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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

(Text with EEA relevance)

{SWD(2012) 267 final}
{SWD(2012) 268 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Background

Drug precursors are chemical substances having a wide variety of licit uses, such as in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents, or aromas. They are traded for legitimate purposes on regional and global markets, but some of them can also be diverted from the licit distribution channels for the illicit manufacture of narcotic drugs.

Therefore, controlling drug precursors is a key component in the fight against narcotic drugs. Taking into account the wide legitimate uses of drug precursors, their trade cannot be prohibited. A specific regulatory framework, both at international and at EU level, has been put in place to monitor their legal trade and to identify suspicious transactions, thus preventing their diversion for illicit use.

Ephedrine and pseudoephedrine are chemical substances used for the manufacture of cold or allergy medicines. These two substances are also the main precursors for the manufacture of methamphetamine[1]. While ephedrine and pseudoephedrine are controlled at international and EU level, the medicinal products containing them are not controlled when they are exported from or transiting through the Union customs territory. They are therefore targeted by drug traffickers as a source of precursors for the illicit manufacture of methamphetamine because the ephedrine or pseudoephedrine contained in these products can be easily extracted (by using cheap home-made equipment and through a simple chemical process).

The fact that medicinal products for human use containing ephedrine or pseudoephedrine are excluded from the provisions of Regulation (EC) 111/2005, which applies to trade in drug precursors between the EU and third countries, has led to a situation where these products could not be stopped or seized by Member States' competent authorities when these products were exported from or transiting through the Union customs territory, even though it was very likely that they would be misused for the illicit manufacture of methamphetamine in their country of destination.

The EU is criticized internationally for not taking adequate control measures across Member States to tackle this weakness. Therefore, the EU is expected to close the loophole in the current legislation as regards the powers conferred to customs and police authorities who can stop and seize ephedrine and pseudoephedrine but cannot stop and seize medicinal products containing ephedrine or pseudoephedrine.

In its Conclusions of 25 May 2010, the Council invited the Commission to present a legislative proposal in this sense.

1.2. Scale of the problem (methamphetamine and its precursors)

In 2009 almost 7400 seizures of methamphetamine, amounting to about 600 kg of the drug, were reported in Europe. Both the number of seizures and quantities increased over 2004-

[1] Methamphetamine is a synthetic drug which belongs to the amphetamines-group. This drug manipulates pleasure centres of the brain and can be more potent than cocaine and usually have a longer lasting effect. Taken as pills, smoked, inhaled or injected, it is particularly attractive to young people because it produces a sense of high energy, a release of social inhibitions and feelings of cleverness, competence and power. The physical and psychological effects (feelings of anxiety, hyper stimulation and paranoia) occur rapidly.

2009. In 2009 illicit methamphetamine laboratories were seized for the first time in several European countries. This is an indication that methamphetamine markets may be expanding in Europe.

At global level, in 2009, North America accounted for nearly half of global seizures of methamphetamine. Seizures in East and South-East Asia rose by more than one third and there are signs that methamphetamine is reaching the region from Africa and the Islamic Republic of Iran. West Africa is also emerging as a new source of methamphetamine for the illicit Asian markets.

Ephedrine and pseudoephedrine are the main precursors for methamphetamine. Seizures of methamphetamine precursors contained in medicinal products have fluctuated considerably from 2007 until 2010. At European level, while in 2007 hardly any preparations were recorded out of the overall quantities seized, in 2008 and 2009 the amount of preparations out of the total quantities seized increased sharply and decreased considerably again in 2010[2].

After the continued increase of seizures of medicinal products from 2007 to 2009, as a result of strengthened controls of medicinal products containing ephedrine and pseudoephedrine in several countries, particularly in Mexico and countries in Central America, the total amount of medicinal products seized worldwide decreased in 2010.

However, the increasing or decreasing level of seizures is only one indicator to illustrate that illicit manufacture is taking place in a given part of the world. The absence of a control mechanism for medicinal products containing ephedrine and pseudoephedrine remains a concern both at European and at global level.

By imposing EU control over these medicinal products, we are aiming to make it more difficult, expensive and risky for criminals to source the chemicals they need to manufacture drugs. This proposal should work as a deterrent: it focuses on preventing the diversion of precursors. It concentrates on the supply reduction of the chemicals to make drugs and not on the supply of the drugs for the consumers.

