



**2023/0129(COD)**

30.10.2023

# **AMENDMENT 22 - 109**

**Draft opinion**  
**Helmut Scholz**  
(PE 753.730v01-00)

Compulsory licensing for crisis management and amending Regulation (EC)  
816/2006subject

Proposal for a Regulation  
(COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

AM\_Com\_LegOpinion

**Amendment 22**  
**Samira Rafaela**

**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 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>. ***The TRIPS Agreement states that each WTO Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences can be granted. The TRIPS Agreement, in Article 31bis, specifically allows for the export of products made with a compulsory license. Over the past two decades, only one export compulsory license has been issued and successfully executed, when in 2007 the Canadian government issued a compulsory licence for HIV medicines for export to Rwanda.***

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

Or. en

**Amendment 23**  
**Geert Bourgeois**

**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

*Amendment*

(3) The possibility of using compulsory licences ***as a last resort*** 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

Aspects of Intellectual Property Rights  
(‘TRIPS Agreement’)<sup>3</sup> *if an unsuccessful attempt has been made to acquire a voluntary licence at reasonable terms and conditions and within a reasonable period of time.*

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

Or. en

**Amendment 24**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**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 Doha Declaration on the TRIPS Agreement and Public Health made clear 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, including the possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency .*

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

Or. en

**Amendment 25**  
**Heidi Hautala**  
on behalf of the Verts/ALE Group

**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 ***and determining the grounds upon which such licences can be granted*** 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

Or. en

**Amendment 26**  
**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**  
**Recital 16**

*Text proposed by the Commission*

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable

*Amendment*

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable

remuneration to the rights-holder.

remuneration to the rights-holder *after careful consideration and analysis of the market.*

Or. en

## **Amendment 27**

**Carles Puigdemont i Casamajó**

### **Proposal for a Regulation**

#### **Recital 20**

##### *Text proposed by the Commission*

(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.

##### *Amendment*

(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level. ***Moreover, the Commission should monitor the patent prices in the market and take note of their status when a crisis situation needing a Union compulsory license arises.***

Or. en

## **Amendment 28**

**Carles Puigdemont i Casamajó**

### **Proposal for a Regulation**

#### **Recital 27**

(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. ***In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.***

(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, ***a thorough and continued monitoring of patent prices market and its status, when the need for a Union compulsory licence arises***, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. ***The Commission should set a first threshold of 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. This percentage should also be under ex-post assessment of the rights-holder, who should be able to demand a higher compensation once the crisis situation has ended that should not exceed 40 %. In any case, the Commission should continue to monitor and assess the patent prices market.***

Or. en

**Amendment 29**  
**Helmut Scholz**

**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).

*Amendment*

(28) Products manufactured under a Union compulsory licence ***should be predominantly used for the supply of*** the internal market, ***notwithstanding the flexibilities included in the TRIPS Agreement***. The Union compulsory ***license*** should therefore ***define criteria for*** the licensee ***as well as the right-holders*** as regards the activities authorised under the licence ***which*** do not ***exceed those agreed*** under ***TRIPS***.

Or. en

**Amendment 30**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Recital 28**

*Text proposed by the Commission*

(28) It is imperative that products manufactured under a Union compulsory

*Amendment*

(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).

licence reach 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>.

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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).

Or. en

## **Amendment 31**

**Heidi Hautala**

on behalf of the Verts/ALE Group

### **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

*Amendment*

(28) It is imperative that products manufactured under a Union compulsory licence **are predominantly destined for** the internal market, **in line with Article 31f of the TRIPS Agreement**. The Union compulsory licence should therefore

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).

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>.

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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).

Or. en

## Amendment 32 Samira Rafaela

### 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

#### *Amendment*

(28) ***Notwithstanding the flexibilities included in the TRIPS Agreement, such as products for export covered under Regulation (EC) No 816/2006,*** products manufactured under a Union compulsory licence ***should be authorised predominantly to*** 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

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).

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).

