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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 products 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

- *Preparation for the trilogue*

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 use¹ and a Regulation on Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency².

¹ 8759/23

² 8758/23

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 proposal³. On 25 October 2023, the European Economic and Social Committee (EESC) adopted its opinion on the proposals⁴.
4. 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.
5. On 4 June 2025, the Permanent Representatives Committee agreed on a mandate⁵ for the Presidency to enter into negotiations with the European Parliament. On 1 October 2025, the Permanent Representatives Committee provided further guidance on several political issues⁶.

³ 15273/23

⁴ 14863/23

⁵ 9270/25

⁶ 13078/25

II. STATE OF PLAY

6. Two rounds of trilogues and 15 technical meetings have been held with the European Parliament and the Commission. These meetings have resulted in provisional agreements on provisions highlighted in green in the 4th column of the 4 column tables.
7. The third political trilogue is scheduled for 11 November and is expected to:
 - confirm the results of work carried out at technical level (the green rows of the annexed 4-column table, updated as per the last technical meeting of 20 and 22 October).
 - provide political guidance, and if possible, reach a preliminary political agreement on (a) Antimicrobials and Antimicrobial resistance (AMR) and (b) Pharmacy exemption.
 - provide political guidance on (c) Regulatory Protection Periods, (d) Market exclusivity for Orphan Medicinal Products, (e) Obligations/requirements for availability of medicines and (f) Bolar provision
 - hold an exploratory political exchange of views on (g) security of supply.

The discussions during the technical inter-institutional negotiations allowed to provisionally identify the following political issues to be discussed:

a. **Antimicrobials and Antimicrobial resistance (AMR)**

- i) **Incentives for development of priority antimicrobials** (Regulation Articles 39a and 39b introduced by the Parliament and Articles 40-43 and/lines 445a-473)

The Council amendments to the transferrable exclusivity voucher for priority antimicrobials (TEV) aim to limit its budgetary impact. This includes the “blockbuster clause” (EUR 490 million.), the limitation to only use in the fifth year of the regulatory data protection period and the reduction of the number of vouchers from 10 to 5.

The European Parliament introduces a modulated extension of regulatory data protection (of 6, 9 or 12 months), depending on the category of pathogen (medium, high and critical on the antimicrobial on the WHO priority pathogens list or an equivalent established at Union level) that the antimicrobial would be addressing. The extension of the data protection period via the voucher would not apply to products already benefitting from the maximum period as set out in article 81 in the European Parliament position.

The European Parliament also proposes additional incentives for the development of antimicrobials. The first would be a milestone payment reward scheme, according to Article 39a. The second additional incentive, proposed by the European Parliament in Article 39b, is a subscription model scheme through voluntary joint procurement agreements, meant to encourage investment in antimicrobials.

ii) **Prudent use of and access to antimicrobials:**

- **the antimicrobial access plan** (Directive Article 17.1.a/line 363), introduced by the European Parliament.
- **the prescription status** (Directive Article 51(1)(e), (2)(d) and 5(b)/line 674, 676e and 687), where the European Parliament adapts the scope of prescriptions to antibiotics and other antimicrobials for which there is an identified risk of AMR and deletes the Member States possibility to waive with regard to other circumstances specified (line 687), while the Council excludes antimicrobials intended for topical use from the scope, with flexibility for Member States to decide to make antimicrobials intended for topical use subject to medical prescription.
- **special information requirements** (Directive Article 69/lines 808-812b), where the Council removes the proposal for the ‘awareness card’ (line 810), while the European Parliament maintains it. The Council introduces the global AMR symbol and additional information on the package leaflet as an alternative to the awareness card.

- b) **The pharmacy exemption** (Directive Article 1(5)(a)/line 171 and Article 1(6)/line 174), where the European Parliament supports the main elements of the Commission proposal, whereas the Council expands the advance preparation beyond hospital-serving pharmacies, which is allowed today in some Member States, and extends the maximum duration to four weeks, with the magistral formula also referring to the preparation of medicines available without a medical prescription, based on the instruction of a doctor or another healthcare professional.
- c) **Regulatory Protection Periods** (Directive Articles 80-83/lines 856-894)

The Council mandate sets the length of the regulatory data protection (RDP) at 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. The Council limits the duration of market protection to two years from the date of expiration of the RDP, except where an additional year is granted for new therapeutic indications that offer a significant clinical benefit.

