Commission expert group on Drug Precursors
Meeting of 1-2 June 2023/item 6

Note of the Commission services on Frequently Asked Questions on EU rules on drug precursors

As discussed in the ad-hoc meeting of the group of experts on 7 March, please, find attached to this note the FAQs document in a clean version.

This document is submitted for endorsement in the meeting of the expert group on 1-2 June 2023.

This is a living document, subject to revision depending on the need. Should you have proposals for new frequently asked questions and answers, please, send them by e-mail to:
GROW-DRUG-PRECURSORS@ec.europa.eu (for Regulation (EC) No 273/2004)
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Annex

Frequently asked questions and answers on the EU rules on drug precursors

This document supports Member States and economic operators in the application of EU rules on drug precursors, more precisely:

- Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors;[1]

- 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]

- Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors, and repealing Commission Regulation (EC) No 1277/2005;[3]

- Commission Implementing Regulation (EU) 2015/1013 of 25 June 2015 laying down rules in respect of Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and of Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Union and third countries in drug precursors.[4]

These FAQs can serve as a first point of reference, providing general answers to the most common questions.

In accordance with Article 10 of Regulation (EC) No 273/2004 and Article 26 of Regulation (EC) No 111/2005, in order to ensure the correct application of the Regulation, each Member State adopts the measures necessary to enable its competent authorities to perform their control and monitoring duties as regards scheduled substances, and may adopt such rules for non-scheduled substances. These national rules may concern obtaining information on any orders for scheduled substances or operations, entering operators' and users' business premises and detaining and seizure of consignments.

This document explains the provisions applicable at EU level. For a comprehensive image of the rules applicable to specific situations, it is recommended to contact the competent national authorities which can provide information on the rules laid down at national level.

This document represents the opinion of the Commission services (GROW/F2 and TAXUD/A5), but may not necessarily represent the official position of the Commission.

This document is not legally binding upon the competent authorities of Member States. Only the Court of Justice of the European Union can give an authoritative interpretation of EU rules.

[1] OJ L 47, 18.2.2004, p. 1.
[2] OJ L 22, 26.1.2005, p. 1.
[3] OJ L 162, 27.6.2015, p. 12.
[4] OJ L 162, 27.6.2015, p. 33.

The first part of the document relates to questions common to both Regulation (EC) No 237/2004 (Intra EU trade in drug precursors) and Regulation (EC) No 111/2005 (trade between the EU and third countries), whereas the second part deals with the intra EU trade, and the third part relates to questions on trade between the EU and third countries.

PART I

Questions pertaining to both Regulation (EC) No 273/2004 (Intra-EU trade) and Regulation (EC) No 111/2005 (Trade between the EU and Third countries)

I.1 Natural products

I.1.1 Are ephedra leaves covered by the EU rules on drug precursors?

Yes, ephedra leaves should be regarded as Category 1 substances.

Natural products containing pure scheduled substances are to be considered themselves scheduled substances and covered by the EU rules on drug precursors, unless they are 'compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means'.

The alkaloids ephedrine and pseudoephedrine are the active constituents of ephedra. It has been shown that these substances can be easily extracted and used for illicit drug manufacturing activities.

Relevant provisions: Article 2 of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005

I.2 Medicinal products

I.2.1 Do manufacturers of medicinal products or other products, which are not scheduled substances, need a licence when they possess Category 1 substances solely used for the manufacture of such products?

Yes, companies wishing to possess Category 1 substances in order to manufacture other products have to obtain a licence as a user. For example, possessing pseudoephedrine and using it to produce certain medicinal products (such as nasal decongestants) requires a licence. The resulting medicinal product is outside the scope of intra-EU trade rules.

Such companies remain users of the scheduled substances which they send to laboratories for analytical purposes, in the context of the transformation of the said substances into medicinal products (or other products). Such an activity is not considered as placing on the market of the said substances. [samples sold to be used as reference samples – this is placing on the market + laboratories performing the analysis – are users]

Similarly, a licence as operator is required to purchase Category 1 substances on the international market.

