COMMISSION IMPLEMENTING REGULATION (EU) 2015/1013

of 25 June 2015

laying down rules in respect of Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors ([1]), and in particular Article 14 thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors ([2]), and in particular Article 6(3), the third subparagraph of Article 9(2) and Article 28 thereof,

Whereas:

(1) Commission Regulation (EC) No 1277/2005 ([3]) lays down provisions for the implementation of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 in the field of drug precursors. Both Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 have been amended after the adoption of Regulation (EC) No 1277/2005 so as to include empowerments to adopt delegated and implementing acts pursuant to Articles 290 and 291 of the Treaty. Therefore, new rules should be adopted in accordance with the new empowerments.

(2) Although Regulation (EC) No 273/2004 deals with domestic trade and Regulation (EC) No 111/2005 deals with international trade, many of the provisions are common to both Regulations. In order to ensure coherence, it is justified to adopt a single implementing act covering both Regulations.

(3) In order to ensure legal certainty and a coherent enforcement of the provisions of this Regulation, it is necessary to give a definition of 'business premises'.

(4) The existing provisions regarding the procedural rules for granting licences, the procedure and format for providing information required to monitor trade, and the format and handling of import and export authorisations have proven to be effective and should therefore, in essence on substance, continue to apply by virtue of this Regulation.

(5) The procedural rules for granting registration to operators and users, as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005, should reflect those for granting licences.

(6) In order to ensure data quality and coherence, and avoid duplication, in the information fed into the European database on drug precursors, each Member State should establish one single contact point transmitting the information to the database. Information should be transmitted without undue delay. Information on a licence or a registration should include the elements necessary for identifying the operator or user holding the licence or registration, as well as the substance(s) covered. Access to the information should be restricted to the minimum necessary for the public authorities' performance of their duties.

(7) Transitional rules should allow the use of paper forms issued before the entry into force of this Regulation in compliance with previous rules until the stocks of such paper forms have been exhausted.

([1]) OJ L 47, 18.2.2004, p. 1.
([2]) OJ L 22, 26.1.2005, p. 1.
([3]) Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 202, 3.8.2005, p. 7).

(8) The measures provided for in this Regulation are in accordance with the opinion of the Drug Precursors Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down uniform procedural rules for the implementation of Regulation (EC) No 273/2004 and of Regulation (EC) No 111/2005 as regards the licensing and registration of operators and users and their listing in the European database on drug precursors, the provision by operators of information required to monitor trade and authorisation of exports and imports in the field of drug precursors.

Article 2

Definitions

For the purposes of this Regulation, 'business premises' shall mean building(s) together with the land occupied by an operator at each single location.

Article 3

Licence granting procedure

1. An operator or user shall submit to the competent authority an application to obtain a licence referred to in Article 3(2) of Regulation (EC) No 273/2004 or Article 6(1) of Regulation (EC) No 111/2005, electronically or in writing as prescribed by the Member State concerned.

An application shall be deemed to be complete when it contains all the information listed in Article 3(2)(b) of Commission Delegated Regulation (EU) 2015/1011 ([1]).

2. When assessing an application to obtain a licence, the competent authority may also take into consideration the results of any previous assessments or audits carried out on the applying operator holding the status of Authorised Economic Operator (AEO) as defined in Article 5a of Council Regulation (EEC) No 2913/92 ([2]), to the extent they are relevant for the examination of the conditions for granting a licence.

By derogation from Article 3(1) of this Regulation, the competent authority may authorise operators holding the status of AEO not to submit all the information listed in Article 3(2)(b) of Delegated Regulation (EU) 2015/1011 when they are submitting an application.

3. The competent authority shall first assess the completeness of an application.

Where an application is not deemed to be complete, the competent authority shall indicate so to the applicant and invite that applicant to provide any missing or relevant additional information.

Where an application is deemed to be complete, the competent authority shall confirm the receipt of a complete application to the applicant.

([1]) Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005 (see page 12 of this Official Journal).

([2]) Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

4. The competent authority shall take a decision to grant or not to grant a licence within 60 working days from the date of receipt of a complete application in the case of a new licence, and within 30 working days in the case of a renewal of a licence.

5. Any decision not to grant a licence shall be reasoned and notified to the applicant electronically or in writing.

6. The licence may cover the operations referred to in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 4

Scope of the licence

The competent authority may grant a licence:

(a) to cover all scheduled substances and all operations per business premises; or

(b) to cover all scheduled substances and all operations per Member State.

Article 5

Format of the licence

A licence referred to in Article 3(2) of Regulation (EC) No 273/2004 or Article 6(1) of Regulation (EC) No 111/2005 shall be issued in the format set out in Annex I to this Regulation.

