

16 October 2025 EMA/332104/2025 Press Office

## Start of union reviews

CHMP meeting of 13-16 October 2025

Table 1. Start of arbitration procedure

| Name                           | INN       | Type of procedure                     | Scope   |
|--------------------------------|-----------|---------------------------------------|---|
| Melatomed and associated names | melatonin | Article 29(4) of Directive 2001/83/EC | The Committee started a referral procedure for Melatomed. The procedure was initiated because of disagreements regarding demonstration of bioequivalence. |