The European Parliament puts the baseline (RDP) period at seven years and a half for new medicines and maintains the market protection period of two years as proposed by the Commission. The European Parliament maintains and adapts the proposed RDP modulation: extends from 6 to 12 months the prolongation granted for addressing an unmet medical need, keeps the 6 months for prolongation for conducting comparative clinical trials and introduces a 6-month prolongation if the product's R&D took place in the EU or in collaboration with EU research entities. The European Parliament caps the cumulated RDP period at 8,5 years.

d) **Market exclusivity for Orphan Medicinal Products** (Regulation Articles 70-72 / lines 679-705)

The Council mandate maintains the current rules on the length of market exclusivity (ME), by discarding the concept of high unmet medical need (HUMN) and aligning the length of market exclusivity to the current duration of 10 years. The Council mandate keeps the proposed ME duration of 5 years for orphan medicines authorised based on bibliographical data.

The European Parliament maintains the proposed concept of HUMN and increases the duration of market exclusivity connected to it to 11 years. It also keeps the proposed ME duration of 9 years for orphan medicines and lowers it to four years for orphan medicines authorised based on bibliographical data.

e) **Obligations/requirements for availability of medicines** (Directive Article 56a introduced by the Council/lines 708a-708r; Articles 58a and 58b introduced by the EP/lines 727a-727r)

The Council mandate established an obligation-based model for innovative medicines which provides that MSs can require the Market Authorisation Holder (MAH) to launch and supply such products on their markets. The modalities would be chosen by the Member States and could include, but are not limited to, requirements for MAH to submit a pricing and reimbursement application, fulfil specific conditions in procurement procedures and establish a roll-out plan. If those obligations are not met, the market protection would not apply in the Member State concerned, and the eventual prolongation of orphan-market exclusivity would not apply either in that Member State. In addition, in such cases, the authorisation of the generic/biosimilar medicinal product could start six years after the marketing authorisation of the innovative medicinal product.

The European Parliament establishes its own obligation system, whereby, upon request by a Member State, a MAH would have to submit pricing and reimbursement application within a deadline. The European Parliament creates a derogation from this system for orphan medicines and ATMPs, as well as exemptions based on the nature or market of the medicinal product. The European Parliament mandate also establishes an EU access medicines notification system to monitor the compliance with the obligations it lays in article 58a.

f) **The Bolar provision** (Directive Article 85.1.ad/line 906c), where the Council has introduced the submission of procurement tenders in the scope of the article.

g) **Security of supply**

The Council has introduced several amendments, most notably regarding: the scope of the shortage prevention plans, which would only be mandatory for medicines identified as critical using a common methodology, and for other medicines identified via delegated acts following a recommendation by the Medicines Shortages Steering Group (Regulation Articles 117, 119.1.a, 123.4a, 126.2a, 127.1, Annex IV); the possibility for Member States to introduce a prior information provision by the wholesalers before distributing a medicinal product to another Member State. (Regulation Article 120.1a); the shortage exemption (Directive Article 3.1a) and the military and defence exemption (Directive Article 3.1b and Regulation Article 115a) from the scope of the legislation; the role of the Commission regarding security of supply (Regulation Articles 126 and 134).

Some of the notable amendments by the European Parliament concern: Member States actively communicating information regarding shortages to healthcare professionals and patients and informing the European Medicines Agency (EMA) about measures taken to mitigate shortages (Regulation Article 121.1.b); patient reporting of shortages (Regulation Article 121.1.ba), the role of the EMA in assessing the mitigation of shortages by Member States (Regulation Article 118.1a) and the codification of the voluntary solidarity mechanism for addressing shortages (Regulation Articles 123 and 130).

III. POLITICAL GUIDANCE ON SUBSTANTIVE ISSUES TO BE DISCUSSED DURING THE TRILOGUE

8. The political issues mentioned above were discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 9 July, 22 September, and 28-29 October.

The Presidency took note of these discussions as well as the guidance provided by Coreper on 1 October and the call for the Presidency to reach an agreement with the European Parliament by the end of this year. Based on the conclusions of those meetings, the Presidency proposes the following.

a) **Antimicrobials and Antimicrobial resistance (AMR)**: It is the Presidency's assessment that an agreement with the European Parliament on the AMR-related topics is within reach in both the Directive and the Regulation. The Presidency believes that a workable compromise might consist of the following:

- i) To keep the Council Mandate on the **Transfer Exclusivity Voucher (TEV)** as a baseline, with an unmodulated extension of regulatory data protection of 12 months, as well as limiting the transfer of vouchers to products with an annual turnover of no more than €490 million.
- ii) As the European Parliament puts great emphasis on providing effective tools to **incentivise the development of novel antimicrobials** in order to fight growing antimicrobial resistance, the Presidency propose to take steps in the European Parliament's direction on this. Based on the discussion in the Working Party the Presidency proposes to show flexibility towards the European Parliament's **concept of a subscription model for joint procurement** on the condition that certain safeguards are ensured for the Member States and that a compromise must respect the Council's principle of fiscal responsibility.
- iii) The concept of making antimicrobials subject to prescription is politically important to the European Parliament. Based on the discussions in the Working Party, the Presidency proposes to show flexibility towards the European Parliament's wording, which emphasises that **all antimicrobials should be subject to prescription**. The Presidency will, however, in accordance with the Council mandate, maintain an exemption that limits unintended consequences of requiring prescriptions for all antimicrobials by allowing **Member States to exempt antimicrobials for topical use from this requirement**.

- iv) The Presidency intends to defend the Council mandate on the Awareness card and the Access plan.

Can delegations support the suggested framework for a provisional agreement on the AMR-provisions as set out above?

- b) **Pharmacy exemption:** It is the Presidency's assessment that an agreement with the European Parliament on the pharmacy exemption is within reach. Based on the guidance from Coreper on 1 October, the Presidency intends to **maintain the Council mandate on a wider scope that includes both pharmacies and hospital- serving pharmacies.** To address EP's concern that the exemption would create a loophole for commercial activities outside of the regulatory approval process, the Presidency intends to show a targeted level of **flexibility** towards accepting a shorter **period** for which medicinal products may be prepared in advance while clarifying that magistral preparation is applicable for preparations for an individual patient where no suitable authorised medicinal product is available.

Can delegations confirm their flexibility for the suggested framework for a provisional agreement on the pharmacy exemption as set out above?

- c) **Market exclusivity for orphan medicinal products, regulatory protection periods and access provisions, including bolar:** The Presidency sees these topics as politically interlinked based on the negotiations thus far with the European Parliament. While these topics are highly political, it is the Presidency's assessment that the political aim of the two mandates are along the same lines. However, for the Presidency to maintain the most important priorities for Member States, some flexibility will be necessary. It is the Presidency's assessment that the next trilogues will be important to task the technical level to ensure landing zones for the trilogue in December. The Presidency therefore seeks political guidance on whether Coreper could in principle be ready to support the following approach.

- i) **On market exclusivity for orphan medicinal products**, the Presidency expects the framework for orphan medicinal products as part of a larger compromise including regulatory protection periods, access provisions and bolar. On this background and based on the discussion in the Working Party the Presidency would like to explore the possibility of reintroducing the concept of High unmet medical need as proposed in EP's mandate, provided that the scope, the criteria attached to it, as well as the differentiation from the existing concept of unmet medical needs, are clear and meaningful.
- ii) **On the Regulatory Protection Periods and the access provision**, the European Parliament has indicated that a simplified framework is necessary if the Council mandate is to be accepted as the basis for a final compromise. The Presidency would therefore like to explore the possibility of simplifying the Councils approach while keeping the core political elements of the mandate.
- iii) **On the Bolar provision**, the positions of the co-legislators are close to each other and aim to achieve the same goal of ensuring fair access to generics as soon as the protection periods expire. The outstanding point from the technical inter- institutional negotiations is the Council's introduction of procurement tenders in the scope of the article. This is set for legal reflection in the European Parliament. The Presidency intends to stick to the Council Mandate on this, however, keeping an open mind for the legal reflection in the European Parliament.

Keeping in mind that an agreement on these provisions is not foreseen at the upcoming trilogue, could delegations however indicate which elements are most important to the European Parliament and under which conditions delegations can show flexibility?

- d) For **Security of supply** there will be an exploratory political exchange of views. Here the Presidency intends to defend the Council Mandate, highlighting the main Council amendments as set out in point 7g of this note. It is the Presidency's expectation that the European Parliament will highlight the need for greater transparency and a more proactive role for MSSG in monitoring and addressing security of supply and the Presidency would therefore ask for Member States' guidance on these issues.

Can delegations provide guidance and indicate under which conditions they could show flexibility regarding the security of supply provisions?

IV. CONCLUSION

10. The Permanent Representatives Committee is invited to examine the Presidency's compromise suggestions as set out in this note and annexed four-column table with a view to provide the Presidency with a mandate for the negotiations with the European Parliament at the upcoming trilogues, scheduled to take place on 11 November 2025.
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