Article 6

Subsequent changes

Where, after a licence has been granted, information provided in the application for that licence, other than information referred to in Article 3(9) of Delegated Regulation (EU) 2015/1011, has changed, the licence holder shall inform the competent authority electronically or in writing within 10 working days following the change.

Where, after the change, the conditions referred to in Article 3 of Delegated Regulation (EU) 2015/1011 continue to be fulfilled, and the information to be changed is contained in the licence, the competent authority shall amend the licence accordingly.

Article 7

Validity, suspension and revocation of licences

1. Where the validity of a licence has expired, or where a license has been revoked, the licence holder shall return a licence which is no longer valid to the competent authority within 10 working days following the date of expiry of validity or the date of revocation.

2. Where a competent authority decides to suspend or revoke a licence, the decision shall be submitted to the licence holder electronically or in writing and shall specify the grounds that justify the suspension or revocation.

Article 8

Special licences

Articles 3 to 7 of this Regulation shall not apply to special licences referred to in Article 3(2) of Regulation (EC) No 273/2004.

Article 9

Registration procedure

1. Articles 3, 4, 6 and 7 shall apply to the procedure for registration pursuant to Article 3(6) of Regulation (EC) No 273/2004 or Article 7(1) of Regulation (EC) No 111/2005.

2. Registration pursuant to Article 3(6) of Regulation (EC) No 273/2004 or Article 7(1) of Regulation (EC) No 111/2005 shall be granted in the format set out in Annex II.

3. By way of derogation from paragraph 2, the competent authority may grant registration on a form printed before the date of entry into force of this Regulation and complying with national rules in place before the date of entry into force of this Regulation until the stocks are exhausted.

4. Paragraphs 1, 2 and 3 shall not apply to special registrations referred to in Article 3(6) of Regulation (EC) No 273/2004.

Article 10

Information required to monitor trade

1. Operators shall provide the information referred to in Article 8(2) of Regulation (EC) No 273/2004 electronically or in writing, as prescribed by the Member State concerned, before 15 February of each calendar year for scheduled substances of Categories 1 and 2 of Annex I to that Regulation.

2. Operators shall provide the information referred to in Article 9(2) of Regulation (EC) No 111/2005 electronically or in writing, as prescribed by the Member State concerned, before 15 February of each calendar year.

3. An operator shall submit the annual reports referred to in paragraphs 1 and 2 even where no transactions have taken place in a given year.

Article 11

Export and import authorisations

1. The export and import authorisations referred to in Article 28 of Regulation (EC) No 111/2005 shall have the format set out in Annex III or IV to this Regulation, respectively.

By way of derogation from the first subparagraph, the box relating to the authorisation number may have a different format in cases where the export or import authorisation is granted by electronic means.

2. An export authorisation shall be established in four copies numbered 1 to 4. Copy No 1 shall be kept by the authority issuing the authorisation. Copies No 2 and No 3 shall accompany the scheduled substance and be presented to the customs office where the customs export declaration is made, and subsequently to the competent authority at the point of exit from the customs territory of the Union. The competent authority at the point of exit shall return Copy No 2 to the issuing authority. Copy No 3 shall accompany the scheduled substances to the competent authority of the importing country. Copy No 4 shall be kept by the exporter.

3. An import authorisation shall be established in four copies numbered 1 to 4. Copy No 1 shall be kept by the authority issuing the authorisation. Copy No 2 shall be sent to the competent authority of the exporting country by the issuing authority. Copy No 3 shall accompany the scheduled substance from the point of entry into the customs territory of the Union to the business premises of the importer, who shall send this copy to the issuing authority. Copy No 4 shall be kept by the importer.

4. One single export or import authorisation shall not cover more than two scheduled substances.

5. An authorisation shall be issued in one or more of the official languages of the Union. Unless it is granted by electronic means, it shall have A4 format and a printed guilloche pattern background making any falsification by mechanical or chemical means apparent to the eye.

6. A Member State may print the authorisation forms itself or have them printed by printers approved by it. In the latter case, each authorisation form must include a reference of such approval and bear the name and address of the printer or a mark by which the printer can be identified.

7. By way of derogation from paragraphs 1-6, a Member State may issue an export or import authorisation on a form printed before the date of entry into force of this Regulation and complying with Commission Regulation (EC) No 1277/2005 until the stocks are exhausted.

8. Export authorisations granted by simplified procedure shall be established using copies No 1, 2 and 4 of the form set out in Annex III. Copy No 1 shall be kept by the authority issuing the authorisation. Copy No 2 and Copy No 4 shall remain with the exporter. The exporter shall indicate details of each export operation on the back side of Copy No 2, in particular the quantity of the scheduled substance of each export operation and the remaining quantity. Copy No 2 shall be presented to the customs office when the customs declaration is made. That customs office shall confirm the details and return Copy No 2 to the exporter.

