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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 747 annex
Subject:	ANNEXES to the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

Delegations will find attached document COM(2025) 747 annexes 1-10.

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Brussels, 3.12.2025
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ANNEXES 1 to 10

ANNEXES

to the

Proposal for a Regulation of the European Parliament and of the Council

on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

{SEC(2025) 328 final} - {SWD(2025) 397 final} - {SWD(2025) 398 final} -
{SWD(2025) 399 final}

ANNEX I

Category 1 drug precursors

Category 1 drug precursors contain or consist of:

Substance	**CAS number**	**CN code**	**CUS number**	**Quantity threshold referred to in Article 9(1), first subparagraph**	**Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)**	**Special conditions on mixtures**
1-phenyl-2-propanone (BMK), also known as phenylacetone	103-79-7	2914 31 00 00	-	-	-	
3'-chloropropiophenone	34841-35-5	2914 79 00 00	-	-	-	
2-bromo-3'-chloropropiophenone	34911-51-8	2915 79 00 00	-	-	-	
4'-methylpropiophenone	5337-93-9	2916 79 00 00	-	-	-	
2-Bromo-4'-methylpropiophenone	1451-82-7	2917 79 00 00	-	-	-	
3'-Methylpr	51772-	2918 79	-	-	-	

Substance	CAS number	CN code	CUS number	Quantity threshold referred to in Article 9(1), first subparagraph	Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)	Special conditions on mixtures
opiophenone	30-6	00 00				
2-Bromo-3'-methylpropiophenone	1451-83-8	2919 79 00 00	-	-	-	
4'-Chloropropiophenone	6285-05-8	2920 79 00 00	-	-	-	
2-Bromo-4'-chloropropiophenone	877-37-2	2921 79 00 00	-	-	-	
Phenyl-2-nitropropene	705-60-2	2922 79 00 00	-	-	-	
N-acetylanthranilic acid, also known as 2-acetamidobenzoic acid	89-52-1	2924 23 00 00	-	-	-	
Isosafrol (cis + trans)	120-58-1	2932 91 00 00	-	-	-	
3,4-	4676-39-	2932 92	-	-	-	

Substance	CAS number	CN code	CUS number	Quantity threshold referred to in Article 9(1), first subparagraph	Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)	Special conditions on mixtures
methylenedioxyphenylpropan-2-one (PMK)	5	00 00				
Piperonal	120-57-0	2932 93 00 00	-	-	-	
Safrole	94-59-7	2932 94 00 00	-	-	-	
N-phenyl-1-(2-phenylethyl)piperidin-4-amine (ANPP)	21409-26-7	2933 36 00 00	-	-	-	
1-(2-phenylethyl)piperidin-4-one (NPP)	39742-60-4	2933 37 00 00	-	-	-	
N-phenylpiperidin-4-amine (4-AP)	23056-29-3	2933 39 99 01	-	-	-	
Ephedrine	299-42-3	2939 41 00 00	-	-	-	
Pseudoephedrine	90-82-4	2939 42 00 00	-	-	-	
Norephed	14838-	2939 44	-	-	-	

Substance	**CAS number**	**CN code**	**CUS number**	**Quantity threshold referred to in Article 9(1), first subparagraph**	**Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)**	**Special conditions on mixtures**
rine	15-4	00 00				
Ergometrine	60-79-7	2939 61 00 00	-	-	-	
Ergotamine	113-15-5	2939 62 00 00	-	-	-	
Lysergic acid	82-58-6	2939 63 00 00	-	-	-	

The salts of the substances listed in this Annex, whenever the existence of such salts is possible and not being the salts of cathine.

The stereoisomeric forms of the substances listed in this category not being cathine, whenever the existence of such forms is possible.

ANNEX II

Category 2 drug precursors

Part I

Individually listed substances

Category 2 drug precursors contain or consist of:

Substance	**CAS number**	**CN code**	**CUS number**	**Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)**	**Special conditions for mixtures**
Red phosphorus	7723-14-0	2804 70 10 00	-		
Hydrochloric acid	7647-01-0	2806 10 00 00	-		
Sulphuric acid	7664-93-9	2807 00 00 00	-		
Potassium permanganate	7722-64-7	2841 61 00 00	-		
Toluene	108-88-3	2902 30 00 00	-		
Ethyl ether	60-29-7	2909 11 00 00	-		
Acetone	67-64-1	2914 11 00 00	-		
Methylethyl ketone (MEK)	78-93-3	2914 12 00 00	-		
Acetic anhydride	108-24-7	2915 24 00 10	-		
Phenylacetic acid	103-82-2	2916 34 00 00	-		
Anthranilic acid	118-92-3	2922 43 00 10	-		

Substance	CAS number	CN code	CUS number	Concentration threshold in mixtures referred to in Article 3(1), point (b)(ii)	Special conditions for mixtures
Piperidine	110-89-4	2933 32 00 00	-		

The salts of the substances listed in this Annex, whenever the existence of such salts is possible, with the exception of salts of hydrochloric acid and sulphuric acid.

Part II
Medicinal products and veterinary medicinal products

Category 2 drug precursors also consist of the following medicinal products:

Products	**CN code**	**CUS number**
Medicinal products and veterinary medicinal products containing pseudoephedrine or its salts	3003 42 00 00	-
Medicinal products and veterinary medicinal products containing ephedrine or its salts	3003 41 00 00	-

ANNEX III

Category 3 drug precursors

Part I
Individually listed substances

Category 3 drug precursors contain or consist of:

