Regulation (EU) No 1259/2013 of the European Parliament and of the Council of 20 November 2013 amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

REGULATION (EU) No 1259/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure[(1)],

Whereas:

(1) On 7 January 2010, the Commission adopted a report, pursuant to Article 32 of Council Regulation (EC) No 111/2005[(2)], on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) Trade in medicinal products is not controlled in the existing Union control system for drug precursors, since they are currently excluded from the definition of scheduled substances.

(3) The Commission report pointed out that medicinal products containing ephedrine and pseudoephedrine were diverted into the illicit drug manufacture outside the Union, as a substitute for internationally controlled ephedrine and pseudoephedrine. The Commission therefore recommended strengthening the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

(4) In its Conclusions of 25 May 2010 on the functioning and implementation of EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(5) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 ('the United Nations Convention'), is deleted as it is already covered by

the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(6) Rules on suspending or revoking the registration of an operator should be introduced in order to match the existing rules for suspending or revoking a licence.

(7) Medicinal products and veterinary medicinal products ('medicinal products') containing ephedrine or pseudoephedrine should be controlled without impeding their legitimate trade. To that end, a new category (Category 4) should be added to the Annex to Regulation (EC) No 111/2005 listing medicinal products containing certain scheduled substances.

(8) The export of medicinal products listed in Category 4 of the Annex to Regulation (EC) No 111/2005, as amended by this Regulation, should be preceded by an export authorisation, and a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(9) Member States' competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

(10) With a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified. To that end, Member States should be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Such non-scheduled substances should be considered as proposed for inclusion in the voluntary monitoring list of non-scheduled substances.

(11) Member States' competent authorities should share between themselves and with the Commission, through the European database on drug precursors ('the European database'), established under Regulation (EC) No 273/2004 of the European Parliament and of the Council[(3)], information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

(12) Regulation (EC) No 111/2005 provides for the processing of data. Such processing may also cover personal data and should be carried out in accordance with Union law.

(13) The processing of personal data for the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the right to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union.

(14) Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council[(4)] and Regulation (EC) No 45/2001 of the European Parliament and of the Council[(5)].

(15) Regulation (EC) No 111/2005 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC[(6)].

(16) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

(17) In order to achieve the objectives of Regulation (EC) No 111/2005, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to set out the conditions for granting licences and registration and for determining cases where a licence or a registration is not required, to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, to determine the information that is required by the competent authorities and by the Commission to allow them to monitor export, import or intermediary activities of operators, to determine the lists of the countries of destination to which exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005 are to be preceded by a pre-export notification, to determine simplified pre-export notification procedures and to establish the common criteria to be applied by the competent authorities, to determine simplified export authorisation procedures and to establish the common criteria to be applied by the competent authorities, and to adapt the Annex to Regulation (EC) No 111/2005 in order to respond to new trends in diversion of drug precursors and to follow any amendment to the tables in the Annex to the United Nations Convention. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) No 1259/2013 of the European Parliament and of the Council. (See end of Document for details)*

(18) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, as amended by this Regulation, implementing powers should be conferred on the Commission, namely to establish a model for licences, the procedural rules on the provision of information that is required by the competent authorities to monitor export, import or intermediary activities of operators, and the measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[(7)].

(19) The delegated and implementing acts adopted pursuant to Regulation (EC) No 111/2005, as amended by this Regulation, should guarantee a systematic and consistent control and monitoring of operators.

(20) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013[(8)].

(21) Regulation (EC) No 111/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 111/2005 is amended as follows:

(1) in the title of the Regulation and in Article 1, in points (d) and (e) of Article 2, in Article 10(1), in the first paragraph of Article 17, in the first paragraph of Article 20 and in Article 25, the noun ‘Community’ is replaced by the noun ‘Union’. In point (e) of Article 2, in point (d) of Article 13(1), in the first subparagraph of Article 14(1), in Article 14(2), in Article 18 and in the first paragraph of Article 22, the term ‘Community customs territory’ is replaced by the term ‘customs territory of the Union’. In the first subparagraph of Article 12(1), the term ‘Customs territory from the Community’ is replaced by the term ‘customs territory of the Union’;

(2) in Article 2:

(a) point (a) is replaced by the following:

(a) “scheduled substance” means any substance listed in the Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances, but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council[(9)] and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council[(10)], except medicinal products and veterinary medicinal products listed in the Annex;;

(b) point (c) is replaced by the following:

(c) "import" means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92[(11)];;

(c) point (j) is replaced by the following:

(j) "natural product" means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(12)];;

(3) the first paragraph of Article 3 is replaced by the following:

All imports, exports or intermediary activities involving scheduled substances, with the exception of substances listed in Category 4 of the Annex, shall be documented by the operator by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.;

(4) Article 5 is replaced by the following:

Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name 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, except substances listed in Category 4 of the Annex, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.;

(5) in Article 6:

(a) paragraph 1 is replaced by the following:

1. Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex, shall hold a licence. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting licences and for determining cases where a licence is not required.;

(b) the following paragraph is added: