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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Pharmaceutical package a) Directive on the Union code relating to medicinal product for human use b) Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency *- Mandate for negotiations with the European Parliament*

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]. The ordinary legislative procedure is applicable. The proposals were accompanied by an impact assessment on which an exchange of views was held under the Spanish

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

Presidency. 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.

2. The general objectives of the two legislative proposals are ensuring 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.

3. 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].

4. The Senate of the Parliament of the Czech Republic submitted a resolution on both the Regulation and the Directive, raising concerns on certain aspects of the package. The Romanian Senate submitted an opinion raising proportionality concerns and making several recommendations. The German Bundesrat supported the structure of the proposals, but also raised concerns on certain aspects. The Italian Chamber of Deputies and the Italian Senate submitted generally positive assessments on the proposals, while also expressing concerns on certain aspects of the proposal.

[3] 15273/23
[4] 14863/23

5. 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.

II. STATE OF PLAY

6. The Swedish Presidency organised one meeting of the Working Party (WP) on Pharmaceuticals and Medical Devices, dedicated to the presentation by the Commission of the pharmaceutical package. The Spanish Presidency organised two WP meetings, dedicated to the examination of the impact assessment, to the presentation of the opinion of the EESC and a subsequent exchange of views. The Belgian Presidency organised fifteen WP meetings, mainly focusing on the 'shortages', 'authorisations' and 'incentives' clusters, including discussions on several revised texts. In addition, Coreper discussed a state of play on the 'shortages cluster' on 29 May 2024[5], and a policy debate took place on the 'incentives cluster' at the EPSCO (Health) Council of 21 June 2024[6]. The Hungarian Presidency also organised fifteen WP meetings, mainly focusing on the 'incentives cluster', but also including in-depth discussions on the clusters related to 'authorisations', 'subject matter and scope', 'governance of the European Medicines Agency', 'orphans and paediatrics' and 'shortages'. Several revised texts were put forward to the WP, a progress report was presented at the EPSCO (Health) Council of 3 December 2024[7], and Coreper held an exchange of views on the state of play[8] of the file on 18 December 2024.

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5 9840/1/24 REV 1.
6 9557/24.
7 14955/24.
8 16051/24.

7. The Polish Presidency organised thirteen WP meetings, opening the remaining parts of the proposals, i.e. the clusters related to 'manufacturing and import', 'pharmacovigilance', 'homeopathics and herbals', 'final provisions and Brexit', 'labelling, advertising and prescriptions' and discussing all previously opened parts of the proposals, as listed in paragraph 6, with the aim to obtain a mandate for negotiations with the European Parliament.

8. Based on the examination of the proposals by the Commission, on written comments from delegations and building on discussions in the WP, intermediate revised texts, the guidance provided by Coreper and the EPSCO (Health) Council, the Presidency put forward full compromise texts, which were examined at the WP meetings of 5, 6 and 12 May 2025.

9. Key issues addressed throughout the entire examination of the package were: the modulation of regulatory protection periods for innovative medicines,; the introduction of an obligation to supply the markets of the EU; the risk of an excessive budgetary impact of the use of the transferable exclusivity voucher; the scope of the exemption to the protection of intellectual property rights (the Bolar exemption); the empowerment of the Commission in the case of shortages of medicinal products; the possibility for Member States to implement the information system concerning the distribution of medicinal products from one market to another; introducing the electronic leaflet in parallel to the paper version, unless the Member State decides to require only the electronic version for some or all medicinal products; ensuring that the Committee for Medicinal Products for Human Use (CHMP) within the European Medicines Agency (EMA) can draw on the appropriate expertise for its opinions; representation of and voting rights for patients and healthcare professionals in the CHMP and the Pharmacovigilance Risk Assessment Committee; technical adaptations in some the pharmacovigilance provisions; clarification of the provisions related to decentralised manufacturing; modification of the provisions on joint inspections; clarification of the exemptions related to officinal formula and magistral formula; framing of the scope of adapted frameworks and regulatory sandboxes; and adjustment of various procedural timelines.

10. Based on comments made during the WP meetings on 5, 6 and 12 May 2025 and on subsequent written comments, the Presidency implemented new changes to the compromise texts. On 21 May 2025, the Permanent Representatives Committee was invited to confirm agreement on these compromise texts in view obtaining a mandate for negotiations with the European Parliament[9]. At that meeting, the Permanent Representatives Committee did not agree on a mandate for negotiations with the European Parliament on the text submitted.

11. Taking into account the concerns expressed by the Member States, the Presidency has prepared a new set of compromise texts contained in documents 9285/25 (for the Directive) and 9286/25 (for the Regulation).

12 Targeted changes were implemented in the text of the proposed Directive, in particular:

– **Articles 80** ***(Regulatory data and market protection)*** **and 81 (***Additional regulatory market protection periods)*: the length of the regulatory data protection has been changed to an unmodulated period of 8 years, as provided for in the existing legislation, while a modulation is applied to the second year of the regulatory market protection period. This modulation covers the following conditions: 1 year of regulatory market protection for a medicine addressing an unmet medical need (UMN) or for cumulatively meeting the conditions of (1) clinical trials in more than one Member State, (2) using a relevant and evidence-based comparator in the clinical trials supporting the initial marketing authorisation application (MAA) and (3) the marketing authorisation applicant demonstrating that MAA has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of an application for the first marketing authorisation outside the Union.

[9] 8487/25

– **Article 207a (*Re-dispensing to the public of unused medicinal products*)**: several changes have been included to provide further safeguards addressing the concerns of several Member States regarding patient safety. The Article has been amended to allow only for re-dispensing of specific medicinal products, and only products bearing safety features, i.e. prescription products. Further safeguarding provisions have also been introduced to secure the safety of the mechanism, most-notably one time re-dispensation.

– **Article 51 (*Medicinal products subject to medical prescription*)**: in paragraph 5, the enumeration was removed to include all options listed in paragraph 1 of possible waivers. Additionally, in the corresponding recital 68 it has been clarified that the possibility of Member States to waive the mandatory prescription-only status of antimicrobials, for example in case of specific low dose formulations, should be strictly limited and well-justified based on public health reasons.

13. Targeted changes were implemented in the text of the proposed Regulation, in particular:

– **Article 5a (*Obligation to supply for centrally authorised medicinal products*)**: in paragraph 1 the link between this Article and Article 56a of the Directive has been clarified related to their reference to centrally authorised products. In paragraph 3 the reference to the possibility of imposing penalties in accordance with Article 172 has been removed (and following this change point 8a in Annex II has been deleted). However, a new paragraph 5 is added, specifying that 4 years following the date of entry into force of the Regulation, the Commission shall, if appropriate, present legislative proposals based on an evaluation in order to amend the Regulation, including the possibility to impose Union penalties. Additionally in paragraph 4 the role of the Commission is specified whenever more than one Member State invokes the provisions of paragraph 3, i.e. the consistent failure of a marketing authorisation holder to comply with the obligations set in this Article with regards to the same medicinal product.

– **Article 122 (*Role of the Agency concerning shortages*) paragraph 2:** it has been specified that the Agency shall establish the list of critical shortages of Union concern. It has also been clarified in the text that the process of the identification of the critical shortages of Union concern and the update of the list is a process fully driven by the Member States, in accordance with the definition of critical shortage of Union concern.

– **Article 134 (*role of the Commission concerning the security of supply)***: a change has been included to replace the empowerment of the Commission to adopt implementing acts with drawing up recommendations.

– **Article 43 (*Duration of application of Chapter III*)**: the number of transferable data exclusivity vouchers (TEV) to be granted by the Commission has been reduced from 10 to 5, to address general concerns regarding the cost efficiency of the proposed mechanism.

III. CONCLUSION

13. In light of the above, the Permanent Representatives Committee is invited to:

– examine the overall compromise texts, as set out in documents 9285/25 (for the Directive) and 9286/25 (for the Regulation) and indicate its agreement on it;

– mandate the Presidency to enter into negotiations with the European Parliament on the basis of this text in view of reaching an agreement at early second reading on the proposals for a Directive on the Union code relating to medicinal products for human use and a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency.

– In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2020[10], and in full consistency with Regulation (EC) No 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

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[10] 9493/20.