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 (Text with EEA relevance)

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

(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 Articles 3(8), 8(3) and 13(2) 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 in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 11(1) and (3), Article 19 and Article 32(2) 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 delegated 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) Licences and registrations which are required for operators willing to carry out activities involving certain substances (drug precursors), which can be used for the illicit

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manufacture of narcotic drugs or psychotropic substances, should be granted only to reliable operators applying for it. These operators should have taken adequate measures aiming at the secure handling and storage of those drug precursors and should have appointed an identifiable responsible officer able to ensure that activities involving these substances take place in compliance with the pertinent legal provisions.

(5) Certain operators dealing with drug precursors for medical use, such as pharmacies and dispensaries of veterinary medicine, could be exempted from the requirement of having been granted a licence or a registration in order to carry out activities involving such substances. The same could be applicable to certain public authorities.

(6) Operators carrying out activities related to drug precursors which are not intended for the Union market, but have been brought into the customs territory of the Union, should provide information showing that the exportation of those substances was made in compliance with relevant International conventions to demonstrate the licit purposes of the corresponding transaction.

(7) Operators established in the Union should provide certain basic details on the activities they have carried out in order to facilitate the monitoring, by the competent authorities, of trade in drug precursors.

(8) For the purposes of minimising the risk of diversion of certain drug precursors, their exportation should be preceded by a pre-export notification and by an export authorisation.

(9) There are frequent changes in relation to the lists of third countries of destination for exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005. In order to allow for a swift update of those lists, in accordance with the criteria for those lists determined in this Regulation, these lists should be published on the website of the Commission.

(10) In order to ease the administrative burden for trade in certain categories of drug precursors, a simplified procedure for pre-export notification and for export authorisation should be provided.

(11) To improve the coordination of the implementation of the monitoring measures, it is appropriate that the Member States provide the Commission regularly with information concerning drug precursors seized or detained.

(12) In order to ensure consistency, legislative coherence and legal certainty, this Delegated Regulation should apply from the same date as the Implementing Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down conditions for granting licences and registrations, determines cases where a licence and a registration are not required, establishes the criteria to demonstrate the licit purpose of a transaction, determines the information required

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to monitor trade, fixes the conditions for determining the lists of the countries of destination for exports of scheduled substances of Categories 2 and 3, establishes the criteria for determining simplified procedures for pre-export notifications and for export authorisations and specifies the requirements concerning the information to be provided on the implementation of the monitoring measures as regards trade in 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

Conditions for granting licences

1 In order to obtain a licence pursuant to Article 6(1) of Regulation (EC) No 111/2005, the operator shall appoint an officer responsible for the trade in scheduled substances listed in Category 1 of the Annex to that Regulation, notify the competent authority of the name and contact details of that officer and notify them immediately of any subsequent modification of this information.

The responsible officer shall ensure that import, export or intermediary activities take place in compliance with the pertinent legal provisions and shall be empowered to represent the operator and to take the decisions necessary for performing that task.

2 The operator concerned shall fulfil all the following requirements and conditions:

a the operator shall take adequate measures against the unauthorised removal of scheduled substances of Category 1 of Annex I to Regulation (EC) No 273/2004 and of the Annex to Regulation (EC) No 111/2005 from the places of storage, production, manufacture and processing of scheduled substances and to secure business premises;

b the operator shall make an application containing the following:

(i) the full name, address, telephone and/or fax numbers and email address of the applicant;

(ii) the full name of the responsible officer and his/her contact details;

(iii) a description of the position and tasks of the responsible officer;

(iv) the full addresses of the business premises;

(v) **[**[X1]the description of all the places where operations described under point (ix) take place;**]**

(vi) information showing that the adequate measures referred to in paragraph 2(a) have been taken;

(vii) the name and the CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005;

(viii) in the case of a mixture or natural product an indication of the following:

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(a) the name of the mixture or natural product;

(b) the name and CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 contained in the mixture or natural product;

(c) the maximum percentage of such scheduled substances in the mixture or natural product;

(ix) a description of the envisaged type of operations referred to in Article 3 of Regulation (EC) No 273/2004 and in Article 6(1) of Regulation (EC) No 111/2005;

(x) an authenticated copy of the Register of companies or activities, where relevant;

(xi) a certificate of good conduct of the operator concerned and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the operations or the information allowing the competent authority to obtain such document.

3 If the operator has already been granted the status of an Authorised Economic Operator in accordance with Article 5a of Council Regulation (EEC) No 2913/92[(4)]; he may indicate the AEO certificate number when making the application for a licence for the purpose of the competent authority being able to take his AEO status into consideration.

4 Upon written request from the relevant competent authority, the applicant shall submit any relevant additional information.

5 Where the applicant is a natural person, points (ii) and (iii) of paragraphs 2(b) shall not apply, and point (iv) of paragraph 2(b) shall only apply where relevant.

6 Without prejudice to measures adopted in accordance with Article 10(1) of Regulation (EC) No 273/2004 and with Article 26(3) of Regulation (EC) No 111/2005, the competent authority shall refuse the granting of the licence if the conditions set out in Article 3(2)(b) of this Regulation are not fulfilled or if there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

7 In the case of trade between the Union and third countries referred to in Regulation (EC) No 111/2005, the competent authority may either limit the validity of the licence to a period not exceeding three years or may require operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled.

The validity of licences issued before the entry into force of this Regulation shall not be affected.

8 A licence shall not be transferable.

9 The licence holder shall apply for a new licence where any of the following are envisaged:

a the addition of a scheduled substance;

b the start of a new operation;

c the change of the location of the business premises where the operations take place.

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In such cases, the existing licence shall cease to be valid on the earlier of the following dates:

(i) **[**[X2]the date of expiry of validity where a term of validity has been fixed in accordance with Article 3(7) of this Regulation or in accordance with Article 3(5) of Regulation (EC) No 273/2004;**]**

(ii) the date of commencement of validity of the new licence.

10 Paragraph 9 shall also apply to licences issued before the date of application of this Regulation.

11 Paragraphs 2 to 6 and 8, 9 and 10 shall also apply for the purpose of obtaining licences pursuant to Article 3(2) of Regulation (EC) No 273/2004, with the exception of special licences.

12 The public authorities referred to in Article 3(2) and (6) of Regulation (EC) No 273/2004 shall comprise customs, police and official laboratories of competent authorities.

Editorial Information

X1 Substituted by Corrigendum to the 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 (Official Journal of the European Union L 162 of 27 June 2015).

X2 Substituted by Corrigendum to 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 (Official Journal of the European Union L 162 of 27 June 2015).

Article 4

Cases where a licence is not required

Pharmacies, dispensaries of veterinary medicine, customs, police, armed forces and official laboratories of competent authorities may be exempted from the requirement of licensing pursuant to Article 6(1) of Regulation (EC) No 111/2005 in so far as these operators use drug precursors within the scope of their official duties.

The operators set out in the first paragraph are also exempted from the following:

(a) the provision of documentation referred to in Article 3 of Regulation (EC) No 111/2005;

(b) the obligation to appoint a responsible officer set out in Article 3(1) of this Regulation.

Article 5

Conditions for granting registrations

1 In order to obtain a registration pursuant to Article 7(1) of Regulation (EC) No 111/2005, the operator shall appoint an officer responsible for the trade in scheduled substances listed in Category 2 of the Annex to that Regulation, notify the competent authority of the name