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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices – <i>Analysis of the final compromise text with a view to agreement</i>

I. INTRODUCTION

1. On 12 November 2020, the Commission submitted the proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices to the Council and to the European Parliament.
2. The proposal is based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

3. The proposal is part of a set of three proposals aiming to strengthen the EU's health security framework and to reinforce the crisis preparedness and response role of key EU agencies. Together they are the first building block of the European Health Union. The proposal was not accompanied by an impact assessment. The objectives of the proposal are to:
- monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address public health emergencies and other major events which may have a serious impact on public health;
 - ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing public health emergencies;
 - provide the structure for the functioning of expert panels that assess high-risk medical devices and provide essential advice in crisis preparedness and management.
4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. While the French Senate raised subsidiarity concerns, the Portuguese and the Spanish Parliaments considered that the proposal complied with the subsidiarity principle.
5. The European Economic and Social Committee and the Committee of the Regions were both consulted. The Committee of the Regions adopted its opinion on the proposal during its 144th plenary session (5-7 May 2021). The European Economic and Social Committee, at its session on 27 April 2021, gave its opinion on “Building a European Health Union”, which included this proposal.
6. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file. The European Parliament appointed MEP Nicolás González Casares (S&D, ES) as Rapporteur. The Plenary voted on the file on 8 July 2021. Council reached a General Approach on 15 June 2021¹. This was the basis for the Presidency to enter into negotiations with the European Parliament in July 2021.

¹ Doc 9764/21

7. After the start of negotiations, it became clear that additional flexibility would be necessary for the Presidency to move forward successfully the discussion with the European Parliament. At its meeting on 24 September 2021, the Permanent Representatives Committee approved a revised mandate².
8. Three trilogues took place on 13 July, 30 September and 28 October 2021. In addition, twelve technical meetings were held on 2, 6, 13, 14, 15, 20 September, on 13, 21, 25, 26 October, and finally on 28 and 29 October 2021.
9. At the last trilogue, on which the Presidency debriefed Coreper at its meeting of 5 November 2021, the co-legislators provisionally agreed on an overall compromise text, set out in document 13307/21.

The main elements of this compromise text are outlined in Section II below. The Presidency considers that the overall compromise package reached with the European Parliament is balanced and that it respects the mandate the Presidency received.

II. COMPROMISE PACKAGE

a) Amendments on patient data and transparency

10. The European Parliament dropped its insistence on having its Amendment 93 on patient data in Article 11(4a) new. Instead of an obligation for Member States to facilitate the collection of patient data and to share this data with the Medicines Shortages Steering Group (MSSG), the co-legislators agreed on a recital referring to the possibility for Member States to collect such data (new recital 13c).

² Doc 11751/1/21 REV 1

11. The co-legislators found a compromise on transparency in Amendment 99 (Article 13(1)(a) new) and in Amendment 140 (Article 27(1)(a) new) where the Council's red line of not publishing voting and dissenting opinions was upheld. Instead, a sentence was added that allows national competent authorities to request dissenting opinions of the members of the MSSG, should the rules of procedure of the MSSG provide for dissenting opinions to be recorded.

b) Amendments on the database and penalties

12. On the database, which is now called the "European Shortages Monitoring Platform" (ESMP) (Article 12a), the co-legislators agreed on a compromise based:

- (i) on the Presidency's alternative option, approved in the revised mandate, "to update the existing database referred to in Article 57(1)i of Regulation 726/2004 with a dataset enabling high level reporting of status of supply, demand and shortages of medicinal products at Union and MS level."
- (ii) on there being no new national databases and no real time monitoring.

This Platform is to be in place 36 months after the Regulation enters into force, which EMA considers feasible.

As part of the compromise for the European Parliament to accept 36 months and to drop its requests for new national databases and real time monitoring, the review clause (Article 30c) was expanded as follows:

- (i) the Commission would present a report on "the remit and functioning of the ESMP" (Article 30c, paragraph 1c);

- (ii) based on this report, the Commission shall consider:
“the need to expand the remit of the ESMP, the need to further facilitate the ESMP interoperability with national and EU systems, the need for national shortages monitoring platforms, and the need to meet any additional requirements to address structural shortages of medicinal products, introduced as part of a revision of Directive 2001/83/EC and Regulation (EC) No 726/2004.”
(Article 30c, paragraph 2d).

13. On penalties, the European Parliament agreed to drop its Amendment 144 and the obligation for Member States to lay down rules on penalties. The co-legislators agreed instead on certain provisions in the review clause whereby:

- (i) the Commission would present a report on “non-compliance with the obligations set out in Articles 10 and 24 of the Regulation” (Article 30c, paragraph 1b).

Under Article 10, market authorisation holders have to provide information to the Agency on request, including on potential or actual shortages of medicinal products, available stocks, forecasts of supply and demand, and prevention and mitigation plans. Under Article 24, medical device manufacturers, or their authorised representatives and, if appropriate, importers and distributors have to do the same for medical devices.

- (ii) based on this report, the Commission would consider the need to propose additional measures to strengthen at EU or national level the compliance with the obligations established in Articles 10 and 24 of this Regulation (Article 30c, paragraph 2c).

c) Other issues

14. The co-legislators also agreed:

- (i) on the definition of “shortage”, Amendment 48, (Article 2(1)(d)), with the following wording:

""shortage" means that supply of a medicinal product for human use that is authorised and placed on the market in a Member State or of a CE-certified medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause"

which reflects that the definition of a shortage when applied to medicinal products refers solely to those medicinal products authorised and placed on the market in a Member State. The term ‘whatever the cause’ is therefore intended to reflect that the underlying causes of shortages are diverse;

- (ii) that the transfer of the expert panels for medical devices from the Commission to EMA would be on 1 March 2022 (Article 28(1)) and that Chapter IV on medical devices, except for this transfer, would apply one year after the entry into force of the Regulation (Article 31(3));
- (iii) on the following technical issues, on the basis of the Council’s position as agreed in the revised mandate:
- the definition of demand, Amendment 47, (Article 2(1)(cb));
 - Article 6.0 defining the main therapeutic groups of medicinal products;

- Treaty language to replace the obligation for Member States to comply with any measures taken at Union level by an obligation to coordinate their actions related to any such measures (Articles 11(4)(a) and 25(4)(b));
- Article 30b on Union funding.

d) Provisional agreements reached at technical level

15. The co-legislators validated, ‘ad referendum’, the provisional agreements reached at technical level.

III. CONCLUSION

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

- to give its approval to the compromise text set out in document 13307/21,

and
- to mandate the Presidency to send a letter to the Chair of the ENVI Committee of the European Parliament confirming that, should the Parliament adopt its position at first reading in accordance with Article 294(3) TFEU and in the exact form set out in document 13307/21 - subject to legal-linguistic revision - the Council would, in accordance with Article 294(4) TFEU, approve the European Parliament's position and the act would be adopted in the wording which corresponds to the European Parliament's position.