Monitoring intra-EU trade in drug precursors

2012/0261(COD) - 20/11/2013 - Final act

PURPOSE: to prevent the diversion from the EU-internal trade of **acetic anhydride**, the main drug precursor for heroin, by extending the registration requirement to include users of the substance, and amending Regulation (EC) No 273/2004 on drug precursors.

LEGISLATIVE ACT: Regulation (EU) No 1258/2013 of the European Parliament and of the Council amending Regulation (EC) No 273/2004 on drug precursors.

CONTENT: this Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.

Definitions: several definitions have been amended such as:

- "**user**": this term has been clarified so that it concerns persons possessing substances for purposes other than placing them on the market (the aim being that it cannot be confused with an operator within the meaning of the Regulation);
- "**scheduled substance**": this term has been clarified so as to delete the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

Registration: more detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances as laid down in the Regulation (EC) No 273 /2004. For **acetic anhydride**, in addition to operators users should also be subject to a registration requirement.

Licence: provisions as regards holding a licence for the placing on the market of a scheduled substance has been clarified. The competent authorities may either limit the validity of the licence to a period not exceeding three years.

For acetic anhydride, operators shall obtain registration from the competent authorities of the Member State in which they are established **before placing the substance on the market.** From 1 July 2015, users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing this substance.

When considering whether to grant registration, the competent authorities shall take into account, in particular, the competence and integrity of the applicant. They shall refuse registration if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances.

Fees: operators and users shall obtain a licence from **the competent authorities of the Member State in which they are established** before they may possess or place on the market scheduled substances. It is also provided that competent authorities may require operators and users to **pay a fee for the application for a licence or for registration**.

Where a fee is levied, competent authorities must consider adjusting the level of the fee depending on the size of the enterprise. Such a fee must be levied in a non-discriminatory manner and **shall not exceed the cost of processing the application**.

Database: a European database on drug precursors shall be created to simplify the reporting by Member States with regard to seizures and stopped shipments, where possible in an **aggregated and anonymised manner and in the least intrusive manner** as regards the **processing of personal data**, taking into account the state of the art of privacy-enhancing technologies and the principle of data limitation. The European database should also serve as a European register of operators and users holding a licence or registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their transactions involving scheduled substances.

The kind of data which can be stored in the European database would be established through delegated acts.

Exchange and processing of personal data: Regulation (EC) No 273/2004 envisages the processing of information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to prevent the diversion of scheduled substances. However, it is specified that the processing of personal data should be carried out in a manner compatible with EU legislation on data protection and, in particular, with requirements relating to **data quality, proportionality, purpose limitation, and rights to information, access, rectification of data, erasure and blocking, organisational and technical measures and international transfers of personal data.**

Operators must not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.

Notification of the competent authorities: operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances. To that end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

Competent authorities will have the power where necessary, to **detain and seize consignments** to prevent the use of **specific non-scheduled substances** for the illicit manufacture of narcotic drugs or psychotropic substances.

Communication from Member States: to permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in **each Member State shall communicate to the Commission** in electronic form via the European database all relevant information on the implementation of the monitoring measures laid down in the Regulation, in particular **as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances** and methods of diversion and illicit manufacture, and their licit trade.

The Commission shall be empowered to adopt delegated acts concerning the requirements and conditions for operators to provide information.

Report: the Commission shall, by 31 December 2019, submit a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

Annex: acetic anhydride, currently scheduled in category 2 of Annex I to Regulation (EC) No 273/2004, should be included in a **new subcategory 2A of Annex** I thereto to allow increased control of its trade. The remaining substances of category 2 of Annex I to Regulation (EC) No 273/2004 should be listed as subcategory 2B of Annex I thereto.

ENTRY INTO FORCE: 30.12.2013.

DELEGATED ACTS: the power to adopt delegated acts shall be conferred on the Commission for a period of **five years from 30 December 2013**. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension.

The European Parliament or the Council may raise objections to a delegated act within a period of two months from the date of notification (this may be extended by two months.) If the European Parliament or Council express objections, the delegated act will not enter into force.