Council of the European Union

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LIMITE

SAN 257
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MI 458
COMPET 492
VETER 62
ENV 476
RECH 204
CODEC 1209
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WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	8216/24
Subject:	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 *- Exchange of views*

In document 9425/24 INIT, page three, the recital 137a should read as follows: (changes compared to 9425/24 INIT are place in *italics*).

(137a) The phenomenon of parallel trade in medicinal products *and the export of medicinal products*, ~~*concerns*~~ *where* medicinal products *are* traded from one Member State to another Member State or third country *can impact the availability of medicinal products in Member States*. While the Court of Justice has ruled that parallel trade fosters the free movement of medicinal products and is therefore beneficial to the internal market , it has also recognised that the need to ensure that a country has reliable supplies for essential medical purposes, in particular a supply of medicinal products to the public that is reliable and of good quality, may, under Article 36 TFEU, justify a restriction on trade between Member States if that objective contributes to protecting human health and human life. Therefore, it should be possible for a Member State to require, for certain medicinal products, to establish a system of notification whenever one of these products leaves the Member State in question to be distributed elsewhere. On the basis of this notification and the information at its disposal, including shortage prevention plans, the Member State should be able to take measures to mitigate shortages. These measures should also be appropriate and proportionate to such objectives and take into account that the principles of the free movement of goods are restricted only for the purpose of safeguarding public health, thus respecting the case law of the Court of Justice of the European Union and the Treaties, notably the provisions on free movement and competition. It is important to recognise that parallel import can contribute to the objective of access to medicines, notably in smaller or vulnerable markets.