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General Secretariat

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NOTE

From:	Presidency
To:	Working Party on Intellectual Property (Patents)
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Subject:	Proposal for a Regulation on Compulsory Licensing for crisis management and amending Regulation (EC) 816/2006 – Presidency note

At the IP Working Party meeting on 8 May 2025, the Presidency will inform delegations about the progress made in the negotiations with the EP on the above-mentioned proposal at the technical meetings held on 29 and 30 April 2025.

At the Working Party meeting, delegations will also be invited to express their views on the open issues set out in Annex I to this note.

Annex II to the note contains an overview of the EP amendments to Article 23, produced by the EP, and is attached for ease of reference.

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During the last two ITM meetings, which were held on 29 and 30 April, systematic progress was made in discussing Articles 4(1)(c), 8(2), 9(3)(a-d) and 14(3a). At the same time, as a consequence of previous discussions, Art. 21 (row 217), Art. 8(1)(a), and (b) (rows 117-118) and Art. 8(1)(f) (row 126) were agreed upon according to the Council's mandate.

The representatives of the INTA committee, on behalf of the EP, also continued explaining the EP's mandate regarding Art. 23.

Below the Presidency presents the drafting proposals made by the Commission (new text marked in blue):

I. Transitional period

- **Art. 14(3a) (row 175a)**

"*The Commission shall notify the rights-holder and the licensee of the termination or expiry of the Union compulsory licence, sufficiently in advance, where appropriate*".

- Additionally, the Commission expanded on the accompanying **recital 33** by adding the following clarification:

"(…) *The Commission should notify the rights-holder and the licensee about the termination of the Union compulsory licence, as well as about its expiry in case the relevant crisis or emergency mode has ended. Where appropriate, advance notification should be provided to enable an orderly termination by the licensee of the activities relating to crisis-relevant products under a Union compulsory licence.* (…)"

The Presidency hopes that the abovementioned drafting proposals are acceptable to the Member States.

II. Criteria for determining remuneration

- **Recital 27 (in reference to Art. 9(3)(a-d) (row 133-137)**

The Commission supported the Council's text on the criteria for determining the renumeration in Art. 9(3)(a-d) but had concerns on the accompanying recital 27 which defines the term economic value, in particular the phrase referring to the "hypothetical amount that a reasonable rights-holder would demand and a reasonable licensee would grant under a voluntary agreement".

In the spirit of compromise the Presidency would also like to ask if the Member States would be open to <u>deleting</u> the section marked in blue:

(27) *The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the adequate remuneration should be determined according to the circumstances of each case, considering the economic value of the exploitation authorised under the licence to the licensee and to the*

Member States concerned by the crisis. To assess such an economic value, the Commission should take into account the expected total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence, *the hypothetical amount that a reasonable rights-holder would demand and a reasonable licensee would grant under a voluntary agreement, as well as any public support received by the rights-holder to develop the invention,. The amount of the remuneration should also take into consideration the degree to which research and development costs have been ~~amortized as well as humanitarian~~ amortised by the rights-holder. This factor should ensure proper remuneration in case where the development costs would not have been appropriately amortised. Depending on the circumstances of the case and where relevant, the Commission may also take account of humanitarian grounds 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~~, taking into consideration general practices and any existing precedents in the relevant field. In the event of a compulsory licence granted ~~on the basis of~~with regard to 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 Union compulsory licence, as the subject matter for ~~the receipt of the~~receiving remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the Union compulsory licence.*

III. Time limit for voluntary agreements

During the last ITMs two alternative drafting suggestions were discussed to address the EP's position to set some kind of time limit to conclude the voluntary licencing agreement. Preliminary exchange was held on the basis of two drafting proposals amending the wording of Art. 4(1)(c) from the Council's mandate:

Art. 4(1)(c) (Council mandate):

Alternative 1: "the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence, including voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products, could not be achieved within a reasonable timeframe and could not ensure access to those products ('measure of last resort');"