9. The operator shall enter the authorisation number and the words 'simplified export authorisation procedure' on the customs declaration for each export operation. Where the customs office of exit is not at the point of exit from the customs territory of the Union, the information shall be provided on the documents accompanying the export consignment.

10. The exporter shall return Copy No 2 to the issuing authority at the latest 10 working days following the expiry of the period of validity of the export authorisation granted by simplified procedure.

Article 12

Listing of operators and users in the European database on drug precursors

1. For the purpose of listing in the European database on drug precursors operators and users which have obtained a licence or registration pursuant to Article 3(7) of Regulation (EC) No 273/2004, each Member State shall nominate one contact point and communicate the contact details to the Commission.

2. The responsible contact point shall transmit the relevant information electronically within 30 working days of having issued the license or the registration. Where the concerned operator or user communicates changes to the relevant information to the competent authority, or where a license or a registration is suspended or revoked, the responsible contact point shall update the information within 30 working days of accepting the changes or suspending or revoking the license or the registration.

3. The Commission shall ensure that:

(a) the electronic transmission of information is secure;

(b) the database is restricted and accessible only to the appointed officers designated by the Member States and to the Commission officials responsible for the European database.

4. The Commission and the competent authorities shall take all necessary measures to ensure that the information on operators and users listed in the database is used only for the purpose of the official duties of the appointed officers and of the Commission officials.

5. Information on operators and users shall include the full name, the address, the licence or registration number, the validity status of the licence or registration, and the name and CN code of the scheduled substances which are covered by the respective licence or registration.

6. The Commission shall keep information on licences and registrations which have expired or have been revoked available in the database for at least three years following the date of expiry of validity or of revocation.

Article 13

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

European Union

Licence

(Article 3(2) of Regulation (EC) No 273/2004)
(Article 6(1) of Regulation (EC) No 111/2005)

		MS: ..... **(Licence Number)**
ORIGINAL	**1. Licence holder** **(name, address, phone, fax, e-mail)**	**2. Issuing authority**
	1a. Additional information	1b. Additional information
	3. Validity	
	Beginning:	**End:**

4. The licence covers the following:

Scheduled substance(s)	CN Code	Operation	Business premises

5. Additional information/conditions

6. Date **Signature** **Stamp**

Name

Notes

1. The layout of the model is not binding.

2. The order numbers and the text of the model are binding. The completion of the boxes marked in bold is mandatory.

3. Details of the boxes:

   Box 1 (Licence holder): The name of the responsible officer may be added.

   Box 3 (validity/end): Specify the term of validity or whether licence holders are obliged to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled.

   Box 4 (scheduled substances): Name of the scheduled substance as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product. Indicate salts, where appropriate.

   Box 4 (CN code): In addition to the CN code, the CAS number may be added.

   Box 4 (operation): Specify export, import and/or intermediary activities. In the case of import, specify whether storage, working, processing, use, usual forms of handling and/or release for free circulation, where appropriate. For operations covered by Regulation (EC) No 273/2004, specify: storage, production, manufacture, processing, trade, distribution and/or brokering.

   Box 4 (business premises): In the case of intermediary activities referred to in Article 2 of Regulation (EC) No 111/2005, the business premises need not be specified.

4. The Member States may provide for boxes for national purposes. These boxes shall be indicated by an order number followed by a capital letter (e.g. 4A).

5. Personal data protection

   Where the European Commission processes personal data contained in this document, Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community Institutions and bodies and on the free movement of such data will apply.

   Where the competent authority of a Member State processes personal data contained in this document, the national provisions implementing Directive 95/46/EC will apply.

   The purpose of the processing of personal data is the monitoring of trade in drug precursors within the Union in accordance to Regulation (EC) No 273/2004 as amended by Regulation (EU) No 1258/2013, and between the Union and third countries in accordance with Regulation (EC) No 111/2005, as amended by Regulation (EU) No 1259/2013.

   The controller with respect to the processing of the data is the national competent authority where the present document has been submitted. The list of competent authorities is published on the website of the Commission:

   http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/drugs_precursors/legislation/national_competent_authorities.pdf

   In accordance with Article 17 of Regulation (EC) No 111/2005 laying down rules for the monitoring of trade in drug precursors between the Union and third countries, without prejudice to applicable provisions on data protection in the Union and for the purpose of controlling and monitoring certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission and the competent authorities of the Member States may share personal data and information contained in the present document with the relevant authorities in third countries.

   The data subject has a right of access to the personal data relating to him or her that will be processed and, where appropriate, the right to rectify erase or block personal data in accordance with Regulation (EC) No 45/2001 or the national laws implementing Directive 95/46/EC.

All requests for the exercise of the right of access, rectification, erasure or blocking shall be submitted to and processed by the competent authorities where the present document was submitted.

