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Working document

Drug Precursors Committee

Subject: Implementation of Regulation (EC) No 111/2005 - Use of simplified customs declarations

Delegations will find attached a working document concerning the exemption from the licensing and registration requirement.

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1. INTRODUCTION

During the 63rd Drug precursor committee (DPC) meeting held on 20th October 2005, a discussion on implementation issues took place. One of the questions raised concerned the issue of "customs declarations for drug precursors subject to an import authorisation". In particular, it was proposed that the simplified customs declaration per "local clearance" should not be allowed in cases where import authorisations for drug precursors are required.

Local clearance means that goods can be declared for a customs procedure through entry into the records of the operator. In this case the customs authorities may waive the requirement that the declarant must physically present the goods to the customs.

The absence of the physical presentation of the goods to the customs was deemed not compatible with the conditions governing the implementation of the import or export authorisation rules. For example, in accordance with the provisions of Regulation (EC) No 111/2005 and Regulation (EC) No 1277/2005 the import authorisation must accompany the goods from the point of entry into the Community customs territory to the business premises. In this case, the customs office where the customs declaration is made or the customs office responsible for the place where the goods receive a customs approved treatment or use, must insert relevant customs references in the import authorisation document. It does therefore not seem possible that the goods can be transported to the operators' premises without their physical presentation to Customs. There was also the concern that the customs declaration in the form of the entry into the operators' records would not offer sufficient guarantees for the prevention of diversion.

On the other hand, other Member States drew attention to their current and positive experience of local clearance and noted that the conditions applied to authorise such simplified procedure are so strict so that they can be deemed to offer sufficient guarantees to prevent diversion and should therefore be applicable in connection with drug precursors.

COM invited those Member States to provide information on the implementation of the conditions applied to authorise "local clearance". The aim of sharing such information would be to have a discussion in the Drug Precursors Committee (DPC) and to examine whether local clearance can be compatible with import and export of drug precursors and, if this was the case, how this can be achieved.

The delegations will therefore find herewith two examples concerning the implementation of the simplified customs declaration per "local clearance" in connection with drug precursors that are subject to an import/export authorisation.

2. IMPLEMENTATION OF "LOCAL CLEARANCE"

2.1. First example (Member State I)

In our administration the procedure of local clearance according to the Community Customs Code is only used for operators that are certified in the "Stairway System".

Certification means that the customs in cooperation with the operator obtain knowledge of (type of) goods and information flows in order to make sure that the quality is high. During this certification period, which lasts for several months, a prior risk assessment of the operator is carried out. The operator is in daily contact with its appointed customs officer. The examination is very thorough and is based on information provided by the operator but also on activities registered by customs and involved competent authorities, in the case of drug precursors, the Medical Products Agency.

The operator has to inform customs about the type of products and the type of activities including e.g. export or import of drug precursors. The operator will only be permitted to use the procedure of local clearance in connection with drug precursors if the registrations and licenses are already available in the customs database. The competent authority, the Medical Products Agency, sends copies of all registrations and licenses electronically to customs as soon as they are issued.

For example, if the registrations or licenses are not available in advance, the customs will not issue a permit to use local clearance. This is also the case if the operator fails to mention the fact that he or she deals with drug precursors.

All transactions made by the so called "certified operator" are checked afterwards by the appointed customs officer. If there has been any unauthorised transaction, there will be an investigation as to what has happened and in serious cases all permits will be withdrawn. In less serious cases the routines will be checked and adjusted.

The process of quality assurance and certification in the "Stairway system" is of course a much more complex procedure as described. We have tried to summarize what's relevant in this case. We're of the opinion that we actually have made our risk assessment beforehand, i.e. before issuing the permit. The risk we run is low, since the operator risks to lose everything concerning his certification, the money, time and credibility he put into the certification is considerable.

2.2. Second example (Member State II)

In the second example the conditions and procedures for using "local clearance" upon import and export are described as follows:

A) IMPORT:

a) Authorisation conditions:

Applications for authorisation of local clearance must be accompanied by the license to import Category 1 drug precursors or proof of registration to import Category 2 drug precursors. Authorisation will only be granted to operators who meet these conditions.

b) Documents to be included in the authorisation:

When importing Category 1 drug precursors, the import authorisation required under Article 20 of Regulation (EC) No 111/2005 must be presented with the proof of authorisation for local clearance.

The supervising customs office must be notified immediately if the licence referred to in Article 6 of Regulation (EC) No 111/2005 for trade in Category 1 drug precursors or the registration referred to in Article 7 of Regulation (EC) No 111/2005 for trade in Category 2 drug precursors is amended or expires.

c) Duties of the supervising customs office:

The documents submitted must be checked for their consistency with the customs declaration per 'local clearance' and their completeness in respect of the declared consignment; after import has been confirmed in Box 18, the import authorisation must be returned to the declarant.

B) EXPORT:

a) Authorisation conditions:

Applications for authorisation of "local clearance" must be accompanied by the licence to export Category 1 drug precursors or proof of registration to export Category 2 or Category 3 drug precursors. Authorisation will only be granted to operators who meet these conditions.

b) Documents to be included in the authorisation:

Category 1 and Category 2 drug precursors and Category 3 drug precursors requiring an export authorisation may not be exported unless an export authorisation has been issued for the consignment under Article 12 of Regulation (EC) No 111/2005.

Drug precursors for which an export authorisation has been granted under the normal procedure:

For each consignment, Copies Nos 2 and 3 of the export authorisation and the other accompanying documents must be presented to the supervising customs office for confirmation before dispatch. The export authorisation confirmed by the supervising customs office (Copies Nos 2 and 3) must accompany the consignment until it actually leaves the Community and must be presented to the customs office of exit along with the commercial document or transport document so that exit can be confirmed.

Drug precursors for which an export authorisation has been granted under the simplified procedure:

For each consignment, Copy No 3 of the export authorisation and the other accompanying documents must be presented to the supervising customs office for confirmation before dispatch. The export authorisation confirmed by the supervising customs office is retained by the exporter. The commercial document or transport document must contain, in addition to the particulars required by Article 3 of Regulation (EC) No 111/2005, the words "**SIMPLIFIED EXPORT AUTHORISATION PROCEDURE"**.

The supervising customs office must also be notified immediately if the licence referred to in Article 6 of Regulation (EC) No 111/2005 for trade in Category 1 drug precursors or the registration referred to in Article 7 of Regulation (EC) No 111/2005 for trade in Category 2 drug precursors is amended or expires.

c) Duties of the supervising customs office:

The supervising customs office must check the consistency of the export authorisation with transport documents before dispatch. The copies of the export authorisation confirmed by customs must be returned to the exporter.

3. SUGGESTED WAY TO PROCEED:

On the basis of two examples concerning the implementation of the simplified customs declaration procedures per "local clearance", it is proposed to have a discussion in the Drug Precursor Committee (DPC) with the aim to identify best practice as regards prevention of diversion and ensuring a Community level of treatment of operators.