Group (1)[1]	Substance IUPAC	Other names	CAS number	CUS number	Maximum quantity threshold for research and innovation referred to in Article 17 (2)	Concentration threshold in mixtures referred to in Article 3(1), point (b) (ii)	Special conditions for mixtures
AA	**Methyl 2-phenyl-3-oxobutanoate**	**Methyl alpha-phenylacetoacetate , CN Code : 2918 30 00, MAPA**	**16648-44-5**	**-**	**-**	**-**	**-**
AA	**Ethyl 2-phenyl-3-oxobutanoate**	**Ethyl alpha-phenylacetoacetate, CN Code : Ex 2918 30 00, EAPA; ethyl 3-oxo-2-phenylbutanoate**	**5413-05-8**	**-**	**-**	**-**	**-**
AB	**2-methyl-3-phenyloxirane-2-carboxylic acid**	**CN Code : 2918 99 90, BMK glycidic acid**	**25547-51-7**	**-**	**-**	**-**	**-**
AB	**Methyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**	**80532-66-7**	**-**	**-**	**-**	**-**

[1] AA: Propylbenzene derivatives, Oxobutanoate esters
AB: Propylbenzene derivatives, Glycidic acid and its esters
AG: Propylbenzene derivatives, Amides
AK: Propylbenzene derivatives, Others
BA: 5-propyl-1,3-benzodioxole (dihydrosafrole) derivatives, Oxobutanoate esters
BB: 5-propyl-1,3-benzodioxole (dihydrosafrole) derivatives, Glycidic acid and its esters

AB	**Ethyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AB	**Propyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AB	**Isopropyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AB	**Butyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AB	**Sec-butyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AB	**Tert-butyl 2-methyl-3-phenyloxirane-2-carboxylate**	**CN Code : 2918 99 90**		**-**	**-**	**-**	**-**
AG	**3-Oxo-2-phenylbutanamide**	**Alpha-phenylacetoacetamide, CN Code : 2924 29 70, APAA**	**4433-77-6**	**-**	**-**	**-**	**-**
AK	**3-Oxo-2-phenylbutanenitrile**	**Alpha-phenylacetoacetonitrile, CN Code : 2926 40 00, APAAN**	**4468-48-8**	**-**	**-**	**-**	**-**
AK	**2-Methyl-2-propanyl 4-oxo-1-piperidinecarboxylate**	**1-boc-4-piperidone, CN Code : 2933 39 99**	**79099-07-3**	**-**	**-**	**-**	**-**
AK	**(1R,2S)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol**	**(1R,2S)-(-)-chloroephedrine, CN Code : 2939 79 90**	**110925-64-9**	**-**	**-**	**-**	**-**
AK	**(1S,2R)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol**	**(1S,2R)-(+)-chloroephedrine, CN Code : 2939 79 90**	**1384199-95-4**	**-**	**-**	**-**	**-**

AK	**(1S,2S)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol**	**(1S,2S)-(+)-chloropseudoephedrine, CN Code : 2939 79 90**	**73393-61-0**	**-**	**-**	**-**	**-**
AK	**(1R,2R)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol**	**(1R,2R)-(-)-chloropseudoephedrine, CN Code : 2939 79 90**	**771434-80-1**	**-**	**-**	**-**	**-**
AK	**2-Methyl-2-propanyl 4-anilino-1-piperidinecarboxylate**	**Tert-butyl 4-anilinopiperidine-1-carboxylate, CN Code : 2933 39 99, 1-boc-4-AP**	**125541-22-2**	**-**	**-**	**-**	**-**
AK	**Diethyl 2-(2-phenylacetyl)propane dioate**	**Diethyl (phenylacetyl) propanedioate, CN Code : 2918 30 00, DEPAPD**	**20320-59-6**	**-**	**-**	**-**	**-**
AK	**Isopropylidene (2-(3,4-methylenedioxyphenyl)acetyl)malonate**	**CN Code : 2932 99 00, IMDPAM; 5-[2-(1,3-benzodioxol-5-yl)acetyl] -2,2-dimethyl-1,3-dioxane-4,6-dione**		**-**	**-**	**-**	**-**
BA	**Methyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoate**	**Methyl 3-oxo-2-(3,4-methylenedioxyphenyl)butanoate, CN Code : Ex 2932 99 00, MAMDPA, methyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoate**	**1369021-80-6**	**-**	**-**	**-**	**-**
BB	**3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylic acid**	**CN Code : 2932 99 00, PMK glycidic acid**	**2167189-50-4**	**-**	**-**	**-**	**-**
BB	**Methyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**	**13605-48-6**	**-**	**-**	**-**	**-**
BB	**Ethyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**	**28578-16-7**	**-**	**-**	**-**	**-**

BB	**Propyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**		**-**	**-**	**-**	**-**
BB	**Isopropyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**		**-**	**-**	**-**	**-**
BB	**Butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**		**-**	**-**	**-**	**-**
BB	**Sec-butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**		**-**	**-**	**-**	**-**
BB	**Tert-butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate**	**CN Code : 2932 99 00**		**-**	**-**	**-**	**-**

The stereoisomeric forms of the substances listed in this Part, whenever the existence of such forms is possible.

The salts of the substances listed in this part whenever the existence of such salts is possible.

Part II
Groups of substances identified in a generic way

SECTION 1
GROUPS OF SUBSTANCES

SECTION 2
SUBSTANCES EXEMPTED IN ACCORDANCE WITH ARTICLE 5(1)(C) OR ARTICLE 37(2)

The following substances are exempt from the groups of substances included in Section 1 of this Part:

Substance (IUPAC)	Other Names	CAS	CUS number

ANNEX IV

Licence referred to in Article 9 and Article 18

1. In order to obtain a licence pursuant to Article 9 or Article 18 of this Regulation, operators shall make an application to the competent authority through the electronic system referred to in Article 35 containing the following:

   (a) the name and contact details of the operator, including postal and electronic address, and telephone number;

   (b) for import and export activities, if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 19 (1) of Regulation (EU) [COM/2023/258 final, 2023/0156 (COD)];

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU)[COM/2023/258 final, 2023/0156 (COD)];

   (d) the name of the responsible officer appointed in accordance with Article 10 of this Regulation, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 1 or, if applicable Category 3 drug precursors are to be possessed or used;

   (f) information showing that the adequate measures referred to in Article 14 have been taken;