Relevant provisions: Article 3(3) of Regulation (EC) No 273/2004; Article 6 of Regulation (EC) No 111/2005

See also the questions in Section II.3.

I.2.2 **Do manufacturers of medicinal products, or other products which are not scheduled substances, need a registration when they use category 2 substances?**

Operators engaged in the placing on the market of substances of category 2 are required to register with the authorities. Users of category 2A substances also need to hold a registration for that purpose.

Use of category 2B substances and manufacturing and placing on the market other products do not require a registration. ".

A registration is required to purchase category 2 substances on the international market.

Relevant provisions: Article 3(6) of Regulation (EC) No 273/2004; Article 7, Regulation (EC) No 111/2005

See also the questions in Section II.3.

I.2.3 Are category 1 substances purchased by pharmacies for the manufacture of medicinal products 'scheduled substances' or medicinal products?

It depends on the intended use of the substance.

As a general rule, such substances would not be considered as medicinal products, but rather as active substances, as they are not administered as such but subject to further production steps.

Therefore, these substances should be considered as scheduled substances, as they have not yet become medicinal products.

There are cases, though, where a substance can fulfil both the definition of active substance and that of medicinal product, notably in the case of certain herbal substances and herbal preparations that can either be used in their present form or used as starting material for the manufacture of another medicinal product.

For instance, ephedrine (also in category 1) is found in ephedra plants (Ephedra sinica) that can be used in traditional medicine. In such cases, the application of the EU drug precursors rules depend on the use of safrole and ephedrine. If they are sold as medicinal products, then they are outside the scope of the drug precursors control and monitoring rules. If they are used as a herbal preparation (mixed with other herbal substances, herbal preparations or other substances) to produce a medicinal product, then the pharmacy buying the two substances and using them as described, is to be considered a user of Category 1 substances within the meaning of the EU rules. The same distinction medicinal product/active substance is relevant for the purchase of such substances on the international market.

Relevant provisions: Article 1(2), (3a), (31) and (32) of Directive 2001/83/EC

I.2.4 Are bulk products sent by manufacturers to external laboratories for testing 'scheduled substances' or medicinal products?

It depends on the intended use of the substance.

When validating various steps in the production, pharmaceutical manufacturers often send to external laboratories products in bulk (e.g. solution or tablets). If the bulk product tested by the laboratory is then to be placed on the market/administered to patients in the same pharmaceutical form and strength, it can be considered it fulfils the definition of medicinal product.

Relevant provisions: Article 1(2) of Directive 2001/83/EC

See also question I.2.5.

I.2.5 Do wholesalers of medicinal products or other products manufactured with **scheduled substances need to register or obtain a licence?**

No. Medicinal products and other products made from scheduled substances, which are not scheduled substances themselves, are not covered as such by intra-EU trade rules.

In the case of external trade, medicinal products containing ephedrine or pseudoephedrine are included in Category 4. No registration is required for the external trade, however an export

authorisation is needed.

Relevant provisions: Article 2(1) of Regulation (EC) No 273/2004, Article 7 of Regulation (EC) No 111/2005

I.3 Licence and registration

I.3.1 Do national authorities issue a licence or a registration per operator/user or per each premises of an operator/users?

The competent authority may grant a licence: (a) to cover all scheduled substances and all operations per business premises; or (b) to cover all scheduled substances and all operations per Member State. If the premises are located in a single Member State, the competent authority may grant the license/registration per operator/user. If the premises are located in different Member State, the operator/user will have to apply in each Member State.

Relevant provisions: Articles 4 and 9(1) of Commission Implementing Regulation (EU) 2015/1103

I.4 Official laboratories

I.4.1 Which laboratories are covered by the wording 'official laboratories of competent authorities'?

