



**2023/0129(COD)**

28.11.2023

# **OPINION**

of the Committee on International Trade

for the Committee on Legal Affairs

on the Proposal for a Regulation of the European Parliament and of the Council  
on Compulsory licensing for crisis management and amending Regulation  
(EC) 816/2006

(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

Rapporteur for opinion: Helmut Scholz

PA\_Legam

## AMENDMENTS

The Committee on International Trade calls on the Committee on Legal Affairs, as the committee responsible, to take the following into account:

### Amendment 1

#### Proposal for a regulation Recital 3

*Text proposed by the Commission*

(3) The possibility of using compulsory licences ***in situations of national emergency or other circumstances of extreme urgency*** is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')<sup>3</sup>.

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214

*Amendment*

(3) The possibility of using compulsory licences is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')<sup>3</sup>. ***The Doha Declaration on the TRIPS Agreement states that each WTO Member has not only the right to grant compulsory licences, but also the freedom to determine the grounds upon which such licences are granted. The TRIPS Agreement, in Article 31bis, specifically allows for the export of products made with a compulsory license. Over the past two decades, a compulsory license for export has only been used once worldwide.***

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214

### Amendment 2

#### Proposal for a regulation Recital 28

*Text proposed by the Commission*

(28) ***It is imperative that*** products manufactured under a Union compulsory licence ***reach only*** the internal market. The Union compulsory licence should therefore ***impose*** clear conditions ***upon*** the licensee as regards the activities authorised under the licence, ***including the territorial reach***

*of those activities. The rights-holder should be able to challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council<sup>9</sup>. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder.*

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<sup>9</sup> Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

conditions *for* the licensee *as well as the rights-holder* as regards the activities authorised under the licence, *which* do not *exceed those agreed under TRIPS*.

Directive 2004/48/EC of the European Parliament and of the Council<sup>9</sup> *should not impede the legitimate production and supply of pharmaceutical* products manufactured under a compulsory *licence as provided by law*.

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<sup>9</sup> Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).

### Amendment 3

#### Proposal for a regulation Recital 29

*Text proposed by the Commission*

(29) A Union compulsory licence *in the context of a Union crisis or emergency mechanism* should *only* be granted to supply the internal market with *crisis-relevant* products. *Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.*

### Amendment 4

#### Proposal for a regulation Recital 30

*Amendment*

(29) A Union compulsory licence *under this Regulation* should be granted to *predominantly* supply the internal market with *relevant* products. A Union compulsory licence *exclusively for export should be permitted under the conditions established in Regulation (EC) No 816/2006.*

(30) Customs authorities should ensure, ***through a risk analysis approach***, that products manufactured under a Union compulsory license are not exported. To identify such products, the ***main source of information to feed such customs risk-analysis*** should ***be*** the Union compulsory license ***itself***. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447<sup>10</sup>. When customs authorities identify a product that is suspected not to comply with the export ***prohibition***, they should ***suspend the export of that product and*** notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export ***prohibition*** within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission ***may*** consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export ***prohibition***, customs authorities should refuse its export.

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<sup>10</sup> Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

(30) Customs authorities should ensure that products manufactured under a Union compulsory license are not exported, ***except when allowed by relevant EU legislation or the flexibilities foreseen in the TRIPS Agreement***. To identify such products, the ***custom authorities*** should ***take into account*** the Union compulsory license. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447<sup>10</sup>. When customs authorities identify a product that is suspected not to comply with the export ***restriction***, they should notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export ***restriction*** within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment, the Commission ***should be able to*** consult the relevant rights-holder ***and other relevant stakeholders***. Where the Commission concludes that a product does not comply with the export ***restriction***, customs authorities should refuse its export.

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<sup>10</sup> Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

## **Amendment 5**

**Proposal for a regulation**  
**Recital 37**

*Text proposed by the Commission*

(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also ***under certain conditions*** for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council<sup>11</sup>. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence ***under***, for the purposes and within

*Amendment*

(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council<sup>11</sup>. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This ***should be further facilitated by reviewing the conditions for issuing compulsory licences for export, in order to make it fully in line with the TRIPS Agreement and its full spectrum of flexibilities. A Union compulsory licence will facilitate the use of this mechanism and all the*** manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than

the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.

one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.

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<sup>11</sup> Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

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<sup>11</sup> Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

## Amendment 6

### Proposal for a regulation Recital 40

#### *Text proposed by the Commission*

(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated

#### *Amendment*

(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation. ***If no***

assessment of this Regulation.