   (g) the name and the CN code of the substances covered by Annex I or Annex III, as applicable;

   (h) in case of mixtures, organisms or substances which occur in nature, their name and the maximum concentration of the substances covered by Annex I or Annex III as applicable;

   (i) the quantity of each substance covered by Annex I or Annex III, as applicable, estimated for transactions or use during a validity period requested for the licences, expressed per year;

   (j) an exhaustive list of the envisaged type of activities referred to in Article 9(1), first subparagraph and their detailed description;

   (k) when requesting a licence for Category 3 drug precursors in accordance with Article 18, a justification for exceeding the maximum threshold set out in Annex III and documents demonstrating the legitimate use;

   (l) an extract from the registry of commerce, if applicable;

   (m) a certificate of good conduct of the operator and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the activities;

   (n) proof of competence in dealing with Category 1 or, if applicable, Category 3 drug precursors, such as a copy of internal procedures on dealing with drug precursors, including notifying suspicious transactions; or other documents demonstrating experience in dealing with Category 1 or, if applicable, Category 3 drug precursors;

   (o) the period for which the licence is requested unless an application is made for a simplified licence in accordance with Article 9(4).

2. Upon request from the relevant competent authority, the operator shall submit any relevant additional information.

3. The competent authority shall issue a licence through the electronic system referred to in Article 35 after performing documentary checks and inspecting the business premises where Category 1 or, if applicable, Category 3 drug precursors are to be possessed or used.

In accordance with Article 9(2), the competent authority shall grant a licence if the operator demonstrates:

(a) competence in dealing with Category 1 or, if applicable, Category 3 drug precursors, including in identifying suspicious transactions, for instance by setting out internal procedures for dealing with Category 1, or, if applicable, Category 3 drug precursors, including notifying suspicious transactions, or otherwise showing experience in dealing with such drug precursors;

(b) integrity by 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.

In accordance with Article 9(4), the competent authority may grant a simplified licence for an unlimited time period to pharmacies and dispensaries of veterinary medicines, importing or exporting Category 1 drug precursors, without inspecting the business premises. In such cases, the provision of the documentation referred to in Article 7 of this Regulation as well as the obligation to appoint a responsible officer set out in Article 10 of this Regulation shall not apply.

4. The licence shall be granted per Member State covering all activities for Category 1 or, if applicable, Category 3 drug precursors and all business premises in that Member State.

The licence shall not be transferable.

5. An operator shall request an update of the licence granted in accordance with point 3 when it intends to:

(a) make available on the market, import, export, perform intermediary activities, use or possess substances covered by Annex I or Annex III, in quantities exceeding those estimated in the application for a period of one calendar year;

(b) make available on the market, import, export, perform intermediary activities, use or possess substances covered by Annex I or Annex III, other than those included in the initial licence;

(c) undertake additional types of activities among the activities referred to in Article 9(1), first subparagraph, which have not been included in the initial licence;

(d) change or extend to new business premises.

The competent authority may decide to update the licence for the remaining period of validity based on documentary checks only.

6. The decision to refuse a licence in accordance with Article 9(2) or to revoke or suspend an existing licence in accordance with Article 9(6) shall be communicated through the electronic system referred to in Article 35, shall be motivated and subject to appeal under the conditions set out in the national law.

7. The operator may request the renewal of a licence in accordance with point 1, for a period of up to three years. The competent national authority may decide to renew a licence based on documentary checks only.

ANNEX V

Registration of information pursuant to Article 9(7) and Article 15

1. The registration pursuant to Article 9(7) or Article 15 of this Regulation shall be made through the electronic system referred to in Article 35 and shall include the following:

   (a) the name and contact details of the external trader, including postal and electronic address, and telephone number;

   (b) if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 19 of Regulation (EU) [COM/2023/258 final, 2023/0156 (COD)];

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU) [COM/2023/258 final, 2023/0156 (COD)];

   (d) the name of the responsible officer appointed in accordance with Article 10, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 2 drug precursors or Category 1 drug precursors, as applicable, are to be stored;

   (f) the name and the CN code of the substances as covered by Part I, of Annex II or of the products referred to in Part II, of Annex II, or of the substances covered by Annex I, as applicable;

   (g) in case of mixtures, organisms or substances which occur in nature, their name and the maximum concentration of the substances covered by Part I, of Annex II, or in Annex I, as applicable;

   (h) the quantity of each substance covered by Annex II or Annex I, as applicable, estimated for transactions during the validity period of the registration for each year;

   (i) an exhaustive list of the envisaged type of activities referred to in Article 9(7) or Article 15(1), first subparagraph, as applicable, and their detailed description;

   (j) the period for which the registration is made, unless the registration is made in accordance with Article 15(3).

2. Pharmacies and dispensaries of veterinary medicinal products may file a registration for an unlimited period of time, in accordance with Article 15(3). In that case, the provision of documentation referred to in Article 7 of this Regulation as well as the obligation to appoint a responsible officer set out in Article 15(6) of this Regulation shall not apply.

3. An external trader shall update the registration, in accordance with Article 15(4), when it intends to:

   (a) import, export, or perform intermediary activities involving substances covered by Annex I or Annex II , as applicable, in quantities exceeding those estimated in the initial registration for a period of one year;

   (b) import, export, or perform intermediary activities involving substances covered by Annex I or Annex II, as applicable, other than those indicated in the initial registration;

(c) undertake additional activities;

(d) change or extend to new business premises.

4. The decision of a competent authority to order the suspension or cessation of the activity in accordance with Article 15(5) of this Regulation shall be communicated through the electronic system referred to in Article 35, motivated and subject to appeal under the conditions set out in the national law.