Or. en

### Amendment 33

**Heidi Hautala**

on behalf of the Verts/ALE Group

### 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*

(29) A Union compulsory licence ***under this Regulation*** should only be granted to ***predominantly*** supply the internal market.

Or. en

**Amendment 34**  
**Samira Rafaela**

**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*

(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should be granted to supply the internal market with crisis-relevant products. **Exports of** products manufactured under a Union compulsory licence **should be permitted under the conditions established in Regulation (EC) No 816/2006.** .

Or. en

**Amendment 35**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**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*

(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should **predominantly** be granted to supply the internal market with **relevant** products. **When** a Union compulsory licence **has been exported to countries with public health emergencies, the whole production should be exported.**

Or. en

**Amendment 36**  
**Geert Bourgeois**

## 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*

(29) A Union compulsory licence ***issued as a last resort*** 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.

Or. en

## Amendment 37

Samira Rafaela

## Proposal for a Regulation

### Recital 30

*Text proposed by the Commission*

(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory licence are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory licence itself. Information on each implementing act granting or modifying a Union compulsory licence 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

*Amendment*

(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory licence ***that are not allowed for export*** are not exported, ***except when allowed by TRIPS flexibilities such as products manufactures in accordance with Regulation (EC) No 816/2006***. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory licence itself. Information on each implementing act granting or modifying a Union compulsory licence 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 suspend the export of that product and notify the Commission immediately. The Commission should

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.

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 **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).

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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).

Or. en

## **Amendment 38**

### **Geert Bourgeois**

#### **Proposal for a Regulation**

##### **Recital 30**

###### *Text proposed by the Commission*

(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

###### *Amendment*

(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).

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 **preferably** within 10 working days, but should **also** have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission **should** 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).

Or. en

## **Amendment 39**

**Heidi Hautala**

on behalf of the Verts/ALE Group

### **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

*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 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 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 licensing 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

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. ***In order to ensure the efficient processing of applications for compulsory licences under Regulation (EC) No 816/2006, Member States should have the ability to put in place adequate purely formal or administrative requirements, such as rules on the language of the application, the form to be used, and rules on applications made in electronic form. Such requirements should not add unnecessary costs or burdens on the applicant and, in any event, should not render the procedure for granting compulsory licences under this Regulation more burdensome than the procedure for the granting of other compulsory licences under the TRIPS Agreement.*** 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. ***Furthermore, empirical evidence demonstrates that certain conditions are difficult to meet.*** 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 line with the TRIPS Agreement. A Union compulsory licence will facilitate the use***



816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.

*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 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 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).

Or. en

**Amendment 40**  
**Samira Rafaela**

**Proposal for a Regulation**  
**Recital 37**

*Text proposed by the Commission*

(37) The possibility of a compulsory

*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 ***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 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

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. A Union compulsory licence*** will facilitate ***the use of this mechanism and 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 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 the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence

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).

under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licensing 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).

Or. en

## **Amendment 41** **Samira Rafaela**

### **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 assessment of this Regulation.

#### *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 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.*

Or. en

**Amendment 42**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**Proposal for a Regulation**

**Article 3 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency ***or for*** addressing the impacts of a crisis or emergency in the Union;

*Amendment*

(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency, addressing the impacts of a crisis or emergency in the Union, ***such as by guaranteeing the continued availability of a product in the Single Market in specific cases where an urgent public interest supersedes the monopoly rights of the patent-holder;***

Or. en

*Justification*

*See case law by German Federal Patent Court, namely case “compulsory licence for an HIV/AIDS drug*

**Amendment 43**

**Samira Rafaela**

**Proposal for a Regulation**

**Article 5 – paragraph 1 – point e**

*Text proposed by the Commission*

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

*Amendment*

***Deleted***

Or. en

#### **Amendment 44**

**Heidi Hautala**

on behalf of the Verts/ALE Group

#### **Proposal for a Regulation**

##### **Article 6 – paragraph 2 – point b**

*Text proposed by the Commission*

(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;

