Ændringsforslag 99
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for Verts/ALE-Gruppen

Betænkning **A9-0042/2024**
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Udstedelse af tvangslicens med henblik på krisestyring og om ændring af forordning (EF) nr. 816/2006
(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

Forslag til forordning
Artikel 11 – stk. 1

Kommissionens forslag	*Ændringsforslag*
Det ***er forbudt*** at eksportere produkter, der er fremstillet i henhold til EU-tvangslicensen***.***	***1.*** Det ***skal begrænses til følgende tilfælde*** at eksportere produkter, der er fremstillet i henhold til EU-tvangslicensen***:***
	(i) eksport af den ikke-overvejende del af farmaceutiske produkter og sundhedsprodukter
	(ii) hvor forordning (EF) nr. 816/2006 finder anvendelse.
	2. Kommissionen fastsætter ved hjælp af en gennemførelsesretsakt betingelserne for, hvornår en ikke-overvejende del af de farmaceutiske produkter og sundhedsprodukter, der er fremstillet i henhold til en EU-tvangslicens, kan eksporteres til tredjelande. Gennemførelsesretsakten vedtages efter den i artikel 24, stk. 2 omhandlede rådgivningsprocedure, og træder i kraft samtidig med den gennemførelsesretsakt om udstedelse af EU-tvangslicens, der er omhandlet i artikel 7, stk. 7.

Or. en

Begrundelse

The use of a Union compulsory license will likely be triggered by situations that would affect not only EU countries but also countries outside of the EU, either in the region or globally. In order to draw the lessons from the Covid crisis, where we have seen that viruses do not stop at national frontiers, this amendment would allow to partially export to non-EU countries pharmaceutical or health products for which a Union compulsory license has been granted

according to this Regulation. Instead of a blank prohibition of exports for all kinds of products subject of a Union compulsory license, this new wording would allow to delineate the exception to the prohibition of export to the category of pharmaceutical and health products, in accordance with the TRIPS Agreement (Article 31(f)). There would be no obligation to export: Member States would still remain free to decide. Member States already have national rules on compulsory licensing and can decide to export pharmaceutical and health products to third countries. This regulation creating a Union compulsory license should entail some level of harmonisation of these rules and practices regarding export, while still leaving the decision to Member States. It is to be noted that the Commission would issue an implementing act aiming to set the guidelines on how these products subject to a Union compulsory license would be exported, wherein the conditions will be specified further.