The legal basis for processing the personal data is Article 33 of Regulation (EC) No 111/2005 and Article 13b of Regulation (EC) No 273/2004.

Personal data contained in the present document shall not be retained longer than necessary for the purposes for which it was collected.

Complaints, in case of conflict, can be addressed to the relevant national data protection authority. The contact details of the national data protection authorities are available on the web-site of the European Commission, Directorate-General for Justice: (http://ec.europa.eu/justice/data-protection/bodies/authorities/eu/index_en.htm#h2-1)

Where the complaint concerns processing of personal data by the European Commission, it should be addressed to the European Data Protection Supervisor: (http://www.edps.europa.eu/EDPSWEB/).

ANNEX II

European Union

Registration

(Article 3(6) of Regulation (EC) No 273/2004)
(Article 7(1) of Regulation (EC) No 111/2005)

		MS: ..... **(Registration Number)**
ORIGINAL	**1. Registration holder** **(name, address, phone, fax, e-mail)**	**2. Issuing authority**
	1a. Additional information	1b. Additional information
	3. Validity	
	Beginning:	**End:**

4. The registration covers the following:

Scheduled substance(s)	CN Code	Operation	Business premises

5. Additional information/conditions

6. Date **Signature** **Stamp**

Name

Notes

1. The layout of the model is not binding.

2. The order numbers and the text of the model are binding. The completion of the boxes marked in bold is mandatory.

3. Details of the boxes:

   Box 1 (Registration holder): The name of the responsible officer may be added.

   Box 3 (validity/end): Specify the beginning and, where relevant, the end of validity.

   Box 4 (scheduled substances): Name of the scheduled substance as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product. Indicate salts, where appropriate.

   Box 4 (CN code): In addition to the CN code, the CAS number may be added.

   Box 4 (operation): Specify export, import and/or intermediary activities. In the case of import, specify whether storage, working, processing, use, usual forms of handling and/or release for free circulation, where appropriate. For operations covered by Regulation (EC) No 273/2004, specify: storage, production, manufacture, processing, trade, distribution and/or brokering.

   Box 4 (business premises): In the case of intermediary activities referred to in Article 2 of Regulation (EC) No 111/2005, the business premises need not be specified.

4. The Member States may provide for boxes for national purposes. These boxes shall be indicated by an order number followed by a capital letter (e.g. 4A).

5. Personal data protection

   Where the European Commission processes personal data contained in this document, Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community Institutions and bodies and on the free movement of such data will apply.

   Where the competent authority of a Member State processes personal data contained in this document, the national provisions implementing Directive 95/46/EC will apply.

   The purpose of the processing of personal data is the monitoring of trade in drug precursors within the Union in accordance to Regulation (EC) No 273/2004 as amended by Regulation (EU) No 1258/2013, and between the Union and third countries in accordance with Regulation (EC) No 111/2005, as amended by Regulation (EU) No 1259/2013.

   The controller with respect to the processing of the data is the national competent authority where the present document has been submitted. The list of competent authorities is published on the website of the Commission:

   http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/drugs_precursors/legislation/national_competent_authorities.pdf

   In accordance with Article 17 of Regulation (EC) No 111/2005 laying down rules for the monitoring of trade in drug precursors between the Union and third countries, without prejudice to applicable provisions on data protection in the Union and for the purpose of controlling and monitoring certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission and the competent authorities of the Member States may share personal data and information contained in the present document with the relevant authorities in third countries.

The data subject has a right of access to the personal data relating to him or her that will be processed and, where appropriate, the right to rectify erase or block personal data in accordance with Regulation (EC) No 45/2001 or the national laws implementing Directive 95/46/EC.

All requests for the exercise of the right of access, rectification, erasure or blocking shall be submitted to and processed by the competent authorities where the present document was submitted.

The legal basis for processing the personal data is Article 33 of Regulation (EC) No 111/2005 and Article 13b of Regulation (EC) No 273/2004.

Personal data contained in the present document shall not be retained longer than necessary for the purposes for which it was collected.

Complaints, in case of conflict, can be addressed to the relevant national data protection authority. The contact details of the national data protection authorities are available on the web-site of the European Commission, Directorate-General for Justice: (http://ec.europa.eu/justice/data-protection/bodies/authorities/eu/index_en.htm#h2-1)

Where the complaint concerns processing of personal data by the European Commission, it should be addressed to the European Data Protection Supervisor: (http://www.edps.europa.eu/EDPSWEB/).

