



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 September 2025  
EMADOC-1700519818-2392927

## Timetable for the procedure

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Levamisole-containing medicinal products

Procedure no: EMA/REF/0000293746

| Procedural step:                                                                                      | Date:                                    |
|-------------------------------------------------------------------------------------------------------|------------------------------------------|
| Notification:                                                                                         | 28 August 2025                           |
| Start of the procedure (PRAC <sup>1</sup> ):                                                          | September 2025 PRAC                      |
| List of questions:                                                                                    | 04 September 2025                        |
| Submission of responses:                                                                              | 09 October 2025                          |
| Re-start of the procedure:                                                                            | 30 October 2025                          |
| Preliminary rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>2</sup> : | 06 November 2025                         |
| Comments:                                                                                             | 13 November 2025                         |
| Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:                   | 19 November 2025                         |
| PRAC list of outstanding issues or recommendation:                                                    | December 2025 PRAC (24-27 November 2025) |

<sup>1</sup> Pharmacovigilance Risk Assessment Committee

<sup>2</sup> Coordination Group for Mutual Recognition & Decentralised Procedures - Human

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