1.3. Consistency with other EU policies

Effectively preventing the diversion of drug precursors to the production of illicit drugs aims to reduce the supply of illicit drugs. It is thus consistent with the drug policy outlined in the EU Drugs Strategy 2005-2012, providing for action to reduce the supply of precursors, and, thereby, decrease the production of drugs.

This initiative aims to regulate the external trade in medicinal products containing ephedrine and pseudo-ephedrine. These products are regulated by Directive 2001/83/EC. However, the objective pursued by that Directive is of a different nature, i.e. to safeguard public health by controlling the production, distribution and use of medicinal products in order to ensure their quality, safety and efficacy. This explains why the control mechanisms foreseen in Directive 2001/83/EC and in Regulation (EC) 111/2005 are different.

The medicinal products legislation has recently been amended by Directive 2011/62/EU which relates to the prevention of the entry into the legal supply chain of falsified medicinal

[2] In 2007, 8mt of these precursors were seized of which nearly 4 % were in the form of medicinal products; in 2008 3,5mt of which 51% were in the form of medicinal products; in 2009 1,4mt of which 43% were in the form of medicinal products; in 2010 2.9mt out of which 3% were in the form of medicinal products. These seizures were made on the basis of national legislation.

products. The Directive addresses *inter alia* the distribution chain for medicines within the EU, importation of active substances, and 'introduction' of medicines, i.e. medicines brought into the customs territory without the intention of placing them on the market. These provisions are focused on preventing products that fall within the definition of *falsified* medicinal products from *entering* the legal supply chain. Given that the principal issue with drug precursors is one of *legitimately* produced products *leaving* the legal supply chain, it is unlikely that these new provisions will make a significant contribution to tackling the issue of controlling medicinal products containing ephedrine or pseudoephedrine being exported or transiting through the EU.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

2.1. Consultation of interested parties

A stakeholder consultation was held. This was not a public consultation, given the sensitivity and the peculiarity of the matter at stake[3]. Only the most concerned stakeholders were therefore consulted, namely national competent authorities (customs, police and health) and the pharmaceutical industry. To avoid providing sensitive information to traffickers, the responses of the stakeholders were treated confidentially.

In response to this consultation the Commission received 31 contributions. Of these, 22 were from national authorities (3 of which were partial replies) and 8 from the industry (6 manufacturing companies and 2 pharmaceutical associations).

In general terms, the industry is satisfied with the current situation but would not be opposed to improve it to the extent that it would not impose increased administrative burden on exporting companies. Among Member States' competent authorities two thirds plead for an amendment of the legislation, though to different degrees, while one third is in favour of maintaining the current situation, thus not amending the legislation.

2.2. Impact Assessment

The impact assessment report identified and assessed policy options aiming to prevent the diversion of medicinal products containing ephedrine or pseudoephedrine to the illicit manufacture of methamphetamine by introducing control measures over these products when traded between the Union and third countries while maintaining their free flow.

The impact assessment report contains five policy options. The first one provides for the so-called "baseline scenario", where the Commission would take no action and the status quo would be maintained. Option 2 considers contributing to improve the situation through voluntary measures by Member States, while options 3, 4 and 5 consider resolving it through compulsory control measures. The last three options have been built as a crescendo as to the number and strength of the control measures envisaged. Another policy option suggesting a trade ban on these products has been considered and discarded without further analysis of its impact.

[3] On the one hand, the subject matter, drug precursors, is not widely known and would have most likely entailed responses concerning the overall drug situation, which would have been irrelevant for this exercise. On the other hand, the problem at stake and the envisaged options only affect a very specific aspect of drug precursor control.

Option 1 should be excluded if the Commission was to respond adequately to the Council's request to address the weaknesses identified in the control system of the drug precursor legislation and to concerns expressed by the international community.

Option 2 would only partially address the identified problem. It suggests voluntary measures which will not be effective unless adopted across all Member States. A compulsory application of these measures cannot be enforced by the instrument foreseen under this option.

Options 3, 4 and 5 would all provide a clear legal basis for competent authorities to stop and/or seize medicinal products containing ephedrine or pseudoephedrine at export from or in transit through the Union customs territory. They would all reduce the criticism expressed by the UN International Narcotics Control Board on the alleged lack of EU action to control these products. They would all increase the chances to prevent the diversion of these products, thus reducing the supply of ephedrine and pseudoephedrine for the illicit manufacture of methamphetamine, though to different degrees.