ANNEX III

EUROPEAN UNION
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

	1	1. Exporter (name and address)	2. AUTHORISATION number: Issued (date): _____ at: _____	
	COPY FOR THE ISSUING AUTHORITY		3. Simplified export authorisation procedure YES ...../NO	
			4. Period of validity: Beginning: End:	
		5. Importer in the country of destination (name and address) Import authorisation No	6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)	
		7. Other Operator(s) (name and address)	8. Customs office where the customs declaration will be made (name and address)	
		9. Ultimate consignee (name and address)	10. Point of exit	11. Point of entry into the importing country
			12. Means of transport	13. Itinerary
		14a. Scheduled Substance		15a. CN-Code
				16a. Net weight
				17a. % of mixture
	1			18a. Invoice number
		14b. Scheduled Substance		15b. CN-Code
				16b. Net weight
				17b. % of mixture
				18b. Invoice number

19. Declaration by the applicant Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	20. (For completion by the customs office where the export declaration is made, unless the simplified export authorisation procedure is applied) Reference number of customs declaration: _____ Stamp:
21. (For completion by issuing authority unless the simplified export authorisation procedure is applied) Box 18 information still required: YES ...../NO ..... Boxes 7, 8, 10-13 information still required: YES ...../NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	22. CONFIRMATION OF EXIT FROM THE EU (For completion by the competent authorities at the point of exit from the customs territory of the Union unless the simplified export authorisation procedure is applied) Date of exit: _____ Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY TO ACCOMPANY THE GOODS TO POINT OF EXIT (*)

2	1. Exporter (name and address)	2. AUTHORISATION number: Issued (date): _____ at: _____	
		3. Simplified export authorisation procedure YES ...../NO	
		4. Period of validity: Beginning: End:	
	5. Importer in the country of destination (name and address) Import authorisation No	6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)	
	7. Other Operator(s) (name and address)	8. Customs office where the customs declaration will be made (name and address)	
	9. Ultimate consignee (name and address)	10. Point of exit	11. Point of entry into the importing country
		12. Means of transport	13. Itinerary
2	14a. Scheduled Substance	15a. CN-Code	
		16a. Net weight	
		17a. % of mixture	
		18a. Invoice number	
	14b. Scheduled Substance	15b. CN-Code	
		16b. Net weight	
		17b. % of mixture	
		18b. Invoice number	

19. Declaration by the applicant Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	20. (For completion by the customs office where the customs declaration is made unless the simplified export authorisation procedure is applied) Reference number of customs declaration: _____ Stamp:
21. (For completion by issuing authority unless the simplified export authorisation procedure is applied) Box 18 information still required: YES ..... /NO ..... Boxes 7, 8, 10-13 information still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	22. CONFIRMATION OF EXIT FROM THE EU (For completion by the competent authorities at the point of exit from the customs territory of the Union unless the simplified export authorisation procedure is applied) Date of exit: _____ Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

Simplified export authorisation procedure			
23. Net weight		26. Customs declarations (reference number and date)	27. (For completion by the customs office where the customs declaration is made) Member State, name and address of the customs office, date, stamp and signature of the officer.
24. Available quantity (1) and partial export quantity (2)	25. Partial export quantity in words		
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY TO ACCOMPANY THE GOODS TO IMPORTING COUNTRY

3

1. Exporter (name and address)

2. AUTHORISATION number:

Issued (date): _____ at: _____

3. Simplified export authorisation procedure YES ...../NO .....

4. Period of validity:

Beginning: End:

5. Importer in the country of destination (name and address)

Import authorisation No

6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)

7. Other Operator(s) (name and address)

8. Customs office where the customs declaration will be made (name and address)

9. Ultimate consignee (name and address)

10. Point of exit

11. Point of entry into the importing country

12. Means of transport

13. Itinerary

3

14a. Scheduled Substance

15a. CN-Code

16a. Net weight

17a. % of mixture

18a. Invoice number

14b. Scheduled Substance

15b. CN-Code

16b. Net weight

17b. % of mixture

18b. Invoice number

19. Declaration by the applicant Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	20. (For completion by the customs office where the customs declaration is made unless the simplified export authorisation procedure is applied) Reference number of customs declaration: _____ Stamp:
21. (For completion by issuing authority unless the simplified export authorisation procedure is applied) Box 18 information still required: YES ..... /NO ..... Boxes 7, 8, 10-13 information still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	22. CONFIRMATION OF EXIT FROM THE EU (For completion by the competent authorities at the point of exit from the customs territory of the Union unless the simplified export authorisation procedure is applied) Date of exit: _____ Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY FOR THE EXPORTER

4

1. Exporter (name and address)

2. AUTHORISATION number:

   Issued (date): _____ at: _____

3. Simplified export authorisation procedure YES ...../NO .....

4. Period of validity:

   Beginning: End:

5. Importer in the country of destination (name and address)

   Import authorisation No

6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)