ANNEX VI

Prior notification under Article 17(2)

1. The prior notification referred to in Article 17(2) of this Regulation shall be made through the electronic system referred to in Article 35 and shall contain at least the following:

   (a) the name and contact details of the operator, including postal and electronic address, and telephone number;

   (b) for import and export activities, if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 19 of Regulation (EU) [COM/2023/258 final, 2023/0156 (COD)];

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU) [COM/2023/258 final, 2023/0156 (COD)];

   (d) the name of the responsible officer appointed in accordance with Article 10 of this Regulation, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 3 drug precursors are to be possessed or used;

   (f) information showing that the adequate measures referred to in Article 14 of this Regulation have been taken;

   (g) the name and the CN code of the substances as covered by Annex III to this Regulation;

   (h) the quantity of each substance covered by Annex III to this Regulation during the validity period of the prior notification;

   (i) in case of mixtures, organisms or substances which occur in nature, their quantity, name and the maximum concentration of the substances covered by Annex III to this Regulation;

   (j) the date when the drug precursor is to be made available on the market, imported, exported, subject to intermediary activities, possessed or used for the first time;

   (k) an exhaustive list of the envisaged type of activities referred to in Article 17(1) of this Regulation and their detailed description;

   (l) details of the transport arrangements, where applicable, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, for exports; the expected point of exit from customs territory of the Union and the point of entry into the importing country and for imports; the expected date of arrival in the customs territory of the Union;

   (m) the names and contact details of the other operators to which the drug precursor is made available, imported, exported, or involved in the intermediary activities.

   (n) a certificate of good conduct of the operator and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the activities;

(o) an extract from the registry of commerce, if applicable.

2. The prior notification shall be presented to the customs office when required by the customs authority.

3. The decision of a competent authority ordering operators to suspend or cease activities covered by the prior notification in accordance with Article 17(5) shall be communicated through the electronic system referred to in Article 35, motivated and subject to appeal under the conditions set out in the national law.

ANNEX VII

External trade (Articles 20 to 24 and 30)

Chapter 1
Import

1. The following information shall be provided in accordance with Article 20:

   (a) the name, the CN code, and the CUS number of the substance covered by Annex I, Annex II, or Annex III or, in the case of a mixture, or an organism or a substance which occurs in nature, its name the eight-digit CN code, and the name and CUS number of any substance covered by Annex I, Annex II or Annex III contained in the mixture, or in the organism or substance which occurs in nature;

   (b) the quantity of the substance and, in the case of a mixture, or an organism or a substance which occurs in nature, the quantity, and, if available, the percentage of any substance covered by Annex I, Annex II or Annex III contained therein;

   (c) the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in 17;

   The quantity notified under Article 20(1) will be valid for a period of 180 calendar days.

Chapter 2
Pre-export notification

2. The pre-export notification referred to in Article 21 shall contain at least the following:

   (a) the names and addresses of the exporter, the importer in the third country, any other operator involved in the export operation or shipment, and the ultimate consignee;

   (b) the name of the drug precursor covered by Annex I, Annex II or Annex III, in the case of a mixture, or an organism or a substance which occurs in nature, its name and eight-digit CN code and the name of any drug precursor covered by the Annex, contained in the mixture, or in the organism or substance which occurs in nature;

   (c) the quantity and weight of the drug precursor and, in the case of a mixture, or an organism or a substance which occurs in nature, the quantity, weight, and, if available, the percentage of any drug precursor contained therein;

   (d) details of the transport arrangements, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, the expected point of exit from customs territory of the Union and the point of entry into the importing country.

3. The certain countries of destination referred to in Article 21(1) to which a pre-export notification for the drug precursors covered by Annex II is required shall include all of the following:

(a) third countries with whom the Union has concluded a specific agreement on drug precursors;

(b) third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the UN Convention ;

(c) third countries which have requested to receive pre-export notifications in accordance with Article 24 of the 1988 UN Convention .

The lists of the countries of destination for export of the drug precursors covered by Annex II referred to in points (a), (b), and (c) shall be published on the Commission's website.

4. The competent authority may send a simplified pre-export notification, in accordance with Article 21(7), covering several export operations for a period of 180 calendar days.

5. The competent authority of the country of export shall supply the information specified in point 2 to the competent authority of the third country of destination.

6. The competent authority shall inform the country of destination accordingly and use the PEN-online system for this purpose.

Chapter 3
Export

7. The following information shall be provided in accordance with Article 22:

(a) the name, CN code and CUS number of the substance covered by Annex I, Annex II or Annex III or, in the case of a mixture, or an organism or a substance which occurs in nature, its name and eight-digit CN code and the name and CUS number of any substance, as covered by Annex I, Annex II or Annex III contained in the mixture, or in the organism or substance which occurs in nature;

(b) the quantity of the substance and, in the case of a mixture, or an organism or a substance which occurs in nature, the quantity, and, if available, the percentage of any substance covered by Annex I, Annex II or Annex III contained therein;

(c) the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in Article 17;

(d) for exports referred to in Article 22(5), a copy of the import authorisation issued by the country of destination.

The quantity notified under Article 22(1) will be valid for a period of 180 calendar days.

Chapter 4
Demonstration of licit purposes

8. The external trader shall provide information that the consignment has left the country of export in accordance with the national provisions in force adopted pursuant to Article 12 of the UN Convention to demonstrate the licit purpose of his transaction pursuant to Article 24.

For that purpose, the external trader may provide the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification as referred to in Article 17 to the competent authority or the customs authority; or the import or export authorisation, or any other official document demonstrating the licit use of drug precursors by the operator from the third country, as the case may be.

Chapter 5
Criteria to determine if there is suspicion of intended use in illicit manufacture of drugs

9. The following non-exhaustive list of criteria indicate an intended use of drug precursors in the illicit manufacture of drugs:

   (a) the substances have not been correctly identified on the labels of the goods or consignment and have not been correctly declared to customs in accordance with Regulation (EU) .../... [COM/2023/258 final, 2023/0156 (COD)], in particular as regards the description of the goods or the CN-codes;

   (b) the substances are included in the Drug Precursors Information Repository as substances with no known legitimate uses.

