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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 3 December 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.

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].

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1 8759/23
2 8758/23
3 15273/23
4 14863/23

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. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) was designated as responsible committee. The rapporteurs are Tiemo Wölken (S&D, Germany) for the Regulation and Dolors Montserrat (EPP, Spain) 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.

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 cluster' and on the 'authorisations cluster', in addition to a policy debate on the 'incentives cluster' at the EPSCO (Health) Council of 21 June 2024.

II. PROGRESS DURING THE HUNGARIAN PRESIDENCY

7. The Hungarian Presidency organised fourteen WP meetings dedicated to the package, spread over more than 20 negotiating days. Further to the progress achieved under the Belgian Presidency[5], detailed discussions took place regarding: the 'incentives cluster', consisting of provisions dealing with the regulatory data and market protection modulations, incentives for orphan and paediatric medicinal products, adapted frameworks, provisions related to regulatory sandboxes, and incentives for the development of priority antimicrobials. This cluster has been discussed at six Council WPs, comprising five compromise texts. Additional topics have been: the 'authorisations cluster', consisting of provisions on national and centralised marketing authorisations (MA); post MA measures, restrictions and variations; the temporary emergency marketing authorisation (TEMA); subject matter and scope; the governance of the European Medicines Agency; the 'shortages cluster', consisting of provisions dealing with shortage management and security of supply of medicinal products; and on provisions dealing with orphan and paediatric medicinal products.

8. Based on the examination of the proposals by the Commission, on written comments from delegations and building on discussions in the WP, in some cases based on several earlier revised texts, the Hungarian Presidency has, in order to address the main issues raised by delegations:

[5] 9557/24

– put forward a further revised text[6] regarding incentives to the WP on 13 November 2024. This was the fifth compromise text prepared by the Hungarian Presidency and aimed at: further adapting the proposed modulation of the regulatory data protection periods to offer meaningful incentives to support needs-based innovation, while reducing the complexity of the proposed system and setting an upper time limit for the period of protection; introducing the possibility for Member States to require marketing authorisation holders (MAHs) to make available and continuously supply medicinal products on their markets, as well as sanctions and the non-application of market protection in the affected Member States, for cases where such requirements are not met; improving the transparency of data and market protection periods; clarifying the conditions that apply to products addressing unmet medical needs; further specifying the activities and decisions to which the exemption to the protection of intellectual property rights (the Bolar exemption) applies; reinstating the current market exclusivity duration for orphan medicines and removing the concept of high unmet medical needs, together with the related extensions of market exclusivity; introducing provisions to monitor the effectiveness of the voucher for priority antimicrobials, and keeping it operational, while limiting the potential costs linked to its transfer;

– put forward a revised text[7] on central marketing authorisations to the WP on 7-8 October 2024, aimed at clarifying various aspects in relation to the marketing authorisation for simplified and more agile regulatory procedures for innovative medicines and generics and biosimilars, digitalisation and better use of data, GMO clinical trials, align emergency authorisations, conditional authorisations and temporary emergency authorisations (TEMA)

[6] 15044/24
[7] 13868/24

– put forward a further revised text[8] on national marketing authorisations (NMA) to the WP on 7-8 November 2024, aimed at: maintaining the current deadline for the completion by the Member States of the procedure for granting a marketing authorisation; requesting the submission of high quality translation of the SMPC, the labelling and the package leaflet from the applicants for a NMA under the decentralised (DCP) and mutual recognition procedures (MRP); streamlining the work of the coordination group for decentralised and mutual recognition procedures (CMDH) and the Committee for Medicinal Products for Human Use (CHMP) with regard to diverging positions in DCP and MRP and to the harmonisation of the SMPC; clarifying the conditions under which deficiencies of the environmental risk assessment can lead to granting an NMA subject to conditions or to the refusal of an NMA;

– put forward a revised text[9] on post-marketing authorisations, restrictions and variations to the WP on 7-8 November 2024, aimed at: clarifying that the environmental risk assessment is not part of the risk management system; introducing the possibility of reducing the burden associated with additional inspections in case of differences in opinion between Member States regarding compliance with manufacturing and importing requirements;

– put forward a revised text[10] on temporary emergency marketing authorisations (TEMA) to the WP on 7-8 November 2024, aimed at: requiring MAHs to replace a TEMA with a standard or conditional marketing authorisations as soon as sufficient supporting data have been generated; leaving the flexibility for Member States to temporarily authorise the use of non-authorised products that are also subject to TEMA; making the link between TEMA assessment and the rolling review by the Emergency Task Force the EMA extended mandate regulation);

[8] 15036/24
[9] 15039/24
[10] 15042/24

– put forward a revised text[11] on shortages to the WP on 12 November 2024 aimed at: clarifying derogations from the provisions of this chapter; making progress in defining the scope of shortage prevention plans (SPP), while avoiding fragmented national approaches, by making SPPs applicable only to medicines identified as critical by the competent authorities of the Member States using the EU methodology, and to other medicines on the basis of the recommendations given by the Medicines Shortages Steering Group (MSSG); introducing the requirement, for medicines not subject to an SPP obligation, that MAH conduct regular and documented risk assessments of potential supply chain risks; clarifying notification requirements in case of parallel trade; framing the limits and conditions for the exercise of implementing powers granted to the Commission to improve the security of supply of critical medicines;

– put forward a revised text on the subject matter and scope to the WP on 21 November 2024 aimed at future proofing classifications and further harmonising exemptions from the pharmaceutical legislation;

– put forward a revised text on the EMA governance on 22 November aimed at modernising the system for scientific and technical assessments, while ensuring high quality assessments on a parity basis in Member States including for advanced therapy medicinal products, paediatric and orphan medicines and while supporting stronger patients' and health professionals' representatives, the voting rights of Member States have been reinforced.

[11] 15067/24

III. CONCLUSION

9. The Hungarian Presidency considers that the latest revised texts, covering close to two-third of the articles in the Pharmaceutical package, are well balanced and constitute a good basis for continued discussion, while acknowledging there are still open issues.

   The main outstanding issues to be resolved in the parts of the proposals examined so far concern: modulation of incentives, ensuring more equal market access and continuous supply to innovative medicinal products for all Member States; ensuring that the combined provisions of the opt-in by Member States to MRP and DCP, and of the requirement that MAHs make available and continuously supply medicinal products on certain markets, do not infringe on companies' freedom to conduct business and are proportionate to the aims pursued; ensuring the sustainability of the costs generated for health systems by the use of the transferable data exclusivity voucher for priority antimicrobials; ensuring that provisions regarding the environmental risk assessment will not affect the availability of well established medicines on the market.

   In addition, the scope of adapted frameworks and sandboxes, the definition of "not-for-profit entities", Union penalties regarding certain notification obligations by MAHs, the limits and conditions for the exercise of implementing powers granted to the Commission to improve the security of supply of critical medicines, as well as the delegated act regarding the SPP require further legal consideration.

10. The Hungarian Presidency aims to put forward a first revised text on orphan and pediatric medicinal products to the WP of 29 November and further revised texts on the shortages and incentives clusters to the WP of 9 December.

11. The Hungarian Presidency aims to continue the negotiations on the proposal and to put forward a combined revised compromise text, bringing together all the parts of the proposals examined so far, together with a state of play, for the Permanent Representatives Committee, to discuss and to take note of, in its meeting of 18 December 2024.