When comparing these three options requiring legislative amendments, option 3 (possibility for authorities to stop suspicious shipments) would generate only minor administrative burden; the same can be expected for option 4 (possibility for authorities to stop suspicious shipments and pre-export notification of legal shipments), while option 5 (full control of trade in medicinal products containing ephedrine and pseudoephedrine) would impose the highest administrative burden for both competent authorities and economic operators. Even though option 5 could be considered the most effective by applying the strictest controls, the requirements would be disproportionate to the objective pursued by the present initiative. The added value provided by option 4 if compared to option 3 is that, under this option, the synergy of two combined measures increases the effectiveness of each individual measure, with a limited additional burden given that the pre-export notification system is up and running and that the number of pre-export notifications that could be seemingly sent per year by Member States' competent authorities is relatively small. Moreover, as pre-export notifications are already compulsory for scheduled substances of category 1, it would seem logical to make them compulsory also for the products containing them, such as medicinal products containing ephedrine or pseudoephedrine.

The impact assessment concluded that option 4 would be the most suitable one to address the identified problem, as it would provide for a legal basis, impose only one extra control requirement and generate hardly any additional administrative burden.

3. LEGAL BASIS AND SUBSIDIARITY

The legal basis of the proposal is Article 207 of the Treaty on the Functioning of the European Union (TFEU). Article 207 defines the EU common commercial policy. Moreover, Article 3(1) of the TFEU provides exclusive competence of the European Union in the area of common commercial policy.

Council Regulation (EC) No 111/2005 lays down rules for the monitoring of trade in drug precursors between the Union and third countries, and therefore falls under the common commercial policy.

4. BUDGETARY IMPLICATION

The proposal will not have an impact on human resources and on the European Union budget and is therefore not accompanied by the financial statement foreseen under Article 28 of the Financial Regulation (Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities).

5. ADDITIONAL INFORMATION

The proposal contains some other amendments aiming at facilitating the implementation of the Regulation and at increasing its effectiveness.

The proposal includes:

- the possibility to amend the Annex to the Regulation in order to react more quickly to new emerging trends in precursors diversion;

- a reference to the database, created by Regulation (EC) No 273/2004 as amended, to simplify the reporting by Member States' authorities in accordance with Article 12(12) of the United Nations Convention;

- a review clause to assess whether the amended Regulation will have been effective to prevent the diversion of medicinal products containing ephedrine or pseudoephedrine;

- the adaptation of the provisions of Regulation (EC) No 111/2005 in accordance with the rules on delegated and implementing acts under the Treaty on the Functioning of the European Union (TFEU).

The Commission has been granted implementing powers under the current Regulation in accordance with Articles 4 and 7 of Decision 1999/468/EC. As this Regulation is being amended, these powers have to be aligned in accordance with Articles 290 and 291 of the TFEU. The alignment in the proposal has been made in accordance with the provisions of the Common Understanding on Delegated Acts between the European Parliament, the Council and the Commission and Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers.

The proposal is subject to the WTO-TBT Agreement, thus subject to a notification to the WTO.

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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 thereof,

Having regard to the proposal from the European Commission,

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

After consulting the European Data Protection Supervisor[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Pursuant to Article 32 of Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors[2], the Commission presented on 7 January 2010 a report to the Council and the European Parliament on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors[3].

(2) The Commission report pointed out that, in the existing Union control system for drug precursors, medicinal products containing ephedrine and pseudoephedrine, whose trade was not controlled, were diverted into the illicit drug manufacture outside the Union, as a substitute to 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 Union customs territory which are diverted for the illicit manufacture of drugs.

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1 OJ C , , p.

2 OJ L 22, 26.1.2005, p. 1.

3 Report from the Commission to the Council and the European Parliament pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 and to Article 32 of Council Regulation (EC) No 111/2005 on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors, COM(2009)709 final.

(3) In its Conclusions on the functioning and implementation of the Union drug precursors legislation of 25 May 2010, the Council of the European Union invited the Commission to make a proposal to amend Council Regulation (EC) No 111/2005 accordingly.

(4) It is important that the definition of scheduled substances be clarified: the term 'pharmaceutical preparation' stemming from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 (hereinafter referred to as the "United Nations Convention") should be replaced by the relevant terminology of the Union legislation, 'medicinal products', and the term 'other preparations' should be deleted as it duplicates the term 'mixtures' already used in the definition.