ANNEX VIII

Reporting in accordance with Articles 32, 33 and 34

1. In accordance with Article 32, the competent authorities and customs authorities shall provide information on:

   (a) total annual seizures of drug precursors;

   (b) the methods of diversion of drug precursors and illicit manufacturing of drugs, including information on stopped shipments and thefts;

   (c) information on administrative and law enforcement authorities responsible for regulating or enforcing national controls of drug precursors.

2. Member States shall provide the information referred to in point 1 and confirm the accuracy of the data provided, by 31 March at the latest, for the previous calendar year.

   Without prejudice to the first subparagraph, the competent authorities or customs authorities shall report significant seizures of drug precursors without delay.

3. The communication of information on seizures in accordance with point 1(a) shall include the following:

   (a) the name of the substances covered by Annex I, Annex II or Annex III, or the name as indicated in the Drug Precursors Information Repository referred to in Article 25, or the IUPAC name, as applicable;

   (b) if known, the origin, provenance and destination of the drug precursors;

   (c) the quantity of the substances, their customs status and the means of transport used, as applicable.

4. Significant seizures within the meaning of Article 33 and point 2 of this Annex cover seizures of significant quantities of scheduled drug precursors or non-scheduled drug precursors included in the Drug Precursors Information Repository, as applicable, or seizures of such drug precursors which point to organised crime taking place in more than one Member State, or seizures of newly discovered substances.

5. Member States shall report the information referred to in point 1 in the electronic system referred to in Article 35.

6. The report referred to in Article 34 shall contain the following:

   (a) information on quantities of scheduled drug precursors subject to legitimate trade and use in the internal market in the previous calendar year;

   (b) information on all seizures in the previous calendar year;

   (c) information on the substances used for the illicit manufacture of drugs and methods of diversion and illicit manufacture;

   (d) information on quantities of scheduled drug precursors subject to legitimate trade for imports and exports in the previous calendar year;

   (e) estimated needs for operators for the subsequent calendar year;

   (f) information on administrative and law enforcement authorities responsible for regulating or enforcing national controls of drug precursors.

The information referred to in points (a) and (e) shall be based on estimations done by operators requesting a licence for Category 1 drug precursors in accordance with Article 9 or Article 18, registering for import, export or intermediary activities in accordance with Article 15 or sending a prior notification for Category 3 drug precursors in accordance with Article 17.

The information referred to in point (d) shall be based on information provided by external traders as per their obligations under Articles 20 and 22. Until the date of application of Articles 20 and 22, the information in point (d) shall be based on the information referred to in point 19 of Annex IX.

The information referred to in points (b), (c) and (f) shall be based on the information provided by competent authorities in accordance with Article 32.

ANNEX IX

Transitional measures for import, export and reporting on external trade (Articles 20, 22, 23, 34, 43(5) and Article 44)

Chapter 1
Export authorisation

1. Exports of drug precursors including exports of drug precursors leaving the customs territory of the Union following their storage in a free zone for a period of at least 10 days, shall be subject to an export authorisation. Where a drug precursor is re-exported within 10 days from the date of its placement in temporary storage or in a free zone, an export authorisation shall not be required.

   The export authorisation shall be issued by the competent authorities of the Member State where the exporter is established.

   By way of derogation from the first subparagraph the following products shall only be subject to an export authorisation when a pre-export notification is required pursuant to Article 21:

   (a) Hydrochloric acid;

   (b) Sulphuric acid;

   (c) Toluene;

   (d) Ethyl ether;

   (e) Acetone;

   (f) Methylethylketone.

2. 2.1. The application for the export authorisation referred to in point 1 shall contain at least the following:

   (a) the names and addresses of the exporter, the importer in the third country, any other operator involved in the export activity or shipment, and the ultimate consignee;

   (b) the name of the substance covered by Annex I, Annex II or Annex III or, in the case of a mixture, an organism or a substance which occurs in nature, its name and eight-digit CN code and the name of any scheduled substance covered by those Annexes, contained in the mixture, or in the organism or substance which occurs in nature;

   (c) the quantity and weight of the drug precursor and, in the case of a mixture, an organism or a substance which occurs in nature, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

   (d) details of the transport arrangements, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, expected point of exit from customs territory of the Union and the point of entry into the importing country;

(e) in the cases referred to in point 6, a copy of the import authorisation issued by the country of destination;

(f) the number of the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in Article 17.

2.2. A decision on the application for the export authorisation referred to in point 1 shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

That period shall be extended if, in the cases referred to in point 6, the competent authorities are obliged to make further enquiries under the second subparagraph of that point.

3. 3.1. If the details of the itinerary and means of transport are not provided in the application, the export authorisation referred to in point 1 shall state that the external trader must supply those details to the customs office of exit or other competent authorities at the point of exit from the customs territory of the Union before the physical departure of the consignment. In such cases the export authorisation shall be annotated accordingly at the time of issue.

Where the export authorisation is presented to a customs office in a Member State other than that of the issuing authority, the exporter shall make available any certified translation of parts or all of the information contained on the authorisation, upon request.

3.2. The export authorisation referred to in point 1 shall be presented to the customs office when the customs declaration is made, or in the absence of a customs declaration, at the customs office of exit or other competent authorities at the point of exit from the customs territory of the Union. The authorisation shall accompany the consignment to the third country of destination.

The customs office of exit or other competent authorities at the point of exit from the customs territory of the Union shall insert the necessary details referred to in point 2(2.1) (d) in the export authorisation and affix its stamp thereon.

4. Without prejudice to measures adopted in accordance with Article 30, the granting of the export authorisation shall be refused if:

(a) details supplied in accordance with point 2.1 are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with point 2.1 are false or incorrect;

(c) in the cases referred to in point 6, it is established that the import of the drug precursor has not been authorised by the competent authorities of the country of destination, or

(d) there are reasonable grounds for suspecting that the drug precursors in question are intended for the illicit manufacture of drugs.