Alternative 2: *"the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence, ~~including voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products,~~ could not ensure access to ~~those~~ crisis-relevant products concerned and, in particular,*

that voluntary licensing agreements to use a protected invention relating to such products could not be concluded within a reasonable time limit (‘measure of last resort’);”

This text change would be accompanied with the clarification sought by the Member States on the possibility to reach a voluntary licencing agreement during the whole procedure and after the Union compulsory licence is granted, which would be introduced in the new Article 7(11) as follows:

“*Without prejudice to paragraph 8, voluntary licensing agreements may be concluded at any time during or after the procedure set out in this Article.***”**

The Presidency would like to ask Member States to indicate their preference between the two alternative drafting propositions.

IV. Amendments to Article 23

Another point which was extensively discussed in the last ITMs was Art. 23 and the EP’s amendments thereof. Both the Presidency and the Commission argued against all of these amendments, pointing out that any changes in the Regulation (EC) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems should only be dictated by their alignment with the new Compulsory licencing Regulation. As a result of the discussion the EP gave up on the following propositions:

- Art. 10(1) rows (227 r, 227 s) and Art. 10(2) (rows 227 t, 227 u) addition of the word *“expected”;*
- Art. 7 (row 227 o) the change of “*shall*” clause into “*may*” clause;
- Art. 10(8) (row 227 w) the deletion of the phrase “(…) *at the request of the rightsholder or* (…)”.

Although the discussions on other items in Art. 23 were inconclusive, the following points were addressed (please refer to the overview in **Annex II**):

- adding the word *“expected”* in Art. 6(3)(c) (row 227 d) and in Art. 6(3)(f)(iii) (row 227 l) as a clarification of *“the amount of pharmaceutical product which applicant seeks to produce under the compulsory licence”* and accordingly *“the quantity of the product required”,* as in the EP’s opinion it creates ambiguity*;*
- changing the term *“authorities in more than one country”* into *“multiple applications to different authorities”* in Art. 6(2) (row 227 b)*;*
- amending the phrase *“evidence of prior negotiation”* with *“efforts to obtain authorisation from”* in Art. 6(3)(c) (row 227 f)*,* so as to make sure the EU Regulation is not more onerous than TRIPS and to adjust the wording to the wording in Article 9;

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- introducing a time limit of two weeks for the rights-holder to provide the competent authority with any relevant information regarding the application in Art. 7 (row 227 o), in order to ensure the procedure would not be prolonged;
- deletion of the word *"satisfy"* in Art. 9(1) (row 227 p*),* as in the EP's opinion it creates ambiguity;
- deletion of the following fragment of the text *"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 products, have been met. The books and records shall include"* in Art. 10(8) (row 227 w) as in the EP's opinion it is a disproportionate burden on the licensee.

With a view to exploring possible room for compromises, Member States are invited to share their views and their degree of flexibility on the aforementioned amendments and indicate which of these propositions may bring any potential added value.

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Compulsory licensing file

EP Position

I. Presentation on Column Amendments format from the INTA opinion

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

Present text	*Amendment*
	-a. Article 6(2) is amended as follows:
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.	***2.*** If the person applying for a compulsory licence is submitting ***multiple*** applications to ***different*** 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 as follows:
(c) the ***amount*** of pharmaceutical product which the applicant seeks to produce under the compulsory licence;	(c) the ***expected quantity*** ~~amount~~ of pharmaceutical product which the applicant ***intends*** ~~***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*
	-a b. Point (e) of Article 6(3) is amended as follows:
(e) where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9	(e) where applicable, evidence of ***efforts to obtain authorisation from*** ~~***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*
	-a c. Point (f) of Article 6(3) is amended as follows:
(f) evidence of a specific request from : [...] indicating the quantity of product required.	(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	*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 shall give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant	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~~***may***~~ give the rights-holder an opportunity***, within a period of two weeks,*** to comment on the application and to provide the competent authority with any relevant information

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information regarding the application.

regarding the application.

