Council of the European Union

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DRAFT STATEMENT OF THE COUNCIL'S REASONS

Subject: Position of the Council at first reading with a view to the adoption of the 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
– Draft Statement of the Council's reasons

I. INTRODUCTION

1. On 26 April 2023 the Commission adopted a proposal for the revision of the pharmaceutical legislation, consisting of a Directive on the Union code relating to medicinal products for human use[1] and a Regulation on Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency[2].

[1] 8759/23
[2] 8758/23

2. On 24 October 2023, the Committee of the Regions (CoR) sent a renunciation letter regarding the consultation on the Regulation due to the little regional or local relevance of this proposal[3]. On 25 October 2023, the European Economic and Social Committee (EESC) adopted its opinion on the proposals[4].

3. At the European Parliament, when the proposals were put forward by the Commission, the Committee on the Environment, Public Health and Food Safety (ENVI) was designated as responsible committee. The ENVI Committee adopted its report on both the legislative proposals on 19 March 2024, which was voted in plenary session on 10 April 2024. The responsibility for both legislative proposals transferred to the newly established Committee on Public Health (SANT) in 2025. The rapporteurs are Tiemo Wölken (S&D, Germany) for the Regulation and Dolors Montserrat (EPP, Spain) for the Directive.

4. On 4 June 2025, the Permanent Representatives Committee agreed on a mandate[5] for the Presidency to enter into negotiations with the European Parliament. On 1 October 2025, the Permanent Representatives Committee provided guidance on several political issues[6]. On 7 November 2025, the Permanent Representatives Committee provided further guidance, as well as a targeted revised mandate[7]. On 10 December 2025, the Permanent Representatives Committee agreed on a revised mandate[8], in order for a final compromise to be reached.

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3 15273/23
4 14863/23
5 9270/25
6 13078/25
7 14576/25
8 15902/25

5. The first trilogue was held on 17 June under the Polish Presidency. Subsequent trilogues took place on 7 October, 11 November and 10 December 2025 under the Danish Presidency. In total, 41 technical meetings took place as part of the inter-institutional negotiations under the Danish and Cyprus Presidencies.

6. At the last trilogue, on which the Danish Presidency debriefed Coreper at its meeting of 19 December 2025, the co-legislators provisionally agreed on an overall compromise agreement.

7. On 6 March 2026, the Permanent Representatives Committee analysed the final compromise texts and confirmed the agreement[9].

8. On 18 March 2026, the European Parliament's SANT Committee voted in favour of the final compromise texts. On 19 March 2026, the Chair of the SANT Committee addressed a letter to the Chair of the Permanent Representatives Committee[10] stating that, should the Council transmit to the European Parliament its position as agreed, subject to legal-linguistic verification, he will recommend to the Plenary that the Council's position be accepted without amendments at Parliament's second reading. The texts annexed to the letter correspond to the texts supported by the Permanent Representatives Committee on 6 March 2026.

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9 6412/26, 6366/26, 6367/26

10 7424/26

II. OBJECTIVE

9. The two legislative proposals aim to adapt and simplify the current regulatory landscape, which consists of one Directive and three Regulations covering both general legislation and specific legislation on medicines for rare diseases and for children.

10. The general objectives of the two legislative proposals are to ensure the quality, safety and efficacy of medicines for EU patients and harmonising the internal market. They specifically aim to promote innovation and ensure access to innovative and affordable medicines; improve security of supply of medicines and address shortages; support innovation and competitiveness through reduced regulatory burden and through a simplified and flexible regulatory framework; and reduce the environmental impact of the pharmaceutical lifecycle.

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

11. The Council's position at first reading on the Regulation contains the following main elements, on which agreement has been found between the co-legislators:

12. The concept of **'breakthrough orphan medicinal products'** is introduced to replace the initial concept of 'high unmet medical needs'. The **market exclusivity period** will be 11 years for breakthrough orphan medicines, and nine years for regular orphan medicinal products.

13. The scope of the **shortage prevention plans** covers prescription medicines, as well as those medicines identified by the Commission via delegated act. Marketing authorisation holders will be required to **notify supply disruptions** as soon as possible and at least six months in advance.

14. A **provision is introduced** whereby **Member States may require wholesalers who intend to distribute a medicinal product in another Member State to provide certain information to the source Member State** about that medicinal product.

15. Member States maintain the central role regarding **measures to improve security of supply of medicines placed on the Union list of critical medicines**. The Commission may, if necessary and in limited cases, draw up recommendations for national measures.

16. A **Voluntary Solidarity Mechanism** aimed at mitigating critical shortages is instituted, which will be driven by Member States and used as a last resort.

17. The use of a **transferable data exclusivity voucher for priority antimicrobials** will provide an unmodulated extension of 12 months of the regulatory data protection for the priority antimicrobial or for another authorised medicine. The use of the voucher will be subject to a clause whereby the annual gross sales of the concerned medicine in the Union during any of the first four years after the granting of the marketing authorisation have not exceeded 490 million euros (the so-called **blockbuster clause**). The provisions regarding the granting, the transfer and use, and the validity of the data exclusivity voucher, will apply for 15 years or until five such vouchers have been granted. The **Commission evaluation** of the provisions on incentives for the development of priority antimicrobials will include an assessment of whether it could be appropriate to adjust the value of the blockbuster clause for inflation or increase of the number of vouchers.

18. A **subscription model for the joint procurement of antimicrobials** is instituted, which is voluntary for Member States and gives the Commission a potential supporting role.

19. **Patient organisations and healthcare professionals' organisations** will each have two representatives and two alternates in the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee, with each group having one vote.

20. The maximum **duration of examination of marketing authorisations applications** will be 180 days.

21. A general duration of 24 months after the date of entry into force of the Regulation will apply to **transitional provisions** without prejudice to specific transition periods. Shorter timelines will apply to certain provisions, including those on availability and security of supply, sandboxes, the Voluntary Solidarity Mechanism and the transferable exclusivity voucher.

IV. CONCLUSION

22. The Council's position supports the aim of the Commission proposal and fully reflects the compromise reached in the negotiations between the Council and the European Parliament, with the support of the Commission

23. Once adopted, the Regulation will contribute to promoting innovation and ensuring access to innovative and affordable medicines; improving security of supply of medicines and address shortages; supporting innovation and competitiveness through reduced regulatory burden and through a simplified and flexible regulatory framework; and reducing the environmental impact of the pharmaceutical lifecycle.