Council of the European Union

Brussels, 21 September 2026
(OR. en)

12263/26

Interinstitutional File:
2023/0132 (COD)

SAN 619
PHARM 143
MI 814
COMPET 993
ENV 992
PI 95
CODEC 1514
IA 209
UK 166

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directives 2001/83/EC and 2009/35/EC **(first reading)** - Adoption of the Council's position at first reading and of the statement of the Council's reasons

1. On 26 April 2023 the Commission submitted its proposal[1], based on Articles 114(1) and 168(4)(c) TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 25 October 2023[2].

3. The Committee of the Regions was consulted and decided not to issue an opinion.

4. The European Parliament adopted its position at first reading on 10 April 2024[3].

1 8759/23 + ADD 1 to 7.
2 14863/23.
3 11754/24.

5. The Permanent Representatives Committee confirmed on 6 March 2026 the provisional agreement reached by the co-legislators on the above Directive[4], after informal contacts had taken place between the Council and the European Parliament.

6. On 18 March 2026, the European Parliament's Committee on Public Health (SANT) confirmed the provisional agreement. Subsequently, its Chair sent a letter to the Chair of the Permanent Representatives Committee stating that the European Parliament should, at its second reading, approve the Council's position at first reading (following a legal-linguistic revision) without amendments[5].

7. The Permanent Representatives Committee is asked to suggest that the Council adopt its position at first reading, as set out in 7106/26, and the statement of reasons, as set out in 7106/26 ADD 1, as an 'A' item at a forthcoming meeting, with Malta abstaining.

8. The statements for the minutes of the Council are set out in the Addendum to this note.

---

[4] 6367/26.
[5] 7424/26.