*Amendment*

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

Or. en

#### **Amendment 45**

**Kathleen Van Brempt, Raphaël Glucksmann**

#### **Proposal for a Regulation**

##### **Article 6 – paragraph 2 – point b**

*Text proposed by the Commission*

(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;

*Amendment*

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

Or. en

#### **Amendment 46**

**Heidi Hautala**

on behalf of the Verts/ALE Group

#### **Proposal for a Regulation**

##### **Article 6 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) the facilitation of exchanges and

*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;

sharing of information with other relevant bodies at Union and national level, as well as at international level, where appropriate;

Or. en

#### **Amendment 47**

**Kathleen Van Brempt, Raphaël Glucksmann**

#### **Proposal for a Regulation**

#### **Article 6 – paragraph 2 – point c**

*Text proposed by the Commission*

(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;

*Amendment*

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

Or. en

#### **Amendment 48**

**Carles Puigdemont i Casamajó**

#### **Proposal for a Regulation**

#### **Article 9 – paragraph 2**

*Text proposed by the Commission*

2. The remuneration shall **not exceed** 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.

*Amendment*

2. The remuneration shall **be set at a first threshold of** 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.

Or. en

#### **Amendment 49**

**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**

**Article 9 – paragraph 3 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(a a) the patent prices market before  
and during the crisis or emergency;***

Or. en

**Amendment 50**

**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**

**Article 9 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3 a. After the end of the situation of  
crisis or emergency, the Commission shall  
allow the rights-holder to demand a  
higher compensation that shall not exceed  
40 % of the total gross revenue generated  
by the licensee.***

Or. en

**Amendment 51**

**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**

**Article 9 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4 a. The rights-holder shall make its  
demand to the Unitary Patent Court with  
the assistance of the Commission.***

Or. en

**Amendment 52**

**Samira Rafaela**

**Proposal for a Regulation**  
**Article 11 – title**

*Text proposed by the Commission*

***Prohibition of export***

*Amendment*

***Destined use of products***

Or. en

**Amendment 53**  
**Heidi Hautala**  
on behalf of the Verts/ALE Group

**Proposal for a Regulation**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

The products manufactured under a Union compulsory licence ***shall be authorised predominantly destined for the supply of the EU internal market, except for products manufactured under a Union compulsory licence destined for export to countries facing public health problems.***

Or. en

**Amendment 54**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

The products manufactured under a Union compulsory licence ***shall be predominantly used for the supply of the internal market. This is without prejudice to products produced for export under a compulsory license, provided for by flexibilities in the TRIPS Agreement.***



**Amendment 55**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

The products manufactured under a Union compulsory licence ***shall be authorised predominantly for the supply of the internal market, except for products manufactured under a Union compulsory license for export to countries facing public health problems.***

**Amendment 56**  
**Samira Rafaela**

**Proposal for a Regulation**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

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

*Amendment*

The products manufactured under a Union compulsory licence ***shall be authorised predominantly for the supply of the internal market, except for products authorised for export.***

**Amendment 57**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 12 – paragraph 2**

*Text proposed by the Commission*

2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the ***prohibition*** laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure ‘export’ in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

*Amendment*

2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the ***requirements*** laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure ‘export’ in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

Or. en

**Amendment 58**

**Helmut Scholz**

**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 license. To assess whether the suspended products correspond to the Union compulsory license,*** the Commission may consult the relevant ***rights-holder***.

*Amendment*

3. Where customs authorities identify a product that may fall under ***requirements*** laid down in article 11, they shall immediately notify the Commission and provide it with all relevant information. The Commission may consult the relevant ***stakeholders***.

Or. en

**Amendment 59**  
**Samira Rafaela**

**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 license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.

*Amendment*

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, ***notwithstanding those covered by Regulation (EC) No 816/2006***, 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 license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder ***and other relevant stakeholders***.

Or. en

**Amendment 60**  
**Heidi Hautala**  
on behalf of the Verts/ALE Group

**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 license. ***To assess whether the suspended products correspond to the Union***

*Amendment*

3. Where customs authorities identify a product that may fall under the prohibition 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 license. ***Before taking a decision***, the Commission may consult the relevant rights-holder.

