Narcotic drugs and psychotropic substances: trade in drug precursors, monitoring and surveillance

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The Commission presents its report on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors. The current regulatory framework of the Community for drug precursors is made up of Regulation (EC) No 273/2004, which lays down harmonised rules for the intra-Community control and monitoring, and Regulation (EC) No 111/2005, which lays down the rules governing the monitoring of the trade between the Community and third countries in drug precursors. The report examines Community legislation, including guidance documents, mutual administrative assistance, the EU Action Plan on Drugs, actions under the Customs 2013 Programme, bilateral agreements and actions at UN level. It describes Commission actions taken to evaluate the implementation and functioning of the Community legislation.

Findings: overall, the provisions of Regulation (EC) No 273/2004, Regulation (EC) No 111/2005 and the implementing rules contained in Regulation (EC) No 1277/2005 function well and reach the objective pursued, i.e. prevention of diversion without creating unnecessary barriers to the legitimate trade activities for the scheduled drug precursors. Control and monitoring focus on operators rather than on each transaction. The implementation and functioning of the common licensing system introduced for intra-Community trade and for the trade between the Community and third countries for operators handling precursors in Category 1 (the most sensitive substances) proves to work efficiently from both the competent authorities' and industry's perspectives.

However, the registration requirement for operators handling somewhat **less sensitive precursors in Category 2** both as regards intra-Community trade and trade between the Community and third countries appears to be insufficient to allow adequate control by competent authorities and prevention of diversion from the important volume of intra-Community trade within these substances. In fact, end-users of Category 2 substances, who do not place on the market the substances, are neither required to register nor to report the quantities they buy for their own end-use. Thus they are hardly known to competent authorities. It is also very difficult for manufacturers or brokers of Category 2 substances to exercise their obligation to check the legitimacy of their customers and of the reported end-use of the substance and consequently to notify as appropriate any suspicious transaction to the competent authorities. The control by competent authorities of the legitimacy of operators is difficult and even more when the manufacturers /brokers and the end-users of the Category 2 substances are based in different Member States, and when the trade chain involves more than two entities based in more than one Member State. These problems have been highlighted particularly for **acetic anhydride**, a key precursor for illicit heroin manufacture.

The evaluation found **differing interpretation of some legislative provisions** that would need to be addressed in order to facilitate their correct harmonised implementation within the Community. This includes in particular the application of existing thresholds for exemption of registration for mixtures containing Category 2 substances in accordance with Article 6 of (EC) No 273/2004, when compared to the wording of Article 14 of Regulation (EC) No 1277/2005.

The provisions regarding the **frequency of reporting** by the operator to the competent authorities does not provide sufficient basis for carrying out the control and monitoring duties. An overview of the legal trade movements constitutes an important instrument to detect suspicious consignments.

Pharmaceutical preparations / medicinal products for human use containing drug precursors are currently excluded from the scope of the drug precursor legislation. The manufacture, import and wholesale distribution of medicinal products, including products for export is subject to an authorisation, specific obligations and regular inspections in line with Community pharmaceutical legislation (Directive 2001/83 /EC). Therefore it is considered that these activities should be under sufficient systematic control by Member States' competent authorities. However, such manufacturers, importers and wholesale distributors are not subject to specific pre-notification requirements from drug precursors' legislation when exporting those medicinal products which contain drug precursors. This has led to a situation where in some Member States exports and transit/transhipments of pharmaceutical preparations/medicinal products containing drug precursors - in particular **ephedrine or pseudoephedrine** - have not been seized even though it was very likely that they would be misused for illicit drug manufacture.

There appear to be further minor weaknesses related to the precursor legislation regarding the **external trade**. These include in particular the lack of flexibility for competent authorities as regards the period required to wait for the response to pre-export notifications, the lack of simplified authorisation procedures for repetitive consignments between well-known operators in the Community and in the EFTA countries, and the need to further streamline the authorising procedures with the electronic customs environment.

Recommendations: the Commission suggests the following:

- improving harmonised implementation of the current legislation;
- enhancing reporting by increasing the reporting frequency and using modern secured electronic means of exchanging information;
- modifying some requirements for Category 2 substances specifically for acetic anhydride;
- ensuring appropriate control of pharmaceutical preparations/medicinal products containing ephedrine or pseudo-ephedrine;
- improving procedural requirements with regard to the risk of diversion.

The Commission notes that any option pursued would need to be carefully examined in particular towards its impact on economic operators legally trading those substances for legitimate purposes and its effectiveness in preventing their diversion for the illicit drug manufacture.