Monitoring EU/third country trade in drug precursors

2012/0250(COD) - 27/09/2012 - Legislative proposal

PURPOSE: to regulate the external trade in medicinal products containing ephedrine and pseudo-ephedrine and amending Council Regulation (EC) No 111/2005.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: drug precursors are chemical substances having a wide variety of licit uses, such as in the synthesis of plastics, pharmaceuticals, cosmetics, perfumes, detergents, or aromas. They are traded for legitimate purposes on global markets, but some of them can also be diverted from the licit distribution channels for the illicit manufacture of narcotic drugs. Taking into account the wide legitimate uses of drug precursors, their trade cannot be prohibited.

Ephedrine and pseudoephedrine are chemical substances used for the manufacture of cold or allergy medicines. These two substances are also the main precursors for the manufacture of methamphetamine. While ephedrine and pseudoephedrine are controlled at international and EU level, the medicinal products containing them are not controlled when they are exported from or transiting through the Union customs territory. They are targeted by drug traffickers as a source of precursors for the illicit manufacture of methamphetamine because the ephedrine or pseudoephedrine contained in these products can be easily extracted.

Extent of the problem: in 2009, almost 7 400 seizures of methamphetamine, amounting to about 600 kg of the drug, were reported in Europe. Both the number of seizures and quantities increased over 2004-2009. In 2009, illicit methamphetamine laboratories were seized for the first time in several European countries. This is an indication that methamphetamine markets may be expanding in Europe.

Seizures of methamphetamine precursors contained in medicinal products have fluctuated considerably from 2007 until 2010. At European level, while in 2007 hardly any preparations were recorded out of the overall quantities seized, in 2008 and 2009 the amount of preparations out of the total quantities seized increased sharply and decreased considerably again in 2010. After the continued increase of seizures of medicinal products from 2007 to 2009, as a result of strengthened controls of medicinal products containing ephedrine and pseudoephedrine in several countries, particularly in Mexico and countries in Central America, the total amount of medicinal products seized worldwide decreased in 2010.

However, the increasing or decreasing level of seizures is only one indicator to illustrate that illicit manufacture is taking place in a given part of the world. The absence of a control mechanism for medicinal products containing ephedrine and pseudoephedrine remains a concern both at European and at global level.

Medicinal products for human use containing ephedrine or pseudoephedrine are excluded from the provisions of Regulation (EC) 111/2005, which applies to trade in drug precursors between the EU and third countries. This has led to a situation where these products could not be stopped or seized by Member States' competent authorities when these products were exported from or transiting through the Union customs territory, even though it was very likely that they would be misused for the illicit manufacture of methamphetamine in their country of destination.

Directive 2011/62/EU which relates to the prevention of the entry into the legal supply chain of falsified medicinal products addresses the distribution chain for medicines within the EU, importation of active substances, and 'introduction' of medicines, i.e. medicines brought into the customs territory without the intention of placing them on the market. These provisions are focused on preventing products that fall within the definition of falsified medicinal products from entering the legal supply chain. Given that the principal issue with drug precursors is one of legitimately produced products leaving the legal supply chain, it is unlikely that these provisions will make a significant contribution to tackling the issue of controlling medicinal products containing ephedrine or pseudoephedrine being exported or transiting through the EU.

The EU is criticised internationally for not taking adequate control measures across Member States to tackle this weakness.

By imposing EU control over these medicinal products, this proposal is aiming to make it more difficult, expensive and risky for criminals to source the chemicals they need to manufacture drugs. The proposal should work as a deterrent: it focuses on preventing the diversion of precursors. It concentrates on the supply reduction of the chemicals to make drugs and not on the supply of the drugs for the consumers.

IMPACT ASSESSMENT: the impact assessment report identified and assessed five policy options:

- Option 1: "baseline scenario": the status quo would be maintained.
- Option 2: voluntary measures by Member States to improve the situation.
- Option 3: giving authorities power to stop suspicious shipments.
- Option 4: giving authorities power to stop suspicious shipments and pre-export notification of legal shipments.
- Option 5: full control of trade in medicinal products containing ephedrine and pseudoephedrine.

The impact assessment concluded that Option 4 would be the most suitable one to address the problem, as it would: (i) provide for a legal basis, (ii) impose only one extra control requirement and (iii) generate hardly any additional administrative burden. The proposal notes that even though Option 5 could be considered the most effective by applying the strictest controls, the requirements would be disproportionate to the objective pursued by the present initiative. The added value provided by Option 4 compared to Option 3 is that, under the former Option, the synergy of two combined measures increases the effectiveness of each individual measure.

LEGAL BASIS: Article 207 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal provides that any export of medicinal products containing ephedrine or pseudoephedrine should be preceded by a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination. The pre-export

notification system is up and running and measures are already compulsory for scheduled substances of Category 1. The proposal contains compulsory measures for the products containing Category 1 substances, such as medicinal products containing ephedrine or pseudoephedrine.

Member States' competent authorities will be given the powers to stop or seize those products when there are reasonable grounds for suspecting that they are intended for the illicit drug manufacture, when they are exported, imported or in transit. At the moment, most customs authorities can only seize ephedrine or pseudoephedrine as raw substances.

The European Database on drug precursors created by Regulation (EC) No 273/2004 will be used to:

- simplify Member States reporting with regard to seizures and stopped shipments in accordance with Article 12(12) of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988;
- establish a European register of operators holding a licence or a registration, which will facilitate verification of the legitimacy of their transactions involving scheduled substances and enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances.

The proposal contains some other amendments aiming at facilitating the implementation of the Regulation and at increasing its effectiveness, the main ones being:

- the possibility of amending the Annex to the Regulation in order to react more quickly to new emerging trends in precursors diversion;
- a review clause to assess whether the amended Regulation will have been effective to prevent the diversion of medicinal products containing ephedrine or pseudoephedrine;
- the adaptation of the provisions of Regulation (EC) No 111/2005 in accordance with the rules on delegated and implementing acts under the Treaty on the Functioning of the European Union (TFEU).

BUDGETARY IMPLICATIONS: the proposal will not have an impact on human resources and on the European Union budget and is therefore not accompanied by a financial statement.

DELEGATED ACTS: in order to achieve the objectives of Regulation (EC) No 111/2005, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union will be delegated to the Commission for specific purposes listed in the text.