***compulsory licence has been granted within a timespan of five years, an automatic evaluation should be triggered which reviews and adjusts where necessary, among others, the conditions for issuing compulsory licences.***

#### **Amendment 7**

##### **Proposal for a regulation Article 5 – paragraph 1 – point e**

*Text proposed by the Commission*

*Amendment*

**(e) be limited to the territory of the Union;**

***deleted***

#### **Amendment 8**

##### **Proposal for a regulation Article 6 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

**(b) the analysis of *the crisis-relevant* information gathered by Member States or the Commission and aggregated data received by other *crisis-relevant* bodies at Union and international level;**

**(b) the analysis of *all relevant* information gathered by Member States or the Commission and aggregated data received by other *relevant* bodies at Union and international level;**

#### **Amendment 9**

##### **Proposal for a regulation Article 6 – paragraph 2 – point c**

*Text proposed by the Commission*

*Amendment*

**(c) the facilitation of exchanges and sharing of information with other relevant *bodies and other crisis-relevant* bodies at Union and national level, as well as at international level, where appropriate;**

**(c) the facilitation of exchanges and sharing of information with other relevant bodies at Union and national level, as well as at international level, where appropriate;**

#### **Amendment 10**



**Proposal for a regulation**  
**Article 11**

*Text proposed by the Commission*

***Prohibition of export***

The ***export of*** products manufactured under a Union compulsory licence ***is prohibited***.

*Amendment*

***Destined use of products***

***1. The products manufactured under a Union compulsory licence shall be destined predominantly for the supply of the internal market, except for products exclusively destined for export under Regulation 816/2006.***

***2. The Commission shall, by means of an implementing act, set out the conditions under which a non-predominant part of the products manufactured under a Union compulsory licence may be exported to third countries. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2) and enter into force at the same time as the implementing act granting the Union compulsory licence, referred to in Article 7(7).***

**Amendment 11**

**Proposal for a regulation**  
**Article 12 – paragraph 3**

*Text proposed by the Commission*

3. Where customs authorities identify a product that may fall under ***the prohibition*** laid down in Article 11, they ***shall suspend its export. Customs authorities*** shall immediately notify the Commission ***of the suspension*** and provide it with all relevant information to enable ***it*** to establish whether the product was manufactured under a Union compulsory licence. ***To assess whether the suspended products correspond to the Union compulsory licence***, the Commission may consult the relevant rights-holder.

*Amendment*

3. Where customs authorities identify a product that may fall under ***restrictions*** laid down in Article 11, they shall immediately notify the Commission and provide it with all relevant information to enable ***the Commission*** to establish whether the product was manufactured under a Union compulsory licence. ***Before taking a decision to suspend the export***, the Commission may consult the relevant rights-holder ***and other relevant stakeholders***.

## Amendment 12

### Proposal for a regulation Article 12 – paragraph 5

*Text proposed by the Commission*

5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the **prohibition** laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.

*Amendment*

5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the **restrictions** laid down in Article 11, customs authorities shall not authorise its release for export. The Commission shall inform the concerned rights-holder of such non-compliance.

## Amendment 13

### Proposal for a regulation Article 12 – paragraph 6 – introductory part

*Text proposed by the Commission*

6. Where the **release for export of a product has not been authorised**:

*Amendment*

6. Where the **Commission concludes that a product manufactured under a Union compulsory license does not comply with the restrictions laid down in Article 11**:

## Amendment 14

### Proposal for a regulation Article 12 – paragraph 6 – point a

*Text proposed by the Commission*

(a) where appropriate **in view of the crisis or emergency context**, the Commission may **require customs authorities to oblige** the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.

*Amendment*

(a) where appropriate, the Commission may **request** the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law

## Amendment 15

### Proposal for a regulation Article 12 – paragraph 6 – point b

*Text proposed by the Commission*

(b) in all other cases, **customs authorities** may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. **Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.**

*Amendment*

(b) in all other cases, **the Commission** may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law.

## Amendment 16

### Proposal for a regulation Article 23 – paragraph 1 – point -a (new) Regulation (EC) 816/2006 Article 6 – paragraph 2

*Present text*

2. If the person applying for a compulsory licence is submitting applications to authorities **in more than one country** for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.

