



27 February 2025  
EMA/CHMP/488796/2023 – Rev. 4

## Timetable for the procedure

### Referral under article 31 of Directive 2001/83/EC

Azithromycin-containing medicinal products for systemic use

Procedure no: EMEA/H/A-31/1532

<b>Procedural step:</b>	<b>Date:</b>
Notification:	30 October 2023
Start of the procedure (CHMP <sup>1</sup> ):	November 2023 CHMP
List of questions:	09 November 2023
Submission of responses:	01 February 2024
Re-start of the procedure:	22 February 2024
Rapporteur/co-rapporteur assessment reports circulated to CHMP:	04 April 2024
Comments:	11 April 2024
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	17 April 2024
CHMP list of outstanding issues, CHMP request for PRAC <sup>2</sup> advice and CHMP list of questions to IDWP <sup>3</sup> :	April 2024 CHMP
Submission of responses:	29 August 2024

<sup>1</sup> Committee for Medicinal Products for Human Use

<sup>2</sup> Pharmacovigilance Risk Assessment Committee

<sup>3</sup> Infectious Diseases Working Party



<b>Procedural step:</b>	<b>Date:</b>
PRAC advice to CHMP:	05 September 2024
Re-start of the procedure:	19 September 2024
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	26 September 2024
Comments:	03 October 2024
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	09 October 2024
CHMP list of outstanding issues:	October 2024 CHMP
Submission of responses:	09 January 2025
Re-start of the procedure:	30 January 2025
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	06 February 2025
Comments:	13 February 2025
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	19 February 2025
CHMP list of outstanding issues:	February 2025 CHMP
Submission of responses:	03 April 2025
Re-start of the procedure:	26 April 2025
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	30 April 2025
Comments:	08 May 2025
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	14 May 2025
CHMP opinion:	May 2025 CHMP