*compulsory license*, the Commission may consult the relevant rights-holder.

Or. en

**Amendment 61**  
**Geert Bourgeois**

**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 license. To assess whether the suspended products correspond to the Union compulsory license, the Commission *may* consult the relevant rights-holder.

*Amendment*

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 license. To assess whether the suspended products correspond to the Union compulsory license, the Commission *shall* consult the relevant rights-holder.

Or. en

**Amendment 62**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 12 – paragraph 4**

*Text proposed by the Commission*

*4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of*

*Amendment*

*deleted*

*the following conditions is fulfilled:*

*(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;*

*(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.*

Or. en

### **Amendment 63**

**Heidi Hautala**

on behalf of the Verts/ALE Group

### **Proposal for a Regulation**

#### **Article 12 – paragraph 4 – point b**

*Text proposed by the Commission*

*Amendment*

*(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.*

*deleted*

Or. en

### **Amendment 64**

**Samira Rafaela**

### **Proposal for a Regulation**

#### **Article 12 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

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.

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, ***notwithstanding exceptions listed in Regulation (EC) No 816/2006***, customs authorities shall not authorise its release for export. The Commission shall inform the

concerned rights-holder of such non-compliance.

Or. en

#### **Amendment 65**

**Heidi Hautala**

on behalf of the Verts/ALE Group

#### **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 prohibition laid down in Article 11, the Commission shall inform the concerned rights-holder of such non-compliance.

Or. en

#### **Amendment 66**

**Helmut Scholz**

#### **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 ***requirements*** laid down in Article 11 the Commission shall inform the concerned rights-holder of such non-compliance ***and:***

Or. en

**Amendment 67**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 12 – paragraph 5 – point a (new)**

*Text proposed by the Commission*

*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.***

Or. en

**Amendment 68**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 12 – paragraph 5 – point b (new)**

*Text proposed by the Commission*

*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.***

Or. en

**Amendment 69**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 12 – paragraph 6**

*Text proposed by the Commission*

*Amendment*

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

***deleted***

***(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.*

*(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.*

Or. en

*Justification*

*(a) and (b) of this paragraph are moved up under paragraph 5.*

**Amendment 70**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**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 licence does not comply with the prohibition laid down in Article 11*:

Or. en

**Amendment 71**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**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 in view of the crisis or emergency context, 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.

Or. en

**Amendment 72**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**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.

Or. en

**Amendment 73**

**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**

**Article 13 – paragraph 1**

*Text proposed by the Commission*

1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall

*Amendment*

1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall

act and cooperate with each other in good faith when performing rights and obligations under this Regulation.

act and cooperate with each other in good faith when performing rights and obligations under this Regulation. ***The Commission shall set structures to facilitate dialogue between the rights-holder and the licensee.***

Or. en

**Amendment 74**  
**Carles Puigdemont i Casamajó**

**Proposal for a Regulation**  
**Article 13 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2 a. In case of the impossibility to reach an agreement on the final remuneration, the Commission shall accompany the rights-holder and the licensee to the Unitary Patent Court for it to reach a final sentence on the remuneration.***

Or. en

**Amendment 75**  
**Kathleen Van Brempt, Raphaël Glucksmann**

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

*Present text*

*Amendment*

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

***(-a a) Paragraph (2) of Article 6 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

the quantities and importing countries concerned.

importing countries concerned.

”

Or. en

### *Justification*

*This requirement was introduced to inform the competent authority receiving a request for export under a compulsory license if the entity requesting the export has submitted requests for export under a compulsory license on the same product in multiple countries. It aimed to prevent that the requesting government receives several times the amount needed through multiple applications in different countries. The use of a Union Compulsory license for export under Regulation 816/2006 will cover more than one country. This requirement therefore needs to be updated to bring it in line with the creation of an EU wide Compulsory License. The proposed language places the focus on the number of applications rather than countries, as such an EU wide application can count as one application.*

### **Amendment 76**

**Heidi Hautala**

on behalf of the Verts/ALE Group

### **Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 6 – paragraph 2

*Text proposed by the Commission*

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 a) Paragraph (2) of Article 6 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.