*Amendment*

**-a. Article 6(2) is amended as follows:**

**2. If the person applying for a compulsory licence is submitting multiple applications to authorities for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.**

## Amendment 17

### Proposal for a regulation Article 23 – paragraph 1 – point -a a (new) Regulation (EC) 816/2006 Article 6 – paragraph 3 – point c

*Present text*

*Amendment*

**-a a. Point (c) of Article 6(3) is amended**

(c) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

*as follows:*

(c) the *expected* amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

## **Amendment 18**

### **Proposal for a regulation**

#### **Article 23 – paragraph 1 – point -a b (new)**

Regulation (EC) 816/2006

Article 6 – paragraph 3 – point e

*Present text*

*Amendment*

(e) where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9

**-a b. Point (e) of Article 6(3) is amended as follows:**

(e) where applicable, evidence of *efforts of* prior negotiation with the rights-holder pursuant to Article 9;

## **Amendment 19**

### **Proposal for a regulation**

#### **Article 23 – paragraph 1 – point -a c (new)**

Regulation (EC) 816/2006

Article 6 – paragraph 3 – point f

*Present text*

*Amendment*

(f) evidence of a specific request from : [...] indicating the quantity of product required.

**-a c. Point (f) of Article 6(3) is amended as follows:**

(f) evidence of a specific request from: [...] indicating the *expected* quantity of product required.

## **Amendment 20**

### **Proposal for a regulation**

#### **Article 23 – paragraph 1 – point -a d (new)**

Regulation (EC) 816/2006

Article 7

*Present text*

The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority **shall** give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

**Amendment 21**

**Proposal for a regulation**

**Article 23 – paragraph 1 – point -a e (new)**

Regulation (EC) 816/2006

Article 9 – paragraph 1

*Present text*

1. The applicant shall provide evidence to **satisfy** the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

**Amendment 22**

**Proposal for a regulation**

**Article 23 – paragraph 1 – point -a f (new)**

Regulation (EC) 816/2006

Article 10 – paragraph 1

*Present text*

1. The licence granted shall be non-assignable, except with that part of the

*Amendment*

**-a d. Article 7 is amended as follows:**

The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority **may** give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

*Amendment*

**-a e. Article 9(1) is amended as follows:**

1. The applicant shall provide evidence to the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

*Amendment*

**-a f. Article 10(1) is amended as follows:**

1. The licence granted shall be non-assignable, except with that part of the

enterprise or *goodwill which enjoys* the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.

enterprise or *organisation that makes use of* the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.

## Amendment 23

### Proposal for a regulation

#### Article 23 – paragraph 1 – point -a g (new)

Regulation (EC) 816/2006

Article 10 – paragraph 2

#### *Present text*

2. The amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.

#### *Amendment*

*-a g. Article 10(2) is amended as follows:*

2. The *expected* amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.

## Amendment 24

### Proposal for a regulation

#### Article 23 – paragraph 1 – point -a h (new)

Regulation (EC) 816/2006

Article 10 – paragraph 8

#### *Present text*

8. The competent authority may *at the request of the rightsholder or* on its own initiative, if national law allows the competent authority to act on its own initiative, request *access to books and records kept by* the licensee, *for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the*

#### *Amendment*

*(-a h) Article 10(8) is amended as follows:*

8. The competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, *request from* the licensee proof of exportation of the product, through a declaration of exportation, certified by the customs authority concerned, and proof of importation from one of the bodies referred

*products, have been met. The books and records shall include* proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).

to in Article 6(3)(f).

## Amendment 25

### Proposal for a regulation

#### Article 23 – paragraph 1 – point a

Regulation (EC) 816/2006

Article 18a – paragraph 1

*Text proposed by the Commission*

1. The Commission may grant a compulsory licence *where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.*

*Amendment*

1. The Commission may *also* grant a compulsory licence *of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.*

## Amendment 26

### Proposal for a regulation

#### Article 23 – paragraph 1 – point a

Regulation (EC) 816/2006

Article 18a – paragraph 2

*Text proposed by the Commission*

2. Any person may submit an application for a compulsory licence under paragraph 1. *The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.*

*Amendment*

2. Any person may submit an application for a compulsory licence under paragraph 1. *The application shall fulfil the following requirements:*

- (a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;*
- (b) the non-proprietary name of the*

*pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;*

*(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;*

*(d) the importing country or countries;*

*(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;*

*(f) evidence of a specific request from:*

*(i) authorised representatives of the importing country or countries; or*

*(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or*

*(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries.*

## Amendment 27

**Proposal for a regulation**  
**Article 23 – paragraph 1 – point a**  
 Regulation (EC) 816/2006  
 Article 18a – paragraph 3

*Text proposed by the Commission*

3. The compulsory licence granted in accordance with paragraph 1 ***shall be subject to the conditions set out in Article 10 and*** shall specify that it is applicable to the whole territory of the Union.