For the purpose of EU drug precursors rules, the notion 'competent authorities' designates competent authorities in the field of drug precursors. These 'competent authorities' can be law enforcement authorities, customs, inspectorates and authorities entitled to receive registrations and issue licences and import/export authorisations.

The 'official laboratories' of these competent authorities are those designated in pursuance to national legislation, regulations or administrative provisions, or appointed by public bodies entitled to perform specific work for the benefit of these 'competent authorities'. All other public laboratories (e.g. scientific research laboratories) cannot be considered 'official laboratories of competent authorities'.

Official laboratories may be granted special licences or registration in accordance with the intra-EU rules and may be exempted from the obligation to obtain a licence or registration in accordance with the external trade rules.

Relevant provisions: Article 3(2) and (6) of Regulation (EC) No 273/2004; Article 3(12) of Commission Delegated Regulation (EU) 2015/1011

PART II
Questions pertaining to the implementation of Regulation (EC) No 273/2004 (Intra-EU Trade)

II.1 The notion of operator and user

II.1.1 What is the difference between an 'operator' and a 'user'?

The main difference between an 'operator' and a 'user' is that the operator places on the market the scheduled substances, while the user does not. The notion of 'user' is quite comprehensive, and covers all kinds of professional use other than placing on the market.

This distinction is important as the obligations of operators and users are not the same.

Thus, both operators and users need a licence for Category 1 substances, but only operators have the obligation to keep the relevant documentation and obtain the customer declaration. In addition, operators need a registration for category II substances, which users, only need to obtain for category 2A.

Both operators and users may be exempted from their obligations when their transactions involving category 2 substances do not exceed the quantities indicated in Annex II to Regulation (EC) No 273/2004 over a period of one year.

Relevant provisions: Article 2(c), (d) and (h) of Regulation (EC) No 273/2004

See also questions in Section II.2.

II.2 Obligations of users

II.2.1 Are users of Category 2 substances required to obtain a registration?

Users are required to be registered only for possessing substances of subcategory 2A. Extending this obligation to all Category 2 substances would go beyond the legislation.

Relevant provisions: Article 3(6) of Regulation (EC) No 273/2004

II.2.2 *Do users of category 2 have to sign a customer declaration for possessing any Category 2 substances or only for substances of subcategory 2A?* The requirement concerning a customer declaration applies for all category 2 substances.

Thus, operators have to obtain such a declaration from their customers (be they other operators or users), to which they supply category 1 or category 2 substances. The declaration states the specific use(s) of such substances and has to include all the information set out in the model laid down in the EU rules.

Such a customer declaration is not required if customers inform their suppliers that they fulfil the conditions for being exempted from certain obligations (i.e. if the annual amounts do not exceeded certain thresholds).

Relevant provisions: Articles 4 and 6 of Regulation (EC) No 273/2004 and Annex II to this Regulation; Article 7 of Commission Delegated Regulation (EU) 2015/1011 and point 1 of Annex III to this delegated Regulation

II.2.3 Do users of subcategory 2A substances have the obligation to take adequate measures against the unauthorised removal of such substances and secure business premises? Check cat 1

Not according to EU rules, but such obligations may be laid down in national rules.
The EU rules lays down an obligation for the operator with a licence to take adequate measures against the unauthorised removal and to secure business premises. These obligations are not laid down for granting a registration. Nevertheless, it is indicated that the national authorities may request information on such measures before granting a registration.
This means that, if under the national rules there is such an obligation, then the national authorities may condition the granting of a registration in accordance with the EU rules on fulfilling this obligation.

Relevant provisions: Article 3(2)(a) and (b)(vi), Article 5(2) and (4) of Commission Delegated Regulation (EU) 2015/1011.

II.3 Reporting obligations on users of substances of category 1 or 2

II.3.1 Do users of Category 1 or 2 substances have reporting obligations under EU rules?

No. The EU rules requires operators to inform the competent authorities in a summary form of the quantities of scheduled substances used or supplied to third parties.

