



5 September 2023  
EMA/30819/2021 rev.1  
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
26/04/2023	01/06/2023	22/06/2023	29/06/2023	06/07/2023	12/07/2023	20/07/2023
25/05/2023	29/06/2023	20/07/2023	27/07/2023	03/08/2023	09/08/2023	17/08/2023***
22/06/2023	27/07/2023	17/08/2023	24/08/2023	31/08/2023	06/09/2023	14/09/2023
20/07/2023	24/08/2023	14/09/2023	21/09/2023	28/09/2023	04/10/2023	12/10/2023
17/08/2023***	21/09/2023	12/10/2023	19/10/2023	26/10/2023	02/11/2023	09/11/2023

<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.



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
14/09/2023	26/10/2023	16/11/2023	23/11/2023	30/11/2023	06/12/2023	14/12/2023
12/10/2023	07/12/2023	28/12/2023	04/01/2024	11/01/2024	17/01/2024	25/01/2024
09/11/2023	04/01/2024	25/01/2024	01/02/2024	08/02/2024	14/02/2024	22/02/2024
14/12/2023	01/02/2024	22/02/2024	29/02/2024	07/03/2024	13/03/2024	21/03/2024
25/01/2024	07/03/2024	28/03/2024	04/04/2024	11/04/2024	17/04/2024	25/04/2024
22/02/2024	11/04/2024	02/05/2024	08/05/2024	16/05/2024	22/05/2024	30/05/2024
21/03/2024	09/05/2024	30/05/2024	06/06/2024	13/06/2024	19/06/2024	27/06/2024
25/04/2024	06/06/2024	27/06/2024	04/07/2024	11/07/2024	17/07/2024	25/07/2024
30/05/2024	04/07/2024	25/07/2024	01/08/2024	08/08/2024	14/08/2024	22/08/2024***
27/06/2024	01/08/2024	22/08/2024	29/08/2024	05/09/2024	11/09/2024	19/09/2024
25/07/2024	29/08/2024	19/09/2024	26/09/2024	03/10/2024	09/10/2024	17/10/2024
22/08/2024***	26/09/2024	17/10/2024	24/10/2024	31/10/2024	06/11/2024	14/11/2024
19/09/2024	24/10/2024	14/11/2024	21/11/2024	28/11/2024	04/12/2024	12/12/2024
17/10/2024	12/12/2024	02/01/2025	09/01/2025	16/01/2025	22/01/2025	30/01/2025
14/11/2024	09/01/2025	30/01/2025	06/02/2025	13/02/2025	19/02/2025	27/02/2025
12/12/2024	06/02/2025	27/02/2025	06/03/2025	13/03/2025	19/03/2025	27/03/2025
30/01/2025	07/03/2025	28/03/2025	03/04/2025	10/04/2025	16/04/2025	25/04/2025
27/02/2025	03/04/2025	24/04/2025	30/04/2025	08/05/2025	14/05/2025	22/05/2025
27/03/2025	01/05/2025	22/05/2025	28/05/2025	05/06/2025	11/06/2025	19/06/2025
25/04/2025	05/06/2025	26/06/2025	03/07/2025	10/07/2025	16/07/2025	24/07/2025
22/05/2025	03/07/2025	24/07/2025	31/07/2025	07/08/2025	13/08/2025	21/08/2025***
19/06/2025	31/07/2025	21/08/2025	28/08/2025	04/09/2025	10/09/2025	18/09/2025
24/07/2025	28/08/2025	18/09/2025	25/09/2025	02/10/2025	08/10/2025	16/10/2025
21/08/2025***	25/09/2025	16/10/2025	23/10/2025	30/10/2025	05/11/2025	13/11/2025
18/09/2025	23/10/2025	13/11/2025	20/11/2025	27/11/2025	03/12/2025	11/12/2025
16/10/2025	11/12/2025	01/01/2026	08/01/2026	15/01/2026	21/01/2026	29/01/2026

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
13/11/2025	08/01/2026	29/01/2026	05/02/2026	12/02/2026	18/02/2026	26/02/2026
11/12/2025	05/02/2026	26/02/2026	05/03/2026	12/03/2026	18/03/2026	26/03/2026
29/01/2026	05/03/2026	26/03/2026	01/04/2026	09/04/2026	15/04/2026	23/04/2026
26/02/2026	02/04/2026	23/04/2026	30/04/2026	07/05/2026	13/05/2026	21/05/2026
26/03/2026	07/05/2026	28/05/2026	04/06/2026	11/06/2026	17/06/2026	25/06/2026
23/04/2026	04/06/2026	25/06/2026	02/07/2026	09/07/2026	15/07/2026	23/07/2026
21/05/2026	02/07/2026	23/07/2026	30/07/2026	06/08/2026	12/08/2026	20/08/2026***
25/06/2026	30/07/2026	20/08/2026	27/08/2026	03/09/2026	09/09/2026	17/09/2026
23/07/2026	27/08/2026	17/09/2026	24/09/2026	01/10/2026	07/10/2026	15/10/2026
20/08/2026***	24/09/2026	15/10/2026	22/10/2026	29/10/2026	04/11/2026	12/11/2026
17/09/2026	22/10/2026	12/11/2026	19/11/2026	26/11/2026	02/12/2026	10/12/2026