5. The competent authorities may suspend or revoke an export authorisation whenever there are reasonable grounds for suspecting that the drug precursors are intended for the illicit manufacture of drugs.

6. Whenever, under an agreement between the Union and a third country, exports are not to be authorised unless an import authorisation has been issued by the competent authorities of that third country for the drug precursor in question, the Commission

shall communicate to the competent authorities of the Member States the name and address of the competent authority of the third country, together with any operational information obtained from it.

The competent authorities in the Member States shall satisfy themselves as to the authenticity of such import authorisation, if necessary by requesting confirmation from the competent authority of the third country.

7. The period of validity of the export authorisation within which the goods must have left the customs territory of the Union shall not exceed six months from the date of issue of the export authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

8. The simplified procedures in point 9 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 drug precursors.

9. 9.1. Following an application by the external trader concerned the competent authority may grant an export authorisation by means of a simplified procedure in cases of frequent exports of one specific drug precursor covered by Annex II involving the same exporter established in the Union and the same importer in the same third country of destination covering a specific time period of either 6 or 12 months.

Such simplified export authorisation may only be granted in the following cases:

(a) where during previous exports the external trader has shown the capacity to fulfil all obligations in relation to those exports, and has not committed any offences against relevant legislation;

(b) where the competent authority can satisfy itself as to the licit purposes of those export activities.

9.2. The application for a simplified export authorisation shall contain at least the following:

(a) the names and addresses of the exporter, the importer in the third country, and the ultimate consignee;

(b) the name of the substance covered by Annex II, or, in the case of a mixture, an organism or a substance which occurs in nature, its name and CN code and the name of any substance covered by Annex II, contained in the mixture, or the organism or substance which occurs in nature;

(c) the maximum quantity of the drug precursors intended for export;

(d) the intended specific time period for the export activities.

9.3. The competent authority shall take the decision on the application for simplified export authorisation within a period of 15 working days from the date on which it received the required information.

9.4. In case of emergency medical care, where the conditions under point 9(9.1), points (a) and (b) of this Article are fulfilled, the competent authority shall take the decision on the application for simplified export authorisation for exports of the drug precursors referred to in Part II, of Annex II immediately or at the latest within 3 working days after receipt of the application.

Chapter 2
Import authorisation

10. Imports of drug precursors covered by Annex I or Annex III shall be subject to an import authorisation. An import authorisation may only be granted to an external trader established in the Union. The import authorisation shall be issued by the competent authorities of the Member State where the importer is established.

However, where the drug precursors referred to in the first subparagraph are unloaded or transhipped, placed under temporary storage, stored in a free zone, or placed under the external Union transit procedure, such import authorisation shall not be required.

11. 11.1. The application for the import authorisation referred to in point 10 shall contain at least the following:

(a) the names and addresses of the importer, the exporter of the third country, any other operator involved and the ultimate consignee;

(b) the name of the substance covered by Annex I or Annex III or, in the case of a mixture, an organism or a substance which occurs in nature, its name and the eight-digit CN code and the name of any scheduled substance, covered by those Annexes, contained in the mixture, or in the organism or substance which occurs in nature;

(c) the quantity and weight of the drug precursor and, in the case of a mixture, or an organism or a substance which occurs in nature, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

(d) if available, details of the transport arrangements, such as methods and means of transport, and date and place of envisaged import activities, and

(e) the number of the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in Article 17.

11.2. A decision on the application for an import authorisation shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

12. The import authorisation shall accompany the consignment from the point of entry into the customs territory of the Union to the premises of the importer or ultimate consignee.

The import authorisation shall be presented to the customs office when the drug precursors are declared for a customs procedure.

Where the import authorisation is presented to a customs office in a Member State other than that of the issuing authority, the importer shall make available any certified translation of parts or all information contained on the authorisation, upon request.

13. Without prejudice to measures adopted in accordance with Article 30, the granting of the import authorisation shall be refused if:

(a) details supplied in accordance with point 11 are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with point 11 in the application are false or incorrect, or

(c) there are reasonable grounds for suspecting that the drug precursors are intended for the illicit manufacture of drugs.

14. The competent authorities may suspend or revoke the import authorisation whenever there are reasonable grounds for suspecting that the drug precursors are intended for the illicit manufacture of drugs.

15. The period of validity of the import authorisation within which the drug precursors must have been entered into the customs territory of the Union shall not exceed six months from the date of issue of the import authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

Chapter 3
Export and import authorisations

16. 16.1. The export and import authorisations referred to in Chapter 1 and Chapter 2 of this Annex shall have the format set out in point 17 or point 18 of this Annex, 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.

16.2. 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 drug precursor 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.

16.3. 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 drug precursor 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.

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

16.5. 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.

16.6. 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.

16.7. By way of derogation from points 16.1 to 16.6, 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 Implementing Regulation (EC) No 2015/1013 until the stocks are exhausted.

16.8. Export authorisations granted by means of the simplified procedure referred to in point 9.1 shall be established using copies No 1, 2 and 4 of the form set out in point 17. 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 activity on the back side of Copy No 2, in particular the quantity of the scheduled substance of each export activity 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.

16.9. The external trader shall enter the authorisation number and the words 'simplified export authorisation procedure' on the customs declaration for each export activity. 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.

16.10. 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 means of the simplified procedure referred to in point 9.1.

17.

EUROPEAN UNION
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS **EXPORT AUTHORISATION**

COPY FOR THE ISSUING AUTHORITY

1

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, email)

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 **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, email)

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

2

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 **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, email)

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

3

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 **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, email)
	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 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:

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, email).

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, email) of any other external trader involved in the export activity such as transporters, intermediaries, customs agents.

6. Box 9: Enter full name and address (phone, fax, email) 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 activities, 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 drug precursor covered by Annex I, Annex II or Annex III, the commercial name of the medicinal product covered by Part II, of Annex II, 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 an organism or a substance which occurs in nature, 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 drug precursor as stated in Annex I, Annex II and Annex III.

