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# **Drug Precursors Committee**

**Subject: Reporting obligations**

Delegations will find herewith a concise working paper concerning the requirements of users of scheduled substances with regard to reporting obligations.

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Article 17 of Regulation (EC) No 1277/2005 requires operators to inform the competent authorities in a summary form of the quantities of scheduled substances **used or supplied**, and in the case of supply, of the quantity supplied to each third party.

One delegation asked whether the reporting obligations set out by this Article apply to all users of substances of category 1 and 2.

Article 17 of Regulation 1277/2005 applies to **operators**, which according to Regulation 273/2004 are defined as “*any legal and natural person engaged in the placing on the market of scheduled substances*”.

As regards **category 2 substances**, legal or natural person supplied with such substances only for own use, but not placing any quantity of them on the market, do not fall under the definition of operators, hence they are not subject to Article 17 of Regulation (EC) No 1277/2005.

However, it must be kept in mind that an operator is not defined as such in relation to a particular scheduled substance but instead, **as long as this natural or legal person is engaged in the placing on the market of any scheduled substance**, he must comply with Article 17 of Regulation (EC) No 1277/2005. He should therefore inform the competent authorities in a summary form of the quantities of all scheduled substances supplied to third parties or used, even for those substances that are not supplied to third parties but only intended for own use.

Furthermore, the wording of Article 3(6) of Regulation (EC) No 273/2004 (“*operators engaged in the placing on the market of scheduled substances of category 2 of Annex I shall be required to register and update with the competent authorities without delay the addresses of the premises at which they manufacture or from which they trade in these substances, before placing them on the market.*”) clearly indicates that a natural or legal person becomes an operator before placing any scheduled substance on the market – in fact, as soon as he registers with the authorities. As a result, natural or legal persons having registered with the authorities in order to place category 2 substances on the market are subject to Article 17 of Regulation 1277/2005, and should therefore automatically report each year to the competent authorities on quantities used or supplied to third parties for each scheduled substance mentioned in their registration, even if some of these quantities equal to zero.

As regards **category 1 substances**, operators also have to inform the competent authorities of the quantities of all scheduled substances supplied to third parties or used, even for those substances that are not supplied to third parties but only intended for own use. According to the wording of Article 3(2) of Regulation (EC) No 273/2004, which is comparable to the wording of Article 3(6), natural or legal persons having been granted a license in order to place category 1 substances on the market fall under the definition of operators and the obligation of Article 17 of Regulation (EC) No 1277/2005. Therefore, they should automatically report to the competent authorities on quantities used or supplied to third parties for each scheduled substance mentioned in the licence granted to them, even if some of these quantities equal to zero.

The obligations of natural or legal persons only using but not placing on the market scheduled substances, including category 1 substances, are less clear. It seems that such

natural or legal persons do not fall under the definition of operators and therefore, are not subject to any reporting obligations. Delegations are invited to provide their own interpretation of this question. If it turned out that reporting from such “mere users” was desirable, although not required by the Regulation, this issue would have to be addressed during the review process.

However, it is worth noting that Article 10(1) (a) of Regulation (EC) No 273/2004 requires Member States to adopt the measures necessary to enable their competent authorities to obtain information on any orders for scheduled substances or operations involving such substances. This subparagraph does not mention operators and can therefore be used to obtain information from users not falling under the definition of operators.