## 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
25/05/2023	16/06/2023	22/06/2023	06/07/2023	11/07/2023	13/07/2023	20/07/2023
22/06/2023	14/07/2023	20/07/2023	03/08/2023	08/08/2023	10/08/2023	17/08/2023***
20/07/2023	11/08/2023	17/08/2023	31/08/2023	05/09/2023	07/09/2023	14/09/2023
17/08/2023***	08/09/2023	14/09/2023	28/09/2023	03/10/2023	05/10/2023	12/10/2023
14/09/2023	06/10/2023	12/10/2023	26/10/2023	31/10/2023	02/11/2023	09/11/2023
12/10/2023	10/11/2023	16/11/2023	30/11/2023	05/12/2023	07/12/2023	14/12/2023
09/11/2023	22/12/2023	28/12/2023	11/01/2024	16/01/2024	18/01/2024	25/01/2024

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	19/01/2024	25/01/2024	08/02/2024	13/02/2024	15/02/2024	22/02/2024
25/01/2024	16/02/2024	22/02/2024	07/03/2024	12/03/2024	14/03/2024	21/03/2024
22/02/2024	22/03/2024	28/03/2024	11/04/2024	16/04/2024	18/04/2024	25/04/2024
21/03/2024	26/04/2024	02/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
25/04/2024	24/05/2024	30/05/2024	13/06/2024	18/06/2024	20/06/2024	27/06/2024
30/05/2024	21/06/2024	27/06/2024	11/07/2024	16/07/2024	18/07/2024	25/07/2024
27/06/2024	19/07/2024	25/07/2024	08/08/2024	13/08/2024	15/08/2024	22/08/2024***
25/07/2024	16/08/2024	22/08/2024	05/09/2024	10/09/2024	12/09/2024	19/09/2024
22/08/2024***	13/09/2024	19/09/2024	03/10/2024	08/10/2024	10/10/2024	17/10/2024
19/09/2024	11/10/2024	17/10/2024	31/10/2024	05/11/2024	07/11/2024	14/11/2024
17/10/2024	08/11/2024	14/11/2024	28/11/2024	03/12/2024	05/12/2024	12/12/2024
14/11/2024	27/12/2024	02/01/2025	16/01/2025	21/01/2025	23/01/2025	30/01/2025
12/12/2024	24/01/2025	30/01/2025	13/02/2025	18/02/2025	20/02/2025	27/02/2025
30/01/2025	21/02/2025	27/02/2025	13/03/2025	18/03/2025	20/03/2025	27/03/2025
27/02/2025	22/03/2025	28/03/2025	11/04/2025	16/04/2025	18/04/2025	25/04/2025
27/03/2025	18/04/2025	24/04/2025	08/05/2025	13/05/2025	15/05/2025	22/05/2025
25/04/2025	16/05/2025	22/05/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
22/05/2025	20/06/2025	26/06/2025	10/07/2025	15/07/2025	17/07/2025	24/07/2025
19/06/2025	18/07/2025	24/07/2025	07/08/2025	12/08/2025	14/08/2025	21/08/2025***
24/07/2025	15/08/2025	21/08/2025	04/09/2025	09/09/2025	11/09/2025	18/09/2025
21/08/2025***	12/09/2025	18/09/2025	02/10/2025	07/10/2025	09/10/2025	16/10/2025
18/09/2025	10/10/2025	16/10/2025	30/10/2025	04/11/2025	06/11/2025	13/11/2025
16/10/2025	07/11/2025	13/11/2025	27/11/2025	02/12/2025	04/12/2025	11/12/2025
13/11/2025	26/12/2025	01/01/2026	15/01/2026	20/01/2026	22/01/2026	29/01/2026
11/12/2025	23/01/2026	29/01/2026	12/02/2026	17/02/2026	19/02/2026	26/02/2026

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
29/01/2026	20/02/2026	26/02/2026	12/03/2026	17/03/2026	19/03/2026	26/03/2026
26/02/2026	20/03/2026	26/03/2026	09/04/2026	14/04/2026	16/04/2026	23/04/2026
26/03/2026	17/04/2026	23/04/2026	07/05/2026	12/05/2026	14/05/2026	21/05/2026
23/04/2026	22/05/2026	28/05/2026	11/06/2026	16/06/2026	18/06/2026	25/06/2026
21/05/2026	19/06/2026	25/06/2026	09/07/2026	14/07/2026	16/07/2026	23/07/2026
25/06/2026	17/07/2026	23/07/2026	06/08/2026	11/08/2026	13/08/2026	20/08/2026***
23/07/2026	14/08/2026	20/08/2026	03/09/2026	08/09/2026	10/09/2026	17/09/2026
20/08/2026***	11/09/2026	17/09/2026	01/10/2026	06/10/2026	08/10/2026	15/10/2026
17/09/2026	09/10/2026	15/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
15/10/2026	06/11/2026	12/11/2026	26/11/2026	01/12/2026	03/12/2026	10/12/2026