*Amendment*

3. The compulsory licence granted in accordance with paragraph 1 shall specify that it is applicable to the whole territory of the Union ***and shall be subject to the following conditions:***

- (a) The licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions as set out in this paragraph;***
- (b) The expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or***



*countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere;*

*(c) The duration of the licence shall be indicated;*

*(d) The licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question;*

*(e) Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States;*

*(f) Before shipment to the importing country or countries cited in the application, the licensee shall post on a website the following information:*

*(i) the quantities being supplied under the licence and the importing countries*

*to which they are supplied;*  
*(ii) the distinguishing features of the product or products concerned.*  
*The website address shall be communicated to the competent authority.*

*(g) If the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale and/or distribution of the products;*

*(h) The competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, request from the licensee proof of exportation of the product, through a declaration of exportation, certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 18a(2)(e);*

*(i) The licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the competent authority as follows:*

*(i) in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf;*

*(ii) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence.*

*(j) The licence conditions are without prejudice to the method of distribution in the importing country.*

*Distribution may be carried out for example by any of the bodies listed in Article 18a (2)(f) and on commercial or non-commercial terms including completely without charge.*

## Amendment 28

### Proposal for a Regulation

#### Article 23 – paragraph 1 – point a

Regulation 816/2006/EC

Article 18a – paragraph 5 – second subparagraph

#### *Text proposed by the Commission*

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to ***the impacts of the*** public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).

#### *Amendment*

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).

## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Compulsory licensing for crisis management and amending Regulation (EC) 816/2006
<b>References</b>	COM(2023)0224 – C9-0151/2023 – 2023/0129(COD)
<b>Committee responsible</b> Date announced in plenary	JURI 12.6.2023
<b>Opinion by</b> Date announced in plenary	INTA 12.6.2023
<b>Associated committees - date announced in plenary</b>	5.10.2023
<b>Rapporteur for the opinion</b> Date appointed	Helmut Scholz 24.5.2023
<b>Discussed in committee</b>	19.9.2023
<b>Date adopted</b>	28.11.2023
<b>Result of final vote</b>	+: 20 –: 13 0: 1
<b>Members present for the final vote</b>	Barry Andrews, Anna-Michelle Asimakopoulou, Tiziana Beghin, Geert Bourgeois, Saskia Bricmont, Daniel Caspary, Paolo De Castro, Markéta Gregorová, Heidi Hautala, Danuta Maria Hübner, Karin Karlsbro, Martine Kemp, Miapetra Kumpula-Natri, Bernd Lange, Margarida Marques, Gabriel Mato, Sara Matthieu, Emmanuel Maurel, Carles Puigdemont i Casamajó, Samira Rafaela, Catharina Rinzema, Inma Rodríguez-Piñero, Helmut Scholz, Joachim Schuster, Mihai Tudose, Kathleen Van Brempt, Marie-Pierre Vedrenne, Jörgen Warborn, Iuliu Winkler, Jan Zahradil, Juan Ignacio Zoido Álvarez
<b>Substitutes present for the final vote</b>	Michiel Hoogeveen, Javier Moreno Sánchez, Ralf Seekatz

**ANNEX: ENTITIES OR PERSONS  
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that he has received input from the following entities or persons in the preparation of the opinion, until the adoption thereof in committee:

<b>Entity and/or person</b>
Health Action International
Medicins sans Frontieres
Drugs for Neglected Diseases Initiative
Medicines Law & Policy
University of Amsterdam
Pramiti Parwani (University of Amsterdam)
Representatives from Unit C.4 – Intangible Economy (DG GROW)

The list above is drawn up under the exclusive responsibility of the rapporteur.

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

20	+
NI	Tiziana Beghin, Carles Puigdemont i Casamajó
Renew	Barry Andrews, Samira Rafaela, Marie-Pierre Vedrenne
S&D	Paolo De Castro, Miapetra Kumpula-Natri, Bernd Lange, Margarida Marques, Javier Moreno Sánchez, Inma Rodríguez-Piñero, Joachim Schuster, Mihai Tudose, Kathleen Van Brempt
The Left	Emmanuel Maurel, Helmut Scholz
Verts/ALE	Saskia Bricmont, Markéta Gregorová, Heidi Hautala, Sara Matthieu

13	-
ECR	Geert Bourgeois, Michiel Hoogeveen, Jan Zahradil
PPE	Anna-Michelle Asimakopoulou, Daniel Caspary, Martine Kemp, Gabriel Mato, Ralf Seekatz, Jörgen Warborn, Iuliu Winkler, Juan Ignacio Zoido Álvarez
Renew	Karin Karlsbro, Catharina Rinzema

1	0
PPE	Danuta Maria Hübner

Key to symbols:

+ : in favour

- : against

0 : abstention