



## **EUROPEAN COMMISSION**

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# **Drug Precursors Committee**

**Subject: Pharmacies**

Delegations will find herewith a concise working paper concerning the application of the provisions of Regulation 273/2004 to pharmacies.

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Some questions were raised by delegations concerning the application of the Community legislation on drug precursors to pharmacies.

### **1. What are the legal requirements of pharmacies that intend to buy a substance of category 1 from a Community operator?**

- Article 3 (2) of Regulation (EC) No 273/2004 requires operators to obtain a licence before they may possess or place on the market substances of category 1. In the case of pharmacies, this licence can be a special licence.
- Article 3 (3) of Regulation (EC) No 273/2004 requires licensed operators to only sell to natural or legal persons who hold such a licence.

As a consequence, pharmacies need to obtain a special licence in order to be supplied with substances of category 1. The exemption provided for in Article 12 of Regulation (EC) No 1277/2005 gives Member States all flexibility to decide upon the procedures to be followed by operators applying for such a special licence.

Moreover,

- Article 4 (1) of Regulation (EC) No 273/2004 requires operators to obtain a customer declaration in order to supply a customer with a substance of category 1. This customer declaration must indicate the specific uses of the substance.
- Article 4 (3) of that Regulation foresees that a copy of the declaration, certified to be a true copy of the original, must accompany category 1 substances being moved within the Community.

As a consequence, any operator (wholesaler, distributor...) that intends to supply a pharmacy with a substance of category 1 must obtain from it a customer declaration for every single transaction and must enclose a certified copy of this declaration to the shipment. Unless this operator does not himself benefit from the exemptions provided for in Article 6 of Regulation (EC) No 273/2004, he must keep the customer declaration for at least three years after the end of the calendar year when the transaction occurred.

This allows competent authorities to carry out backtracking investigations on the basis of documents supporting transactions that involved pharmacies.

### **2. What are the legal requirements of pharmacies that intend to buy a substance of category 2 on the EU internal market?**

As universities (cf. working document ENTR/G2(2006)29813), pharmacies that buy, possess and use substances of category 2 but do not place them on the market do not fall under the definition of operators, and do not have to register premises.

However, they have to provide a customer declaration to the operator that supplies them with the category 2 substance for every single transaction, or for several transactions provided that the criteria set down in Article 4 (2) of Regulation (EC) No 273/2004 are fulfilled.

### **3. What are the legal requirements of pharmacies that intend to import a substance of category 1 or 2 from a third country?**

According to Article 13 of Regulation (EC) No 1277/2005, pharmacies are exempted from the requirements of licensing and registration under the scope of Regulation (EC) No 111/2005. However, they need an import authorisation for imports of category substances.

This inconsistency will probably have to be addressed during the review of the legislation.