### 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
22/06/2023	28/06/2023	03/07/2023	06/07/2023	11/07/2023	13/07/2023	20/07/2023
20/07/2023	26/07/2023	31/07/2023	03/08/2023	08/08/2023	10/08/2023	17/08/2023***
17/08/2023***	23/08/2023	28/08/2023	31/08/2023	05/09/2023	07/09/2023	14/09/2023
14/09/2023	20/09/2023	25/09/2023	28/09/2023	03/10/2023	05/10/2023	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	30/11/2023	05/12/2023	07/12/2023	14/12/2023
14/12/2023	03/01/2024	08/01/2024	11/01/2024	16/01/2024	18/01/2024	25/01/2024
25/01/2024	31/01/2024	05/02/2024	08/02/2024	13/02/2024	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
22/02/2024	28/02/2024	04/03/2024	07/03/2024	12/03/2024	14/03/2024	21/03/2024
21/03/2024	03/04/2024	08/04/2024	11/04/2024	16/04/2024	18/04/2024	25/04/2024
25/04/2024	08/05/2024	13/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
30/05/2024	05/06/2024	10/06/2024	13/06/2024	18/06/2024	20/06/2024	27/06/2024
27/06/2024	03/07/2024	08/07/2024	11/07/2024	16/07/2024	18/07/2024	25/07/2024
25/07/2024	31/07/2024	05/08/2024	08/08/2024	13/08/2024	16/08/2024	22/08/2024***
22/08/2024***	28/08/2024	02/09/2024	05/09/2024	10/09/2024	12/09/2024	19/09/2024
19/09/2024	25/09/2024	30/09/2024	03/10/2024	08/10/2024	10/10/2024	17/10/2024
17/10/2024	23/10/2024	28/10/2024	31/10/2024	05/11/2024	07/11/2024	14/11/2024
14/11/2024	20/11/2024	25/11/2024	28/11/2024	03/12/2024	05/12/2024	12/12/2024
12/12/2024	08/01/2025	13/01/2025	16/01/2025	21/01/2025	23/01/2025	30/01/2025
30/01/2025	05/02/2025	10/02/2025	13/02/2025	18/02/2025	20/02/2025	27/02/2025
27/02/2025	05/03/2025	10/03/2025	13/03/2025	18/03/2025	20/03/2025	27/03/2025
27/03/2025	03/04/2025	08/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
25/04/2025	30/04/2025	05/05/2025	08/05/2025	13/05/2025	15/05/2025	22/05/2025
22/05/2025	28/05/2025	02/06/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
19/06/2025	02/07/2025	07/07/2025	10/07/2025	15/07/2025	17/07/2025	24/07/2025
24/07/2025	30/07/2025	04/08/2025	07/08/2025	12/08/2025	14/08/2025	21/08/2025***
21/08/2025***	27/08/2025	01/09/2025	04/09/2025	09/09/2025	11/09/2025	18/09/2025
18/09/2025	24/09/2025	29/09/2025	02/10/2025	07/10/2025	09/10/2025	16/10/2025
16/10/2025	22/10/2025	27/10/2025	30/10/2025	04/11/2025	06/11/2025	13/11/2025
13/11/2025	19/11/2025	24/11/2025	27/11/2025	02/12/2025	04/12/2025	11/12/2025
11/12/2025	07/01/2026	12/01/2026	15/01/2026	20/01/2026	22/01/2026	29/01/2026
29/01/2026	04/02/2026	09/02/2026	12/02/2026	17/02/2026	19/02/2026	26/02/2026
26/02/2026	04/03/2026	09/03/2026	12/03/2026	17/03/2026	19/03/2026	26/03/2026
26/03/2026	01/04/2026	06/04/2026	09/04/2026	14/04/2026	16/04/2026	23/04/2026

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
23/04/2026	29/04/2026	04/05/2026	06/05/2026	11/05/2026	13/05/2026	21/05/2026
21/05/2026	03/06/2026	08/06/2026	11/06/2026	16/06/2026	18/06/2026	25/06/2026
25/06/2026	01/07/2026	06/07/2026	09/07/2026	14/07/2026	16/07/2026	23/07/2026
23/07/2026	29/07/2026	03/08/2026	06/08/2026	11/08/2026	13/08/2026	20/08/2026***
20/08/2026***	26/08/2026	31/08/2026	03/09/2026	08/09/2026	10/09/2026	17/09/2026
17/09/2026	23/09/2026	28/09/2026	01/10/2026	06/10/2026	08/10/2026	15/10/2026
15/10/2026	21/10/2026	26/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026

(\*) 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) at that stage

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