A natural or legal person that would only use such substances without placing them on the market would not fall under the definition of 'operators' and consequently, will not have such an obligation.
However, a natural or legal person should be considered an operator as long as it is engaged in the placing on the market of scheduled substances. In such a case, it must report annually quantities used or supplied. If such an operator also holds a licence or registration, it has to report quantities used or supplied even if they equal to zero, for all substances mentioned in the licence or registration.

In addition, the national legislation of EU Member States may set out reporting obligations for users of drug precursors, to enable the competent authorities to perform their monitoring and control duties.

Relevant provisions: Articles 8(2) and 10(1) of Regulation (EC) No 273/2004; Article 9 of Commission Delegated Regulation (EU) 2015/1011

II.3.2 May competent authorities request users to report any suspicious activities which might lead to the diversion of drug precursors in the illicit production of drugs, such as thefts?

It depends on the national legislation.

At EU level, only operators have the obligation to notify any suspicious circumstances that might suggest that drug precursors might be diverted towards the illicit production of drugs. There is no corresponding obligation for users.

However, Member States may adopt national rules laying down additional obligations for users, to enable the competent authorities to perform their monitoring and control duties.

Relevant provisions: Article 10 of Regulation (EC) No 273/2004

II.4 Universities

II.4.1 Do universities need a licence when dealing with Category *1* substances*?*

Yes. The EU rules require both **operators and users to obtain a licence from competent authorities before they possess or place on the market Category 1 substances.**

In addition, operators holding a licence have to sell only to operators or users who also hold a licence and have signed a customer declaration.

Relevant provisions: Article 3(2) and (3) and Article 4 of Regulation (EC) No 273/2004

See question II.1.1 and the questions in Section II.3.

II.4.2 Do universities need a registration when dealing with Category 2 substances?

Yes, in certain situations.

Operators engaged in the placing on the market of Category 2 substances are required to register with the authorities.

Users of **subcategory 2A substances also need a registration.**

Users of subcategory 2B substances, meaning natural or legal persons buying and using such drug precursors, but not engaged in their placing on the market, do not need a registration.

As a consequence, universities do not need to register when only buying, using, and/or possessing subcategory 2B substances, but they need a registration for subcategory 2A substances.

Relevant provisions: Article 3(6) of Regulation (EC) No 273/2004

See question II.1.1 and the questions in Section II.3.

PART III
Questions pertaining to the implementation of Regulation (EC) N° 111/2005 (Trade between the EU and Third countries)

III.1 Import and export authorisation

III.1.1 Are operators exempted from licence and registration requirements also exempted from import/export authorisation requirements?

No. The exemption does not cover the obligation of import/export authorisation.

III.1.2 Are the import/export authorisation models set out in the Implementing Regulation binding when granting via electronic means?

Yes. The EU rules allow granting authorisations via electronic means. The authorisation forms are binding with regard to the layout. Only when authorisations are granted via electronic means, the box relating to the authorisation number may be adapted.

Relevant provisions: Article 11(1), Regulation (EC) No 2015/1013.

III.2 Intermediary activities

III.2.1 Operator A, established in the EU, directly exports to Operator B in a third country. Operator C, established in the same EU country, is the official sales contractor indicated on the import authorisation of the third country. However, Operator C is just an 'accommodation address'. Who is the 'exporter'?

The exporter is the person by whom or on whose behalf the customs declaration is made.

Relevant provisions: Article 2(2), Regulation (EC) No 111/2005, and Article 1(19), Regulation (EU) 2015/2446.

Examples of intermediary activities

III.2.2 Operator trades in category 3 substances and claims that they are intermediaries and not exporters and thereby not obligated to register.

[Invite delegates to bring forward concrete examples. Deadline end of November.]

III.3 Import and export requirements

III.3.1 Drug precursors are brought in an EU free zone for warehousing and subsequent distribution to different operators in the EU. Is an import authorisation required?

No import authorisation is required when bringing the goods into free zone.