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

(6) Medicinal products containing ephedrine or pseudoephedrine should therefore be controlled without impeding their legitimate trade.

(7) To this end, any export of medicinal products containing ephedrine or pseudoephedrine should be preceded by a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(8) Member States' competent authorities should be given the powers to stop or seize those products when there are reasonable grounds for suspecting that they are intended for the illicit drug manufacture, when they are exported, imported or in transit.

(9) With a view to enabling Member States to react more quickly with regard to new emerging trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified.

(10) The European Database on drug precursors should be used to simplify the reporting by Member States with regard to seizures and stopped shipments, to establish a European register of operators holding a licence or a registration, which will facilitate verification of the legitimacy of their transactions involving scheduled substances and to enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances.

(11) Regulation (EC) No 111/2005 envisages the processing of data. Such processing of data may also cover personal data which should be carried out in accordance with Union Law.

(12) 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 of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[4] as amended by Council Decision 2006/512/EC[5].

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4 OJ L 184, 17.7.1999, p. 23.

5 OJ L 200, 22.7.2006, p. 11.

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

(14) In order to achieve the objectives of Regulation (EC) No 111/2005, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in order to lay down provisions determining cases where a licence is not required and to set out further conditions for granting licences, to establish the conditions for exemptions from the controls of certain categories of operators and of operators engaged in the export of small quantities of scheduled substances listed in Category 3, 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 to monitor export, import or intermediary activities of operators, to determine the countries of destination to which exports of scheduled substances of Category 2 and 3 of the Annex should be preceded by a pre-export notification, to determine simplified pre-export procedures and to establish the common criteria thereof, to determine the countries of destination to which exports of scheduled substances listed in Category 3 of the Annex should be subject to an export authorisation, to determine simplified export authorisation procedures and to establish the common criteria thereof, and to introduce additional substances into the Annex to this Regulation, as well as other amendments necessary to respond to new trends of drug precursor diversion. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level.

(15) 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 Council.

(16) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, implementing powers should be conferred on the Commission, namely to establish a model for licences. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers.[6]

(17) Since this Regulation is based on the common commercial policy, the examination procedure should be used for the adoption of the implementing acts.

(18) 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) Article 2 is amended as follows:

[6] OJ L 55, 28.2.2011, p. 13.

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

"(a) 'scheduled substance' means any substance used for the illicit manufacture of narcotic drugs or psychotropic substances and listed in the Annex, including mixtures and natural products containing such substances. This excludes natural products and mixtures 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 and medicinal products within the meaning of Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council[7];"

(b) point (j) is deleted.

(2) Article 6 is amended as follows:

(a) in paragraph 1, the third subparagraph is replaced by the following:

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

(b) the following paragraphs 3 and 4 are added:

"3. The Commission shall establish a model for licences by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

4. The delegated acts referred to in the third subparagraph of paragraph 1 and the implementing acts referred to in paragraph 3 shall guarantee a systematic and consistent control and monitoring of operators."

(3) Article 7 is amended as follows:

(a) in paragraph 1, the following subparagraph is added:

"In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant."

(b) paragraph 2 is replaced by the following:

"2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to establish the conditions for exemption from the controls of certain categories of operators and of operators engaged in the export of small quantities of scheduled substances listed in Category 3, ensuring that the risk of diversion of scheduled substances is minimised."

(c) The following paragraph 3 is added:

"3. The registration may be suspended or revoked by the competent authorities whenever the conditions under which the registration was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances."

[7] OJ L 311, 28.11.2001, p. 67.

(4) In Article 8, paragraph 2 is replaced by the following:

"2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, in order to ensure that all movements of scheduled substances within the Union customs territory can be monitored by the competent authorities and the risk of diversion be minimised."

(5) In Article 9,

(a) The following is added at the end of paragraph 1:

"To this end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction, such as:

- the name of the scheduled substance;

- the quantity and weight of the scheduled substance; and

- the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

This information will only be used for the purposes of preventing the diversion of scheduled substances."

(b) Paragraph 2 is replaced by the following:

"2. Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the information that is required by the competent authorities in order to allow them to monitor those activities, including rules on how to provide such information in electronic form to a European database, where appropriate."