13. Box 16a, 16b: for Category 4, enter the total net weight of the drug precursor 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 drug precursors covered by Annex I, Annex II or Annex III.

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 activity.

3. Box 23: Indicate the authorised maximum quantity and net weight. For drug precursors in Part II, of Annex II, enter the total net weight of the drug precursor 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 drug precursors in Part II, of Annex II, enter the total net weight quantity of the drug precursor 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.

18.

EUROPEAN UNION
GOODS SUBJECT TO IMPORT CONTROL

DRUG PRECURSORS **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, email 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 IMPORT CONTROL

DRUG PRECURSORS **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, email 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

2

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 IMPORT CONTROL

DRUG PRECURSORS **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, email of responsible officer)
	6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
	8. Ultimate consignee	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	12. 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 IMPORT CONTROL

DRUG PRECURSORS **IMPORT AUTHORISATION**

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, email 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
4	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:

COPY FOR THE IMPORTER

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, email).

4. Box 6: Enter full name and address (phone, fax, email) of any other external trader involved in the import activity 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, email) 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 the name of the substance covered by Annex I, Annex II or Annex III the commercial name of the medicinal product covered by Part II, of Annex II, the number of units in the consignment, the number of tablets/ampoules in each unit, the content of the drug precursor in a single unit (per tablet/ampoule) or in the case of a mixture or an organism or a substance which occurs in nature enter the name and the 8 digit CN code, as well as the commercial name.

10. Boxes 11a, 11b: Identify packages and drug precursors with precision (e.g. 2 cans of 5 litres each). In the case of a mixture, an organism or a substance which occurs in nature, or preparations, indicate the commercial name concerned.

11. Boxes 12a, 12b: Enter the 8 digit CN code of the drug precursor as stated in Annex I, Annex II or Annex III.

Box 13 a, 13b: for drug precursors in Part II, of Annex II, enter the total net weight of the drug precursor 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, in accordance with the rules 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 of the Member State concerned, this declaration is equivalent to the engagement of responsibility, under the provisions in force in the Member State concerned, 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.

Chapter 4
Reporting

19. 1. The competent authorities of the Member States shall provide to the Commission the information in point 6, point (d), of Annex VIII on quantities of scheduled drug precursors subject to legitimate trade for imports and exports in the previous year in electronic form.

2. External traders shall provide the competent authorities with information in summary form about their export, import or intermediary activities referred to in point 19.3 before 15 February of each calendar year. An external trader shall submit the annual reports even where no transactions have taken place in a given year.

3. External traders shall inform the competent authorities about the following:

(a) exports of drug precursors subject to an export authorisation;

(b) all imports of scheduled drug precursors of Annex I, Annex II and Annex III;

(c) all intermediary activities involving scheduled drug precursors of Annex I, Annex II and Annex III.

4. The information referred to in point 19.3(a) shall be organised by making reference to the countries of destination, quantities exported and the reference numbers of the export authorisations as the case may be.

5. The information referred to in point 19.3(b) shall be organised by making reference to the third country of export and the reference number of the import authorisations as the case may be.

6. The information referred to in point 19.3(c) shall be organised by making reference to the third countries involved in these intermediary activities and the export or import authorisation as the case may be. External traders shall provide further information, upon request of the competent authorities.

7. The competent authorities shall treat the information referred to in this Article as confidential business information.

ANNEX X

Correlation table

Part I
Correlation with Regulation (EC) No 273/2004

20.

Regulation (EC) No 273/2004	**This Regulation**
Article 1	Article 1
Article 2, point (a)	Article 2, point (3), Article 3(1), point (b)(i), Article 3(1), point (c), Article 3(3), point (c), Article 3(3), point (d)
Article 2, point (b)	Article 2, point (4)
Article 2, point (c)	Article 2, point (11)
Article 2, point (d)	Article 2, point (26)
Article 2, point (e)	Article 2, point (36)
Article 2, point (f)	-
Article 2, point (g)	-
Article 2, point (h)	Article 2, point (12), Article 2, point (26)
Article 2, point (1)	-
Article 3(1)	Article 10, Article 15(5), Article 19(3), point (a)
Article 3(2), first sentence	Article 9(1), first subparagraph
Article 3(2), second and third sentence	-
Article 3(3)	Article 13
Article 3(4)	Article 9(2)
Article 3(5), first and second sentences	Article 9(3)
Article 3(5), third sentence	Article 9(4)
Article 3(5), third sentence	
Article 3(6), (6a), (6b), (6c), (6d), (7)	-
Article 3(8)	Article 37(4)
Article 4	-

Regulation (EC) No 273/2004	**This Regulation**
Article 5(1) and (2)	Article 7(1)
Article 5(3) and (4)	-
Article 5(5)	Article 7(2)
Article 5(6) and (7)	-
Article 6	-
Article 7, first paragraph	Article 11, Article 15(7), Article 19(4)
Article 7, second paragraph	-
Article 8(1)	Article 8
Article 8(2)-(4)	-
Article 9(1)	-
Article 9(2)	Article 25(2)
Article 9(3)	-
Article 10(1)	Article 29
Article 10(2)	-
Article 10(3)	Article 28(2)
Article 11(1)	Article 27(1)
Article 11(2)	Article 27(2)
Article 12	Article 31
Article 13(1)	Article 32
Article 13(2)	Article 37(4)
Article 13(3)	Article 34
Article 13a(1)(a)	Article 35(2), point (d)
Article 13a(1)(b)	Article 35(2), point (a)
Article 13a(1)(c)	-
Article 13a(2) and (3)	Article 36

Regulation (EC) No 273/2004	**This Regulation**
Article 13a(4)	-
Article 13b	Article 36
Article 14(1)(a)	-
Article 14(1)(b)-(c) and (2)	Article 35(8)
Article 14a	Article 40
Article 15	Article 37(1)
Article 15a	Article 38
Article 16(1)	Article 31, third paragraph
Article 16(2)	-
Article 16(3)	Article 41
Article 17	Article 42
Article 18	Article 45

Part II
Correlation with Regulation (EC) No 111/2005

20.1.

