

Monitoring EU/third country trade in drug precursors

2012/0250(COD) - 20/11/2013 - Final act

PURPOSE: to regulate the external trade in medicinal products containing ephedrine and pseudo-ephedrine and amending [Council Regulation \(EC\) No 111/2005](#) laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

LEGISLATIVE ACT: Regulation (EU) No 1259/2013 of the European Parliament and of the Council amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.

CONTENT: this Regulation aims to strengthen the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

To this end, the following measures are provided:

- **control of medicinal products containing certain scheduled substances:** medicinal products and veterinary medicinal products containing ephedrine or pseudo-ephedrine must be included in the definition of scheduled substances. A new category of substances was created (category 4) in the annex of the Regulation in which this type of medicinal product must be included;
- **preventing diversions involving non-scheduled substances:** with a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, Member States would be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Member States' competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

It should be noted that this Regulation **clarifies the definition of a scheduled substance:** in this regard, 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 ('the United Nations Convention'), is deleted 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.

Labelling of products: operators must ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex (Medicinal products and veterinary medicinal products containing ephedrine or its salts) indicating their name or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, contained in the mixture or in the natural product.

Licensing and registration procedure: operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances shall hold a licence or a registration as the case may be, depending on the category of product. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence or a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

Database: competent authorities should share between themselves and with the Commission, through the European database on drug precursor), established under Regulation (EC) No 273/2004, information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a **European register of operators holding a licence or registration** which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

Processing of personal data: Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council and Regulation (EC) No 45/2001 of the European Parliament and of the Council.

Communication with Member States: the competent authorities in each Member State must communicate to the Commission in electronic form via the European database in a timely manner all relevant information on the implementation of the monitoring measures laid down in this 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.

Report: the Commission shall submit by 31 December 2019 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: the list of scheduled substances has been amended and a new Category 4 has been inserted for medicinal products containing ephedrine or pseudo-ephedrine.

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.