However, depending on the third country of export, the export might not take place, unless the competent authority in the Member State of Operator A has issued an import authorisation/'letter of no objection'.

An import authorisation will be required when placing the goods under the release for free circulation procedure if these are category 1 substances.

Relevant provisions: Article 8, Regulation (EC) No 111/2005.

III.3.2 Drug precursors are brought into the EU in temporary storage and are subsequently re-exported to a third country. Are authorisations required?

No import or export authorisation is required, but the demonstration of the licit purposes may be required.

Depending on the third country of export, the export might not take place, unless the competent authority of Member State of Operator A has issued an import authorisation/'letter of no objection'.

Relevant provisions: Articles 8 and 12, Regulation (EC) No 111/2005 and Article 8, Regulation (EU) 2015/1011.

III.3.3 Is an import authorisation required for drug precursors under customs transit?

No import authorisation is required when goods are placed under the customs transit procedure. However, authorities may require the operator to demonstrate the licit purposes of the transaction.

Relevant provisions: Articles 8, 20(2), Regulation (EC) No 111/2005 and Article 8, Regulation (EU) 2015/1011 .

III.3.4 Can the import authorisation requirement be avoided by transhipment/temporary storage?

No. As soon as the goods are being placed in the EU market, an import declaration and import authorisation remain required, if applicable.

For transhipment and temporary storage, the operator must always be in the position to demonstrate the licit purposes of the transaction.

Relevant provisions: Article 8 Regulation (EC) No 111/2005.

III.4 Export

III.4.1 On what basis can the competent authority extend the period of 15 working days to take a decision on the application for an export authorisation?

The time-limit of 15 working days for deciding whether to authorise the export can only be extended in cases where an import authorisation is required by a third country. The 15 working days period starts from the moment that the competent authority considers the application to be complete.

Where a pre-export notification is required, the competent authority should give 15 working days to the country of destination to respond.

In order to meet both time-limits, the competent authority should start the pre-export notification the latest at the day it considers that the export authorisation application is complete.

Relevant provisions: Articles 11 and 13(2), Regulation (EC) No 111/2005.

III.4.2 Which is the responsible authority for certifying the physical departure?

Copies 2 + 3 of the export authorisation must accompany the goods and must be presented to the customs office where the export declaration is made and then to the competent authorities at the point of exit. The 'competent authorities at the point of exit' means those authorities designated by the Member States as being responsible. This can be Customs or other authorities competent for border control.

Relevant provisions: Article 11, Regulation (EC) No 2015/1013.

III.4.3 Is it possible to use the Export Control System for drug precursor purposes?

Yes, as long as the ECS certifies correctly the exit of the drug precursors.

III.4.4 How can control be ensured when drug precursors leave a customs warehouse?

The entry into a customs warehouse is subject to import authorisation. The requirement upon discharge depends on the subsequent activity.

Case A) Entry into a new suspensive regime (except for transit and free zone) requires an import authorisation.

Case B) Entry into transit or free zone entails the requirement to be able to demonstrate the licit purposes of the transaction.

Case C) Re-export requires an export authorisation.

Case D) Placing in the EU market requires an import authorisation.

Relevant provisions: Articles 8, 12, 20, Regulation (EC) No 111/2005.

III.5 Export of medicinal products

III.5.1 Shall exports of medicinal products for human use and for veterinary use containing ephedrine/pseudoephedrine be preceded by an export authorisation/pre-export notification:
a) if they are carried by passengers for personal use in reasonable quantities?
b) if they are on board of ships – stocking of the dispensaries – to ensure the health of crew and passengers in reasonable quantities?
c) if they are carried by NGOs or other organisations for emergency relief?

a) No. the EU legislation does not cover products held by passengers for personal use. It only covers commercial transactions and economic operators.

b) No. This corresponds to 'ship supplies'. No export declaration is required for VAT or excise duty exempted ship supply.
See: Articles 269 and 279, Regulation (EU) No 952/2013

c) Yes. Customs declarations remain applicable for emergency relief. Customs duties may be lifted, but all safety and security measures remain applicable.