Or. en

### **Amendment 77**

**Samira Rafaela**

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 6 – paragraph 3– point c

*Present text*

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

*Amendment*

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

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

"

Or. en

*(Regulation 816/2006/EC)*

**Amendment 78**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 6 – paragraph 3 – point c

*Present text*

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

*Amendment*

***(-a b) Point (c) Article 6(3) is amended as follows :***

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

Or. en

**Amendment 79**

**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**

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

*Present text*

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

*Amendment*

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

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

"

Or. en

*Justification*

*Particularly in a crisis as an outbreak of infectious disease, it may be quite difficult to estimate the exact amounts needed. At the stage of application (requesting a compulsory licence) it is important to leave some flexibility on the amount. Similarly Paragraph 2.i of Article 31Bis ask for a notification to the WTO TRIPS Council, ahead of issuing the compulsory license, specifying “the names and expected quantities of the product(s) needed”.*

**Amendment 80**  
**Samira Rafaela**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a c (new)**  
Regulation (EC) No 816/2006/EC  
Article 6 – paragraph 3 – point e

*Present text*

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

*Amendment*

***(-a c) 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;

"

Or. en

**Amendment 81**  
**Heidi Hautala**

on behalf of the Verts/ALE Group

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 6 – paragraph 3 – point e

*Present text*

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

*Amendment*

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

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

Or. en

**Amendment 82**

**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 6 – paragraph 3 – point e

*Present text*

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

*Amendment*

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

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

"

Or. en

*Justification*

*Article 6.3.eArticle 31Bis of the TRIPS agreement, which is the basis for this requirement, requires that a requesting party has made efforts for prior negotiations, there is no requirement that actual negotiations have taken place or have been concluded unsuccessfully. This nuance is important as with the current language (requiring actual negotiations) right holding companies can avoid entering into negotiations, for example by not answering letters or not being present in meetings, thereby making it impossible to meet this requirement and/or obstructing or delaying the process.*

**Amendment 83**  
**Samira Rafaela**

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006/EC

Article 6 – paragraph 3 – point f

*Present text*

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

*Amendment*

**Article 23a**

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

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

"

Or. en

**Amendment 84**  
**Samira Rafaela**

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006/EC

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*

***(-a e) 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.

"

Or. en

**Amendment 85**

**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**

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

Regulation (EC) No 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*

***(-a e) Article 7 is amended as follows:***

"The competent authority shall notify the rights-holder without delay of the application for a compulsory licence.

"

Or. en

*Justification*

*Neither the TRIPS agreement nor Article 31bis require the competent authority to allow the rights holder to “comment” to an application for a compulsory license. The TRIPS agreement and Article 31Bis do require efforts for prior negotiations with the rights holder (which can be waived in case of an emergency), prior to the application of a compulsory license.*

**Amendment 86**

**Heidi Hautala**

on behalf of the Verts/ALE Group

**Proposal for a Regulation**

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

Regulation (EC) No 816/2006

Article 7

*Present text*

*Amendment*

***(-a e) 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 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.***

The competent authority shall notify the rights-holder without delay of the application for a compulsory licence.

Or. en

**Amendment 87**  
**Samira Rafaela**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a f (new)**  
Regulation (EC) No 816/2006/EC  
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*

***(-a f) Paragraph (1) of Article 9 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

"

Or. en

**Amendment 88**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a g (new)**  
Regulation (EC) No 815/2006  
Article 10– paragraph 1

*Present text*

*Amendment*

(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

***(-a g) Paragraph (1) of Article 10 is amended as follows:***

"(1) The licence granted shall be non-assignable, except with that part of the enterprise or ***non-profit that makes use of*** the licence, and non-exclusive. It shall contain the specific conditions set out in ***the relevant Articles of the TRIPS Agreement*** to be fulfilled by the licensee

"

Or. en

*Justification*

*Repeating requirements of Article 31bis of the TRIPS Agreement would make the text unnecessarily long and detailed;*

#### **Amendment 89**

**Heidi Hautala**

on behalf of the Verts/ALE Group

#### **Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a g (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 1

*Present text*

*Amendment*

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.

