



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 August 2025
EMA/CHMP/252119/2025

Committee for medicinal products for human use (CHMP)

Agenda for the extraordinary meeting on 25 August 2025

Chair: Bruno Sepodes – Vice-Chair: Outi Mäki-Ikola

25 August 2025, 10:00 -13:00, 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).



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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 25 August 2025. See 25 August 2025 CHMP minutes (to be published post September 2025 CHMP meeting).

1.2. Adoption of agenda

CHMP agenda for extraordinary CHMP meeting to be held on 25 August 2025

2. Oral Explanations

2.1. Re-examination procedure oral explanations

2.1.1. Winlevi - Clascoterone - EMEA/H/C/006138

Cassiopea S.p.A.; indicated for the topical treatment of acne vulgaris in adults and adolescents

Scope: Oral explanation

Action: Oral explanation to be held on 25 August 2025 at 10:15

Opinion adopted 25.04.2025. List of Outstanding Issues adopted on 27.03.2025, 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

See 3.1

3. Initial Applications

3.1. Re-examination of initial application procedures under Article 9(2) of Regulation no 726/2004

3.1.1. Winlevi - Clascoterone - EMEA/H/C/006138

Cassiopea S.p.A.; indicated for the topical treatment of acne vulgaris in adults and adolescents

Scope: Opinion

Action: For adoption

Opinion adopted 25.04.2025. List of Outstanding Issues adopted on 27.03.2025, 12.12.2024, 17.10.2024. List of Questions adopted on 22.02.2024.

See 2.1

4. Any other business

4.1. AOB topic