III.5.2 Can the simplified procedure provided for in Article 19 be used for medicinal products?

Yes, if the conditions to grant an export authorisation by simplified procedure for category 3 and 4 substances are fulfilled.

Relevant provisions: Articles 12, Regulation (EC) No 2015/1011.

III.5.3 Is it possible to introduce derogations for small consignments of medicinal products (e.g. less than 10 or 100 boxes)?

No.

Firstly, it is important to define what a small consignment is (e.g. can less that 100 boxes really be considered as small consignment?).

Secondly, derogation from export authorisation and/or pre-export notification for small consignments as such is not foreseen in the basic act. However, the quantity can be used as a criterion to grant the simplified procedure for export authorisation and for pre-export notification.

III.5.4 Shall homeopathic medicinal products[5] containing ephedrine and pseudo-ephedrine be considered as medicinal products of category 4?

Homeopathic medicinal preparations are covered by heading 3004 as medicaments if they meet the wording of the heading and fulfil the conditions laid down in Additional Note 1 to Chapter 30 which is summarised as follows: "*Heading 3004 includes homeopathic medicinal preparations if they bear on the label, packaging or on the accompanying user directions the following statements of:*
(a) the specific diseases, ailments or their symptoms for which the product is to be used;
(c) dosage; and
(d) mode of application.

Instead of a concentration of the active substance the indication of the degree of dilution (e.g. D6) is required according to the CNENs (Combined Nomenclature Explanatory Notes) to this Additional Note.

As heading 3003 covers "*Medicaments (…) not put up in measured doses or in forms or packings for retail sale*", it can be rather tricky to unambiguously classify homeopathic medicinal preparations under this heading. Customs would always need additional information from the economic operator. For instance, as products falling under this heading are usually presented in bulk or big bags without specific labels or leaflets, without further indication on the use of the product and the amount of the ephedrine contained (e.g. due to very low amount a laboratory analysis would very likely not indicate the contained ephedrine but only the carrier substances), the classification for customs purposes may be outside Chapter 30 (e.g. Chapter 17 or 21). Therefore, customs would rely in such cases on the information given by the importer on contained amounts of ephedrine and on the use.

Due to the usually rather low amount of active substances in homeopathic medicinal preparations it seems that such preparations are unlikely to be used for the illicit manufacture of drugs by extracting the chemical substances they contain (if so, a lot of them would be needed).

Additional information requested:

As regards the indicated "shift" of classified products from Chapter 30 to Chapter 21 products not fulfilling the conditions stipulated by Additional Note 1 to Chapter 30 cannot be classified under heading 3004 as medicaments. But this is the case since the entering into force of this

[5] ***Homeopathic medicinal product:*** **Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles (Directive 83/2001, article 1 on Definitions).**

Additional Note in 2001. Most of such goods are thus classified as "food preparations, not elsewhere specified or included" (not as "food supplements") under heading 2106. The classification in the Combined Nomenclature is determined for customs purposes. Actually, there is no definition of the term "food supplements" in the customs legislation. However, for the purposes of the internal market issues, there is a Directive on "food supplements" in place[6].

III.5.5 Are export of waste medicinal products and waste veterinary medicinal products containing ephedrine and pseudoephedrine (products unfit for their original intended purpose due to, for example, expiry of shelf date) under Combined Nomenclature code 30 06 92 00 covered by Category 4?

Medicaments of codes 3003[7] and 3004[8] clearly exclude goods of headings 3006. Therefore, category 4 does not cover waste medicinal products[9].

However, waste medicinal products (containing ephedrine or pseudoephedrine), even though unfit for their intended pharmaceutical purpose, can still be used for the illicit manufacture of drugs (by extracting the ephedrine/pseudoephedrine).

Meantime, the Directive on medicinal products for human use and Regulation on medicinal products for veterinary use foresee :

"Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired".

