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 Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
– 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 Directive contains the following main elements, on which agreement has been found between the co-legislators:

12. The duration of **regulatory protection** is maintained at eight years for basic data protection and a maximum of 11 years of total protection periods, except the case of vouchers provided for in the Regulation, which can lead to 12 years. The modulation of incentives will apply to market protection. The incentives for a second year of market protection for products containing a new active substance are structured as three alternative combinations of two criteria: comparative clinical trials and 'early application in the EU'; comparative clinical trials and clinical trials in more than one Member State; or, when comparative clinical trials are not possible, clinical trials in more than one Member State and 'early application in the EU'. A second year of market protection can also be granted for products that fulfil an unmet medical need.

13. Member States will be able to **require marketing authorisation holders (MAHs) to launch and supply innovative products** on their markets. Market protection for products that do not comply with the request within three years will not apply. Member States may require the MAHs to do one or more of the following: submit a valid pricing and reimbursement application, fulfil specific requirement related to procurement procedures, and/or establish a roll-out plan. The mechanism under this provision is linked to the needs of patients in the concerned Member State. Exceptional and unforeseeable circumstances are recognised as possible reasons for MAHs not being able to comply with their obligations. The triggering of the provision regarding the scrapping of market protection is linked to the moment of the request made by the Member State, with a deadline of three years.

14. Applications to procurement tenders are included in the scope of the Article related to the protection of intellectual property rights (**the Bolar exemption**).

15. All **antimicrobials** will be subject to prescription; Member States will be able to exempt antimicrobials for topical use.

16. In the beginning of the package leaflet of antimicrobials, a section will be included containing the **global AMR symbol** together with specific information about the product and AMR. Where Member States decide that the package leaflet is made available in electronic format only, the information shall be made available to patients in paper format (in the form of an **'awareness card'**), unless the Member State concerned decides otherwise in duly justified cases.

17. All pharmacies are included in the scope of the **advance preparation of magistral formulas of medicinal products**; in specific cases, Member States may allow pharmacies to prepare magistral formulas in advance for a baseline period of up to seven days, or when duly justified, for a period of up to three weeks.

18. The validity of **marketing authorisations issued by the competent authorities of Malta** based on the MAs originally granted by the United Kingdom will be extended by three years and six months from the time of entering into force of the Directive.

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

20. A general duration of 24 months after the date of entry into force of the Directive will apply to **repeals and transitional provisions,** except for certain provisions, such as those relating to the requirement to make the package leaflet available electronically.

IV. CONCLUSION

21. 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.

22. Once adopted, the Directive 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.