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Amendment 21

Proposal for a regulation
Article 23 – paragraph 1 – point -a e (new)
Regulation (EC) 816/2006
Article 9 – paragraph 1

Present text	*Amendment*
	-a e. Article 9(1) is amended as follows:
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**.**	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 22

Proposal for a regulation
Article 23 – paragraph 1 – point -a f (new)
Regulation (EC) 816/2006
Article 10 – paragraph 1

Present text	*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.	1. The licence granted shall be non-assignable, except with that part of the enterprise or goodwill which enjoys ~~***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	*Amendment*
	-a g. Article 10(2) is amended as follows:
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.	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	*Amendment*
	-a h. Article 10(8) is amended as follows:
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 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).	8. The competent authority may, at the request of the rightholder or on its own initiative**,** if national law allows the competent authority to act on its own initiative*,* ***request*** ~~***from***~~ the licensee ***to provide documents, such as*** 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), in order to demonstrate that that the terms of the licence, and in particular those relating to the final destination of the products, have been met.

Amendment 25

Proposal for a regulation

Article 23 – paragraph 1 – point a
Regulation (EC) 816/2006
Article 18a – paragraph 1

Text proposed by the Commissiont	*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 ***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	*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) and shall specify the Member States to be covered by the compulsory licence.***	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:

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	(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 Commissiont	*Amendment*
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.	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	*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 ***the impacts of the*** public health problems, the Commission shall adopt	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

immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).	applicable implementing acts in accordance with the procedure referred to in Article 18b (3).

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II. Consolidated text format - from JURI Text Adopted

Article 23

Amendments to Regulation (EC) No 816/2006

Regulation (EC) No 816/2006 is amended as follows:

(-a) Article 6(2) is replaced by the following:

"***(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.***" **[Am. 82]**

(-aa) Point (c) of Article 6(3) is replaced by the following:

"***(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;***" **[Am. 83]**

(-ab) Point (e) of Article 6(3) is replaced by the following:

"*(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;*" **[Am. 84]**

(-ac) Point (f) of Article 6(3) is replaced by the following:

"*(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, indicating the expected quantity of product required." **[Am. 85]**

(-ad) Article 7 is replaced by the following:

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"*Article 7*

Rights of the rights-holder

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." **[Am. 86]**

(-ae) Article 9(1) is replaced by the following:

"***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.***" **[Am. 87]**

(-af) Article 10(1) is replaced by the following:

"***1. 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 set out in paragraphs 2 to 9 to be fulfilled by the licensee.***" **[Am. 88]**

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(-ag) Article 10(2) is replaced by the following:

"*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.*" **[Am. 89]**

(-ah) Article 10(8) is replaced by the following:

"*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 to in Article 6(3)(f).*" **[Am. 90]**

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(a) The following Article 18a is inserted:

"Article 18a

Union compulsory licence

1. The Commission may ***also*** grant a compulsory licence ~~where the activities of~~***of patents relating to the*** manufacture ~~and sale~~***of pharmaceutical products*** for export ~~spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State~~***to countries with public health problems***. **[Am. 91]**

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.~~***contain the following information:***

(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;

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(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

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(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries. **[Am. 92]**

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. ***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;

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(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;

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(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 or special colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the 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;

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(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 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 in the form of 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), point (e);

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(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), point (f), and on commercial or non-commercial terms including completely without charge. **[Am. 93]**

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4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.

5. The Commission is empowered to adopt implementing acts in order to:

   (a) grant a compulsory licence;

   (b) reject the application for a compulsory licence;

   (c) amend or terminate the compulsory licence.

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)." **[Am. 94]**

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(b) The following Article 18b is inserted:

"Article 18b Committee Procedure

1. The Commission shall be assisted by a committee ('the Compulsory Licensing Committee'). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply."

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