Regulation (EC) No 111/2005	**This Regulation**
Article 1, first paragraph	Article 1
Article 1, second paragraph	-
Article 2, point (a)	Article 2(3); Article 3(1), point (a), Article 3(1), point (b)(i); Article 3(1), point (c); Article 3(3), point (c); Article 3(3), point (d).
Article 2, point (b)	Article 2 (4)
Article 2, point (c)	Article 2 (13)
Article 2, point (d)	Article 2 (14)
Article 2, point (e)	Article 2 (25)
Article 2, point (f)	Article 2 (26)
Article 2, point (g)	Article 2 (30)
Article 2, point (h)	Article 2 (29)
Article 2, point (i)	Article 2 (33)
Article 2, point (j)	Article 2 (7)
Article 2, point (k)	Article 2 (36)
Article 3, first subparagraph	Article 7(1)
Article 3, second subparagraph, point (a)	Article 7(1), point (a)
Article 3, second subparagraph, point (b)	Article 7(1), point (b)
Article 3, second subparagraph, point (c)	Article 7(1), point (c)
Article 4, first sentence	Article 7(2)
Article 4, second and third sentences	Article 6(2)

Regulation (EC) No 111/2005	This Regulation
Article 5	Article 11 Article 15(7); Article 19(4)
Article 6 (1), first sub-paragraph	Article 9(1), first subparagraph
Article 6 (1), second subparagraph	Article 9(2)
Article 6 (1), third subparagraph	Article 37(4)
Article 6 (2)	Article 9(6)
Article 7 (1) first subparagraph	Article 15(1), first subparagraph
Article 7 (1), second subparagraph	-
Article 7 (1), third subparagraph	Article 37(4)
Article 7 (2)	Article 15(5)
Article 8 (1)	Article 24
Article 8 (2)	Article 37(4)
Article 9 (1)	Article 8(1); Article 8(2)(1)
Article 9 (2), first subparagraph	-
Article 9 (2), second subparagraph	Article 37(4)
Article 9 (2), third subparagraph	Article 35(8) and Article 35(9)
Article 10 (1)	-
Article 10 (2) (a)	-
Article 10 (2) (b)	Article 25
Article 10 (3)	-

Regulation (EC) No 111/2005	This Regulation
Article 10 (4), first sentence	Article 33(1)
Article 10 (4), second sentence	-
Article 10 (5)	Article 37(1)
Article 11 (1), first subparagraph, first sentence	Article 21(1)
Article 11 (1), first subparagraph, second sentence	Article 37(4)
Article 11 (1), second subparagraph	-
Article 11 (2), first subparagraph	Article 21(5)
Article 11 (2), second subparagraph	Article 21(6)
Article 11 (3), first sentence	Article 21(7)
Article 11 (3), second sentence	Article 37(4)
Article 12 (1), first subparagraph	Article 22(1)
Article 12 (1), second subparagraph	-
Article 12 (1), third subparagraph	-
Article 12 (2)	-
Article 13	-
Article 14	-
Article 15 (a)	-
Article 15 (b)	-
Article 15 (c)	Article 22(6)
Article 15 (d)	Article 22(6)
Article 16	-

Regulation (EC) No 111/2005	This Regulation
Article 17, first subparagraph	Article 22(5)
Article 17, second subparagraph	-
Article 18, first sentence	-
Article 18, second sentence	-
Article 19	-
Article 20, first subparagraph	Article 20(1)
Article 20, second subparagraph	Article 20(4)
Article 21	-
Article 22	-
Article 23	-
Article 24	-
Article 25	Article 20(1)
Article 26 (1)	Article 30(1)
Article 26 (2)	Article 30(3)
Article 26 (3), introductory sentence	Article 30(6), introductory sentence
Article 26 (3), point (a)	Article 30(6), point (a)
Article 26 (3), point (b)	Article 30(6), point (b)
Article 26 (3), point (c)	Article 30(6), point (c)
Article 26 (3a), first subparagraph	Article 30(2)
Article 26 (3a), second and third subparagraphs	Article 33(1)
Article 26 (3b), introductory sentence	Article 30(6), introductory sentence
Article 26 (3b), point (a)	Article 30(6), point (a)

Regulation (EC) No 111/2005	This Regulation
Article 26 (3b), point (b)	Article 30(6), point (b)
Article 26 (4)	Article 30(8)
Article 26 (5)	Article 9 (8)
Article 27, first sentence	Article 27(2)
Article 27, second sentence	Article 27(1)
Article 28, first sentence	Article 35(8)
Article 28, second sentence	Article 35(9)
Article 29	-
Article 30	Article 40
Article 30a	Article 37(1) Article 37(2)
Article 30b (1)	Article 38(1)
Article 30b (2)	Article 38(2)
Article 30b (3)	Article 38(3)
Article 30b (4)	Article 38(5)
Article 30b (5)	Article 38(6)
Article 31, first sentence	Article 31, first subparagraph
Article 31, second sentence	Article 31, second subparagraph
Article 32 (1)	-
Article 32 (2)	Article 37(4)
Article 32 (3)	Article 34
Article 32 (4)	Article 41
Article 32a, points (a) and (b)	Article 35(1), Article 35 (2)
Article 32a (c)	-
Article 33	Article 36
Article 34, first subparagraph	Article 42(1)

Regulation (EC) No 111/2005	This Regulation
Article 34, second subparagraph	Article 42(2)
Article 35, first subparagraph	Article 45, first paragraph
Article 35, second subparagraph, first sentence	Article 45, second paragraph
Article 35, second paragraph, second sentence	Article 45, third subparagraph
Article 35, second subparagraph, third sentence	-
Article 35, third subparagraph	Article 45, fourth subparagraph