(6) Article 11 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

"1. All exports of scheduled substances listed in Category 1 of the Annex, exports of scheduled substances listed in Category 2 and 3 of the Annex to certain countries of destination and all exports of medicinal products containing ephedrine or pseudoephedrine, shall be preceded by a pre-export notification sent from the competent authorities in the Union to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the list of the countries of destination in order to minimise the risk of diversion of scheduled substances and medicinal products containing ephedrine or pseudoephedrine, by ensuring systematic and consistent monitoring of exports of such substances and products to those countries."

(b) paragraph 3 is replaced by the following:

"3. Simplified pre-export notification procedures may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances and of medicinal products containing ephedrine or pseudoephedrine. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities."

(7) In Article 12(1), the third subparagraph is replaced by the following:

"However, exports of scheduled substances listed in Category 3 of the Annex shall only be subject to an export authorisation where pre-export notifications are required, or where those substances are exported to certain countries of destination. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the list of such countries of destination in order to ensure an appropriate level of control."

(8) Article 19 is replaced by the following:

"Article 19

Simplified procedures to grant an export authorisation may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities."

(9) Article 26 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Without prejudice to the provisions of Articles 11 to 25 and to paragraphs 2 and 3 of this Article, the competent authorities of each Member State shall prohibit the introduction of scheduled substances, as well as of medicinal products containing ephedrine or pseudoephedrine, into the Union customs territory or their departure from it, if there are reasonable grounds for suspecting that such substances and products are intended for the illicit manufacture of narcotic drugs or psychotropic substances."

(b) the following paragraph 3a is added:

"3a. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions with non-scheduled substances, in particular:

(a) to obtain information on any orders for or operations involving non-scheduled substances;

(b) to enter operators' business premises in order to obtain evidence of suspicious transactions with non-scheduled substances."

(10) Article 28 is replaced by the following:

"Article 28

In addition to the measures referred to in Article 26, the Commission shall be empowered to lay down, where necessary, by means of implementing acts, measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors for the purpose of preventing the diversion of such substances, in particular with regard to the design and use of export and import authorisation forms. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2)."

(11) Article 29 is deleted.

(12) Article 30 is replaced by the following:

"Article 30

1. The Commission shall be assisted by the Drug Precursors Committee (hereinafter referred to as the 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 5 of Regulation (EU) No 182/2011 shall apply."

(13) The following Articles 30a and 30b are inserted:

"Article 30a

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b in order to adapt the Annex to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow an amendment to the tables in the Annex to the United Nations Convention.

Article 30b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 6(3) third subparagraph, 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19, 28 and 30a shall be conferred for an indeterminate period of time from *[OPOCE insert date of entry into force of this amending Regulation]*

3. The delegation of powers referred to in Articles 6(3) third subparagraph, 7(2), 8(2), 9(2), 11(1) and (3), 12(1), (19), 28 and 30a may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and the Council.

5. A delegated act adopted pursuant to Articles 6(3) third subparagraph, 7(2), 8(2), 9(2), 11(1) and (3), 12(1), (19), 28 and 30a shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of

that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council."

(14) In Article 32, the third subparagraph is replaced by the following:

"The Commission shall evaluate the implementation and functioning of Articles 11 and 26 insofar as they concern medicinal products containing ephedrine or pseudoephedrine and Article 30a by *[OPOCE insert date 5 years after entry into force of this amending Regulation]*".

(15) The following Article 32a is inserted:

"Article 32a

Database

The Commission shall use a European Database on drug precursors, as established by Regulation (EC) No 273/2004 of the European Parliament and of the Council[8], with the following functions:

(a) facilitating the communication of information pursuant to Article 32 first subparagraph, as well as the reporting to the International Narcotics Control Board pursuant to Article 32 second subparagraph;

(b) managing a European register of operators, which have been granted a licence pursuant to Articles 6(1) or registration pursuant to Articles 7(1);

(c) enabling operators to provide the competent authorities with information about their export, import or intermediary activities according to Article 9(2)."

(16) Article 33 is replaced by the following:

"Data protection provisions

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with Directive 95/46/EC and under the supervision of the public independent authority of the Member State referred to in Article 28 of this Directive.

2. The processing of personal data by the Commission, including for the purpose of the European Database referred to under Article 32a, shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor."

Article 2

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

[8] *OJ L 86, 24.3.2004, p. 21*

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*