In other words, these products can no longer be marketed. As this is managed by the MS in their national legislation, interested stakeholders should check if anything is laid down at national level to monitor the waste medicinal products containing ephedrine or pseudoephedrine.

For customs classification purposes, code 3006 92 00 does not provide currently for any subdivisions and no subdivision could be envisaged as it would imply an inappropriate level of detail.

Relevant provisions: Article 127b, Directive 2001/83/EC and Article 117, Regulation 2019/6 ~~Directive 2001/82/EC. 82 replaced by regulation 2019/6~~

RELEVANT FOR COMPETENT AUTHORITIES ONLY

III.6 Pre-export notification, PEN

III.6.1 How shall MS competent authorities fill in boxes 14a and 14b, 15a, 16a, 17a and 18a of Export Authorisations (and boxes 11a and 11b, 12a, 13a, 14a en 15a of Imports Authorisations) and the corresponding information on the Pre-export notifications

[6] Consolidated version of Directive 2002/46/EC: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0046:20111205:EN:PDF

[7] 3003: Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put in measured doses or in forms or packing for retail sale

[8] 3004: Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packing for retail sale.

[9] Note 4 (k) to Chapter 30 of the Combined Nomenclature : waste pharmaceuticals, that is, pharmaceutical products which are unfit for their original intended purpose due to, for example, expiry of shelf life;

Online (PEN-Online) for medicinal products?

Boxes 14a /11a : name of the scheduled substance according to the Annex to Regulation 111/2005 as amended, the commercial name of the medicinal product, the number of units in the consignment, the number of tablets/ampoules in each unit, the content of the substance in a single unit (per tablet/ampoule);

Boxes 14b / 11b: as above, when there is more than one product;

Boxes 15a/12a : CN code of the scheduled substance (according to the applicable CN)

Boxes 16a/13a : total net weight of the scheduled substance contained in the consignment of medicinal products;

Boxes 17a/14a : % of mixture– not applicable for medicinal products as medicinal products are not mixture. Nothing changes in the way MS used to fill in this Box.

Boxes 18a/15a : invoice number (as normal)

As far as the PEN Online system is concerned, the INCB has recently sent out to MS a short explanation on how PEN online should be filled in concerning preparations (= medicinal products). They are updating the system as the technology used is now obsolete but the actual information required will remain the same. The INCB also recalls that each box should be used for what it is provided for and that all other remarks should be indicated under 'Other remarks'.

Correspondence between an export authorisation and PEN Online:

Box 14a covers field 11 (name of the scheduled substance), field 12 (medicinal product) and field 43 (the number of units in a consignment, the number of tablets/ampoule in each unit and the content of the substance in a single unit);

Box 16a covers field 14 (total net weight of the scheduled substance contained in the consignment of medicinal products).

Relevant provisions: Annex III to Regulation (EU) 2015/1013.

III.7 Bilateral drug precursor agreements

III.7.1 With which countries did the EU conclude bilateral agreements requiring import authorisations prior to export?

Currently, two bilateral drug precursor agreements provide for the verification of the import authorisation. These are the EC/Turkey agreement OJ L 64 p. 28 of 7.3.2003, and the EC/Mexico agreement OJ L 77 p. 22 of 1997.

Relevant provisions: Article 17(1), Regulation (EC) 111/2005.

III.7.2 Is a non-objection or no reply in PEN equivalent to an import authorisation?

Yes, if the notification in PEN was expressed in such a way that it complies with bilateral agreement, a no reply in PEN may be considered equivalent to granting an import authorisation by the importing Contracting Party. For example, the EC/Turkey agreement stipulates that the competent authority of the exporting Contracting Party shall forward a copy of the export authorisation to the competent authority of the importing Contracting Party and the export shall be authorised only when the importing Contracting Party has given its consent. The UN PEN online system is an online exchange of information.

Relevant provisions: Article 2(3) EC/Turkey agreement, OJ L 64 p. 28 of 7.3.2003.