***(-a g) Paragraph (1) of Article 10 is amended as follows :***

1. The licence granted shall be non-assignable, except with that part of the enterprise or ***non-profit organisation that makes use of*** the licence, and non-exclusive. It shall contain the specific conditions to be fulfilled by the licensee, ***as laid down by the relevant Articles of the TRIPS Agreement.***

Or. en

*(AM aims at amending paragraph 1 and deleting paragraphs 2, 3, 4, 5, 6, 7 & 8 of Article 10*

*of Regulation 816/2023. This implies a renumbering (not change of wording) of existing paragraphs 9 (should become new paragraph 2) and paragraphs 10 (should become new paragraph 3).)*

*Justification*

*The existing paragraphs 2 to 8 introduce additional burdens to the TRIPS Agreement, such as as the requirement for companies to open their books on the request of the patent holder, which may act as a deterrent for companies to produce under this mechanism and 2) dot include all available agreed options for export under the TRIPS agreement (e.g. TRIPS article 31.F states that compulsory licenses shall be authorized predominantly for the supply of the domestic market and that a significant portion of products produced under any compulsory license for domestic use can be exported to third countries without burdensome procedural restrictions. The best way to ensure all TRIPS provisions are fully available to EU actors it is to do a direct reference to TRIPS, rather than try to interpret them.*

**Amendment 90**

**Heidi Hautala**

**Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a h (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 2

*Present text*

*Amendment*

***(–a h) Paragraph (2) of Article 10 is deleted.***

Or. en

**Amendment 91**

**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**

**Article 23 – paragraph 1 –a h (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 2

*Present text*

*Amendment*

***(–a h) Paragraph 2 of Article 10 is deleted.***

*Justification*

*have additional requirements to the TRIPS agreement (TRIPS+) such as that (generic) companies may need to open their books on the request of the rightsholder (patent holder) which may act as a deterrent for generic companies to produce under this mechanism,*

**Amendment 92**

**Samira Rafaela**

**Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a h (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 h) Paragraph (2) of Article 10 is amended as follows:***

"2. The amount of product(s) manufactured under the licence shall not exceed what is ***expected to be*** 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 93**

**Heidi Hautala**

**Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a i (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 3

*Present text*

*Amendment*

***(-a i) Paragraph (3) of Article 10 is deleted.***

Or. en

**Amendment 94**

**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**

**Article 23 – paragraph 1 –a i (new)**

Regulation (EC) 816/2006

Article 10–paragraph 3

*Present text*

*Amendment*

***(-a i) Paragraph 3 of Article 10 is deleted.  
"***

Or. en

*Justification*

*It does not cover the full spectrum of options for export under the TRIPS agreement such as article 31.F which states that compulsory licenses shall be authorized predominantly for the supply of the domestic market, this article provides that a significant portion of products produced under any compulsory license for domestic use can be exported to third countries without burdensome procedural restrictions.*

**Amendment 95**

**Heidi Hautala**

**Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a j (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 4

*Present text*

*Amendment*

***(-a j) Paragraph (4) of Article 10 is  
deleted.***

Or. en

**Amendment 96**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 23– paragraph – a j (new)**  
Regulation (EC) No 816/2006  
Article 10– paragraph 4

*Present text*

*Amendment*

***(-a j) Paragraph 4 of Article 10 is deleted***  
***"***

Or. en

*Justification*

*repeat requirements of article 31bis of the TRIPS agreement making the text unnecessarily long and detailed*

**Amendment 97**  
**Heidi Hautala**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a k (new)**  
Regulation (EC) No 816/2006  
Article 10 – paragraph 5

*Present text*

*Amendment*

***(-a k) Paragraph (5) of Article 10 is deleted.***

Or. en

**Amendment 98**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a k (new)**  
Regulation (EC) 816/2006  
Article 10– paragraph 5

