022	07/10/2022	13/10/2022
13/10/2022	19/10/2022	24/10/2022	26/10/2022	31/10/2022	04/11/2022	10/11/2022
10/11/2022	23/11/2022	28/11/2022	02/12/2022	07/12/2022	09/12/2022	15/12/2022
15/12/2022	04/01/2023	09/01/2023	13/01/2023	18/01/2023	20/01/2023	26/01/2023
26/01/2023	01/02/2023	06/02/2023	10/02/2023	15/02/2023	17/02/2023	23/02/2023
23/02/2023	08/03/2023	13/03/2023	17/03/2023	22/03/2023	24/03/2023	30/03/2023
30/03/2023	05/04/2023	10/04/2023	14/04/2023	19/04/2023	21/04/2023	26/04/2023
26/04/2023	03/05/2023	08/05/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
25/05/2023	31/05/2023	05/06/2023	09/06/2023	14/06/2023	16/06/2023	22/06/2023
22/06/2023	28/06/2023	03/07/2023	07/07/2023	12/07/2023	14/07/2023	20/07/2023
20/07/2023	26/07/2023	31/07/2023	04/08/2023	09/08/2023	11/08/2023	17/08/2023***
17/08/2023***	23/08/2023	28/08/2023	01/09/2023	06/09/2023	08/09/2023	14/09/2023
14/09/2023	20/09/2023	25/09/2023	29/09/2023	04/10/2023	06/10/2023	12/10/2023
12/10/2023	18/10/2023	23/10/2023	26/10/2023	31/10/2023	03/11/2023	09/11/2023
09/11/2023	22/11/2023	27/11/2023	01/12/2023	06/12/2023	08/12/2023	14/12/2023
14/12/2023	03/01/2024	08/01/2024	12/01/2024	17/01/2024	19/01/2024	25/01/2024
25/01/2024	31/01/2024	05/02/2024	09/02/2024	14/02/2024	16/02/2024	22/02/2024
22/02/2024	28/02/2024	04/03/2024	08/03/2024	13/03/2024	15/03/2024	21/03/2024
21/03/2024	03/04/2024	08/04/2024	12/04/2024	17/04/2024	19/04/2024	25/04/2024
25/04/2024	08/05/2024	13/05/2024	17/05/2024	22/05/2024	24/05/2024	30/05/2024
30/05/2024	05/06/2024	10/06/2024	14/06/2024	19/06/2024	21/06/2024	27/06/2024

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
27/06/2024	03/07/2024	08/07/2024	12/07/2024	17/07/2024	19/07/2024	25/07/2024
25/07/2024	31/07/2024	05/08/2024	09/08/2024	14/08/2024	16/08/2024	22/08/2024***
22/08/2024***	28/08/2024	02/09/2024	06/09/2024	11/09/2024	13/09/2024	19/09/2024
19/09/2024	25/09/2024	30/09/2024	04/10/2024	09/10/2024	11/10/2024	17/10/2024
17/10/2024	23/10/2024	28/10/2024	31/10/2024	06/11/2024	08/11/2024	14/11/2024
14/11/2024	20/11/2024	25/11/2024	29/11/2024	04/12/2024	06/12/2024	12/12/2024

(\*) 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)

(\*\*\*) Decision to be taken on whether August meetings can be replaced by written procedure as needed