



Council of the  
European Union

Brussels, 10 November 2023  
(OR. en)

15273/23

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**Interinstitutional File:**  
**2023/0131(COD)**

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SAN 650  
PHARM 143  
MI 956  
COMPET 1092  
VETER 101  
ENV 1276  
RECH 494  
CODEC 2099  
IA 296

#### COVER NOTE

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From: Secretary-General of the European Committee of the Regions  
date of receipt: 24 October 2023  
To: Ms Thérèse BLANCHET, Secretary-General of the Council of the  
European Union

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Subject: 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  
*- Renunciation letter from the Committee of the Regions (CoR)*

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Delegations will find attached a renunciation letter from the Committee of the Regions (CoR)  
regarding consultation on file 2023/0131 (COD).

E-MAIL



**European Committee  
of the Regions**

The Secretary-General

IM 011946 2023  
24-10-2023

Brussels, date of official registration  
SGCab/DTAv – D/998 (2023)

Thérèse Blanchet  
Secretary-General  
Council of the European Union  
Rue de la Loi / Wetstraat 175  
1049 Bruxelles / Brussel

Dear Secretary-General,

On behalf of the President of the European Committee of the Regions (CoR), Vasco Alves Cordeiro, I would like to thank you for your referral request, dated 21.09.2023, regarding the following dossier:

*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 - COM (2023) 193 - 2023/0131 COD.*

The CoR's Commission for Natural Resources (NAT) decided at its meeting on 1 June 2023 not to issue an opinion on this proposal and not to include the dossier into the ongoing work of the CoR. The proposal has little regional or local relevance; the procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency are a matter dealt with by competent European and national authorities.

Should you require any further information, please do not hesitate to contact the NAT secretariat ([nat@cor.europa.eu](mailto:nat@cor.europa.eu)).

Yours sincerely,

Petr Bližkovský

Cc: Vasco Alves Cordeiro, President of the European Committee of the Regions  
Didier Seeuws, Director-General of the Council of the European Union

Rue Belliard/Belliardstraat 101 | 1040 Bruxelles/Brussel | BELGIQUE/BELGIË | Tel. +3223822009 | [sgcab-cor@cor.europa.eu](mailto:sgcab-cor@cor.europa.eu)  
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Electronically signed by BLIZKOVSKY Petr on 23/10/2023 12:24