*Present text*

*Amendment*

***(-a k) Paragraph 5 of Article 10 is deleted.  
"***

Or. en

*Justification*

*Repeating requirements of article 31bis of the TRIPS agreement makes the text unnecessarily long and detailed; Have additional requirements to the TRIPS agreement (TRIPS+) such as that (generic) companies may need to open their books on the request of the rightsholder (patent holder) which may act as a deterrent for generic companies to produce under this mechanism, does not include the full spectrum of options for export under the TRIPS agreement such as article 31.F, which states that compulsory licenses shall be authorized predominantly for the supply of the domestic market. This article provides that a significant portion of products produced under any compulsory license for domestic use can be exported to third countries without burdensome procedural restrictions.*

**Amendment 99  
Heidi Hautala**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point –a l (new)**  
Regulation (EC) No 816/2006  
Article 10 – paragraph 6

*Present text*

*Amendment*

***(-a l) Paragraph (6) of Article 10 is  
deleted.***

Or. en

**Amendment 100  
Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 23 – paragraph 1- point -a l (new)**  
Regulation (EC) No 816/2006  
Article 10– paragraph 6

*Present text*

*Amendment*

***(-a l) Paragraph 6 of Article 10 is deleted.***

Or. en

*Justification*

*Repeating requirements of article 31bis of the TRIPS agreement makes the text unnecessarily long and detailed; Have additional requirements to the TRIPS agreement (TRIPS+) such as that (generic) companies may need to open their books on the request of the rightsholder (patent holder) which may act as a deterrent for generic companies to produce under this mechanism, does not include the full spectrum of options for export under the TRIPS agreement such as article 31.F which states that compulsory licenses shall be authorized predominantly for the supply of the domestic market, this article provides that a significant portion of products produced under any compulsory license for domestic use can be exported to third countries without burdensome procedural restrictions.*

#### **Amendment 101**

**Heidi Hautala**

#### **Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a m (new)**

Regulation (EC) No 816/2006

Article 10 – paragraph 7

*Present text*

*Amendment*

***(-a m) Paragraph (7) of Article 10 is deleted.***

Or. en

#### **Amendment 102**

**Kathleen Van Brempt, Raphaël Glucksmann**

#### **Proposal for a Regulation**

**Article 23 – paragraph 1 – point –a n (new)**

Regulation (EC) No 816/2006

Art 10–paragraph 8



*Present text*

*Amendment*

***(-a n) Paragraph 8 of Article 10 is deleted.  
"***

Or. en

**Amendment 103  
Heidi Hautala**

**Proposal for a Regulation  
Article 23 – paragraph 1 – point –a n (new)  
Regulation (EC) No 816/2006  
Article 10 – paragraph 8**

*Present text*

*Amendment*

***(-a n) Paragraph (8) of Article 10 is  
deleted.***

Or. en

**Amendment 104  
Samira Rafaela**

**Proposal for a Regulation  
Article 23 – paragraph 1 – point a  
Regulation (EC) No 816/2006  
Article 18a – paragraph 1**

*Text proposed by the Commission*

*Amendment*

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.***

1. The Commission may ***also*** grant a compulsory licence.

Or. en

**Amendment 105**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point a**  
Regulation (EC) No 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.

Or. en

**Amendment 106**  
**Samira Rafaela**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point a**  
Regulation (EC) No 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 requirements laid down in Article 6 (3).

Or. en

**Amendment 107**  
**Heidi Hautala**  
on behalf of the Verts/ALE Group

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point a**

*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 requirements laid down in Article 6 (3).

Or. en

**Amendment 108**  
**Kathleen Van Brempt, Raphaël Glucksmann**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point a**  
Regulation (EC) No 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 requirements laid down in Article 6 (3).

Or. en

*(see wording of art 18 a -2 of (EC) NO 816/2006)*

**Amendment 109**  
**Helmut Scholz**

**Proposal for a Regulation**  
**Article 23 – paragraph 1 – point a**  
Regulation (EC) No 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 be subject to the conditions set out in ***the TRIPs Agreement of the WTO and not impose any additional requirements.***

Or. en