Amandman 99
Heidi Hautala
u ime Kluba zastupnika Verts/ALE-a

Izvješće **A9-0042/2024**
Adrián Vázquez Lázara
Obvezno licenciranje za upravljanje krizom i izmjena Uredbe (EZ) br. 816/2006
(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

Prijedlog uredbe
Članak 11. – stavak 1.

Tekst koji je predložila Komisija	*Izmjena*
Zabranjuje se izvoz proizvoda koji se proizvode na temelju obvezne licencije Unije***.***	***1.*** Izvoz proizvoda koji se proizvode na temelju obvezne licencije Unije ***ograničava se na sljedeće slučajeve:***
	i. izvoz neprevladavajućeg dijela farmaceutskog ili zdravstvenog proizvoda,
	ii. u slučajevima primjene Uredbe (EZ) br. 816/2006.
	2. Komisija provedbenim aktom utvrđuje uvjete pod kojima se neprevladavajući dio farmaceutskih ili zdravstvenih proizvoda proizvedenih na temelju obvezne licencije Unije može izvoziti u treće zemlje. Provedbeni akt donosi se u skladu sa savjetodavnim postupkom iz članka 24. stavka 2. i stupa na snagu istodobno s provedbenim aktom kojim se izdaje obvezna licencija Unije iz članka 7. stavka 7.

Or. en

Obrazloženje

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.