7. Other Operator(s) (name and address)

8. Customs office where the customs declaration will be made (name and address)

9. Ultimate consignee (name and address)

10. Point of exit

11. Point of entry into the importing country

12. Means of transport

13. Itinerary

4

14a. Scheduled Substance

15a. CN-Code

16a. Net weight

17a. % of mixture

18a. Invoice number

14b. Scheduled Substance

15b. CN-Code

16b. Net weight

17b. % of mixture

18b. Invoice number

19. Declaration by the applicant Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	20. (For completion by the customs office where the customs declaration is made unless the simplified export authorisation procedure is applied) Reference number of customs declaration: _____ Stamp:
21. (For completion by issuing authority unless the simplified export authorisation procedure is applied) Box 18 information still required: YES ..... /NO ..... Boxes 7, 8, 10-13 information still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	22. CONFIRMATION OF EXIT FROM THE EU (For completion by the competent authorities at the point of exit from the customs territory of the Union unless the simplified export authorisation procedure is applied) Date of exit: _____ Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

Notes

I.

1. The authorisation shall be completed in one of the official languages of the Union; if it is hand-written, it shall be completed in ink in capital letters.

2. Boxes 1, 3, 5, 7, 9 to 19 are to be provided by the applicant at the time of the request; however, the information required in boxes 7, 8 and 10 to 13 and 18 may be supplied at a later stage, if the information is not known at the time of the request. In this case, the information for box 18 is to be supplemented at the latest when the export declaration is made and the supplementary information for boxes 7, 8, 10 to 13 is to be given to the customs or other authority at the point of exit from the customs territory of the Union at the latest before the physical departure of the goods.

3. Boxes 1, 5, 7 and 9: Enter full names and addresses (phone, fax, e-mail).

4. Box 5: Enter reference number to the import authorisation document of the third country importer, (for example a 'letter of no-objection', import permit, other statement of the third country of destination), where appropriate.

5. Box 7: Enter full name and address (phone, fax, e-mail) of any other operator involved in the export operation such as transporters, intermediaries, customs agents.

6. Box 9: Enter full name and address (phone, fax, e-mail) of the person or company to which the goods are delivered in the country of destination (not necessarily the end-user).

7. Box 10: Give the name of the Member State, port, airport or border point, where appropriate.

8. Box 11: Give the name of the country, port, airport or border point, where appropriate.

9. Box 12: Specify all means of transport to be used (e.g. lorry, ship, plane, train, etc.). In the case of an export authorisation covering several export operations, this box need not be filled in.

10. Box 13: Give as full details as possible of the route to be taken.

11. Boxes 14a, 14b: Enter name of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005, the commercial name of the medicinal product listed in Category 4, the number of units in the consignment, the number of tablets/ampoules in each unit, the content of the scheduled substance in a single unit (per tablet/ ampoule) or in the case of a mixture or natural product, enter the name and the 8 digit CN code, as well as the commercial name.

12. Boxes 15a, 15b: Enter the 8 digit CN code of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005.

13. Box 16a, 16b: for Category 4, enter the total net weight of the scheduled substance contained in the consignment of medicinal products.

14. Box 19:

— Indicate in block letters the name of the applicant or, where appropriate, of the authorised representative who signs this application.

— The signature by the applicant or authorised representative, according to the modalities provided for by the Member State concerned, indicates that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of penal provisions, this declaration is equivalent to the engagement of responsibility, under the provisions in force in the Member States, in respect of the following:

  — the accuracy of the information given in the declaration;

  — the authenticity of any documents attached;

  — the observance of all the obligations inherent in the export of scheduled substances listed in the Annex to Regulation (EC) No 111/2005.

— Whenever the authorisation is issued by means of a computerised procedure, that authorisation may not contain the signature of the applicant in this box, if the application as such contains such signature.

II. (Simplified export authorisation procedure)

1. In the case of a simplified export authorisation procedure, boxes 7, 8, 10 to 13 and 18 need not be completed.

2. On the backside of copy No 2, boxes 24 to 27 must be completed for each export operation.

3. Box 23: Indicate the authorised maximum quantity and net weight. For Category 4, enter the total net weight of the scheduled substance contained in the consignment of medicinal products.

   Column 24: Indicate the quantity available in part 1 and the quantity of the partial export quantity in part 2. For Category 4, enter the total net weight quantity of the scheduled substance contained in the consignment of medicinal products.

   Column 25: Indicate the partial export quantity in words.

   Box 26: Reference number and the date of the customs declaration.

Personal data protection

Where the European Commission processes personal data contained in this document, Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community Institutions and bodies and on the free movement of such data will apply.

Where the competent authority of a Member State processes personal data contained in this document, the national provisions implementing Directive 95/46/EC will apply.

