16 March 2026
EMA/CHMP/46712/2026
Human Medicines Division

Committee for medicinal products for human use (CHMP)

Agenda for the extraordinary meeting on 16 March 2026
Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

16 March 2026, 14:00-17:00, virtual meeting

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CHMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CHMP members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
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Table of contents

1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the CHMP extraordinary plenary session to be held 16 March 2026. See 16 March 2026 CHMP minutes (to be published post March 2026 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for extraordinary CHMP meeting to be held on 16 March 2026

2. Oral Explanations

2.1. Re-examination procedure oral explanations

2.1.1. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.

Scope: Oral explanation

Action: Oral explanation to be held on 16 March 2026 at 14:15

Opinion on 11.12.2025. List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 3.1

2.1.2. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.

Scope: Oral explanation

Action: Oral explanation to be held on 16 March 2026 at 14:15

Opinion adopted on 13.11.2025. Request for Supplementary Information adopted on 25.04.2025, 30.01.2025.

See 4.1

3. Extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

3.1. Re-examination procedure of extension of marketing authorisation according to Annex I of Commission Regulation (EC) No 1234/2008

3.1.1. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/X/0039

Vanda Pharmaceuticals Netherlands B.V.

Scope: "Extension application to introduce a new pharmaceutical form associated with new strength (4 mg/ml oral solution). The new formulation is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in paediatric patients 3 to 15 years of age. The RMP (version 5.0) is updated in accordance."

Action: For adoption

Opinion adopted on 11.12.2025. List of Outstanding Issues adopted on 18.09.2025, 24.07.2025. List of Questions adopted on 27.02.2025.

See 2.1

4. Type II variations - variation of therapeutic indication procedure according to Annex I of Commission Regulation (EC) No 1234/2008

4.1. Re-examination of Type II variation; variation of therapeutic indication procedure according to Commission Regulation (EC) No 1234/2008

4.1.1. Hetlioz - Tasimelteon - Orphan - EMEA/H/C/003870/II/0040

Vanda Pharmaceuticals Netherlands B.V.

Scope: "Extension of indication to include the treatment of nighttime sleep disturbances in adults with Smith Magenis Syndrome (SMS) for HETLIOZ, based on results from study VP-VEC-162-2401. This is a double-blind, randomized, two-period crossover study evaluating the effects of tasimelteon vs. placebo on sleep disturbances of individuals with Smith-Magenis Syndrome (SMS). As a consequence, sections 4.1, 4.5, 5.1, 5.2 and 5.3 of the SmPC are updated. The Labelling and Package Leaflet are updated in accordance. The RMP version 5.0 has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. As part of the application, the MAH is requesting a 1-year extension of the market protection.", Request for 1 year of market protection for a new indication (Article 14(11) of Regulation (EC) 726/2004)

Action: For adoption

Opinion adopted on 13.11.2025. Request for Supplementary Information adopted on 25.04.2025, 30.01.2025.

See 2.1