European Parliament
2024-2029

TEXTS ADOPTED

P10_TA(2026)0391

Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency

European Parliament legislative resolution of 25 November 2026 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (07105/2/2026– C10-0243/2026 – 2023/0131(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (07105/2/2026– C10-0243/2026),

– having regard to the opinion of the European Economic and Social Committee of 25 October 2023[1],

– after consulting the Committee of the Regions,

– having regard to its position at first reading[2] on the Commission proposal to Parliament and the Council (COM(2023)0193),

– having regard to Article 294(7) of the Treaty on the Functioning of the European Union,

– having regard to the provisional agreement approved by the committee responsible under Rule 75(4) of its Rules of Procedure,

– having regard to Rule 68 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on Public Health (A10-0296/2026),

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1 OJ C C/2024/879, 6.2.2024, ELI: http://data.europa.eu/eli/C/2024/879/oj.
2 OJ C C/2025/1329, 13.3.2025, ELI: http://data.europa.eu/eli/C/2025/1329/oj.

1. Approves the Council position at first reading;

2. Notes that the act is adopted in accordance with the Council position;

3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.