The purpose of the processing of personal data is the monitoring of trade in drug precursors within the Union in accordance to Regulation (EC) No 273/2004 as amended by Regulation (EU) No 1258/2013, and between the Union and third countries in accordance with Regulation (EC) No 111/2005, as amended by Regulation (EU) No 1259/2013.

The controller with respect to the processing of the data is the national competent authority where the present document has been submitted. The list of competent authorities is published on the website of the Commission:

http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/drugs_precursors/legislation/national_competent_authorities.pdf

In accordance with Article 17 of Regulation (EC) No 111/2005 laying down rules for the monitoring of trade in drug precursors between the Union and third countries, without prejudice to applicable provisions on data protection in the Union and for the purpose of controlling and monitoring certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission and the competent authorities of the Member States may share personal data and information contained in the present document with the relevant authorities in third countries.

The data subject has a right of access to the personal data relating to him or her that will be processed and, where appropriate, the right to rectify erase or block personal data in accordance with Regulation (EC) No 45/2001 or the national laws implementing Directive 95/46/EC.

All requests for the exercise of the right of access, rectification, erasure or blocking shall be submitted to and processed by the competent authorities where the present document was submitted.

The legal basis for processing the personal data is Article 33 of Regulation (EC) No 111/2005 and Article 13b of Regulation (EC) No 273/2004.

Personal data contained in the present document shall not be retained longer than necessary for the purposes for which it was collected.

Complaints, in case of conflict, can be addressed to the relevant national data protection authority. The contact details of the national data protection authorities are available on the web-site of the European Commission, Directorate-General for Justice: (http://ec.europa.eu/justice/data-protection/bodies/authorities/eu/index_en.htm#h2-1)

Where the complaint concerns processing of personal data by the European Commission, it should be addressed to the European Data Protection Supervisor: (http://www.edps.europa.eu/EDPSWEB/).

ANNEX IV

EUROPEAN UNION
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE ISSUING AUTHORITY

1	1. Importer (name and address)	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
		3. Period of validity: Beginning: End:
	4. Exporter (name and address)	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
	6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
	8. Ultimate consignee (name and address)	9. Point of entry into the Customs territory of the Union
		10. Methods/Means of transport

1	11a. Scheduled Substance	12a. CN-Code
		13a. Net weight
		14a. % of mixture
		15a. Invoice number
	11b. Scheduled Substance	12b. CN-Code
		13b. Net weight
		14b. % of mixture
		15b. Invoice number

16. Declaration by the applicant

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority)

Boxes 7, 9, 10 still required: YES ..... /NO .....

Signature: _____

Function: _____

Date: _____Stamp:

18. (For completion by the customs office in the Union)

Customs reference _____ (declaration of entry into the procedure or reference number to the custom approved treatment or use)

Signature of officer: _____

Function: _____

Place: _____ Date: _____ Stamp:

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE AUTHORITY IN THE COUNTRY OF EXPORT

2	1. Importer (name and address)	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
		3. Period of validity: Beginning: End:
	4. Exporter (name and address)	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
	6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
	8. Ultimate consignee (name and address)	9. Point of entry into the Customs territory of the Union
		10. Methods/Means of transport

	11a. Scheduled Substance	12a. CN-Code
		13a. Net weight
		14a. % of mixture
2		15a. Invoice number
	11b. Scheduled Substance	12b. CN-Code
		13b. Net weight
		14b. % of mixture
		15b. Invoice number

16. Declaration by the applicant)

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority) Boxes 7, 9, 10 still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	18. (For completion by the customs office in the Union) Customs Reference _____ (declaration of entry into the procedure or reference number to the custom approved treatment or use) Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY TO ACCOMPANY THE GOODS	**3**	1. Importer (name and address)	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
			3. Period of validity: Beginning: End:
		4. Exporter (name and address)	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
		6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
		8. Ultimate consignee (name and address)	9. Point of entry into the Customs territory of the Union
			10. Methods/Means of transport
		11a. Scheduled Substance	12a. CN-Code
			13a. Net weight
			14a. % of mixture
	3		15a. Invoice number
		11b. Scheduled Substance	12b. CN-Code
			13b. Net weight
			14b. % of mixture
			15b. Invoice number
		16. Declaration by the applicant) Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	

17. (For completion by issuing authority) Boxes 7, 9, 10 still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	18. (For completion by the customs office in the Union) Customs Reference _____ (declaration of entry into the procedure or reference number to the custom approved treatment or use) Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN UNION

GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE IMPORTER

4	1. Importer (name and address)	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
		3. Period of validity: Beginning: End:
	4. Exporter (name and address)	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
	6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
	8. Ultimate consignee (name and address)	9. Point of entry into the Customs territory of the Union
		10. Methods/Means of transport

	11a. Scheduled Substance	12a. CN-Code
		13a. Net weight
		14a. % of mixture
4		15a. Invoice number
	11b. Scheduled Substance	12b. CN-Code
		13b. Net weight
		14b. % of mixture
		15b. Invoice number

16. Declaration by the applicant)

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority) Boxes 7, 9, 10 still required: YES ..... /NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	18. (For completion by the customs office in the Union) Customs Reference _____ (declaration of entry into the procedure or reference number to the custom approved treatment or use) Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

Notes

1. The authorisation shall be completed in one of the official languages of the Union. If it is hand-written, it shall be completed in ink in capital letters.

