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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Pharmaceutical package: Proposal for a 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 Proposal for a 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 *- Progress report*

Delegations will find in Annex a progress report on the proposals mentioned above, to be presented at the EPSCO (Health) Council on 21 June 2024 with a view to inviting the Council to take note of it.

This report has been drawn up under the responsibility of the Presidency and is without prejudice to particular points of interest or further contributions from individual delegations. It sets out the work done so far by the Council's preparatory bodies and gives an account of the state of play as regards the examination of the above mentioned proposal.

ANNEX

Information from the Presidency on the progress achieved in the examination of the Revision of the pharmaceutical package

I. BACKGROUND

1. On 26 April 2023, the Commission adopted a proposal for the revision of the pharmaceutical legislation, consisting of a Regulation on Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency[1] and a Directive on the Union code relating to medicinal products for human use[2]. 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. The proposals are based on Articles 114(1) and 168(4)(c) of the Treaty of Functioning of the European Union.

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.

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

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.

5. 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.

6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file. The rapporteurs are Tiemo Wölken (S&D, Germany) for the Regulation and Pernille Weiss (EPP, Denmark) for the Directive. 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.

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

II. PROGRESS DURING THE BELGIAN PRESIDENCY

7. During the Belgian Presidency, nineteen WP meetings will have taken place by the date of the Council and two more are foreseen before the end of the Presidency. Detailed discussions took place mainly regarding the 'shortages cluster', consisting of provisions in the Regulation and the Directive dealing with shortage management and security of supply of medicinal products. The WP also discussed the 'incentives cluster', consisting of the regulatory data and market protection modulations, incentives for orphan and paediatric medicinal products and adapted frameworks, including the provisions related to regulatory sandboxes. As of June, the WP started discussing the 'authorisation cluster', focusing on relevant Articles of Chapter II of the proposed Directive and Chapter II of the proposed Regulation, as well as related definitions.

8. Regarding the shortages cluster, based on the examination of the proposals by the Commission, on written comments from delegations and building on discussions in the WP on several revised texts, the Belgian Presidency has put forward a revised text[5] on the shortages cluster to the Working Party on 21 May 2024.

[5] 9425/24

9. The text aims to address the main issues raised by delegations during the examination of the proposals at technical level, by: introducing the possibility for Member States to establish a notification system for certain medicinal products leaving their markets and to take measures to prevent or mitigate shortages, while safeguarding free movement and the internal market, on the basis of the information available to them and with a view to guarantee a stable and safe supply of medicinal products; clarifying the relationship between general notifications and notifications related to shortage management to be made by marketing authorisation holders (MAHs) and adapting certain notification deadlines; further detailing, for critical medicinal products for which MAHs intend to withdraw the marketing authorisation, the procedure for offering to transfer the marketing authorisation to a third party; introducing the possibility for financial penalties to be imposed by the Commission on MAHs for failure to notify a decision to permanently cease or temporarily suspend the marketing of a medicine, or permanently withdraw the marketing authorisation for a product; prioritising the setting up by MAHs of shortage prevention plans (SPP) for products on the Union list of critical medicines, while leaving Member States the option of requesting SPPs for further medicinal products; clarifying the responsibilities of the European Medicines Agency (EMA), the MSSG within the Agency and the Commission in dealing with critical shortages of Union concern; and enhancing clarity as regards the interplay between national lists of critical medicines and the Union list of critical medicines.

10. Following the latest discussions in the Working Party on the shortages cluster on 21 May 2024, the Permanent Representatives Committee, at its meeting of 29 May 2024, took note of a further revised text on the cluster, of the state of play and the principles discussed so far, as well as of the remaining open issues laid down therein.

11. Regarding the incentives cluster, the Presidency presented two revised texts, which aimed to address the main issues raised by delegations during the examination of the proposals at technical level, including the market access incentive, the granting of certain incentives under market protection, rather than data protection periods, the conditions applying to products addressing unmet medical needs, and the exemption to the protection of intellectual property rights.

12. Regarding the authorisations cluster, the Presidency has started the detailed examination of the proposals and aims to submit a first revised text at technical level before the end of June.

III. CONCLUSION

13. The Belgian Presidency considers that the latest revised text on the shortages cluster discussed by Coreper on 29 May 2024 is well balanced following successful work at the WP, while acknowledging there are still open issues. The outstanding issues to be resolved concern:

- in the Regulation: the scope of products to which an obligation to have in place an SPP would apply; the grounds for and rules applying to the notification system for medicinal products leaving national markets; the limits and conditions for the exercise of implementing powers granted to the Commission to improve the security of supply of medicines; the scope of the obligation to offer the transfer of marketing authorisations for medicines being withdrawn from the market; the role of the EMA and its expert bodies in the security of supply governance system; whether the EMA should be able to request additional information on critical medicinal products directly from pharmacies; whether the EMA should publish a compilation of the lists of critical medicines identified by Member States; the possibility derogating, for national security reasons, from the provisions establishing a notification system for certain medicinal products leaving national markets, for products authorised by Member States on public health grounds;

- in the Directive: the actors to which MAHs would be required to ensure appropriate stock levels and continued supply; the possible conflict between provisions regarding the access of national authorities to wholesalers' premises and constitutional law in specific Member States.

14. On the incentives cluster, the Belgian Presidency considers that the main outstanding issues to be resolved are the interplay between regulatory data protection and market protection, the principle of modulation of incentives, as well as the specific incentives, in particular the one on market launch, and the interpretation of (high) unmet medical needs. Key questions regarding this cluster will be addressed during the policy debate at the EPSCO Council (Health) of 21 June 2024.

15. Discussions on the authorisations cluster were opened in June by the Belgian Presidency.