2. Boxes 1, 4, 6, 8 and 11 to 16 are to be provided by the applicant at the time of the request; however, information as required in boxes 7, 9, 10 and 15 may be supplied at a later stage. In this case, this information is to be supplemented at the latest when the goods are entered into the customs territory of the Union.

3. Boxes 1, 4: Enter full names and addresses (phone, fax, e-mail).

4. Box 6: Enter full name and address (phone, fax, e-mail) of any other operator involved in the import operation such as transporters, intermediaries, customs agents.

5. Box 8: Enter full name and address of the ultimate consignee. The ultimate consignee may be identical with the importer.

6. Box 7: Enter name and address (phone, fax, e-mail) of the third country authority.

7. Box 9: Give the name of the Member State and the port, airport or border point.

8. Box 10: Specify all means of transport to be used (e.g. lorry, ship, plane, train, etc.).

9. Boxes 11a, 11b: Enter name of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005, the commercial name of the medicinal product listed in Category 4, the number of units in the consignment, the number of tablets/ampoules in each unit, the content of the scheduled substance in a single unit (per tablet/ ampoule) or in the case of a mixture or natural product enter the name and the 8 digit CN code, as well as the commercial name

10. Boxes 11a, 11b: Identify packages and substances with precision (e.g. 2 cans of 5 litres each). In the case of a mixture, a natural product or preparations, indicate the commercial name concerned.

11. Boxes 12a, 12b: Enter the 8 digit CN code of the scheduled substance as stated in the Annex of Regulation (EC) No 111/2005.

    Box 13 a, 13b: for Category 4, enter the total net weight of the scheduled substance contained in the consignment of medicinal products.

12. Box 16:

    — Indicate in block letters the name of the applicant or, where appropriate, of his authorised representative who signs this application.

— The signature by the applicant or his authorised representative, according to the modalities provided for by the Member State concerned, indicates that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of penal provisions, this declaration is equivalent to the engagement of responsibility, under the provisions in force in the Member States, in respect of the following:

the accuracy of the information;

the authenticity of any documents attached;

the observance of all other obligations.

— Whenever the authorisation is issued by means of a computerised procedure, that authorisation may not contain the signature of the applicant in this box, if the application as such contains such signature.

13. Personal data protection

Where the European Commission processes personal data contained in this document, Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community Institutions and bodies and on the free movement of such data will apply.

Where the competent authority of a Member State processes personal data contained in this document, the national provisions implementing Directive 95/46/EC will apply.

The purpose of the processing of personal data is the monitoring of trade in drug precursors within the Union in accordance to Regulation (EC) No 273/2004 as amended by Regulation (EU) No 1258/2013, and between the Union and third countries in accordance with Regulation (EC) No 111/2005, as amended by Regulation (EU) No 1259/2013.

The controller with respect to the processing of the data is the national competent authority where the present document has been submitted. The list of competent authorities is published on the website of the Commission:

http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/drugs_precursors/legislation/national_competent_authorities.pdf

In accordance with Article 17 of Regulation (EC) No 111/2005 laying down rules for the monitoring of trade in drug precursors between the Union and third countries, without prejudice to applicable provisions on data protection in the Union and for the purpose of controlling and monitoring certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission and the competent authorities of the Member States may share personal data and information contained in the present document with the relevant authorities in third countries.

The data subject has a right of access to the personal data relating to him or her that will be processed and, where appropriate, the right to rectify erase or block personal data in accordance with Regulation (EC) No 45/2001 or the national laws implementing Directive 95/46/EC.

All requests for the exercise of the right of access, rectification, erasure or blocking shall be submitted to and processed by the competent authorities where the present document was submitted.

The legal basis for processing the personal data is Article 33 of Regulation (EC) No 111/2005 and Article 13b of Regulation (EC) No 273/2004.

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Complaints, in case of conflict, can be addressed to the relevant national data protection authority. The contact details of the national data protection authorities are available on the web-site of the European Commission, Directorate-General for Justice: (http://ec.europa.eu/justice/data-protection/bodies/authorities/eu/index_en.htm#h2-1)

Where the complaint concerns processing of personal data by the European Commission, it should be addressed to the European Data Protection Supervisor: (http://www.edps.europa.eu/EDPSWEB/).